REPORTER'S RECORD
DAILY COPY VOLUME 5
CAUSE NO. D-1-GV-04-001288

STATE OF TEXAS, ex rel. ALLEN JONES, Plaintiffs,	)	IN THE DISTRICT COURT
VS.	)	TRAVIS COUNTY, TEXAS
JANSSEN, LP, JANSSEN PHARMACEUTICA, INC., ORTHO-McNEIL PHARMACEUTICAL, INC., McNEIL CONSUMER & SPECIALTY PHARMACEUTICALS, JANSSEN ORTHO, LLC, and JOHNSON & JOHNSON, INC., Defendants.	)	250TH JUDICIAL DISTRICT

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JURY TRIAL

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On the 13th day of January, 2012, the following proceedings came on to be heard in the above-entitled and numbered cause before the Honorable John K. Dietz, Judge presiding, held in Austin, Travis County, Texas:

Proceedings reported by machine shorthand.

A P P E A R A N C E S

Assistant Attorneys General
Antitrust & Civil Medicaid
Fraud Division
Ms. Cynthia O'Keeffe
SBOT NO. 08505000
Mr. Patrick K. Sweeten
SBOT NO. 00798537
Ms. Eugenia Teresa La Fontaine Krieg
SBOT NO. 24062830
Mr. Raymond C. Winter
SBOT NO. 21791950
Mr. Reynolds Bascom Brissenden, IV
SBOT NO. 24056969
P.O. Box 12548
Austin, Texas 78711-2548
Phone: (512) 936-1304
ATTORNEYS FOR THE STATE OF TEXAS

FISH & RICHARDSON, P.C.
Mr. Tommy Jacks
SBOT NO. 10452000
One Congress Plaza
111 Congress Avenue, Suite 810
Austin, Texas 78701
Phone: (512) 472-5070

- AND -

FISH & RICHARDSON, P.C.
Mr. Tom Melsheimer
SBOT NO. 13922550
Ms. Natalie Arbaugh
SBOT NO. 24033378
Mr. Scott C. Thomas
SBOT NO. 24046964
Ms. Clarissa Renee Skinner
SBOT NO. 00791673
1717 Main Street
Suite 5000
Dallas, Texas 75201
Phone: (214) 747-5070
ATTORNEYS FOR RELATOR, ALLEN JONES

A P P E A R A N C E S

SCOTT, DOUGLASS & McCONNICO, L.L.P.
Mr. Steve McConnico
SBOT NO. 13450300
Ms. Kennon Wooten
SBOT NO. 24046624
Mr. Asher B. Griffin
SBOT NO. 24036684
Mr. Steven J. Wingard
SBOT NO. 00788694
Mr. Bryan D. Lauer
SBOT NO. 24068274
Mr. Sam Johnson
SBOT NO. 10790600
600 Congress Avenue, Suite 1500
Austin, Texas 78701-2589
Phone: (512)495-6300

- AND -

LOCKE LORD BISSELL & LIDDELL, LLP
Mr. John P. McDonald
SBOT NO. 13549090
Mr. C. Scott Jones
SBOT NO. 24012922
Ms. Ginger L. Appleberry
SBOT NO. 24040442
Ms. Cynthia Keely Timms
SBOT NO. 11161450
2200 Ross Avenue, Suite 2200
Dallas, Texas 75201
Phone: (214) 740-8000
ATTORNEYS FOR DEFENDANTS JANSSEN

I N D E X

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JANUARY 13, 2012

PLAINTIFFS' WITNESSES

EXHIBITS OFFERED BY PLAINTIFFS

PROCEEDINGS

JANUARY 13, 2012

(Jury not present)

MR. JACKS: Your Honor, at this time plaintiffs would offer, first, Exhibit 2223, an exhibit which contains call notes of Jeff Dunham, the former employee of Janssen.

MR. McCONNICO: Your Honor, we object under Texas Rule of Evidence 802, hearsay, does not meet any of the exceptions to the hearsay rule under 803. We also object under Texas Rules of Evidence 402, 401, 403, for lack of foundation and no relevancy.

THE COURT: It's overruled.

(Plaintiffs' Exhibit 2233 admitted)

MR. JACKS: Your Honor, we next offer Plaintiffs' Exhibit 148, which is an exhibit which contains a compilation of call notes relating to child and adolescent -- the subject of child and adolescent promotion, and we offer Plaintiffs' 148.

MR. McCONNICO: Your Honor, we also again object under Texas Rule of Evidence 802 that these -- this compilation is hearsay, does not meet any of the hearsay exceptions under Texas Rule of Evidence 803. We also object under Texas Rule of Evidence -- Rules of Evidence 401, 402 and 403 as not relevant, and no

foundation for the admissibility of these exhibits has been laid.

THE COURT: I'm sorry, Mr. McConnico. I cannot help myself. That was a well-thought-out, lucid, cogent objection. It's overruled.

MR. McCONNICO: Yes, sir. But I appreciate the compliment.

THE COURT: You're welcome.

(Plaintiffs' Exhibit 148 admitted)

MR. JACKS: And finally, plaintiffs offer Plaintiffs' Exhibit 149, which is a compilation of call notes relating to the issue of the superiority -- superiority claims.

MR. McCONNICO: And again, we object under Texas Rules -- Rule of Evidence 802 that this is hearsay. It does not meet any of the hearsay exceptions under Texas Rule of Evidence 803. It is not relevant under Texas Rules of Evidence 401, 402 and 403. And the foundation has not been laid for the admissibility of this exhibit.

THE COURT: I just wanted to say to the record on the entire package of this that these are documents that are going to be introduced during the testimony of Mr. Friede, I believe.

MR. JACKS: They will be -- they will be

discussed in the testimony of Mr. Friede to some degree, Your Honor. My goal was to go ahead and move for their admission now to save time before the jury and not have to go through this procedure, but I'll follow the Court's -- I'll do whatever the Court --

THE COURT: Well, I was just trying to point out that this -- this discussion concerning the admissibility of these documents relates in part to the discussion that occurred at the end of yesterday --

MR. JACKS: Yes, sir.

THE COURT: -- concerning the admissibility of Mr. Friede's testimony and what he reviewed. And in addition to overruling that, part of the Court's calculus in admitting these is it appears to the Court that these are 801(e) -- I'm sorry, (d)(2) -- (d)(2)(b) documents. Okay. They tell me that the jury is here now.

MR. McCONNICO: I will also add, Your Honor, these are an improper compilation, both exhibits, because they were compiled in the order that they're presented to the Court by the attorneys and not in the normal course of business.

THE COURT: Okay.

MR. McCONNICO: Judge, do we need -- is that objection overruled?

THE COURT: Oh, it is.

(Plaintiffs' Exhibit 149 admitted)

(Jury present)

THE COURT: Everyone be seated, please. Mr. Jacks.

MR. JACKS: Yes, Your Honor. At this time plaintiffs call Mr. Arnold Friede.

THE COURT: Normally I would -- there's a front door here. Normally I would waive the making of the oath, but under the circumstances, I need to swear you in.

(The witness was sworn)

THE COURT: There's a front door, and then if you'll kind of pull the microphone over in front of you.

ARNOLD FRIEDE,

having been first duly sworn, testified as follows:

DIRECT EXAMINATION

BY MR. JACKS:

Q. Would you tell us your name, please.

A. Arnold I. Friede.

Q. Mr. Friede, where do you live?

A. I live in New York City.

Q. Are you an attorney?

A. I am.

Q. Licensed to practice somewhere?
A. Yes.
Q. In -- and in what states are you licensed to practice?
A. I'm licensed to practice in California, Connecticut, the District of Columbia and Maryland.
Q. All right. I want to discuss your background briefly, but first, what is your area of expertise in the law?
A. I'm a food and drug lawyer, food and drug law lawyer.
Q. All right. What -- where were you born, sir?
A. I was born in Germany.
Q. And where in Germany?
A. It was in a displaced person's camp for holocaust survivors near Munich, Germany.
Q. Did you -- obviously at some point you and your family immigrated to the United States; is that true?
A. That's correct. When I was two and a half years old, my parents immigrated to Pittsburgh, Pennsylvania.
Q. Is that where you grew up?
A. That's where I grew up.
Q. I need for you to tell us about your educational background beyond high school in Pittsburgh.

A. I attended the University of Pittsburgh where I received a BS degree in mathematics in 1970. Afterwards, I attended the George Washington University law school in Washington, D.C.

Q. Upon graduation from law school, what did you do?

A. I was a -- a law clerk for two years in -- a little more than two years in federal court, one year as a law clerk for now deceased Judge Lydick in the U.S. District Court for the Central District of California in Los Angeles. And then for a little more than a year, I was a law clerk for a newly-created federal court called the Judicial Panel on Multidistrict Litigation in Washington, D.C.

Q. After completing your clerkships, what was your next step in the law?

A. I was an attorney, an associate chief counsel in the FDA chief counsel's office in Rockville, Maryland.

Q. And in doing that job, what sorts of things did you work on for the Food and Drug Administration?

A. Well, in general, we had I would say three areas of responsibility. One would be in enforcement litigation where the government would initiate actions against either companies or products that were

allegedly, you know, in violation of the law. We would also be involved in administrative types of hearings that were nonjudicial but that was in the confines of the agency. And also, many of us, including myself, had a role in advising various constituent parts of the agency. In my case, I was the designated liaison counsel for something called the Bureau of Radiological Health, which is now a part of the FDA Center for Medical Devices.

Q. All right. Thank you. I'm going to be asking you some questions in a bit about something called misbranding. As a food and drug lawyer, do you know what that is?

A. I do.

Q. During the time you were with the FDA in the office of chief counsel, did you deal with issues concerning misbranding?

A. I did.

Q. Would you please explain to the jury what misbranding is, please.

A. In general, misbranding refers to a labeling or advertising for a product that is false or misleading. And it also includes the concept of promoting a drug for a use that is not FDA approved.

Q. Now, I'm going to take this in bite-size

chunks. In a bit I want to ask you some things about what it takes to get a drug approved, but right now you mentioned a word that I want to ask you about, and that's the word "promoting." Is that a word of significance in your field of law?

A. It is, because FDA regulates promotional activities by regulated entities.

Q. Okay. If you would, please, Mr. Friede, would you tell the jury what promote or promotional means in your world?

A. It's actually a relatively simple concept, and that is if you're promoting something, you're trying to sell it. You're affirmatively trying to market the regulated article for some particular purpose.

Q. Okay. And a regulated article in the context of this lawsuit would be, say, a prescription drug?

A. Prescription drug would be a regulated article in FDA parlance, yes.

Q. All right. And then when did -- I know you left the FDA at some point. When was that?

A. It was in 1978.

Q. Thirty-three, coming up to -- coming up on 34 years ago?

A. Don't remind me how long ago it was.

Q. All right. Well, we were all young once. In

the years since, what have you done professionally, please, sir? And let's try to keep this short because we're going to move things along today if we can.

A. Well, I've been a lawyer in regulated -- FDA-regulated industries from beginning in 1978 through 2000 -- through the beginning of 2008 for three different companies. I also was a food and drug lawyer in private law practice, and I now have my own FDA law consulting firm.

Q. In the years between 1978 and 2008 when you worked in the industry, you said you've worked for three companies over that span. What were the companies?

A. One was called Richardson-Vicks, which was a diversified company including a variety of products, prescription drugs, over-the-counter drugs, like the Vicks cough/cold line of products, cosmetics, things of that sort. I also worked for a company called Unilever, which has a variety of businesses including things like Vaseline Intensive Care Lotion and a medical device business, a cosmetic business, an over-the-counter drug business, a food business of which I was at one time general counsel. And then I worked as a lawyer for Pfizer Pharmaceuticals for ten years from 1998 through January of 2008.

Q. And then you went into private practice and

eventually your own private consulting business; is that correct?

A. That's correct, yes.

Q. In the course of your career, have you also been active in professional or industry organizations?

A. Yes, I have. I have been -- I've served on numerous committees of various trade associations, including the Pharmaceutical Research and Manufacturers Association, which is the principal trade association representing the prescription drug industry. I've also served as the chair of the food, drug and cosmetic law section of the New York State Bar. I was -- served on the advisory -- on the board of trustees for the Food and Drug Law Institute, which is the major nonpartisan educational --

THE REPORTER: I'm sorry. Please repeat right where you're at.

A. -- Food and Drug Law Institute, which is the major nonpartisan organization that represents the food and drug law community. Also, when I lived in Chicago when I was with Unilever, I founded an organization called the Greater Chicago Food and Drug Law Association. I've been, you know, an active participant in the food and drug law community for a long time.

Q. Okay.

THE COURT: Give me one minute.

MR. JACKS: Yes.

Q. (BY MR. JACKS) In your years when you worked for -- as a lawyer for the companies like Richardson-Vicks, Unilever, Pfizer, did you in any of those positions deal with issues concerning misbranding?

A. Yes.

Q. Did you in those positions advise your client -- your company for which you worked about issues of misbranding?

A. I did.

Q. And what -- when you were called upon to give advice about misbranded products, what sort of advice would you give if asked --

A. Well, I would --

Q. -- by those who employed you?

A. I would evaluate the proposed promotional material, for example, and advise the company whether I thought that the representations were false or misleading or off label or otherwise, you know, violated the law.

Q. What would be the consequences to the companies you worked for potentially if their products were misbranded because they were false or misleading or were promoted off label?

A. FDA has a number of remedies that it can invoke. It can cease the product. It can file for an injunction. It can criminally prosecute the company and responsible corporate officials. It can send compliance correspondence to the company. So there are a variety of consequences.

Q. In -- I haven't asked you about publications. Have you written or spoken on subjects of promotion of pharmaceutical products and misbranding?

A. Yes. I've written and spoken extensively in that area. By my count, there probably have been in the last four years some 90 to 100 occasions in which I've either written or have spoken publicly on FDA-related issues.

Q. In the course of your career over the past 33 years, would it be fair to say that except for your participation -- you mentioned one organization that was nonpartisan. Tell me, what did you mean by that?

A. Well, that it was a forum where individuals from all sides, from industry, from government, academia, could meet in sort of a neutral way to discuss and debate issues of food and drug law, could develop publications of interests, symposia, educational events, just a meeting ground.

Q. And except for that sort of thing, would it be

fair to characterize your career since leaving the FDA through your years with those companies and in private practice as being a lawyer serving industry -- regulated industries?

A. I represented regulated industry to a large extent, yes.

Q. Have you ever been retained to serve as an expert witness before this case?

A. No.

Q. Have you ever testified as an expert witness before this case?

A. No.

Q. Mr. Friede, I -- you were asked by the State of Texas and me as counsel for Mr. Jones to serve as an expert consultant for us in this case; is that true?

A. That's true.

Q. And we're going to get into what you did during that term, during the time you've worked on the case. Did we have an understanding that we would be billed for the time you spent on the case?

A. Yes.

Q. And at what rate are you billing, sir?

A. I'm billing at the rate of $525 an hour.

Q. All right. And in the course of your preparation on this case -- let me ask you first, about

how long have you been working on this case?

A. Since mid August of 2010.

Q. Okay. So a year and a half, thereabouts?

A. Approximately.

Q. And over the course of that time, what sorts of things have you done to prepare yourself to be familiar with the case so that you could write a report, give depositions and eventually come here today?

A. Well, I've reviewed thousands of documents. I have -- of all kinds, including the marketing materials, business plans, training materials. I've reviewed deposition transcripts of any number of individuals involved in this case, including sales representatives from Janssen, their managers. I've looked at reports from experts, physician transcripts from experts. I've looked at thousands of call notes. So I've looked at a variety of promotional materials over a very long period of time. So I've looked at a very significant amount of information over the course of that -- that period of time.

Q. All right. I'm not going to bring them all out because it's quite bulky, but did -- we've got two boxes plus a stack this big, plus a small stack of exhibits that were admitted earlier today by the Court, Plaintiffs' Exhibits 148, 149 and 2223. Have you

reviewed the materials in those exhibits?

A. Yes.

Q. And I may ask you a little more detail about them later, but let me go ahead. Did you also prepare in this case at an earlier time a report containing your findings and what you'd reviewed at that time?

A. Yes, I did.

Q. And about when did you do that?

A. The report was finalized and submitted on approximately November the 1st of 2010.

Q. So some 14 months or so ago?

A. Yes.

Q. Have you also appeared at a deposition where opposing counsel were able to question you at length?

A. Yes.

Q. And about when was that done?

A. That was in January of 2011.

Q. So almost exactly a year ago?

A. Right.

Q. And for about how long were you examined? The attorney questioned you for --

A. Slightly in excess of a day and a half.

Q. In -- I want to get back to a discussion of the issue of misbranding. You told the jury -- explained what misbranding is. You explained that it's a

violation of law. I need to ask you something about that law. Is -- how long has the federal law concerning misbranding been in place?

A. The Federal Food, Drug and Cosmetic Act, which is the law that regulates misbranding, was passed in 1938, and there was a predecessor law that goes back to 1906 that also had a similar concept.

Q. In the course of your review of materials in this case, have you reviewed materials where some of these studies -- let's say off-label promotion are discussed by individuals within Janssen in internal documents?

A. I have reviewed documents that reflect promotional activity, that is, that is off label.

MR. JACKS: Let me ask if Plaintiffs' Exhibit 271 could be brought up, please, Mr. Lawrence.

Q. (BY MR. JACKS) And Plaintiffs' Exhibit 271 dated February 8th, 2002, subject policy on promotion of products and healthcare compliance, is that a document you've seen before?

A. Yes.

Q. And it is from someone named Alex Gorsky. And from your review of materials in this case, do you recall at what level of the company Mr. Gorsky was in as of this time in 2002?

A. Yes. He was at that time the president of Janssen Pharmaceutica, Inc.

Q. I'm not going to read all this in the interest of time, but if you'd look at the last sentence displayed --

MR. JACKS: Excuse me, Mr. Barnes. I think we -- oh, that's all right. I think everyone can see that. I hope so.

Q. (BY MR. JACKS) Do you see the sentence that begins "Promotion of"?

A. Yes.

Q. And it reads, "Promotion of unsupported or off-label claims are not only illegal, but comprise the reputation of Janssen and of Johnson & Johnson in providing quality healthcare products and information to providers and patients." Is -- would you agree or disagree with Mr. Gorsky about that statement --

A. I would --

Q. -- at least as it relates to the law part?

A. I would agree with it.

Q. All right. What -- he says "promotion of unsupported or off-label claims." Do you see that?

A. I do.

Q. What in your world does unsupported claims mean as it relates to pharmaceutical products?

A. Well, I would interpret unsupported to refer to claims that are either false or misleading or possibly to claims that do not have the -- the right kind of supporting evidence.

Q. Not supported by the science?

A. Correct.

Q. And I said I wanted to ask you some questions about how a drug comes to be approved by the FDA. We've talked about FDA approval. Is that something you're familiar with?

A. Yes.

Q. Let's say I'm a drug company and I've got a new product and I've had research done on it, and I'm ready to come to the FDA and try to get approval for my drug. What do I have to prove to the satisfaction of the FDA to get that approval?

A. Well, what you would do is you would -- you would submit something called a new drug application in which you would attempt to demonstrate based on the evidence that you had accumulated and the studies that you had conducted that there was substantial evidence that the drug was safe and effective for the indications in the labeling that you had proposed for the drug.

Q. Okay. There are words you're going to use that mean things to you that may not mean things to other

folks. Indications. What does indications mean in the context of applying to get my drug on the market?

A. An indication is what the drug is intended to treat so that you are indicated for a particular disease.

Q. Okay. So if -- if my drugs -- drug is for people that have asthma, the indication would be for something that had to do with asthma?

A. Correct.

Q. Now, let's say my drug is a drug that -- there are already some drugs similar to mine on the market, but I've got another one that I want to bring through, and I think -- I may think mine's the best of them all. Is that what I have to prove to the FDA?

A. No.

Q. What do I have to prove?

A. You just have to prove that your drug is in and of itself safe and effective, which ordinarily involves comparison between your drug and the sugar pill typically called a placebo.

Q. So if I'm bringing, say, a new antipsychotic to the market, I don't have to prove that my antipsychotic is safer or more effective than the other antipsychotics that are already on the market?

A. Not to get the drug approved as an

antipsychotic.

Q. I only have to prove that my drug meets standards of safety and is more effective than the sugar pill?

A. You have to prove that your drug is effective, which ordinarily means that it's better than a -- than a sugar pill. And then you have to prove that it's safe, which means that the benefits of the drug outweigh whatever risks the drug entails.

Q. So to get down the brass tacks in the case of Risperdal, would it be true to say that it was not incumbent upon Janssen to show that Risperdal was superior to Haldol or any of the other drugs on the market as of the time it was going through the approval process?

A. That's correct, in order to get approved.

Q. Now, let me ask you something. You've talked about indications. Are there -- does the approval process have anything to do with what kinds of patients a drug can be used in?

A. Yes.

Q. Are these what the FDA will approve the drug to be used in?

A. What groups the FDA will approve the drug to be used in, yes.

Q. If my drug is approved for use in adults, does that mean it's also approved for use in children?

A. No.

Q. If I want to get approval to use my drug in children, what do I need to do as far as the FDA is concerned?

A. You would have to conduct clinical trials that prove that your drug is safe and effective for use in children for the indications that you are proposing.

Q. If I haven't done that but meanwhile I am promoting my drug for use in children, is that something I can legally do?

A. That would be an example of off-label promotion. That's illegal.

Q. If -- now, I understand from prior testimony in this case that a physician can prescribe a drug off label if in his or her judgment that's the appropriate thing to do in a particular case; is that true?

A. That's correct.

Q. As someone who's served in the FDA and in industry, are you aware of some of the policies underlying these laws?

A. Yes.

Q. And what's the policy reason why it's okay for a doctor to write a prescription for a drug that's off

label but it's not permissible for me, the drug company, to go promote or to sell the drug to the doctor for an off-label use or use in an off-label patient population?

A. On the one hand, FDA does not regulate the practice of medicine and the Congress hasn't given FDA that authority. On the other hand, when it comes to drug companies promoting the drug off label, the policy is that -- to encourage studies to be conducted, to prove scientifically that the drug is safe and effective before the drug company affirmatively goes out and tries to sell it for that purpose.

Q. When you were at the FDA, you worked on a compound called Laetrile. Do I remember that right?

A. Yes. It was -- it was really just apricot pits that were being promoted as a bogus cancer cure.

Q. Can you imagine reasons why not being able to promote a substance off label is a good idea?

A. Yes, I can imagine such reasons.

Q. Now, you also, in addition to off-label promotion, said that promoting a drug through the use of false or misleading information is considered misbranding; is that true?

A. That's true.

Q. I want to ask you some questions about the approval process in this case. Did you have an

opportunity in the course of your work on this case to review documents -- FDA documents that addressed the kind of to and fro between the FDA and the company during the approval process about what could and couldn't be said in the labeling and in the promotional materials?

A. Yes.

MR. JACKS: Let me ask that Plaintiffs' Exhibit 61 be displayed, please.

Q. (BY MR. JACKS) Do you recall having reviewed a memorandum from a Dr. Paul Leber with the division of neuropharmacological drug products at the FDA about the approval and/or approval action memorandum concerning Risperdal?

A. Yes.

Q. And was that addressed to Dr. Robert Temple, the director of the office of drug evaluation?

A. Yes, it was.

Q. I'm going -- again, I'm not going to go through this entire document with you, but let me ask you to concentrate, if you would, please, on the -- let's say the first full paragraph, I think it is.

MR. JACKS: Yeah, I'm sorry, it is the second page, Mr. Barnes. Thank you. Let's pause here.

Q. (BY MR. JACKS) Do you recall having reviewed

this, Mr. Friede?

A. Yes.

Q. It begins by talking about what Janssen -- what Janssen insists. I'm not going to go through all that, but let me ask you to look at the sentence that begins, "The division has refused to accede to Janssen's demands because it believes that side-by-side presentation of data obtained on Risperdal and haloperidol assigned subjects invites a comparison that leads to the conclusion that Risperdal has been shown to be superior to haloperidol when, in fact, it has not."

Is the labeling of a product -- how is that usually arrived at between the company and the FDA?

A. Well, there's usually -- the company will usually submit its proposed labeling. There'll be some negotiation and discussion between the company and FDA about the approvability of the labeling as proposed by the company. And typically, there is a -- there is a --

THE COURT: You may just push it just a tad more away from you, a little bit more, a little bit more.

A. Typically, there's a --

Q. (BY MR. JACKS) It's a good thing you didn't pursue a career in broadcasting.

A. Yes, I didn't do that.

Q. All right. That's all right. You're doing fine.

A. Okay. So typically, there is some give-and-take between the company and the FDA over the specific contours of the final labeling.

Q. Okay. And at least at the time this was written, does it look as if they had come to an impasse?

A. Yes, they had come to an impasse about particular aspects of the labeling.

Q. Did Dr. Leber explain why the FDA itself was taking the view it was in his memorandum?

A. Yes. In the remainder of the memorandum, he explains his --

Q. Let's actually get the next paragraph up, and I think that might help the jury follow your testimony.

And for the record, let me read this. "In the division's view, none of the three studies that are a source of the data bearing on the two products is by design capable of adducing the kind and quality of evidence necessary to support a robust, externally valid conclusion about their relative benefits or risks."

And we'll get through this and I'm going to ask you some questions about it. Continuing, "The firm, although acknowledging the validity of the division's critique of the design of their three

investigations, will not alter its position. Janssen's view is that the haloperidol data, provided they are accompanied by a statement which warns they cannot serve as a basis for a valid comparison of the relative risks and benefits of Risperdal and haloperidol, may be presented without the risk of misleading prescribers. Negotiations, thus, are at an impasse, one that will not be overcome through further discussions."

Is this common or uncommon in your experience for things to break down to a point where an agreement about the label is impossible?

A. I would say it's relatively uncommon.

Q. And you've reviewed the approval letter in this case?

A. I have.

MR. JACKS: Plaintiffs' Exhibit 1, please, Mr. Barnes.

Q. (BY MR. JACKS) And do you recognize Plaintiffs' Exhibit 1 as the front page of the approval letter issued by the Food and Drug Administration with a date of December 29, and we know that's 1983, and received by the company January 4th of 1994?

A. Yes, December 29, 1993 approval letter.

Q. Oh, yeah. That's what I meant to say. Thank you, sir. We both need keepers.

MR. JACKS: If we could look at the last page, please, Mr. Barnes.

Q. (BY MR. JACKS) In the paragraph that begins "At the present time." And the jury has seen this before, but there are some things in it that I need to ask you about. "At the present time we would consider any advertisement or promotional labeling for Risperdal false, misleading or lacking fair balance under Sections 502(a) and 502(n) of the Act if there is presentation of data that conveys the impression that risperidone is superior to haloperidol or any other marketed antipsychotic drug product with regard to safety or effectiveness."

First question, before you began working on this case, had you ever seen that sort of language in an FDA approval letter?

A. I had not seen that specific kind of admonition in an FDA approval letter.

Q. Next question. When it says the Act, is that the Food, Drug and Cosmetic Act?

A. Yes.

Q. The one that goes back to 1938?

A. Yes.

Q. What's Section 502(a) about?

A. Section 502(a) has to do with labeling that's

false or misleading.

Q. Okay. And 502(n), is that --

A. 502(n) has to do with advertising that fails to include information in accordance with FDA's regulations.

Q. So let's look at 502(a). Tell me if this is right or not. Is the message here that the FDA is saying that Risperdal is misbranded if it is promoted through the use of presentation of data that conveys the impression that risperidone is superior to haloperidol or any other marketed antipsychotic drug with regard to safety or effectiveness?

A. Yes.

Q. That's what it boils down to?

A. Correct.

Q. Let's go, please, to Plaintiffs' Exhibit 2216. And this is -- is this a document you had reviewed, Mr. Friede?

A. Yes.

Q. It's from Mike Walsman. And from your review of materials in this case, do you know what position or what level of the company he was in?

A. Yes. He was head of the CNS sales force for Janssen.

Q. All right. Now, you said CNS sales force?

A. Right.

Q. And that's -- is that the sales force that was responsible for promoting Risperdal?

A. Yes. That was the sales force for central nervous system drugs that included Risperdal.

Q. All right. And does Mr. Walsman say to the CNS sales force, "It is very important when you are discussing Risperdal with a medical professional not to make any claims of superiority to Haldol or other neuroleptics."

First of all, is that consistent with the FDA's statement in the approval letter?

A. Yes, that statement would be consistent.

Q. And then does Mr. Walsman also proceed to say what the salesperson should do if a medical professional asks you how Risperdal compares to Haldol? Does he tell them how they should answer?

A. Yes.

Q. And the -- what they're permitted to say he says is: "Doctor, Haldol was included in Risperdal clinical trials as an internal reference, but the dose of Haldol was not optimized. Therefore, it would be inappropriate to compare Haldol to Risperdal."

So that was the official position?

A. That was the official Janssen position.

Q. All right.

MR. JACKS: Now, let me ask that Plaintiffs' Exhibit 62 be brought up, please.

Q. (BY MR. JACKS) This is a letter from the FDA to Ms. Ruth Wasserman, same person to whom the approval letter was addressed, I believe, and it relates to the -- what's called the introductory campaign. What's this letter about?

A. Well, in general, companies submit their proposed launch materials to FDA for review and comment before actually using them in the marketplace for a new drug.

Q. And when you say launch materials of the launch of a drug, it's its first entry to the market after being approved by the FDA?

A. Right, the inception of sales that I would refer to as the launch of the product.

Q. All right. Let me ask that we look at -- I think the bottom Bates number is 61, is the ending number. Okay. And do you see a section called "Comparisons to haloperidol"?

A. I do.

Q. And what's the first sentence say?

A. It says that all comparisons to haloperidol are unacceptable.

Q. All right. So the FDA's reiterating what it said a couple months before in the approval letter?

A. Correct.

Q. In the course of your work, did we ask you to review the evidence in this case to determine whether or not Janssen heeded the -- observed the prohibition of the FDA not to market Risperdal in a way that suggested it was safer or more effective than Haldol or any of the other drugs on the market?

A. Yes.

Q. I need to ask you about, how did you decide to go about making that determination in your own mind?

A. Well, you know, I -- in general, I looked at three categories of information: What was -- what were the companies' plans? Did it plan to communicate a superiority message to Haldol? How did the company train its people? Did it train them to make a superiority claim versus Haldol? And three, I looked at evidence about what actually took place in the field, a variety of evidence, to decide if in fact the company, through its representatives, communicated a message of superiority versus Haldol.

Q. Okay. And why did you feel it was important to look at these various levels as opposed to just, say, going through the call notes to look to see what people

were saying?

A. Well, for both legal and practical reasons, you look at what the company intended, the intended use, what they are going in objective for, and you see, well, did they -- did they try to execute those objectives by training their people in a way that was consistent with those objectives, and then did they implement that training through their behavior in the field. So you look at all of that, and then you compare that against the legal and regulatory standard, and you say, well, in the aggregate, did all of this -- how does all of this match up.

Q. All right.

MR. JACKS: Let's go, if we could, Mr. Barnes, to Plaintiffs' Exhibit 2.

Q. (BY MR. JACKS) And at the top of the first page, there is the caption "Risperdal (risperidone) Business Plan." Is this a document you reviewed?

A. Yes.

Q. And were you able to tell in what year this document was created?

A. This was created sometime in 1994, or late 1993 or 1994.

Q. Okay. At about the time the drug was coming onto the market or sometime soon thereafter?

A. Correct.

MR. JACKS: And if we could, Mr. Barnes, I want to focus our attention on the page ending in 986 on the Bates numbers at the bottom, please, sir.

Q. (BY MR. JACKS) And do you see, first, "Risperdal Strategy" there? And then do you see, number two, the word "Positioning"?

A. Yes.

Q. Now, in the years you were in the companies, you were in the legal department, I suppose.

A. Correct.

Q. Do all the drug companies have marketing departments?

A. They do.

Q. Is positioning -- does that sound to you more like a marketing term?

A. That's a marketing term.

Q. All right. I'm going to read some of this, and then I'll ask you about it. "Product positioning will support the aforementioned key strategic components. The positioning of Risperdal is:" And then there's a quotation. "Risperdal is the only first choice antipsychotic agent due to its efficacy for a broad range of symptoms, a safety and tolerability profile unmatched by any other antipsychotic, as a result of its

unique serotonin-dopamine antagonist mechanism."

Now, that's what they said; is that right?

A. Correct.

Q. When you see words like "the only first choice antipsychotic agent" or "a safety and tolerability profile unmatched by any other antipsychotic," as one who's advised pharmaceutical companies about this sort of thing, does this seem consistent or inconsistent with what the FDA was telling them they couldn't do?

A. Well, it's inconsistent with the admonition not to make comparisons to haloperidol or any other antipsychotic drug.

Q. Let me read the last sentence. "Medical education and promotion programs planned for 1994-1995 are designed to support these two platforms."

What are -- let's talk about medical education programs. Are they about education or are they about promotion or sometimes both?

A. Well, they can be about education, but they can also be utilized as a vehicle for affirmatively promoting a drug.

Q. And you said you also looked at sales training materials; is that right?

A. That's correct.

MR. JACKS: Let me ask that Plaintiffs'

Exhibit 1671 be brought up, please.

Q. (BY MR. JACKS) Is Plaintiffs' Exhibit 1671 entitled "The Risperdal Learning Program Module VI, Selling Considerations, Lesson 1, The Competition" an example of training materials you reviewed?

A. Yes.

Q. And were you able to determine in about what year this was created?

A. This was created sometime in 2004.

Q. I think you're doing the same -- you've been hanging around me just a little bit and already you're saying 2000, but I think you mean 19.

A. 1994. I apologize.

Q. That's all right. At our age, we've got to stick together on these things.

MR. JACKS: Let me ask you to turn to Page 251 and 252. Let's begin with 251 as the ending Bates numbers, please, Mr. Barnes.

Q. (BY MR. JACKS) And at the top of the page, do you see "Risperdal Versus Conventional Antipsychotics"?

A. That's correct.

Q. And then what's the next heading below that?

A. The "Disadvantages of Conventional Antipsychotics."

Q. And the -- what's the first -- the first

disadvantage of conventional antipsychotics -- and by the way, conventional antipsychotics includes drugs like Haldol, true?

A. That's my understanding.

Q. And so the first disadvantage that's listed is "Dopamine antagonists have little or no effect on negative symptoms of schizophrenia." Do you see that?

A. I see that.

Q. And the next one below that refers to extrapyramidal -- I have to go this -- through this one slowly. "Extrapyramidal" symptoms -- or "reactions." So another disadvantage of the conventionals is they say, "Extrapyramidal reactions are common, especially with higher potency agents and higher doses of drug."

Now, if we may go down near the bottom, do you see the "Intolerance of side effects of conventional antipsychotics can prevent use of therapeutically effective doses of the drug"? So this is about disadvantages.

MR. JACKS: May we go to the next page, please, Mr. Barnes?

Q. (BY MR. JACKS) And what do we see is the heading at the top of the -- this paragraph?

A. "Advantages of Risperdal."

Q. So in the sales training manual, the

salespeople, in the module about selling considerations and the competition, are being coached on the disadvantages of drugs like Haldol versus the advantages of drugs like Risperdal. "Risperdal treats both positive and negative symptoms of schizophrenia," they say. And then the next one below that, "Risperdal is associated with a low incidence of EPS."

Now if -- question: If the sales force being thus trained were then to go out and promote Risperdal as having the advantages of treating both positive and negative symptoms where drugs like Haldol don't and the advantage of low EPS where drugs like Haldol have a higher incidence, would that be consistent or inconsistent with the FDA's statement in the approval letter that we saw just a minute ago?

A. That would be inconsistent with FDA's statement.

Q. Let me move forward to Plaintiffs' Exhibit 396. Is this a document you reviewed, Mr. Friede?

A. Yes.

Q. It's entitled a "Sales Training Update." And I guess that speaks for itself. It's about sales training, true?

A. Correct.

Q. And among the sales forces is the CNS sales

force. And it's addressed to the Risperdal sales force in particular from sales training dated September 27, 1996 on the subject of "Risperdal training tips #2 - key selling points." You with me?

A. Yes.

MR. JACKS: Now, if you would, Mr. Barnes, let's go to the first Page 966 in the Bates range.

Q. (BY MR. JACKS) And do you see a heading called "Selling Points"?

A. Yes.

Q. And under the heading of "Efficacy," they say "Superior efficacy in positive and negative symptoms." So it's not the negative alone just now; it's also the positive. That's what they're telling them, right?

A. Correct.

Q. And then they talk to them about cost-effectiveness and how Risperdal has a net positive impact on systems cost, may cost more by the dose but saves money on the system. Is that what this seems to be about?

A. Yes.

MR. JACKS: May we go to the next page, please.

Q. (BY MR. JACKS) Do you see the key messages?

A. Yes.

Q. And for "Efficacy," the key message appears to be "Risperdal positive and negative symptoms," and then there's the little greater than sign or better than sign, "Haldol." Is -- is that correct?

A. That's correct.

MR. JACKS: Now, let's go back to the first page, Mr. Barnes, if we could, please, and the first paragraph.

Q. (BY MR. JACKS) The -- do you see the sentence that begins -- well, the first sentence says, "This is the second newsletter you will receive in a series dedicated to building and sharpening your Risperdal selling skills. The focus of this newsletter is to provide you with key selling objectives, strategies and points that should be the basis of every Risperdal sales call." And then the first selling objective is to establish Risperdal as the first-line antipsychotic.

Now, if training the sales force to this effect, does that appear to you to be consistent or inconsistent with the FDA's prohibition concerning false and misleading promotion?

A. That would be inconsistent.

MR. JACKS: Let me -- let -- Mr. Barnes, can you bring up -- there's something at the top of the page, very top of the page there on this day.

Q. (BY MR. JACKS) "For your information, not to be used in a selling situation." Now, is that consistent or inconsistent with what they just told them in the first paragraph?

A. That's inconsistent with what they told them in the first paragraph.

MR. JACKS: Let's go to the next page, Mr. Barnes, down at the bottom of it this time.

Q. (BY MR. JACKS) What does that look like to you, Mr. Friede?

A. It looks like what it is, which is a rubber stamp where the ink has not been completely inked on the page.

Q. Let's go to the last -- the fourth page of this document, bottom left corner.

A. Again, that appears to be the incomplete rubber stamping of the -- of that particular page.

Q. You've been in this industry a long time, Mr. Friede. You've seen practices of this sort before?

A. I have.

Q. What's going on here? On the one hand, they're telling them to use this in every selling situation, and on the other hand, they've got this stamp saying not to be used in a selling situation.

A. Well, it's -- it's basically a pro forma kind

of thing to try to provide some cover should there be questions raised later on.

Q. Let me go, if we may -- I wanted to ask you some questions about some call notes that are part of Plaintiffs' Exhibit 149. And I -- the date of this last sales training was in 1996; is that correct?

A. As I recall.

Q. The one we just looked at.

A. Yes, as I recall.

Q. All right. Now, let me ask you something about these call notes. You said you'd looked at thousands of call notes over the time you've worked on this case. Now, did you ever undertake a statistical analysis of the call notes to see how the call notes that contain off-label messages compared with the call notes that didn't and what percentage this was of that and the other? Did you do that?

A. No.

Q. I think you've already explained this, but let me be sure we're all clear about it. What was significant to you about looking to see what was going on with the call notes after having first looked at the training materials and the business plan?

A. You're basically trying to evaluate whether the behavior in the field was or was not consistent with

both the business plan and the training provided to the field. So looking at some call notes is one way of doing that. There are other ways of evaluating that as well.

Q. Now, is this an example of a -- one form of a call note that you -- that you've seen?

A. Yes.

Q. And what -- for those of us who've never worked in this industry, what is a call note in this context?

A. Well, a call note basically -- and it had different shapes and forms at various times depending on the company, but it provides a mechanism for the sales representative to provide some kind of limited report about the actual encounter between the representative and the doctor.

Q. All right. And from your review of the -- you said you've read the testimony of a number of the sales representatives and managers for that matter in this case. From your review of those materials, was it a requirement of the company that sales personnel complete call notes relatively soon after each call?

A. Yes.

Q. And that they do their best to record accurately the encounter with the physician or the customer?

A. Yes.

Q. And did you -- well, let's go to this call note, and I'm not going to go through the whole form because it's got a lot of boxes on it, but there's one box where the representative can enter information.

MR. JACKS: If you can go down, Mr. Barnes, I'm actually looking at the next box down. Yes, sir.

Q. (BY MR. JACKS) And so the -- this information would be an example of a field available on a call note; is that right?

A. That's correct.

Q. Okay. And the -- I want to go through some of these with you. And what I'm going to do -- I'm going to go through some of these with you. And in the interest of time, I'm going to concentrate on the -- what I'll call the -- the summary field, and then I'm going to ask you some questions.

THE COURT: We'll do that when we return in ten minutes. Thank you.

MR. JACKS: Thank you.

(Recess taken)

(Jury present)

THE COURT: Be seated.

Q. (BY MR. JACKS) Mr. Friede, we introduced

earlier and you and I referred to Exhibits 2223, 148 and 149. And I believe you said you had reviewed the call notes contained in those exhibits; is that correct, sir?

A. Yes.

Q. And I didn't make -- I didn't ask you this question, but I will now. Were all of those call notes Texas calls, calls on Texas physicians?

A. Yes, as far as I recall.

Q. Then next question: Are -- are you used -- are you familiar with the term detail or detailing or detailed as it relates to pharmaceutical sales representatives?

A. Yes.

Q. And what was -- when a -- have you heard in fact sales representatives called detail person?

A. Yes.

Q. What does detail mean in your world?

A. Well, it originated when -- just to describe the fact that sales representatives would provide doctors with the details about a particular drug they were selling. So the verb is detailing and then they became detail men.

Q. And women?

A. And women. Detail persons.

Q. Let me ask -- we're going to go through -- as I

mentioned before the break, I'm going to ask with Mr. Barnes' help, some -- that some of the call notes from Exhibit 149, which is this stack, be displayed. And for what I think will be obvious reasons, we're not going to go through all of them. And I'm going to concentrate on the message portion, first from Page 54 of the exhibit, and I'm going to focus only on the part that pertains to our subject matter right here.

And so detailed efficacy number one: Only SDA superior in positive and negative symptoms versus Haldol.

All right. Next one, Page 55. And this, by the way -- the first one was dated October 8th, 1996 on Page 54, this one dated January 20, 1997. Detailed only one to prove more effective than Haldol in positive and negative symptoms.

The next one, Page 56, the date is May 15th, 1997. Effectiveness in positive/negative, p/n, symptoms relief, benefits over Haldol.

Next one dated October 2, 1997, Page 57. Positive/negative symptoms associated with schizophrenia effectiveness of Risperdal in those areas how we differ from conventional.

Next one, Page 68, this one dated July 9, 1998. Discussed the Risperdal core message, low EPS,

proper dosing to minimize EPS, weight gain, and efficacy versus Haldol in positive symptoms.

Next one Page 77, date October 13th, 1998. Elder care sales message, Risperdal for geriatric patients, explained Ris, Risperdal, only med superior to Haldol 4 positive/negative symptoms.

Now, question: First, we viewed the 1996 sales training materials. Do you recall that?

A. Yes.

Q. Do you recall the key message that was displayed there?

A. Yes.

Q. Do or do not the messages I just read into the record appear to be consistent with the training?

A. Yes, they are consistent with the training that was provided.

Q. Next question: As with the training materials, do these messages seem to be consistent or inconsistent with the FDA statement in the approval letter and beyond that comparisons to Haldol in terms of safety and effectiveness would be deemed false and misleading?

A. They're inconsistent with FDA's admonition.

Q. Now, I don't want to -- I'm going to ask if you remember this rather than go back and look at it, but do you remember that the approval letter said at the

present time we would consider comparisons to Haldol be false and misleading? Do you remember that part?

A. Yes.

Q. Now, we're up to -- this last call note was in October of 1998. And I want to look at a document next and ask whether the FDA altered its position in that time.

MR. JACKS: Can you bring up Plaintiffs' Exhibit 70, please?

Q. (BY MR. JACKS) Is Exhibit 70 a document that you've reviewed, Mr. Friede?

A. Yes.

Q. And it bears a date up in the right-hand corner of January 5th, I believe, 1999, and it's addressed to the director of regulatory affairs at the Janssen Research Foundation. And I'm going to ask you about something on another page, but before I do, the -- is -- what sort of letter is this letter in FDA parlance?

A. This is what would be called a notice of violation that is issued by the division of drug marketing, advertising and communications, which is the constituent part of FDA responsible for reviewing pharmaceutical advertising and promotional material.

Q. All right. And we can see from the middle of the paragraph down through the next several lines that

this part of the FDA has reviewed certain materials, sales aids and ads and so forth submitted by Janssen; is that correct?

A. That's correct.

Q. And just to read the last bit, "Has concluded that these materials are false and misleading and/or lacking in fair balance and in violation of the Food, Drug and Cosmetic Act and the regulations promulgated thereunder." So that's what this letter is about, correct?

A. Correct.

MR. JACKS: Let me ask you, Mr. Barnes, if you would, please, to move to Page 4.

Q. (BY MR. JACKS) And do you see a heading called "Comparative Claims"?

A. Yes.

Q. So this is the FDA speaking in this notice of violation letter in 1999. "Materials that state or imply that Risperdal has superior safety or efficacy to other antipsychotics due to its receptor antagonist profile are false or misleading because the mechanism of action of Risperdal is unknown, as is the correlation of the specific receptor antagonism to the clinical effectiveness and safety of the drug."

Now, then, do you recall back in the 1994

business plan there was mention of the unique serotonin dopamine antagonist mechanism?

A. Yes.

Q. And I think in one of the call notes we just reviewed, the one on Page 54, it said detailed efficacy, number one, only SDA -- that's serotonin-dopamine antagonist -- superior positive and negative systems versus Haldol.

Now, question: Going back to the notice of violation letter from January of 1999, does it appear to you that the FDA still maintains the same position or has changed its position concerning comparisons with other antipsychotics in terms of Risperdal being superior in safety and efficacy?

A. Well, it's consistent with the FDA's earlier admonition and -- it's consistent with FDA's earlier admonition.

Q. So the FDA still takes the view that comparisons to haloperidol and other antipsychotic drugs in terms of superiority and safety or effectiveness still would be false and misleading?

A. Whether based on mechanism of action or for any other reason.

MR. JACKS: Let's go, please, Mr. Barnes, to -- back to some of the call notes that were made in

the few months after this January 1999 letter was received by the director of regulatory affairs at Janssen.

Q. (BY MR. JACKS) First looking at the call note the next month, February 23 of 1999 from a Janssen sales representative in Texas. And as before, I'm going to read the relevant part. Elder care Risperdal versus Haldol dosing, explained safer more effective than Haldol.

Next page, 82, March 5, 1999. Risperdal core message, efficacy/safety/dosing, left PI. That's package insert info; is that right?

A. Correct.

Q. Better/safer than Haldol.

Next, Page 83, March 26th, 1999. Discussed Risperdal over Haldol, safety and effectiveness, DC patient on Haldol and Rx, prescribed Risperdal oral solution one milligram while I was there.

Next, Page 84, this one dated April 16, 1999. Full Risperdal versus Haldol, efficacy and EPS.

Next, May 11, 1999. About 20 patients at Ashford Hall, sell against Haldol for efficacy and safety.

Next, June '99, June 2, '99. Very interactive today, says he uses more Haldol and what are

advantages of Risperdal versus Haldol, went over safety and efficacy, keep hammering on this point.

Next, and I'll end with this one, Page 89, December 12, 2001. Risperdal, reminded safer than Haldol, but still superior efficacy.

Now, Mr. Friede, question: One, does it appear that these messages are consistent with ones conveyed in the sales training materials we reviewed earlier?

A. Yes.

Q. Next, does it appear that these messages are consistent or inconsistent with the FDA's statements in the approval letter, the 19 -- February 1994 letter saying all comparisons to Haldol are unacceptable, and the 1999 letter that we just looked at, the notice of violation letter?

A. These are inconsistent with those admonitions.

Q. When you stack up the business plan, training materials, call notes we've reviewed, tell me, fair or not to describe this as off-label marketing?

A. I would describe it as false or misleading of a promotion.

Q. All right. And does that amount to misbranding?

A. It does.

Q. Is that a violation of federal law?
A. It is.
MR. JACKS: Let me next pull up Exhibit 82, please.
Q. (BY MR. JACKS) Is Exhibit 82 a document you reviewed before, sir?
A. Yes.
Q. And the date on this one -- I'm not sure if it's on the first page. Sometimes on these you have to go to the very back of the letter, but I believe this is January 11th, 2002. Does that fit with your recollection, sir?
A. Yes. I believe there's a date on the very last page, an electronic date.
Q. All right. And let me ask that we look at -- tell me first, do you remember this document well enough to describe what it's generally about?
A. Yes.
Q. What is it?
A. This had to do with a supplemental application that Janssen had submitted to include certain information in the labeling for Risperdal.
Q. Okay. Now, we've got a thing going on here that I think you can be heard, but when you stare at the screen, I'm not certain whether everyone can hear you,

so just a word to the wise there. But bottom of the page, let me pull up some language. So now you said this was a supplemental application. And so the application that got the drug on the market was the first application, and this is the supplemental application?

A. Correct.

Q. And they're seeking a change in their label or package insert?

A. Correct.

Q. And the -- and -- and do you understand from your review of the materials what it was that made Janssen want to get a change in their label?

A. Yes.

Q. What was it?

A. They had the results of a -- of a study in hand that they thought supported a -- some modification of the labeling to include a specific comparison to -- to Haldol, to haloperidol.

Q. Okay. And do you remember what that study was called?

A. That was called the Csernansky study.

Q. Now, the FDA talking: "We have replaced specific mention of the drug haloperidol with the term 'active comparator' since we did not review study 79

from the standpoint of comparative claim, but rather as a study solely to establish the longer-term efficacy of risperidone. It is an adequate trial from that narrow standpoint, but not as a basis for a comparative claim, nor would one such study be sufficient, even if it were judged adequate for evaluating" -- "for evaluating a comparative claim."

So bottom line, did the FDA allow Janssen to compare its drug Risperdal with Haldol, specifically as a result of this submission?

A. No.

Q. The -- let me go next to a sales training document, Exhibit 127. And is this one of the materials you reviewed?

A. Yes.

Q. It's obvious from the title that it pertains to sales training for the CNS sales force.

MR. JACKS: May we go, Mr. Barnes, to the page ending in 510 in this document? Let's see. That's where we are.

Q. (BY MR. JACKS) Do you see this table contained in the sales training materials?

A. Yes.

Q. And it's referring to the efficacy or the effectiveness of atypical antipsychotics. And which is

the first one listed?

A. Risperdal.

Q. And going across, what is said about Risperdal in terms of its effectiveness as compared to Haldol?

A. Well, they're training the sales team that Risperdal is superior to Haldol on both the positive and the negative symptoms of schizophrenia.

Q. All right. Now, have you reviewed some of the Texas call notes that -- from 2002, 2003 following the FDA's letter we just looked at and in some cases following this sales training?

MR. JACKS: And let me ask that Exhibit 149, Page 108 be brought up, July 3rd, 2002.

Q. (BY MR. JACKS) And these are some in which it's difficult to get everything on the screen. So with the agreement of counsel, we've listed the exact wording out of the little box, because otherwise, you couldn't read it on the screen. And the parts that -- highlighting didn't work well on these slides, so we put in red ink the parts to which we'll give attention.

First, Discussed the Csernansky with him, long-term treatment with Risperdal for schizo/shiz pat. versus Haldol. Risperdal has better efficacy, fewer side effects and keeps patient from having a break more so than Haldol. He said great and left.

The next one, which I believe will be -- now, this was Plaintiffs' Demonstrative Exhibit 201. The next, Plaintiffs' Demonstrative Exhibit 202, which corresponds to Page 109 in Exhibit 149. And again, "Showed Csernansky" --

THE COURT: Excuse me a second. May I see counsel over here?

(Discussion off the record)

Q. (BY MR. JACKS) Mr. Friede, to make our record clear, what we're seeing now are -- is the exact language lifted from the message field on Texas call notes to Texas physicians contained in Plaintiffs' Exhibit 149; is that correct?

A. That's my understanding, yes.

Q. And the first one we look at was, for the record, Plaintiffs' Demonstrative Exhibit 201. We call it a demonstrative exhibit when it's not the call note itself. And that represented Page 108 of the Plaintiffs' Exhibit 149. And then the next one we looked at is Plaintiffs' Demonstrative Exhibit 202 from Page 109 of the same exhibit, 149.

And on this one, the highlighted part reads Risperdal discussed benefits versus Haldol.

Next one, Plaintiffs' Demonstrative Exhibit 203 from Page 110. Discussed benefits of

Risperdal versus conventionals like Haldol.

Plaintiffs' Demonstrative Exhibit 204. And this corresponds -- is that -- the page number I believe is -- is it 16?

MR. JASON: Yes, sir.

MR. JACKS: Thank you.

Q. Discussed the Csernansky with him, long-term treatment with Risperdal for schizo/shiz patient versus Haldol. Risperdal has better efficacy, fewer side effects and keeps patient from having a break -- we've already done that one -- more so -- I apologize.

Plaintiffs' Demonstrative 205 from Page 237.

MR. JONES: We've already done that one too.

MR. JACKS: Okay. Well, good heavens. Then let me try to make sure I've got one that we haven't seen.

Q. (BY MR. JACKS) Plaintiffs' Exhibit 149 from Page 246, Demonstrative Exhibit 206. Discussed symptom control leveraging -- I'm going to start that over. Discussed symptom control leveraging Csernansky and Risperdal's relapse rate versus Haldol.

Now, question: First, is -- are these messages consistent or inconsistent with the FDA's

determination in the 2002 letter that the company Janssen would not be permitted to mention Haldol or make direct comparisons to Haldol in its label but could only describe an active comparison? Consistent or inconsistent?

A. Inconsistent.

Q. Now, would that be false and misleading? Would it be off label? What would it be in regulatory terms?

A. FDA would regard that as false or misleading.

Q. All right.

MR. JACKS: Thank you, Mr. Barnes.

Q. (BY MR. JACKS) Let me move to a different subject with you, Mr. Friede. From your review, are you aware that there came a time in 2003 when the federal Food and Drug Administration required all manufacturers of the newer class of drugs, the atypical antipsychotics, to put new warning information in their package inserts or their label concerning issues of weight gain and diabetes?

A. Yes.

MR. JACKS: And if I may have Exhibit 2168 brought up, please.

Q. (BY MR. JACKS) Is this the letter by which the FDA informed Janssen in particular that this label change would be required in term -- in the drug

Risperdal?

A. Yes.

Q. And did the FDA state in general terms in this letter why these changes were being required for Risperdal and the other manufacturers of the newer generation products?

A. Yes.

Q. And without going through this in excruciating detail, did they generally say that it was for safety reasons?

A. Yes.

Q. Did they say that in the second paragraph, "We believe the safe use of Risperdal can be enhanced by informing prescribers and patients about these events"? Actually, that's in the third paragraph. I apologize.

A. Yes.

Q. And in the paragraph after that, did they say that they were requesting the changes to furnish adequate information for the safe and effective use of the drug?

A. Yes.

Q. Now, did this company, Janssen, take any action after receiving that letter from the FDA? Did the company do anything in response to being told it was going to have to put these changes in its label?

A. Yes.

Q. Let me bring up Plaintiffs' Exhibit 98, please, sir. Is Plaintiffs' Exhibit 98 a document you reviewed, Mr. Friede?

A. Yes, it is.

Q. And it's dated November 10, 2003?

A. It is.

Q. And it's addressed "Dear Healthcare Provider"; is that right?

A. That's correct.

Q. And in the first sentence, they point out that the FDA "has requested all manufacturers of atypical antipsychotics to include a warning regarding hyperglycemia and diabetes mellitus in their product labeling." Did I read that right first?

A. Yes, you did.

Q. Okay. Now, was this a request or was this a requirement, as a practical matter?

A. As a practical matter, it was a requirement that if the manufacturer didn't accede to, they would withdraw the approved application.

Q. Okay. Now, the -- and they go on to say further in this letter that they are attaching updated prescribing information for Risperdal or risperidone; is that correct?

A. Yes.

Q. Okay. And in fact, was there attached to the letter, as you understand it, a copy of the new package insert with the new information contained in it?

A. Yes, it's my understanding that there was.

Q. All right. Now, we're going to see some language from this letter in the next exhibit, so I'm not going to go through it twice, but let me ask you this question. Are you familiar with "Dear Doctor" letters or "Dear Healthcare Provider" letters?

A. Yes.

Q. From your review of the information in this case, were you aware that this letter was sent to physicians and pharmacists throughout the country?

A. Yes. It's my understanding that it was sent to about 700,000 healthcare providers.

Q. All right. And are you also aware from your review of the evidence in this case that it was sent to some 18,000 Medicare providers in Texas?

A. Yes.

Q. Now, it's been pointed out to me that I said Medicare instead of Medicaid. These were to Medicaid providers, were they not?

A. That's correct.

Q. All right. Now, have you advised clients in

situations where the FDA has requested a labeling change and the client wants to send out a "Dear Healthcare Provider" or a "Dear Doctor" letter?

A. Yes.

Q. Have you given them advice about whether they -- it might be a good idea to run that by the FDA first or not?

A. Yes. Depending on the circumstances, it may well be a good idea.

Q. What about these circumstances?

A. Well, if FDA is specifically mandating a change in labeling, and particularly given the nature of this particular letter which was talked about I think, then it would have made a lot of sense for them to get FDA's review and clearance before sending this particular letter.

Q. Did --

MR. JACKS: Let's show Exhibit 939, please, Plaintiffs' Exhibit 939.

Q. (BY MR. JACKS) Is this among the materials you reviewed in this case, Mr. Friede?

A. Yes. Could I see the second page, please?

Q. Yes.

A. Yes, I've seen this -- this particular document.

Q. All right. And is this a document that was sent -- a letter sent to Janssen from the FDA?

A. Yes. This letter went to Janssen shortly after Janssen disseminated its November 10, 2003 letter.

Q. Shortly after?

A. Shortly after.

Q. So Janssen had already sent its letter before getting this letter?

A. Correct.

Q. And this letter to the FDA is saying that they think the safe use of Risperdal drug products can be enhanced by informing prescribers and patients of the addition of the hyperglycemia and diabetes mellitus labeling information under warnings and requests you issue a letter communicating this important information, i.e., a "Dear Healthcare Professional" letter. So the FDA says please do this, and Janssen's already done it?

A. It appears that Janssen preempted FDA's direction to do so.

Q. Now, let's go, please, to Plaintiffs' Exhibit 138. You've reviewed this letter?

A. Yes, I have.

Q. And I don't have to ask you what kind of letter it is because it says it's a warning letter; is that right?

A. That's correct.

Q. Now, earlier we talked about the January 1999 letter as a notice of violation letter, and this one's a warning letter. What's the difference?

A. Well, in FDA's hierarchy of enforcement activities, a warning letter is a much more stringent kind of a notification from FDA than a mere notice of violation.

Q. All right. Now, the -- this letter was sent, I believe, in April of 2004; is that your understanding?

A. Sometime thereabouts, yes.

Q. All right. It'll have a date, but they always -- did they do this when you were at the FDA, they put the date on the back of the -- on the last page of the letter?

A. The reason they do that is because, given the multiple internal reviews, including supervisory reviews that go into this letter, it's often not certain what the exact date of the issuance would be, so that by putting them on the last page, they don't have to necessarily change the text of the letter so that it facilitates the internal review process.

Q. Okay. I'm not sure I'm buying that, but I'll take your -- don't have a choice, do we?

All right. Plaintiffs' Exhibit 138, let's

look at the first paragraph, please. I'm not going to read all this, but I'm going to read part of it. Again, this is the division of drug marketing, advertising and communications. And they say they've reviewed the "Dear Healthcare Professional" letter of November 10, 2003 and they say that they've concluded that the "Dear Healthcare Provider" letter is false or misleading in violations of Sections 502(a) and 201(n) of the Federal Statute --

A. Correct.

Q. -- is that right? Now, 502(a) we've seen before because that was in the approval letter; is that right?

A. Yes.

Q. And that's the -- tell us again what that one's about.

A. That has to do with labeling that is false or misleading in any particular.

Q. And what about 201(n)? What's that section about?

A. 201(n) is a very important section of the law because it says that -- that something can be false and misleading not only because of what you say, but also because of what you fail to say. And so it's a key concept in food and drug law that something can be

misleading -- both affirmatively misleading and misleading because it fails to tell you important information, important information about the drug or the consequences of using the drug.

Q. All right. Now, there is a long sentence here. It says -- first of all, they talk about failing to disclose. Is that what Section 201(n) is about?

A. Yes.

Q. Failing to disclose the addition of information relating to hyperglycemia and diabetes mellitus to the approved product labeling package insert. So the first thing -- tell me if I'm right about this -- that the FDA is saying is false and misleading is not providing in the letter back in November sufficient information about the addition of this new warning --

A. Correct.

Q. -- is that right?

A. Correct.

Q. The next one starts off, "Minimizes the risk of hyperglycemia-related adverse events, which in extreme cases is associated with serious adverse events including ketoacidosis, hyperosmolar coma and death." Stop there. So that's the second thing that they're saying is false and misleading?

A. Correct.

Q. Okay. Next, "Fails to recommend regular glucose control monitoring to identify diabetes mellitus as soon as possible." Now, is that something that the new warning advised doctors they needed to do?

A. Yes. The need for regular monitoring to identify these patients who were at risk, that was a key reason for the new warning requirement.

Q. All right. Next, "And misleadingly claims that Risperdal is safer than other atypical antipsychotics." Have I got that one right?

A. Correct.

Q. Now, the -- there were statements made I think on the first day of this trial in court that with respect to comparisons to other atypical antipsychotics, that Janssen really had gotten it right because three years later the FDA made another manufacturer put a more stringent warning in its label that Janssen didn't have to put in. Are you familiar with that change of events in general terms?

A. Yes.

Q. Okay. Now, is that the only aspect of Janssen's "Dear Healthcare Professional" letter that the FDA found to be false and misleading, the comparison to other atypicals?

A. No. There were -- as we've just discussed,

there were three additional areas of concern. And even with respect to the comparison, there was a concern that went beyond the comparison to the specific drug you were talking about.

MR. JACKS: Now, can we go to the next page of this exhibit, please?

Q. (BY MR. JACKS) All right. And the -- there's mention on this page that I think the -- the language that the FDA required manufacturers to add was in a section called the warnings section; is that right?

A. That's correct.

Q. The warnings section of the package insert?

A. That's correct.

Q. Now, we've been talking about package inserts, and I assume in your years in the industry, you know what package inserts are and you've seen them before.

A. Yes.

Q. In fact, those of us who go to the pharmacy and get certain kinds of medicines, we get them ourselves, too.

A. Precisely.

Q. Now, this is one for Risperdal. And so that's what a package insert's all about, right?

A. Correct.

Q. Now, the warnings section, where had -- had

there been mention of diabetes before 2003 in the labels concerning Risperdal?

A. There had been.

Q. Now, actually I need to ask you a question. Have you yourself reviewed package insert or labeling information about Risperdal over a period of years?

A. I have.

Q. And are those -- did you review something in what's called the *Physician's Desk Reference*?

A. I reviewed the package inserts as they appeared for a number of years in a compendium called the *Physician's Desk Reference*.

Q. Okay. And I believe that there are some exhibits in evidence about that, but for now let's move on.

What section of the package insert were they in before 2003?

A. They were in a section of the package insert called the adverse reactions section.

Q. All right. How is that different from the warnings section?

A. Well, you know, in the hierarchy of information that FDA wants doctors to know about and in the manner in which the information is actually presented in the package insert, the warnings are the more significant

component of the labeling than are the adverse reactions.

Q. All right.

MR. JACKS: Now, let's go down to the next paragraph of this page if we may. And actually, let's bring up the next one, too, please, Mr. Barnes, so we can see it better.

Q. (BY MR. JACKS) Now, this is the language that the FDA required the manufacturers to put in their package inserts; is that true?

A. That's correct.

Q. All right. And the -- the second paragraph pertains to monitoring patients regularly for the worsening of glucose control; is that right, sir?

A. That's correct. It refers to the various categories of patients and the need for monitoring in those various categories.

Q. And for patients who have risk factors for diabetes, such as obesity -- that's like people that gain a lot of weight and so forth -- the advice is that they should undergo fasting and blood glucose testing at the beginning of treatment and periodically during treatment. And they go on to talk about monitoring in more detail in the subsequent parts of what the FDA wanted doctors to be warned about?

A. Precisely. The agency wanted doctors to be -- keep very close track of these patients for signs of weight gain or -- and diabetes.

Q. Now, if we go to the next page, I believe, at the next page of the letter at the top, is there a section called "Omission of material information"?

A. Yes.

Q. And this is talking about the "Dear Healthcare Provider" letter, and it says that Janssen's letter didn't communicate the fact that -- the potential consequences of diabetes and hyperglycemia or the recommendation of glucose control monitoring for Risperdal. Is that one of the things that the FDA is saying they found to be false and misleading about Janssen's letter?

A. Right, and one of the material omissions from Janssen's letter.

Q. Now, Janssen's letter, did it set out the language that the FDA required so that doctors could look at the very first page of the letter and see what the recommendations were about glucose control monitoring in all these types of patients?

A. No.

Q. Instead, they attached the label or the package insert?

A. They did attach the package insert.

Q. And the next sentence says, "Instead, as discussed below, the letter," Janssen's letter, "minimizes risks associated with Risperdal and claims that Risperdal is safer than other atypical antipsychotics, when this has not been demonstrated by substantial evidence or substantial clinical experience," right?

A. Correct.

Q. Let's go to the next paragraph that they're talking about, the one entitled "Minimization of Risks/Misleading Comparative Claim." Okay. Now, here, they're quoting from Janssen's letter, right?

A. Correct.

Q. And so they say Janssen's letter says "hyperglycemia-related adverse events have infrequently been reported in patients receiving Risperdal." That's the first thing they say?

A. That's what Janssen said in its letter.

Q. All right. Now, I'm going to need to ask you about the next couple of sentences. "Although confirmatory research is still needed, a body of evidence from published peer-reviewed epidemiology research," and then there's eight footnotes there, "suggests that" Janssen -- "that Risperdal is not

associated with an increased risk of diabetes when compared to untreated patients or patients treated with conventional antipsychotics."

Now, let's go down to what the FDA says about that. "This statement suggests that Risperdal does not increase the risk of diabetes, contradicting the warning in the revised package insert and minimizing the risks associated with the drug including hyperglycemia-related adverse events such as ketoacidosis, hyperosmolar coma and death, and minimizing the importance of blood glucose control monitoring."

Now, is that statement by the FDA yet another reason why the FDA found this to be false and misleading communication to all these physicians?

A. Yes. FDA's explaining the reason why it concluded in part that the "Dear Healthcare Provider" letter itself was false and misleading.

Q. Next paragraph, the FDA now is talking about the references cited in Janssen's letter. That's -- remember the footnotes one through eight? Is that what they're talking about?

A. Precisely.

Q. The FDA says that those references "do not represent the weight of the pertinent scientific"

evidence. "That evidence, as explained above, indicates an increased risk of hyperglycemia-related adverse events and diabetes with Risperdal."

So do you, as someone who's been involved in the regulatory business on both sides, the FDA side and the industry side, understand this to be yet another reason why the FDA says this letter is false and misleading?

A. Why the Janssen letter is false and misleading, yes.

Q. Thank you. Next they say, "In addition, this statement does not accurately describe the results of the cited studies. Two of the studies actually show an increased risk of diabetes and hyperglycemia with Risperdal."

So if -- I'm not going to ask you whether the FDA is right about that or not because you haven't read these studies and you're not a doctor. But if in fact it's the case that two of the studies that Janssen referenced actually show an increased risk of diabetes and hyperglycemia with Risperdal, the only way a doctor who's getting the letter would know that is if he went down and read all the studies, true?

A. Yes.

Q. Now, if we may, let's proceed to the -- let me

ask you a question. Does the FDA warning letter apply only to some kinds of Risperdal and not others? For example, we know there was an oral solution. We know there were tablets. We know there was something called the M-Tab that would dissolve in your mouth. An injectable form came out in 2003. Is the FDA saying that some of these have been promoted in a false and misleading way or all of them?

A. Well, what the FDA is saying is that the "Dear Healthcare Provider" letter is false and misleading, and the "Dear Healthcare Provider" letter did not differentiate between the different forms, dosages, put-ups of Risperdal. So what FDA is saying is that all of the -- the drug put-ups and presentations are misbranded.

Q. Now, let me go to Page 4, please, and then we'll move to a different issue. Okay. "Conclusions and Requested Actions." The FDA "requests that Janssen immediately cease the dissemination of promotional materials for Risperdal that contain claims the same as or similar to those described above."

And let me stop there. Promotional materials. When you look at this sort of thing as an expert in food and drug law, you see things we might not. Can you tell from looking at this letter whether

the FDA was treating Janssen's "Dear Healthcare Provider" letter back in November as being promotional in nature?

A. Absolutely was treating it as being promotional, which it was.

Q. And how can you tell that that's how the FDA regarded that letter?

A. Well, you can tell because they are -- they have authority only over promotional claims in this context. They're referring to it as promotional in this context. If we go back to the beginning of the letter, I think they even refer to it as promotional in that context. They are concerned about advertising this drug by communicating this information to doctors.

Q. So they weren't treating this as a scientific communication, but rather as a promotional communication; is that fair?

A. That's fair.

Q. That brings to mind, you talked about CME programs, medical education programs, and I asked you whether those are educational or promotional. And I think your answer boiled down to it depends; is that right?

A. That's correct.

Q. If a -- if a medical education program is used

to promote the drug and false and misleading things are said or off-label things are said, is that a violation of the law?

A. It is.

Q. Let's go, please, to the last page of this letter from the FDA, and I want simply to see two things. First, the FDA says if you don't correct this, there may be more actions to follow. And secondly, this was sent by the director of the division at the FDA that oversees this kind of marketing activity; is that right?

A. Correct.

Q. And who was its copy to?

A. There is a copy of the letter to William Weldon, who is and remains the CEO of Johnson & Johnson, which is the parent company of Janssen.

Q. Okay. Was then and is now?

A. Correct.

Q. Let's go, please, to Plaintiffs' Exhibit --

MR. JACKS: Will you bring up the correction letter?

Q. (BY MR. JACKS) Plaintiffs' Exhibit 105 dated July 21st, 2004. What is this?

A. This is a copy of a communication that Janssen sent in response to FDA's demand letter to rectify the miscommunication that it engaged in previously.

Q. And do they say -- and we're not going to go through this letter in detail -- but that they've been asked to contact you, the healthcare provider, because Janssen Pharmaceutica Products "recently received a warning letter concerning the promotion of Risperdal (risperidone). This letter provides important corrective information about Risperdal relating to hyperglycemia and diabetes mellitus."

Now, anywhere in this letter does Janssen deny that their November 10, 2003 letter was in fact a letter about the promotion of Risperdal?

A. Not as far as I recall.

Q. You've read it?

A. Yes.

Q. And you don't see anywhere in it where they deny that they back in November had sent out a promotional letter?

A. They don't deny that.

MR. JACKS: And if you'll go to the next page, please, of the correction letter.

Q. (BY MR. JACKS) And at the top of the page, do they say -- and actually, I'm looking at this paragraph above this one, sir. "In order to provide you," the healthcare professional, "with complete and accurate information regarding hyperglycemia and diabetes

mellitus relative to Risperdal, please be advised that Risperdal Prescribing Information was updated with the addition of the warning in November 2003." And then what's just below that?

A. Immediately below that is the text of the FDA mandated warning.

Q. So, unlike the first letter, in this letter the warning itself and all of the instructions about monitoring patients for their safety are contained in the body of the letter, not in a package insert?

A. Correct. Here, they specifically called out the FDA mandated warnings to the physicians' attention.

Q. I'm going to shift gears with you.

MR. JACKS: Would you bring up Plaintiffs' Exhibit 13?

Q. (BY MR. JACKS) You mentioned the *Physician's Desk Reference* earlier. And is this a -- Plaintiffs' Exhibit 13 the first page of a 1995 *Physician's Desk Reference*?

A. Yes.

Q. And did you in fact review -- and inside here is a reproduction of the label or the package insert for lots of drugs but including Risperdal?

A. Yes, as it existed at the time.

Q. And did you review these for the years

beginning 1995 going through 2009?

A. Through 2006.

Q. Oh, 2006. I apologize. And up until 2006, was there anything in the labeling or the package insert about Risperdal that related to its use in children?

A. Yes.

Q. And in substance, what was said in all those years --

A. In all those years --

Q. -- about the use of Risperdal with children?

A. In all those years, the labeling said that the effectiveness of Risperdal has not been established in children.

MR. JACKS: Can we go to the fourth page? I believe it'll be in the center column near the top.

Q. (BY MR. JACKS) And that's what you're referring to?

A. Yes. I failed to say that it said safety in children had not been established as well.

Q. And this was in 1995, but is it the case that the label -- the package insert for Risperdal for all the years, 1994, '5, '6, up through -- until after the time when they got their first indication in October 2006, that this is what the company had to say about the safety and effectiveness of Risperdal for use in

children?

A. Yes.

Q. And did -- you've described before some things you did to determine whether Janssen had or had not engaged in misbranding or in preventing false and misleading information relating to the superiority of its drug. Now we're going to focus on their conduct with respect to their promotion of their drug for use in children. Are you with me?

A. Yes.

Q. How did you go about examining the conduct of the company and the management of its employees with respect to promoting Risperdal for use in kids?

A. Well, I approached it in the very same manner. I looked at the three levels of behavior. I looked at what did they plan to do. I looked at how did they train their people. And I looked at what did they actually do in the field.

MR. JACKS: Let's go to -- back to that 1994 business plan, Plaintiffs' Exhibit 2. And if you'll pull up Page 983, please, Mr. Barnes.

Q. (BY MR. JACKS) This is the business plan, Risperdal business plan from 1994. And do you see in -- and you've reviewed this we know. Did you see this discussion of market expansion?

A. I did.

Q. "To establish Risperdal as a broad-use product in several market segments, it becomes necessary to demonstrate safety" -- let me back up -- "to demonstrate safety and efficacy of Risperdal through small scale trials, investigator-initiated proposals and pilot studies covering the following patient segments."

Now, I don't suppose you have to be a food and drug expert to know what market expansion is about. But let me ask you about the -- what are small scale trials?

A. Those would be, you know, trials or clinical studies with a very small number of patients as distinguished from, say, a robust trial that you would conduct to gain approval for a drug.

Q. Investigator initiated proposals, what's that about?

A. Oftentimes clinicians might approach a company and say, hey, I want to study drug x for condition y.

Q. And what are they looking for?

A. They might be genuinely interested in looking at the properties of the drug and are looking for some support from the company. There could be a variety of motivations that a clinician would have for wanting to investigate a compound.

Q. Financial support being one kind of support?
A. Financial support. They might be looking for drug supplies, things of that sort.
Q. Okay. Now, I'm not going to go through all these indications, but what's the last of the patient segments for which the business plan speaks of expanding the market?
A. Well, they're talking about supporting current labeling for use of Risperdal in children.
Q. Well, and, of course, in 1994 there was no current indication for Risperdal in the use of children, correct?
A. That's true.
Q. Do they speak in the next paragraph of the possibility that they might have to change the current labeling?
A. They do not.
Q. Well, you can't see my little red dot here, but --
MR. JACKS: Let's highlight this sentence, please, Mr. Barnes.
Q. (BY MR. JACKS) Do you see the sentence --
A. Oh, I'm sorry. They do.
Q. -- that talks about the business purpose for conducting these market expansion studies is to support

broad use strategic objective by seeding the literature and, if appropriate, changing current labeling?

A. Yes.

Q. All right.

A. You are correct. I was mistaken.

Q. All right. And what about seeding the literature? Is that a term with which you're familiar?

A. Yes.

Q. And in fact, is it a term that is defined in Janssen's own documents?

A. Yes. Janssen does address it in some documents that I've seen.

MR. JACKS: Can we bring up Plaintiffs' Exhibit 1601, please?

Q. (BY MR. JACKS) 1601 is about healthcare compliance questions; is that right?

A. Correct.

Q. Healthcare compliance meaning what?

A. Well, it's a program that Janssen implemented or developed to help them ensure compliance with healthcare laws.

MR. JACKS: Okay. If we may go to Page 712, the last three numbers of the Bates number, please.

Q. (BY MR. JACKS) And do you see there what

Janssen says seeding studies are all about?

A. Yes.

Q. So seeding studies as used in the business plan is studies with limited scientific value generally designed to promote product utilization are prohibited?

A. Yes, that's what -- that's their policy.

Q. Okay. Let's go back to the business plan, please. For the business purpose of conducting market expansion studies, seeding the literature is one of the tactics they include in their plan, fair?

A. That's a fair statement.

Q. All right. Last sentence of this -- on this screen, "Market expansion studies also support Risperdal as the market leader, facilitates reimbursement." What's that about?

A. Well, these drugs are often used, as they were here, in populations that are covered by various government healthcare programs such as the Medicaid Program and the proposition being asserted here that these kind of studies that they are describing here would help secure and ensure reimbursement by the state agencies -- the government agencies that provide reimbursement for these uses.

Q. Like Medicaid?

A. Like Medicaid.

MR. JACKS: May we go, please, to Plaintiffs' Exhibit 433?

Q. (BY MR. JACKS) And while that exhibit's being put up, let me ask you, Mr. Friede -- and if you would, please, turn around so you're talking to these people and not your TV screen. They mentioned as a part of their business plan trying to change the label. Do you recall that?

A. I recall that.

Q. Did there come a time when they tried to change the label about using Risperdal in children?

A. Yes, there did.

Q. Did they try to do that in 1996, specifically by submitting a supplemental new drug application in August of that year?

A. They did.

Q. And they were seeking -- I'm not going to go through all this, but were they seeking to have the FDA let them include information about using Risperdal in children in their product labeling?

A. They were.

Q. If they had succeeded in that, could they legally promote Risperdal for use in children?

A. Depending on what the precise language was that was included in the labeling, yes.

MR. JACKS: All right. Now, if -- if we may, Mr. Barnes, on the first page, go down to the -- this paragraph that starts "Your supplement proposes." Let's bring that up.

Q. (BY MR. JACKS) "Your supplement proposes the expansion of Risperdal use into pediatric patients, however, you never state for what child or adolescent psychiatric disorders Risperdal would be intended. Indeed, you acknowledge that you have not provided substantial evidence from adequate and well-controlled trials to support any pediatric indications nor developed a rationale to extend the results of studies conducted in adults to children. Your rationale for proposing this supplement appears to be simply that, since Risperdal is being used in pediatric patients, this use should be acknowledged in some way in labeling."

Now, did the FDA let them do this?

A. No. The FDA denied their request for the language permitting use in pediatric populations.

MR. JACKS: And may we go to the second page, please, Mr. Barnes?

Q. (BY MR. JACKS) And the FDA in fact says to Janssen you have provided no data. "There were no specific safety findings of sufficient concern among the

meager safety data submitted to justify adding any information to labeling about the safety experience with this drug in the pediatric age group."

To -- going on, "To permit the inclusion of the proposed vague references to the safety and effectiveness of Risperdal in pediatric patients and nonspecific cautionary advice about how to prescribe Risperdal for unspecified target indications would serve only to promote the use of this drug in pediatric patients without any justification. Consequently, this supplement is not approved."

Could the FDA have been any clearer about this?

A. I don't think so.

Q. Did you review evidence to see what Risperdal -- what Janssen's personnel were doing in Texas during these years, 1994, '5, '6, on into the late '90s with respect to promoting Risperdal for use in children?

A. Yes. I reviewed a good deal of evidence on that subject.

Q. Did you review testimony from a man named Jeff Dunham who was a sales representative for Janssen in Texas?

A. I did.

Q. Did you review testimony from Dr. Valerie Robinson, a child and adolescent psychiatrist upon whom Mr. Dunham made calls?

A. I did.

Q. And did -- was it -- what understanding did you have from Dr. Robinson's testimony about what kind of patients she helped?

A. Dr. Robinson treated only pediatric patients, only children and adolescents.

Q. Did you review testimony indicating whether Mr. Dunham was aware of that?

A. I did.

Q. Did you review call notes showing Mr. Dunham's calls on Ms. Robinson?

A. I reviewed call notes that showed the dates of various calls that Mr. Dunham made on Dr. Robinson.

Q. In years spanning from 1994, the first year the drug was out, to 2002; is that right?

A. Yes.

Q. About how many calls, if you remember, did he make to Dr. Robinson during that time?

A. Somewhere between 95 and 100, on that order.

Q. And did the evidence indicate whether or not Mr. Dunham was authorized by his company to make those calls?

A. Well, all the evidence that I saw in Mr. Dunham's deposition and all of the other evidence showed that sales representatives exclusively called on those doctors who they were directed to call upon by the company in their sales call plans.

Q. Did the evidence indicate whether or not Mr. Dunham himself was aware that Ms. Robinson -- or Dr. Robinson had a children's practice?

A. Not only was he aware of that, but he himself elected to have his own daughter treated by Dr. Robinson.

Q. All right. Did you look at call notes from the time period 1996, about the time that the FDA was telling Janssen they had no evidence to support the safety of -- or effectiveness of using Risperdal in children?

A. I did.

Q. Let me ask that we bring up from Plaintiffs' Exhibit 148 -- let's start with Page 3. And again, we're going to follow the same convention as we did before, Mr. Friede, where we focus on the message field.

Had a nice discussion about Lieberman data and data in children. He seems to be impressed with child data.

Next one, June 10, 1996, talked about

Risperdal in child.

Next one -- that was Page 7. Next one, Page 9, June 17, 1997, discussed its utilization in children.

Next one, Page 11, August 27th, 1997, Risperdal detailed efficacy, low dosages in kids and elderly.

Next one, Page 16. This is a long one and I'm going to read only the part that's pertinent. I reminded her that Risperdal was the number one prescribed atypical for children, was the best tolerated at low doses and had the best results. She agreed but did state that all the drugs induced weight gain. I agreed but told her that children are less likely to develop Type 2 than some of the others. She agreed and said it was her first line.

Next one, Page 30.

THE COURT: Excuse me, Mr. Jacks. Do y'all have what she was singing?

MR. JACKS: You know, and I don't know what OWC is.

THE COURT: Well, let's not speculate. So, ladies and gentlemen, I'll see y'all back shortly before 1:30.

(Jury not present)

THE COURT: Mr. Friede, you may step down.
THE WITNESS: Thank you so much.
(Recess taken)
(Jury not present)
THE COURT: Bring the jury in, and they can share in this frivolity.
John, is there another big expert besides Glenmullen that we've got in this?
MR. McDONALD: Rosenthal.
THE COURT: But where y'all have objected?
MR. McDONALD: No, I don't think so. We'll have some more objections that we'll raise before we get into it.
THE COURT: All right.
(Jury present)
THE COURT: Thank y'all. Be seated. Mr. Jacks.
MR. JACKS: Thank you, Your Honor.
Q. (BY MR. JACKS) Mr. Friede, before the break, we had gone through some call notes, and now I'd like to move to some questions about sales training having to do with child and adolescent psychiatrists. Do you have before you Exhibit 127?
A. I do.
Q. And the first page of that's being displayed on

the screen. You've got a hard copy in front of you; is that correct?

A. I do.

Q. You informed me during the lunch hour that your bifocals and that screen aren't all that compatible with one another; is that correct?

A. At times, that's correct.

Q. All right. So we'll see if this works better. This document is -- the title is self-evident. And if you would, please, turn to the page that ends with the numbers 495 in the Bates page range. Do you see that page?

A. I do.

Q. Okay. The -- this obviously appears to be some sort of a slide deck. Is that what it looks like to you?

A. Yeah. It appears to be a slide deck that was used as part of a sales training program for the Janssen central nervous system sales force.

Q. Okay. And the title slide in this screen is called what?

A. It deals with child and adolescent physicians.

Q. Okay. And in -- in the call notes you've reviewed, by the way, did you sometimes see a code for specialties in -- in a field in those call notes?

A. I did.

Q. And among the codes in that field, did you see one called CHP?

A. Yes.

Q. Did you review evidence that told you what that code meant?

A. Yes. There was testimony that CHP was the abbreviation for child and adolescent psychiatrists.

Q. All right. Now, let's -- we now have on the screen the next slide. It's on this same page in the exhibit, but the next slide in the set. And would you please tell the jury if there's anything in this particular slide that's of significance to you in connection with the inquiries you were asked to make in this case?

A. Okay. Let's recall that I'm looking at this for the purpose of assessing whether or not there is off-label promotion to children and whether or not this evidence is some sort of training to the field sales personnel to do that. So looking at that slide, the first bullet point says "Can be covered by both M- & I-reps." And I know that I-reps refers to the sales representatives that call on institutional accounts. The M-representatives refer to the sales reps that call on other accounts. So to me, this is saying this is

about using this information to -- as part of the sales activities that these M- and I-reps will be engaged in.

Q. Okay. And let me ask you -- you say institutional reps. What kinds of institutions, from your review of the evidence, did they call on?

A. State mental health facilities, things of that order.

Q. Like mental hospitals?

A. Mental hospitals, things of that -- that order, other than -- facilities other than individual practitioners' offices.

Q. Okay. Now, let me ask you then to proceed with this slide and tell the jury if there's anything else that was of significance to your inquiry.

A. Well, you can see in the next bullet point that they're telling the sales force that Risperdal can be used to provide treatment to patients who are under the age of 18. So that, to me, communicates that this is -- that they're instructing them that this drug should be detailed to those doctors who they're calling on for pediatric patients, children and adolescents.

Q. Anything else in this slide that is of significance to you for your purposes?

A. Yes. If you move on to the next bullet point, we're talking about most are diagnosed with a behavioral

disorder or a mood disorder. And let's recall that certainly as of 2002 Risperdal was only indicated for the treatment of schizophrenia. So here you have information to the sales -- to the child and adolescent sales force advising them that most child patients of the physicians they're going to be calling on have -- do not have schizophrenia; they have behavioral disorders or mood disorders. It's some evidence that the drug would be -- that they're training to use the drug for -- in those conditions.

MR. McDONALD: Your Honor, may we approach?

(Discussion off the record)

Q. (BY MR. JACKS) Mr. Friede, let me ask that we take a look at the next -- not the next slide, but the -- I guess the next one on the next page, which would be I believe page ending in 96, 496. Are you with me?

A. Yes, I am.

Q. Did you see anything in this particular slide that was of relevance to your inquiry?

A. Well, I did. Sort of contradictory from the previous slide, there's an acknowledgment here that there are no indications for use of Risperdal in children and adolescents.

Q. All right.
A. By the same token, they had previously been instructing their people to call on child and adolescent psychiatrists to promote the drug.
Q. All right. And then if --
MR. JACKS: Actually, Your Honor, may we approach again?
(Discussion off the record)
Q. (BY MR. JACKS) Mr. Friede, I'll tell you what. We're going to try to move on from this exhibit. Let me ask you simply this question. Do you see the heading "Key Strategies"?
A. I do.
Q. What's the first word in the first bullet point under "Key Strategies"?
A. "Sell."
Q. Let me ask you, sir -- if we will move on to the next slide in this group. And again, we're going to try to move through this quickly. Do you see the third bullet on this page saying "Be a resource to the C&A psychiatrists"?
A. I do.
Q. That's child and adolescent, of course.
A. That's correct.
Q. The second entry is samples and coupons. Does

that have any significance to you in connection with your inquiries?

A. Well, what they're telling the sales reps to do is to provide -- as I read it, to provide samples of the drug as well as coupons that they can provide to the patients to use at the pharmacy; and therefore, they're telling the doctors, these child and adolescent psychiatrists, to use this drug in their pediatric patients.

Q. Okay. We're done with that exhibit. Now, let me ask you -- there are some more call notes that I need to discuss with you, Mr. Friede, but before I do, you said that one of the exhibits you reviewed was Plaintiffs' Exhibit -- I believe it's 148, which is in these boxes and relates to call notes from Texas sales representatives that are pertinent somehow to the issue we're discussing right now, which is calls upon child and adolescent psychiatrists. Now, you said you reviewed those; is that correct?

A. That's correct.

Q. It's a daunting volume, assuming those boxes are full, and I think they are. What -- could you generally explain to the jury kind of how that exhibit is organized in general terms?

A. Well, there are about 180 distinct call notes

that have some information -- some text information in a field that permits the representative to provide observations. The remainder of those call notes perhaps even -- shouldn't even be called call notes because all they are is an indication that the representative called on a CHP, a child and adolescent psychiatrist, but the predominant part of those call notes do not provide any place where the rep can actually put in any kind of free text.

Q. Okay. So of what significance to you was that body of the call notes, that is, those where the representative wasn't given the option of saying what happened on the call but did record the specialty of the physician upon whom the call was made?

A. Well, you look at it in the total context of things. They've got a business plan to call on these people, these child and adolescent psychiatrists, to promote the drug for use in children. They're training their people to promote the drug in children, and they're calling on these people. And the only rational conclusion is that they're calling on these people to promote the drug in children in precisely the way their business plans and their training laid out.

Q. When you use the word calls, to some of us that means something like this (indicating). Is that what

you're referring to or something else?

A. I'm referring to -- in sales parlance in the pharmaceutical industry, a call usually refers to an in-person visit by a sales rep, a detail.

MR. JACKS: Okay. Let me ask that Exhibit 148 beginning at Page 60 be brought to the screen.

Q. (BY MR. JACKS) And this -- we are now back to some of these call notes that -- and if we may, may we first see the call note itself before we go to the readable version, because there's something I need to ask you about it? And that is in -- is there a place where the sales representative's name appears in the next to the last box on the right-hand side?

A. Yes. In the column that's second from the right there is a -- two lines there with the rep -- it says rep first name. In this case it's Tiffany, rep, last name Moake.

Q. Okay. And we know that this is a call note created April 29, 2003; is that right?

A. That's correct. We see the date in the third column. It says call date, 29 April 2003.

MR. JACKS: Okay. And we may now go, please, Mr. Barnes, to the version that folks can read, at least that I can read.

Q. (BY MR. JACKS) And by the way, is Tiffany Moake a name that's familiar to you from your review of the case?

A. Yes. I've read her deposition and I've seen many, many call notes from her.

Q. Okay. We will run through these. The first -- and this is Plaintiffs' Demonstrative Exhibit 212. Continued with John's call and spoke of new areas to use Risperdal. Used JCAP to show augmentation to stimulants with low dose NS for host aggression. This seemed to spark some interest. So we might need to elaborate here since he sees so many kids. Also reminded of oral solution for hospital patients and kids.

Next from Page 69. This too is one of Ms. Moake's call notes dated May 30th, 2003 Plaintiffs' Demonstrative Exhibit 213. Core M&A with M-Tab intraorally, need to push utilization in his population of kids and on impatient. I'm betting that was meant to be inpatient, but...

Next one from Page 70 of the same exhibit, Plaintiffs' Demonstrative Exhibit 214 dated June 6th of 2003. Discussed M-Tab for ease of care with children and closed here over Seroquel.

Next from Page 71 of the same exhibit, Plaintiffs' Demonstrative 215, intro to M-Tab and she

thought of every reason not to use, mainly cost and insurance, but I closed her on specific noncompliant patients and kids with difficulty swallowing.

Next, Page 74, the same exhibit, Plaintiffs' Demonstrative 216. Pushed M-Tab for kids. He is still using Risperdal with ADHD meds for explosive behavior as his primary means of controlling symptoms closed here over Seroquel.

Next, on Page 86 of the same exhibit, Plaintiffs' Demonstrative 217. Full M-Tab and agreement to push on parents for new starts with their kids.

Next, Page 90 of the same exhibit. This is Plaintiffs' Demonstrative -- and I've lost the demonstrative number. 218. Pushed M-Tab for kids.

Next. And this is from Page 105, Plaintiffs' Demonstrative 219, November 6th, 2003. Discussed benefit of Risperdal in special population versus Seroquel, Zyprexa. Got agreement on safety efficacy in children.

Let me pause there. As before, what observations do you have, Mr. Friede, about this series of call notes?

A. Well, I think it seems pretty clear that individually and collectively they show that Janssen was affirmatively promoting Risperdal for use by children

and adolescents.

Q. And this in 2003, two thousand -- before there was any -- three years before there was any FDA approval?

A. Yes, during the time that these call notes cover, absolutely.

Q. Let's go, please, next -- and I'd like to see the actual call note, not the slide, on Page 110 from this same group. And here let's focus on the representative's name. This is a person named Laura Haughn, is that right?

A. That's correct.

Q. Did you review information concerning Ms. Laura Haughn?

A. I did. And in addition to a number of call notes from her, I also read her deposition transcript.

Q. All right. In the case of Ms. Moake's calls that we've just seen and Ms. Haughn's which we're about to see, were these Texas sales representatives calling on Texas doctors?

A. Yes.

Q. And we'll go now to the slide that's more easily read, and this is from Page 110. This is February 4th, 2004, Plaintiffs' Demonstrative 221. Discussed using Risperdal oral/M-Tab in adolescent and

children patients.

Next, on Page 123, same exhibit, Plaintiffs' Demonstrative 222. Reviewed MOA -- mechanism of action; is that right?

A. That's correct.

Q. -- of Risperdal M-Tab and why it's ideal for children and adolescents.

Next, 126, from the same exhibit, Plaintiffs' Demonstrative 223, April 12th, 2004. Discussed why Risperdal is better choice for children and adolescents than Abilify.

And one more from Page 131, April 26th, 2004, Plaintiffs' Demonstrative Exhibit 224. Go over why Abilify shouldn't be used in kids, review why Risperdal is best choice for children and adolescent patients.

Mr. Friede, what observations do you have about this series of call notes from Ms. Haughn?

A. Again, I think what we see is that she's behaving in very specific accord with both the strategy laid out by Janssen and the specific training that she was provided to promote this drug for use in children.

Q. You've said that you read Ms. Haughn's testimony. Did you also see other documents that she generated?

A. Yes.

Q. Let me ask that we display -- and, Mr. Friede, let me hand you Plaintiffs' Exhibit 101. And I'll take this one back. What is Plaintiffs' Exhibit 101, Mr. Friede?

A. Well, if we look at the page that begins with the last three numbers 507, what we see is this is an e-mail chain that was initiated by sales representative Laura Haughn on Monday, May 24th, and she's reporting to the other members -- the other sales representatives in her district.

Q. Which district was she in, based on your understanding of her testimony?

A. You know, as I sit here, I can't remember if it was San Antonio or Houston or Dallas. I just don't recall specifically what district she was in.

Q. No bother. The first addressee is someone named Tone Jones. Is that a name you recognize?

A. Yes. Tone Jones was a district manager I believe in Houston, in the Houston area.

Q. Let me ask that we scroll down then to the next -- to the body of the e-mail -- or actually, the subject matter, first of all.

A. Well, she's talking --

Q. Okay. What is the subject line?

A. Abilify recap.

Q. Is there -- let me read the first sentence here, and I'm going to ask you some questions about it. "Just wanted to pass along a few things I learned about Abilify at Advanced Sales Training (taken from Abilify's sales aid) and from Dr. Alice Mao (Risperdal and Abilify speaker)."

Now, is there anything about that that's of any significance to you?

A. Well, you know, it's important that she is saying that the information that's being recounted here is something that she learned at -- at advanced sales training that appears to be something that was provided to her by Janssen.

Q. All right. Now, when you -- is there a portion of this particular e-mail that she's addressing to her team that deals at all with the subject we're on, which has to do with children and adolescents?

A. There is.

Q. And what does it say?

A. There's a statement that Abilify is targeted at children and adolescents and that the company is trying to develop this as a niche market for themselves, that company.

Q. So the manufacturer of Abilify is targeting

children and adolescents and is trying to create a niche for itself in that market? Is that what it boils down to?

A. That -- correct.

Q. And then -- I'm not going to go through Abilify's selling messages, but does she recount them?

A. She talks about Abilify selling messages and recounts a number of other things that are relevant.

Q. And so she talks about their selling messages, their weaknesses and so on. Now, let me ask if you would, please, go to the closing part of this e-mail. And once again, I'll ask you if there's information that's pertinent to you at the -- toward the end of Ms. Haughn's e-mail to her team.

A. Well, she's talking about very specific attributes of the disease in children and -- for example, she says children and adolescents have a higher number of dopamine receptors than adults and need higher dopamine antagonism, and she says that Abilify can't effectively offer this because of its specific mechanism of action, and then it goes on to say that Risperdal is the best choice per Dr. Mao.

Q. All right. And then how does she close her message to her team?

A. Well, she closes it in a somewhat

contradictory. In the first instance she says "I hope this information is helpful in your selling efforts." And then she goes on to say, "Don't use in selling situations, just for your educational purposes." And then further she goes on to say in the P.S., "Let's beat the everliving, everloving hell out of Abilify!!! (sorry for the ad-lib, that's just the Aggie coming out in me)."

Q. Okay. Does the "Don't use in selling situations" at the end of an e-mail and saying that she hopes this is helpful in your selling efforts ring any bells with you?

A. Well, it's very reminiscent of the rubber stamp that we saw on the earlier sales training information.

Q. Let's go to the next e-mail in the chain, going up the line, as we do with e-mails in chronological order.

A. And this is --

Q. Hang on one second. So let's let the screen catch up. And who's the author of this e-mail?

A. This is Tone Jones who, he says there, is the Houston district manager, Laura Haughn's boss.

Q. All right. And does he -- what does he have to say about the job she did?

A. Well, he's congratulating her on doing a nice

job and looking for insightful -- looking for opportunities to provide and -- to partner and provide insightful information to her team.

Q. All right. Let's go up the line.

A. The next --

Q. Just a minute, Mr. Friede. You're now looking at the page instead of the screen, which is an improvement, but we need to let the screen catch up with you. All right. Now, this is from a person named Rob Kraner. Is that a name that you've run across?

A. Yes. He's the -- a regional business director for Janssen in the south, and he was Tone Jones' boss.

Q. Okay. So we're climbing the corporate ladder here?

A. Precisely.

Q. And he copied someone named Dave Meek. Is that a name you recognize?

A. Yes.

Q. And who's Dave Meek?

A. Dave Meek was the overall field sales director for Central Nervous System sales in Janssen.

Q. All right. And is he too complimentary of Laura Haughn for the recap on Abilify?

A. Yes. Mr. Kraner is telling Laura that she's done a nice job and that he couldn't agree more with the

very last line of the e-mail, which presumably refers to let's beat the everliving, everloving hell out of Abilify.

Q. I suppose that's what he's complimenting her for. And let's go on up the corporate ladder one more rung. And who authors this e-mail?

A. This is Dave Meek, who is the field sales director for Central Nervous System sales in Janssen.

Q. All right. And then he is addressing RBD team. So that's what group?

A. That's the group that Rob -- that's the Regional Business Director group, and that's the group that Rob Kraner who had initially copied me is part of.

Q. Okay. Let me ask you, first of all, to read the second paragraph of CNS Field Sales Director Meek's message to the regional business director team.

A. "Abilify is gaining ground primarily with child and adolescent psychiatrists and we need to make sure that Risperdal is growing with this customer segment. Let's make it happen."

Q. So this is the -- one of the top sales executives in the company writing the regional sales directors in the company. How does this match up with the idea that Mr. Alex Gorsky, as we saw early on, said that off-label selling is illegal and the company

shouldn't be doing it?

A. Well, it's absolutely inconsistent with what Mr. Gorsky said in his memorandum.

Q. Is it consistent in any way with the law?

A. At that point in time, Risperdal was not approved by FDA for use in child and adolescent patients. This e-mail chain evidences their intention to promote the drug in that -- in that population. As we see from the activity in the field, they did do that, and thus, it doesn't comport with the law.

Q. May we go back to one of the last of Laura Haughn's messages we looked at before? It's Plaintiffs' Demonstrative 224. It's April 26th, 2004, the month just before this e-mail string. What other product is she selling against?

A. She's selling against Abilify.

Q. In what patient population?

A. Well, she's -- she is selling against Abilify in child and adolescent patients.

Q. Mr. Friede, the -- we've seen some of the activities of the FDA with respect to this company in 1993, '94, '96 in turning down their application for a label expansion to include kids, and then on '99, 2002, 2004 warning letter. But some might wonder, why isn't the FDA out policing this kind of activity by sales

representatives of a major pharmaceutical company apparently with the blessings of their top management?

A. Well, as we recounted, they were -- they did do a fair amount of policing. But at the end of the day, FDA, like many government agencies, is very resource constrained and can't pursue all violations simultaneously, even important violations.

MR. JACKS: Your Honor, we'll pass the witness.

CROSS-EXAMINATION

BY MR. McDONALD:

Q. Good afternoon, Mr. Friede.

A. Good afternoon.

Q. We met this morning. It seems like a long time ago.

A. It does.

Q. You told me I had to be nice to you, and I told you if you just said yes, I would, right?

A. You said that.

Q. So that's going to be our deal. It has been a long time, so I want -- I want us all to remember. You worked at the FDA for a couple years in the 1970s?

A. That's correct.

Q. Okay. So it's been quite some time since you've worked at the FDA?

A. Yes.
Q. And while you were at the FDA, you didn't work on Risperdal obviously, right?
A. That's correct.
Q. Okay. And in fact, you didn't work on any antipsychotics while you were at the FDA, right?
A. That's correct.
Q. And you haven't spoken to anybody at the FDA about this case?
A. That's correct.
Q. Or -- and you haven't spoken to anybody at the FDA about the documents you've looked at and testified about, right?
A. That's correct.
Q. And you don't speak for the FDA obviously, right?
A. I don't speak for FDA.
Q. And we talked a lot -- or you talked a lot today about misbranding and other alleged violations of the Food, Drug and Cosmetic Act, right?
A. I spoke about it this morning, yes.
Q. Sure. And it's true that only the FDA can enforce violations of the Food, Drug and Cosmetic Act, correct?
A. That's not entirely correct.

Q. You can't bring an action against a company for violation of the Federal Food, Drug and Cosmetic Act, can you?

A. Not normally.

Q. And the State of Texas can't bring an action against Janssen for violation of the Federal Food, Drug and Cosmetic Act, can it? That's a matter within the purview of the FDA, right?

A. I wouldn't agree with that statement entirely.

Q. What don't you agree about that?

A. There may be -- there may be claims that the State of Texas could assert in certain contexts based on violations of the Federal Food, Drug and Cosmetic Act. I'd have to give that a bit more thought.

Q. They can't bring a direct action for a violation, that is, sue my company directly for a violation of the Federal Food, Drug and Cosmetic Act, can they?

A. Probably not.

Q. Okay.

A. I'd have to give that some more thought.

Q. Thank you. You don't speak for the federal government either, do you?

A. I don't.

Q. Okay. You're just offering your personal

opinions as a lawyer, right?

A. Well, I'm offering my expert opinions as a lawyer.

Q. And you've testified earlier you've been paid $525 an hour by the plaintiffs in this case?

A. Yes.

Q. And how much have you charged them for your time?

A. I haven't computed the total charges.

Q. Got a ballpark?

A. Probably around 400 hours, whatever that would work out to.

Q. A couple hundred thousand dollars?

A. Correct.

Q. You're obviously not a doctor or a psychiatrist, right?

A. That's correct.

Q. Okay. So you're not an expert on antipsychotic medications?

A. That's correct.

Q. You're not --

A. No, not on the science of antipsychotic medications.

Q. All right. You're not here to express any opinion on your own about whether Risperdal is safe or

effective or better or worse than other drugs?

A. Correct.

Q. You're only here to give an opinion on what the FDA may have thought about Risperdal and whether Janssen's claims about Risperdal were consistent with legal and regulatory requirements?

A. That's not correct.

Q. What's not correct about that?

A. Well, I was commenting beyond only what FDA thought about particular behavior.

Q. You're offering your own personal opinion about Janssen's behavior?

A. My opinion as a lawyer, yes.

Q. Just like I can give my opinion as a lawyer?

A. You can certainly provide your opinion.

Q. Sure. You and I can respectfully disagree with one another about my clients' intents, right --

A. Hypothetically --

Q. -- on what's happening?

A. Hypothetically, yes, we could --

Q. Sure, sure.

A. -- hypothetically disagree on some matter.

Q. Sure. A lot of what you've done in this case is review and interpret documents?

A. That's correct.

Q. You've said yourself that interpreting a document without talking to the author can be difficult, right?

A. Can you remind me where I've said that?

Q. Sure. I'll get out your deposition. Do you remember having your deposition taken?

A. Yes. I just don't recall that specific aspect of it. I will agree in general that interpreting documents is a difficult proposition, whether I said it in the deposition or not.

Q. It's difficult without talking to the author about what he or she does, right?

A. That could add to the difficulty, yes.

Q. Sure. Okay. How many doctors -- or Texas doctors did you talk about -- or talk to in this case about what they were told about Risperdal by a Janssen sales rep?

A. I didn't speak to any Texas doctors.

Q. So you didn't ask what they understood about Janssen sales materials?

A. Didn't ask any Texas doctors about what they understood.

Q. What about Texas Medicaid officials? Did you talk to Texas Medicaid officials about what my client told them?

A. No.
Q. You obviously didn't talk to any Janssen sales reps about what they said either, did you?
A. That's correct.
Q. Some of the documents you've talked about with Mr. Jacks were some lengthy PowerPoints, right?
A. Yes.
Q. And generally, PowerPoints would go on with an oral presentation, right?
A. That's correct.
Q. And you obviously weren't there for the oral presentation that went along with what was talked about in this lengthy PowerPoint, right?
A. That's correct.
Q. Okay. So you don't know what the people actually said at the time that the PowerPoint was given, if it even was ever given, right?
A. I don't know what was said, but based on the document, we can conclude that the PowerPoint presentation was given.
Q. How do you know that? How do you know that it's not a draft?
A. It's not marked draft.
Q. How do you -- do you know who went to the PowerPoint?

A. I'm sorry?
Q. Do you know who attended the PowerPoint presentation?
A. I don't know specifically who.
Q. So you don't know if any of the people involved in this case ever saw a particular PowerPoint presentation, right?
A. That's correct.
Q. Okay. How many Janssen employees did you talk to about business plans?
A. None.
Q. Let's look at Plaintiffs' Exhibit 2, then, that you visited about with Mr. Jacks. Do you recall looking at this one?
A. Yes.
Q. Okay. Can you see that okay?
A. Yes.
Q. Okay.
A. I'm trying.
Q. And if you can't, just tell me and I'll slow down for you. What's the date of this?
A. We don't know the specific date, but we do know that it's sometime -- it appears to be sometime in mid 1994, as I recall.
Q. Okay. Who wrote it?

A. We don't know from the face of the document, as I recall, who wrote it.

Q. Who saw it?

A. Don't know exactly who saw it, but we do know that in business, business plans tend to be reviewed by senior company officials.

Q. But you don't know that for sure about this document, do you?

A. Don't know that.

Q. Okay. There's no FDA law about what you can put in a business plan, is there?

A. There's no specific law that governs what you can and cannot put into a business plan.

Q. Okay. You'd agree with me that generally -- well, not even generally, that business plans are forward-looking, that is they look to the future about things that will happen in the future?

A. Well, they can -- they are generally in my experience both forward-looking and backward-looking because to predict the future you have to know something about the past.

Q. But the actions that are in the action items are looking forward to what may happen in the future, correct?

A. I don't want to quibble with you, but I -- I

don't really know how to answer that question. In general, to the extent they're talking about activities that are going to occur in the future, yes, they're forward looking.

Q. Okay. They're -- a business plan is certainly not promotional, is it?

A. In and of itself, it's not promotional.

Q. Okay. Let's look at a page that you looked at with Mr. Jacks, 983. There was a line in here about -- you talked about with Mr. Jacks on seeding the literature if appropriate. Do you recall that?

A. Yes, I recall that. I'm just trying to find the spot in the document.

MR. McDONALD: Chris, it's in the paragraph below the bullet points. There you go.

Q. (BY MR. McDONALD) And you recall that Mr. Jacks compared this language in here about seeding the literature with an HCC document from the mid 2000s?

A. I do.

Q. And that's not a fair comparison, is it, to compare something that's in a business plan in the mid -- or early 1990s with an HCC document ten years later?

A. I wouldn't agree with that's not a fair comparison.

Q. Well, you would agree with me, wouldn't you, that HCC or Health Care Compliance is an ever-evolving policy, I guess?

A. As well as change?

Q. Sure.

A. Compliance obligations change, sure.

Q. Sure. And most -- well, there's a lot of compliance obligations that are internal and even beyond what the law is, right?

A. That's true.

Q. Okay. Let's look at another business plan you looked at, Plaintiffs' Exhibit 1671. Again, you never talked to anybody about this one, right? Or actually, this is a training document. You never talked to anybody about this training aid; right?

A. That's correct.

Q. And so you don't know who received this or who received this training, right?

A. I don't know specifically who received it, that's correct.

Q. Right. And you didn't see any deposition testimony from anybody that they actually attended this training, did you?

A. Well, there was several depositions that I saw where sales representatives testified that immediately

upon being hired by the company, they would be provided with a home study including very specific sales training modules.

Q. I'm asking about this one. Did you see anything of any Texas sales representative that ever received the training that's represented in Plaintiffs' Exhibit 1671?

A. Again, without -- I don't mean to quibble with you, but it may well be that some of the depositions were referring to that specific training. Do I know for sure that that was the training they were referring to? The answer is no.

Q. Okay. And this is -- the title of this module is "Lesson 1, The Competition," right?

A. That's not correct.

Q. Well, Module VI. Did I get that right? VI is six, right?

A. Right.

Q. "Selling Considerations, Lesson 1, The Competition."

A. Right, but when you first said it, you said the title was simply "The Competition," but it's also "Selling Considerations."

Q. Okay. Let's not quibble with each other.

A. Okay.

Q. I'm trying to speed this along.
A. And I'm trying to be --
Q. It's kind of warm in here, and they're impatient, I'm sure and want to get out of here, so let's --
A. I'm not trying to be difficult. I just want to be accurate.
Q. I know you're not. Again, just say yes. And truthfully, this is just a lot of detailed information about the -- of Risperdal's competition, right?
A. Well, certainly there's a lot of information I recall in there about the competition, absolutely.
Q. Sure. There's information about what's in the marketplace from the competition of Risperdal, Haldol and the overview of the antipsychotic market and what other drugs are out there and Risperdal versus conventional antipsychotics. It's just a bunch of educational material about what the competition is of Risperdal, right?
A. I wouldn't agree with that. I'd have to look through it specifically, but there's more than just information about the competition in there.
Q. Don't you think it's prudent for a sales representative for Janssen, if he or she is going to go talk to a doctor, to understand the antipsychotic market

and understand what the competitors' drugs are?

A. Absolutely.

Q. Okay. Let's go to Exhibit 396. I think that you were -- you and Mr. Jacks were looking at the line in here of one, and Mr. Jacks was getting you to point out this selling objective of "Establish Risperdal as the first-line antipsychotic." Do you recall that?

A. We discussed that, yes, I recall that.

Q. Yeah. And you found some problem I guess with that selling objective of establishing Risperdal as the first-line antipsychotic, right?

A. I testified about --

Q. Okay.

A. -- about that, yes.

Q. So let's look at Exhibit -- Defendants' Exhibit 435. Have you ever seen this before?

A. Yes. This is -- I've seen this before.

Q. Okay. And this is -- this is a letter from the FDA approving Janssen's sales aid, correct?

A. This --

Q. I've got a hard copy if it makes it easier.

A. This is a letter approving a revised sales aid after an earlier letter critical of the initial version of that same sales aid.

Q. Okay. It's a letter that approves a particular

sales aid?

A. Yes.

Q. Okay.

MR. JACKS: John, do you have a copy?

Q. (BY MR. McDONALD) And the sales aid is RS012R, right?

A. That's correct.

Q. And let me show you, if my people hand me the right thing, the approved sales aid, which is -- if you'll look on the last page I think. If you'll look at the last page, you'll see that this sales aid is RS012R, right?

A. That's correct.

Q. Okay. So this is the sales aid that was approved by the FDA in this letter that we're looking at on the screen?

A. That is correct.

Q. Okay. And let's look at the second page.

MR. McDONALD: Chris, can you put that up of the sales aid?

Q. (BY MR. McDONALD) The FDA approved Janssen saying that Risperdal is a new first-line option for the treatment of psychosis. Do you see that?

A. It says "a" new first-line option for the treatment of psychosis, yes.

Q. Okay. And so I guess you're quibbling that Janssen's aspirational goal was to be "the" first line and the FDA only said you're "a" first line; is that your --

A. I'm not quibbling or anything. I'm just pointing out that the words on this page are different than the words in the -- in the memorandum you previously showed me.

Q. Clearly, though, the FDA approved Janssen saying that it was a first-line option for the treatment of psychosis, correct?

A. Again, a new first-line option.

Q. And the bullet point, why don't you read it so I don't get it wrong and you quibble with me. "Statistically," can you read that?

A. "Statistically significant improvement of positive symptoms."

Q. The second one?

A. "Statistically significant improvement of negative symptoms" with a footnote.

Q. And the third one?

A. "Extrapyramidal symptoms while dose dependent are comparable to placebo at recommended doses."

Q. Okay. Thank you.

THE COURT: Mr. McDonald, before you

wander into a different area, we're going to take a ten-minute break.

(Recess taken)

(Jury present)

Q. (BY MR. McDONALD) Let's move on to call notes. We had some lengthy discussion about call notes. Do these represent the call notes you looked at in this case?

A. No.

Q. You looked at more than these?

A. Yes.

Q. Okay. How many call notes did you look at?

A. Thousands.

Q. How many thousands?

A. Five to 10,000. A huge number of call notes.

Q. I'll represent to you that we've produced over 500,000 in this case. You didn't review 500,000?

A. No, did not.

Q. Okay. Of the thousands that you looked at, did you pull those from the 500,000 we've produced or did the lawyers do that for you?

A. Some of the ones I retrieved on my own.

Q. And you pulled them yourself out of the 500,000?

A. Yes.

Q. How many -- about how many of the thousands you've looked at fall in that category?
A. A couple hundred.
Q. Okay. And then the rest of the thousands you looked at were pulled by the lawyers for you?
A. That's correct.
Q. Okay. You didn't do some random sampling of the 500,000?
A. No.
Q. Okay. Prior to this case, you've never undertaken an analysis of call notes, right?
A. That's correct.
Q. You'd agree with me in looking at those thousands of call notes that they can be ambiguous, and sometimes looking at them you can't tell who was saying what, right?
A. Some call notes can be ambiguous, yes.
Q. Sure. And some of them are dated days or weeks after the call occurred, right?
A. That's correct.
Q. Okay. And obviously, there are -- I guess this goes -- you and I know this, but I don't -- I'm not sure they do. They're all different, right?
A. I'm not sure what you mean.
Q. All the call notes are -- all the call notes

are different. In fact, you know, you're not going to find identical call notes in this stack, right?

A. That's not correct. On a number of occasions, a field sales representative would in fact use the same terminology over and over again to report his or her encounters with numerous different doctors.

Q. It's going to be a different doctor, a different date, may have some of the same language, but in order to find out whether or not you think there's a violation of the Food, Drug and Cosmetic Act for off-label promotion, you've actually got to look at each individual call note and make that analysis, right?

A. I wouldn't agree with that.

Q. You don't think you have to look at each one to tell whether or not one of them's -- contains something wrong?

A. No. I think you'd have to look -- you can look at other sources. I thought your question was that you could only determine that the call notes were the sole relevant -- sorry if I misunderstood your question.

Q. You did, and it's probably a crummy question, so let me restate it. In order to determine if a call -- if there's something wrong with a call note, you've actually got to look at it and read it and interpret what's in there, right?

A. In general, yes.
Q. Okay. And you've got to do that on an individual basis with the thousands of call notes like you did, right?
A. In order to do what?
Q. In order to see if there's something wrong with them.
A. In order to see if any individual call note is problematic, you'd have to look at that call note.
Q. Okay. So of the thousands that you looked at, how many did you think there was something wrong with them?
A. I couldn't give you a specific number, but certainly a significant number. Given the nature of what these call notes were about, how they were generated, what the instructions were in preparing the notes, I thought there were a significant number of call notes that were problematic.
Q. But you don't know the number?
A. I don't know a specific number of call notes, no.
Q. Okay. Of the thousands of call notes that you looked at, do you know how many of them involved Medicaid providers?
A. I don't.

Q. Do you know how many prescriptions were written to a Medicaid patient as a result of the thousands of call notes you looked at?

A. I don't know the number of prescriptions written as a consequence of the calls that were made by these reps. I don't know that.

Q. And so you -- there's no way to look at a call note and find out or know whether or not, as a result of some particular call, a doctor wrote a prescription to a Medicaid patient as a result of that call, right?

A. I don't agree with that.

Q. So you think that there's a way that we can -- I can find a -- I can pick up a call note here and you could tell me whether or not a doctor wrote a prescription to a Medicaid patient?

A. I couldn't tell you, but there may be ways to derive that information.

Q. Has that been done, to your knowledge?

A. I don't know one way or the other.

Q. Okay. You certainly are not sitting here telling us -- or have the ability to tell us whether or not a doctor wrote a prescription to a Medicaid patient as a result of any particular call; is that true?

A. It's true in part. There are some call notes, as we saw before, which said that the doctor in fact

wrote the prescription for the patient in the presence of the sales rep.

Q. But you don't know if that's a Medicaid patient?

A. No, I don't. That I don't know.

Q. Okay. Well, let's look at a few of these call notes. I know Mr. Jacks went over some of them with you. I'm not going to go over as many with you as he did, but I want to go over a few.

MR. McDONALD: Chris, can you pull up Exhibit 148?

Q. (BY MR. McDONALD) This is what I understand call notes that you gathered that represent alleged violations in the child and adolescent psychiatry market, okay? And let's look at No. 17. And this is a call in -- November 21 of 2006. Do you see that?

A. Yes.

Q. And so that's after --

MR. McDONALD: Go back, Chris, if you would, to the date.

Q. (BY MR. McDONALD) November 21, 2006, that's after Risperdal was approved for the pediatric use for the treatment of autism, correct?

A. I think that there was a more limited indication than the one you just said, but it was

approved for some autism-related uses in November.

Q. All right. Let's look at what was said in this particular call. Major focus on managed care patient and how Risperdal has lowered co-pay, safety and efficacy with Risperdal for children with tying with adult patients, FDA slower to approve for elderly and children.

Do you see that?

A. Yes.

Q. And so since this was after the drug was approved for the use in children for a limited indication, as you agree, why is there something wrong with this call note?

A. Well, it's not clear -- I think this is one of those that are ambiguous -- where -- whether this was being promoted for children in schizophrenia, which would be -- which would remain an off-label use, whether it was promoted in accordance with the very limited indications, so there's some ambiguity in this particular call note.

Q. Yeah. So you can't tell, looking at this call note, whether anything improper happened; is that fair to say?

A. Based on this call note, you can't conclusively say that this was unlawful.

Q. Okay. I'm just pulling these out of your stack.

A. That's fine.

Q. Let's look at 50. And these are just some -- again, there's lots here, so we're certainly not going to go through every one of them. This one's in January of 2003. So that's just before there's an indication, right?

A. Correct.

Q. All right. And so --

MR. McDONALD: Chris, let's look at the --

Q. (BY MR. McDONALD) It's next call objective is the box we're looking at, right?

A. Correct.

Q. Okay. And it says what?

A. Follow-up to have data sent to him on children from professional services.

Q. And what's wrong about that?

A. You don't know specifically that there is anything in particular wrong with that.

Q. In other words -- and so you and I are steep in this industry, so I want to, to the extent we can, help the jury understand. It's not improper for a doctor to ask a sales rep about something off label, right?

A. That's correct.

Q. And so when that happens, one of the things the sale rep can tell the doctor is, "Doctor, we're not indicated for that. We'll have medical affairs give you information that you request" or something like that, right?

A. That's not one of the things; that's the only thing that the sales rep should be communicating to the doctor when he brings up that off-label use.

Q. Well, the sales rep could also just say, "Sorry, Doctor, we're not indicated for that" and move on.

A. He could.

Q. Or listen to the doctor talk and then move on, right?

A. He's typically supposed to say, "Doctor, we're not indicated for that use" and move on.

Q. Okay. But again, there's nothing wrong with this call note that you can tell, right, because -- and this is something that actually probably should have happened, right, if the doctor would have initiated an off-label promotion -- or an off-label discussion?

A. If the doctor initiated the conversation, then this would show that the rep behaved appropriately.

Q. Okay. Let's move on then. Let's go to 13 in this same stack. This is March of 1998.

MR. McDONALD: And Chris, can you show us the text field "comment"? I think it's up there.

Q. (BY MR. McDONALD) Kids.

A. Well, look, the rep is calling on it -- I have to see if this is a child psychiatrist. Can I see the entire text of the --

Q. If you want something blown up, we're happy to do it.

A. I'm just trying to see the field where -- if there is a -- some of them have a description of which -- of who they're calling on. But look, if it says kids, they're calling on a child and adol -- they're calling on a psychiatrist, it's fair to read that as he's promoting the drug for use in children.

Q. Simply because it says "kids"?

A. Yes.

Q. You don't know who's -- if the rep said kids or the doctor said kids. Your comment is if the call note comment box says kids, that's a violation of the Food, Drug and Cosmetic Act?

A. What I said was it was fair to read that as promoting it to children, that that's one fair reading of it. And that would be consistent with all of the other evidence we know about what Janssen's strategy was, what its training was, and it would be fair to read

that as consistent. You've got to look at the whole picture.

Q. It would be nice to have been there and actually seen what happened, too, right, to actually know if there -- anything happened?

A. It might be nice for you to be there. I wouldn't want to spend my time there, but...

Q. You don't -- you don't really know what happened in this call, do you, sir?

A. I don't know specifically.

Q. Okay.

A. But it's very clear that there was a -- something -- some discussion about use of this drug in children. There's no other explanation for the comment.

Q. That's your -- that's your opinion?

A. It's my opinion, absolutely.

Q. Let's go to 15 then. That's kind of similar to this. Just started the patient on low dose Risp, bipolar with a job and doing well. May make it to the dinner. Kids and private practice patient until 6.

How can you tell that the sales rep engaged in off-label promotion in this call?

A. Well, there are a couple of things that are suggestive. One, we know that Janssen was using the low dose Risperdal, particularly the .25 and the 5 --

.5 milligrams as a way of promoting the drug for use in children. So there's probably some discussion, and it's -- there's no conclusive proof here that involves a child population. And he's talking a little bit about perhaps his patients or -- that's all you can really conclude.

Q. You can't conclusively tell us that an off-label promotion occurred at this -- on this sales call, can you?

A. I can't conclusively say that.

Q. Okay. That's all I want to know. How about 230? This is a sales call that occurred --

MR. McDONALD: Chris, if you can put the date. I'm sorry.

Q. (BY MR. McDONALD) January 14th, 1994. And the comment field on this, there isn't one. It's just blank. And I believe this is one of the ones you visited about with Mr. Jacks that there was nothing on the call note, completely blank, but the sales rep was calling on a child and adolescent psychiatrist.

A. Could we see the -- move that to the left so we can see physician practice specialty?

Q. Sure. Sure.

A. Physician practice specialty. And so he's calling on a child and adolescent psychiatrist. And

again, the -- the way I look at these is they're calling on physicians who the lion's share of their patients, perhaps in some cases all of their patients, are child and adolescent psychiatrists -- are children and adolescents.

Q. How do you know that the lion's share of this physician's practice is for children and adolescents?

A. I don't know that specifically, but --

Q. Okay.

A. -- but physicians who are child and adolescent psychiatrists typically have a very substantial proportion of their patients as child and adolescent psychiatry.

Q. But they also see adults too?

A. They may well see adults.

Q. And it's perfectly appropriate for Janssen to call on a child and adolescent psychiatrist who sees adults and have an on-label discussion with that doctor about the use of the drug in his or her adult patients, isn't it?

A. I wouldn't necessarily agree with that.

Q. Why not?

A. Well, this was what I would call the wink-wink nod-nod school of promotion. If a physician -- let's just say the physician has 100 patients in their

practice and they have one adult patient and you're coming in and you're detailing that doctor on the use of the drug, the inference is that that drug is useful for that physician's patient population. I mean, that's certainly one reasonable inference.

Q. And do you know with certainty how often that happened with Janssen sales reps, that they called on child and adolescent psychiatrists who only had one or two adult patients?

A. Well, certainly from the deposition testimony that I've read, you know, most of the patients of the child and adolescent psychiatrists were child -- children and adolescents. That's my understanding.

Q. There's only been one, I believe, child and adolescent psychiatrist whose deposition you read, and that's Dr. Robinson.

A. I read Dr. Robinson's deposition, but I have read the depositions of numerous field sales representatives.

Q. Well, what I --

A. I can't tell you the specific number of patients that any given child and adolescent psychiatrist had who were adults or who were children. I can't tell you that.

Q. We're going to have child and adolescent

psychiatrists that can come in and explain.

A. Good.

Q. You don't know one way or the other, though, how many adult patients any child and adolescent psychiatrist sees, though, right?

A. Don't know that.

Q. Okay. So I want to be sure I understand your position. You believe though, that if a doctor only -- in this case a child and adolescent psychiatrist. If that psychiatrist only sees children, if the sales rep comes to that doctor and has an on-label discussion, never talks about kids, only talks about the drug and use of the approved age, you believe that that still constitutes improper behavior and a violation of the Food, Drug and Cosmetic Act?

A. What I believe is that that reflects the intended use of the drug in a pediatric population, and that intended use -- intended off-label use as well as evidence of actual off-label use together is what constitutes a violation of the federal Food, Drug and Cosmetic Act.

Q. And so you believe that that is a violation of the Food, Drug and Cosmetic Act? I just want to -- I don't want to debate with you. I want to just be sure I understand it.

A. As I described it, yes, collectively, all of that behavior amounts to intended off-label promotion in my view.

Q. On the blank call notes like the one we just looked at, of your stack here, there's thousands of those, right?

A. Lots.

Q. More than the ones that are filled in for child and adolescent psychiatrists are completely blank, right?

A. Well, that's right, because in fact in some cases in many years there was not even a field for the entry of any descriptive information by the field sales representative.

Q. So you have no idea what happened in those calls other than the doctor was a child and adolescent psychiatrist?

A. You have no idea what happened, that's right.

Q. Okay. You also have a stack on superiority. Let's look at those. Exhibit 149 I believe is your stack on superiority. Let's look at 160. This is a call. The date is --

MR. McDONALD: Chris, can you get us the date on here? There you go, right below where you.

Q. (BY MR. McDONALD) Okay. 16 April 2003, okay?

A. Yeah.

MR. McDONALD: And then let's look at the next call objective text, please, Chris.

Q. (BY MR. McDONALD) Why don't you read it. I'll let you do it.

A. HCMHMR staff meeting, quick response, Risperdal patients have compared to Haldol, consider proper dosing to maximize efficacy.

Q. You can't tell who said what in this box, can you? You can't tell if that was the doctor talking or the -- or the sales rep talking, can you?

A. The last clause, I think you can probably conclude that "consider proper dosing to maximize efficacy" is something the sales rep said. The preceding clause, "quick response, Risperdal patients have compared to Haldol," you don't know that that's something -- you don't know conclusively that that's something that the rep said.

Q. And if that's something the doctor said, that's perfectly fine, right?

A. It would depend on what the stimulus was for that -- for that. If he unilaterally blurted that out, you know, that might be okay. If there was a stimulus that elicited that discussion, it probably isn't okay.

Q. You can't sit in here today and tell us

conclusively that there's anything wrong with this call note, though, can you?

A. Conclusively, I can't -- I can't reach a --

Q. Okay.

A. -- a conclusion.

Q. Let's move on. 215. This is September 16th, 2004. Let's look at the box in this one. And again, these are just a few out of your thousands. I think the section you're -- well, let's read the whole thing.

In service, he told me he had used all REM kits, thanked for use, more patients, will do better longer on REM, easy to titrate. Risperdal, fewer side effects, compared Haldol, available, Medicaid.

I guess that's what that is. You can't conclusively tell who was saying what in this call or that this call note is improper, right?

A. Well, I wouldn't totally agree with that, because here what you have is some type of an in-service, which means that the rep and perhaps someone else medically trained went into either an individual's practice or perhaps a group practice or a hospital and that she's describing what took place in the in-service, which presumably is the training that was provided, and she says -- she or he says Risperdal has fewer side effects compared to Haldol. So I think that there's

much -- there's more evidence here where you can conclude that there was a, you know, claim of -- of superiority.

Q. So he told me he had used all kits, thanked for use, more patients will do better longer on REM, easier to titrate, Risperdal fewer side effects compared to Haldol. He told me.

A. Well, in the prior clause before the ellipses, yes, she's referring to what they discussed. In the final clause -- again, we're trying to -- this is not a perfect science. These are not -- these are not transcripts of what took place. So what we're doing is we're trying to look at these things and we're saying, you know, do they provide any kind of relevant information about the nature of the promotional activity that took place? And I would say yes, there is some relevant information here. Is it conclusive? No, but it's absolutely relevant to what the inquiry is.

Q. It's not conclusive?

A. Not conclusive.

Q. Okay. Let's look at 226. And let's look at the call box here, the next call objective. This is -- this is blank. Is there something wrong with this one?

A. Well, what we see is -- in the box that is titled X MAT USD 1 --

Q. Okay.

A. -- we see that there was a discussion there of Csernansky.

Q. Okay.

A. She's indicating -- or the rep is indicating, as I read it, that either discussed or left the Csernansky reprint. You will recall that the Csernansky reprint, as I testified to earlier, was the study that FDA rejected as the basis for the comparative superiority claim versus Haldol. So I think we can conclude that this particular representative left this study which reports on comparative superiority in a way that -- you know, that it runs afoul of FDA's admonition.

Q. And do you know that Janssen -- well, let me back up. Pharmaceutical companies can leave behind reprints with physicians, correct?

A. Under certain circumstances.

Q. Okay. And they seek approval from the FDA or tell the FDA that they're going to leave behind a certain reprint, right?

A. That's not always the case. It was the case at certain times but not the case at other times for reasons I can explain if you want.

Q. And do you know that Janssen had such

communications with the FDA about leaving behind their Csernansky reprint?

A. There may have been some communications with FDA about, you know, the Csernansky reprint.

Q. Okay. And you don't know one way or the other?

A. I don't recall with certainty, no.

Q. So it could have been perfectly appropriate to leave the reprint behind, right?

A. It might have been.

Q. Okay. Let's move on. Let's talk about diabetes. We'll move this along a little bit.

MR. McDONALD: 145, Chris.

Q. (BY MR. McDONALD) Let's just look at the next call objective. Why don't you read that one for us and tell us if you can conclusively tell us that there's something wrong with this call?

A. Could we just focus in on the date? I'm just trying to put this into context.

Q. Oh, sure. I wasn't trying to not show it to you. I was just trying to be quicker.

MR. McDONALD: This is 338. I'm sorry. Go to 338.

A. Well, if I could comment on that.

Q. (BY MR. McDONALD) Sure. Let me just go -- let me move this along, and if your lawyer wants to ask you

something -- because I know I'm going to get in trouble here pretty quickly from Judge Dietz.

The call date is August 2002, right?

A. That's correct.

Q. Okay. And let's look at the next call objective. Can you tell us conclusively what's wrong with this call?

A. You know, it can be read as suggesting that Risperdal is comparatively superior to other drugs.

Q. But you can't conclusively tell us what happened, can you, or that this is a violation of the Act?

A. I certainly can't tell you conclusively what happened in that, you know, in that -- in that sales call.

Q. Okay. All right. Let's move on. You testified about an interaction that the -- that Janssen had regarding a proposed C&A indication in 1997. Do you recall that?

A. Yes.

Q. And Mr. Jacks showed you Exhibit -- Plaintiffs' Exhibit 433, if we can pull that up. Plaintiffs' 433. And do you recall this letter?

A. Yes.

Q. Okay. And this isn't a notice of violation or

a warning letter or anything like that, is it?

A. No.

Q. This is just a communication from the FDA to Janssen about a request that Janssen had made, correct?

A. It is a communication from DDMAC commenting on the proposed launch materials for Risperdal.

Q. Well, commenting on a request that Janssen had made -- hang on. I think I have the wrong one. I apologize. Give me one second. It was easier back in the old days when you had hard copies and I could just hand it to you.

A. Tell me about it.

Q. So bear with me one second. (Brief pause).

82. Let's move on. You talked -- I think we all remember, you had -- you talked about a communication from the FDA in 1997 commenting on Janssen's request for information on a label about the use of the drug in children and adolescents, right?

A. Correct.

Q. And there was nothing -- that letter received by Janssen was not a violation, and it wasn't a warning letter or anything like that, right?

A. It was a response from FDA rejecting -- as I recall, rejecting the supplemental application seeking to expand the label to include information about use in

children.

Q. Okay. What I want to focus on is, why did Janssen make that request? And so let's look at Janssen's request for a supplemental indication. That's Defendants' Exhibit 644. All right. So do you recognize this letter? Have you seen this before?

A. I'm not sure that I've seen this letter before. Thank you.

MR. JACKS: John, do you have a copy? Thank you.

Q. (BY MR. McDONALD) This is a request by Janssen for a label change for pediatric use supplement, right?

A. Appears to be, yes.

Q. Okay. And if you'll look at the second page of why Janssen was making this request, it says "Janssen's rationale for proposing a supplement to the currently approved product label for Risperdal is somewhat complex. Although this submission does not contain data which the agency would normally characterize as substantial evidence, we are nevertheless aware that Risperdal is being utilized in children and adolescents. Hence, we believe the agency's alternative labeling options would not adequately and safely reflect this fact."

Do you understand the predicament that

Janssen was in and why it was seeking this supplementation in that it knew that its drug was being used in children and adolescents and there wasn't anything it could do about it to advise doctors who were using too high of a dose and say, "Doctor, that's too high of a dose to use in a child; you should use a much lower dose"? They were prohibited from having those kind of communications because that was off label. Do you understand that's why this request was made?

A. That's what you're telling me as to why the request was made. I don't have that information.

Q. There wouldn't be anything wrong with making such a request, would it?

A. There's not anything wrong with making such a request, but FDA in its ultimate rejection letter, you know, addressed this specific point that Janssen was raising and explained why, despite the fact that it was being used in children, approval was not appropriate.

Q. And so then Janssen began the process of doing all the studies necessary and ultimately gained FDA -- an FDA indication for use of the drug in children?

A. Well, that's not correct. Again, it only gained approvals for certain very limited indications for use in children, much narrower than the indications for the drug for use in adults.

Q. It did studies and got an indication for, as you say, several narrow uses in children?

A. Ultimately, yes.

Q. Okay. And as a result, it could -- Janssen reps could then tell doctors, "You're dosing too high. You need" -- "this is the proper dose. If you're going to use this drug in children for one of these indications" --

A. They --

Q. -- "this is a proper dose"?

A. Again, you've talked about certain facts that I'm not -- we haven't talked about the specific dosages. Assuming that they talked about using the drug within the approved dosages, within the approved population and within the approved limited indications for use in children, once it was approved for that use, there would be nothing -- nothing wrong with that.

Q. Okay. Because if a company knows its drug is being used off label, I mean, you'd agree that it has a responsibility to try to inform the public about that risk, right?

A. What's the risk that you're referring to?

Q. For example, use of the drug in children and having too high of a dose. If Janssen knows that doctors are prescribing its drug to children with too

high of a dose, don't you think it has the responsibility to try to do something to help that not happen?

A. Well, let me -- the reason I'm stumbling is because when you first asked the question, you introduced the concept of off label and trying to rectify a use that you knew was off label, and now we're talking about a slightly different situation. And look, if a drug company has a -- knows about information -- about safety risks associated with an off-label use, there are many ways that the company can collaboratively with FDA -- and we have some very recent examples of that, where companies can communicate that information appropriately to practitioners in collaboration with FDA or unilaterally even in certain cases.

Q. And one of the things a drug company can do is exactly what Janssen did, and that's in this letter, right? This is one of the things a company could do, right?

A. You mean to seek --

Q. Right, to seek approval from the FDA to be able to tell doctors the proper dosing for the use of the drug in children.

A. Well, if they wanted to tell -- yes, one way to gain permission to tell doctors about appropriate dosing

is to modify the labeling to include that information.

Q. Okay. Let's move on. Let's talk about warning letters that you discussed with Mr. Jacks. We talked about a 1999 letter that was a notice of violation, right?

A. Right. It was uncaptioned, but it was a notice of violation letter.

Q. And again, you didn't talk with anybody about that letter?

A. Did not.

Q. That came from DDMAC?

A. That came, yes, from DDMAC.

Q. Do you know Minnie Baylor-Henry?

A. I do.

Q. Pretty smart?

A. She's a smart and experienced regulatory affairs professional.

Q. Right. You'd agree with me that there's probably not a single pharmaceutical company out there that hasn't received a warning letter or a notice of violation from the FDA, right?

A. I'd agree with that.

Q. And like when you were at Pfizer for a number of years, Pfizer received a number of warning letters and notice of violation from the FDA, right?

A. I'm sure they did.
Q. It's one of the ways the FDA initiates a dialogue with pharmaceutical manufacturers to try to make a change about something, right?
A. Well, in part, it's initiation of a dialogue, yes.
Q. Sure. Warning letters are informal and advisory?
A. I wouldn't agree with that.
Q. Okay. We'll get out the manual then. Let's go to Exhibit 428. Do you recognize this?
A. Yes.
Q. Okay. How about we go to Page 3. And it says "A warning letter is an informal advisory."
A. Yes.
Q. That's the language by the FDA?
A. Right.
Q. Okay.
A. But they're using it in a sense that I -- may not be congruent with the sense that you're using it in.
Q. It's not a final agency action?
A. It's not a final agency action subject to judicial review, that's true.
Q. Okay. And it doesn't commit the agency to do anything?

A. Correct.

Q. Okay. And you said it's -- so a warning letter is not the same as a determination by a judge or a jury that there's been a violation?

A. That's correct.

Q. Okay. Let's -- you looked at Plaintiffs' Exhibit 2168. Let's pull that out. And this is a letter that you testified about that all atypical antipsychotic manufacturers received from the FDA about a label change to include a warning on diabetes, right?

A. They all received similar letters.

Q. And then the next thing Mr. Jacks asked you about was Plaintiffs' Exhibit 98. And this was the Dear Healthcare Provider letter a couple of months later, right?

A. Yes.

Q. In truth, there was a lot of back and forth communication between the FDA and Janssen between the September letter and this letter, right?

A. Yes. Janssen was trying to persuade the FDA that the information should not be applied to Risperdal in the same way that it applied to other drugs.

Q. And in fact, isn't it true that Janssen actually prevailed and there wasn't -- there's not a class warning, is there?

A. I'm not sure what you mean.
Q. Well, is the warning label a warning on diabetes for Janssen's Risperdal the same as Lilly's Zyprexa in November of 19 -- of 2003?
A. There may have been some minor differences between the two.
Q. They're different?
A. I'd have to compare them side by side.
Q. I know you looked at this one, and I think you've commented on it. Let's look at Defendants' Exhibit 441. This is actually the letter that was sent. And if you can go to the -- this talks -- you went over this in detail with Mr. Jacks.
A. Is this different than the version I looked at before?
Q. Well, this version --
MR. McDONALD: Flip the page, if you would, please, Chris.
Q. (BY MR. McDONALD) -- actually gives the references to all the studies that are in the letter, right?
A. It lists the references, yes.
Q. Sure. Makes full disclosure of the peer-reviewed studies that are referenced in the letter, correct?

A. Whether it's full disclosure or not, I don't know, but it lists the studies in some fashion.

Q. Okay.

MR. McDONALD: And go to the next page, Chris.

Q. (BY MR. McDONALD) And attaches the label that has the warning that's been approved by the FDA?

A. Correct.

Q. Okay. So the actual letter that went out to the healthcare providers identified all the studies that were referenced in the letter and attached the FDA-approved package insert that had the FDA-approved warning on diabetes, right?

A. Yes. To that extent, yes.

Q. Okay. So doctors should read the package insert, correct?

A. They should probably read the package insert.

Q. Okay. And it had the new warning in this letter?

A. Had the new warning in it.

Q. Okay. Nonetheless, the FDA sent the warning letter to Janssen. And again, there was dialogue back and forth between Janssen and the FDA about what had occurred, correct?

A. You mean subsequent to the November 10th --

Q. Subsequent to the November 10 warning letter, that was dialogue back and forth between Janssen and the FDA about what should happen next, correct?

A. Correct.

Q. And Janssen sent the corrective letter that you looked at with Mr. Jacks, correct?

A. Yes, after -- after the give-and-take they did send the corrective letter.

Q. And then after Janssen sent out the corrective letter --

MR. McDONALD: Let's pull up Exhibit Defendants' 745.

Q. (BY MR. McDONALD) Well, this is the corrective letter, right?

A. This appears to be the corrective letter, yes.

Q. Right. And then what happened next was the FDA considered this matter closed, correct?

A. I don't think so.

Q. You don't. Okay.

A. Are you talking about the diabetes matter?

Q. Yes.

A. Yes, okay. When you say closed, I mean, that the remedial action that had been requested by the FDA was completed, yes.

Q. Right. And so FDA considered the matter closed

on the warning letter and no further action was taken?

A. No further action that I'm aware of on that warning letter was taken, that's correct.

Q. Okay. All right. They didn't sue Janssen over this letter that it sent, right?

A. Not that I'm aware of.

Q. Okay.

THE COURT: Speaking of getting into trouble.

MR. McDONALD: I'm trying, Your Honor. I'm moving --

THE COURT: Yeah. May I see y'all up here for just a second.

(Discussion off the record)

Q. (BY MR. McDONALD) You've given some testimony about intended use, right?

A. Yes.

Q. Okay. And you've given us a couple of theories under which off-label promotion or promotion of a drug for an indication that has not been approved by the FDA violates the Food, Drug and Cosmetic Act?

A. Correct.

Q. One theory is that the drug is misbranded because its label does not carry adequate directions for an intended use that has not been approved?

A. That's not a theory that I explained at length, but yes, that is one theory for why it's misbranded.

Q. The other I think that you mentioned is that if the drug is promoted off label for an unapproved use, it's considered an unapproved new drug for that intended use?

A. I didn't refer to that in my testimony, but I certainly referred to that in my report.

Q. Okay. Not ever used for which a drug is prescribed is an intended use, true?

A. That's true.

Q. And that's because doctors prescribe drugs off label all the time?

A. That's correct.

Q. It's a common practice, right?

A. Relatively common.

Q. And it's often the standard of care?

A. In certain categories, absolutely.

Q. You'd agree that often a manufacturer may know that its drug is being used or likely being used off label, right?

A. Yes.

Q. But a manufacturer doesn't violate the law by selling a drug knowing that it may be used off label?

A. In and of itself, that knowledge should not

cause the sale of the drug to be off label and illegal.

Q. Okay. Because mere knowledge on the part of the manufacturer that a drug is being used off label is not enough to transform the doctor's off-label use into an intended use, right?

A. I would agree that mere knowledge.

Q. To demonstrate a violation, you need a communication to a targeted audience?

A. You need some sort of affirmative off-label promotion, yes.

Q. You'd agree with me that all new uses are off label until they're approved by the FDA?

A. For a drug that's already approved for a different use?

Q. Yes.

A. If I understand the question, yes, I would agree with that.

Q. Okay. And there's nothing wrong with Janssen or any other pharmaceutical company doing the research necessary to get an approval for a new indication, is there?

A. No, that's precisely what the law is intended to induce.

Q. And so like in this case, for example, there was nothing wrong with Janssen doing the necessary

research in the child and adolescent market necessary to get a new indication from the FDA for Risperdal, was it?

A. You're saying to do --

Q. To do the research. There's nothing wrong with --

A. The clinical research?

Q. Correct.

A. There's nothing wrong with doing clinical studies to get an approval.

Q. And you'd agree with me that it often takes many, many years to get approval -- a new -- approval for a new indication from the FDA?

A. Often the duration of the studies and the review time, yes, it's many years sometimes.

Q. Especially in the child and adolescent sector?

A. It may be a bit more difficult to get approval in that segment given the vulnerability of the patients.

Q. And in fact, you know in this case it took Janssen a long time to get FDA approval for Risperdal in child and adolescent, right?

A. Well, what I don't know is, going back to your earlier question, whether, you know, all the studies were being done and the duration of specific studies, but yes, from the time the drug was first approved in 1993 until there was any approved indication in

children, a long time elapsed. That I know.

Q. Okay. And is there anything wrong with -- in the interim from when Janssen began seeking approval or trying to do the studies necessary in getting the internal workings going and studies and communications with the FDA for use in children until the indication was actually approved by the FDA, okay, is there anything wrong in that period with Janssen having internal business plans and preparing itself for an ultimate indication?

A. There would be nothing wrong in and of itself with that kind of activity.

Q. Okay. I want to talk to you a little bit about non-promotional communications that manufacturers have. There can be circumstances when a manufacturer communicates with a doctor or the public about an off-label use that is non-promotional, right?

A. Limited circumstances, yes.

Q. It can happen?

A. It can happen.

Q. Sure. So, for example, if a doctor asks for information on an off-label use, an unsolicited request, it's okay for the manufacturer to respond giving summaries of data to the doctor, correct?

A. It's okay provided it's done properly.

Q. Okay. And we talked about this a little bit ago. For example, if the doctor raises an off-label topic with a sales representative, a sales representative can refer the doctor to their medical affairs and have this exact kind of communication, right?

A. In general, yes.

Q. And that's common, right?

A. Yes.

Q. Not unique to Janssen to have that kind of practice?

A. Not unique to Janssen.

Q. Happens with all pharmaceutical manufacturers?

A. Yes.

Q. Okay. Sometimes pharmaceutical companies support medical education?

A. They do.

Q. And there's nothing wrong with that, is there?

A. In and of itself, there's nothing wrong with that.

Q. And all pharmaceutical manufacturers do that?

A. By and large, yes.

Q. And the topics in these educational events can be off label, right?

A. There's certain criteria that FDA has

established to determine the independence of continuing medical education so that unless the continuing medical education is in accordance with those standards, then it could be problematic.

Q. If the continuing education is independent and the manufacturer is not dictating the content of the education, then it can be sponsored by the manufacturer but still be off label and it be okay?

A. Right. If the manufacturer doesn't control the content, if there's other indicia of independence, then standing alone it may well be okay.

Q. Right. And those rules have kind of changed and evolved over time?

A. I wouldn't say they've really changed and evolved. They've been in place for a number of years.

Q. So you would agree with me that a company's support of a continuing medical education presentation isn't illegal or wrong just because it happens to be off label?

A. In and of itself, an individual program, assuming that it meets all of the criteria of independence, there's nothing wrong with that in and of itself.

Q. Okay. What about research? There's nothing wrong with pharmaceutical companies supporting research

on its drug, is there?

A. Independent arm's-length legitimate research, no problem.

Q. Happens all the time?

A. Every day.

Q. Commonplace in the industry, right?

A. That's what pharmaceutical companies do; they research drugs.

Q. Right. Because if they don't do it, who's going to do it, right?

A. That's one way of putting it.

Q. Okay. And it's also not a violation for an employee of a pharmaceutical company who's involved in the study to ultimately be an author on a paper of some research, is it?

A. Authorship in and of itself is not an issue -- in and of itself is not an issue for FDA.

Q. Nothing wrong with that as far as the FDA is concerned?

A. I'm only being a bit reluctant because there are other issues about authorship that might be relevant to FDA if the person didn't actually participate in the study and if they were paid a lot of money and didn't divulge it, but authorship standing alone, you know, is not problematic.

Q. Happens all the time, right?
A. Yes.
Q. Okay. When pharmaceutical representatives go and see doctors, they often use what are called sales aids, right?
A. Correct.
Q. Glossy little cards that we've all seen that they show the doctors, right?
A. Sometimes they're in the shape of cards or brochures, folders, things of that sort.
Q. And pharmaceutical manufacturers send those to the FDA to be sure that the FDA doesn't have some objection to those materials, correct?
A. I wouldn't agree totally with that statement.
Q. Pharmaceutical companies send those materials to the FDA, correct?
A. They do send them to the FDA. They're required to send them to the FDA at the time of first use.
Q. Right. And if the FDA finds a problem with them -- if the FDA reviews the materials and they find a problem, they let the manufacturer know?
A. If they review the materials and if they find a problem, they often let the company know.
Q. Okay. If you'll give me one second. (Brief pause) I'll pass you to your counsel. Thank you.

THE COURT: Why don't we all just kind of stand up and let the circulation return to the lower extremities, as Mr. Jacks takes his five-page rebuttal and whittles it down to one.

Were you having trouble picking just the one page?

MR. JACKS: Well, we'll move this along, Your Honor. It is Friday afternoon, and we're going to try to get everyone out of here shortly.

THE COURT: Let's everybody be seated.

REDIRECT EXAMINATION

BY MR. JACKS:

Q. Mr. Friede, you were asked about Defendants' Exhibit 644, which was the letter in which the Janssen company said to the FDA that their reasons in 1996 for wanting to be able to get -- mention the children in their label were fairly complex. Do you remember that?

A. I do.

Q. And they went on to explain, well, there were doctors using their product and they wanted to communicate with them, right?

A. Right.

Q. You pointed out there are legitimate ways to do that without engaging in off-label promotion, right?

A. Correct.

Q. Now, we looked at some of the call notes -- in fact, in 1996, at almost the exact same time when they were telling the FDA that they wanted to put something in their label -- in their label about children, we saw sales representatives that, pursuant to their training and pursuant to business plans of the company, were out promoting Risperdal to those very same physicians; is that right?

A. That's right.

Q. The 1994 business plan also talked about --

MR. JACKS: May we see Plaintiffs' Exhibit 2, please, at Page 983?

Q. (BY MR. JACKS) The business plan in the market expansion discussion about how they wanted to expand to children --

MR. JACKS: And I'll need to go down to the next paragraph below what we've got there, please, Mr. Barnes.

Q. (BY MR. JACKS) -- where they spoke of changing current labeling, do you see that?

A. Yes.

Q. As you read that sentence, do you see any mention of an altruistic purpose, a humanitarian purpose, a safety-based purpose for wanting to change the current labeling?

A. No.
Q. But they talk about a business purpose; is that fair?
A. That's fair.
Q. They talk about market expansion?
A. That's correct.
Q. And let me ask you a few questions about the warning letter. It was sent out in the year 2004 in the month of April; is that right?
A. That's my memory.
Q. That was during the administration of our -- of president George W. Bush; is that correct?
A. That's correct.
Q. And who was the chief counsel of the FDA at that time?
A. The chief counsel was Dan Troy.
Q. And who was Dan Troy?
A. Dan Troy was someone that had been brought in to serve as FDA chief counsel when the republican administration took over the White House.
Q. And what was his legal background?
A. He had been a lawyer immediately before at a law firm called Wiley, Rein & Fielding and had other relevant legal experience.
Q. Who were his clients mainly?

A. Well, and he was -- well, his clients were pharmaceutical companies.

Q. All right. And when he came in, did he make any changes in the practices within the FDA of what kind of hoops people in the agency had to jump through before they could send out a warning letter?

A. He did.

Q. And what were -- what was one of the hoops?

A. Well, one of the requirements that he imposed was that before a warning letter could be sent out, it had to be reviewed and cleared for legal sufficiency by the FDA chief counsel's office.

Q. What effect did that have on the number of warning letters sent out of the agency during those years?

A. Well, there was a substantial decline in the number of such warning letters.

Q. So was the goal to see that only the meritorious ones got sent out?

A. As it was explained at the time, his objective was to make sure that warning letters that were issued were legally sufficient.

Q. And that's the hurdle that this warning letter had to jump; is that right?

A. That's correct.

MR. JACKS: Now, may we see Plaintiffs' Exhibit 271, please?

Q. (BY MR. JACKS) This is Mr. Gorsky's, the president of the company's message about off-label promotion and promotion through the use of unsupported claims; is that right?

A. That's correct.

Q. And he said that promotion of unsupported or off-label claims are not only illegal, but they comprise -- I think he may have meant to say compromise the representation of Janssen and of Johnson & Johnson in providing quality healthcare products and information to providers and patients.

Now, did Mr. Gorsky say, well, now, this is something we're not going to do if there's a final agency action and a jury trial in a court proceeding? Did he say that?

A. No.

Q. Is the conduct that led to the issuance of the warning letter according to the FDA itself illegal?

A. Yes. The FDA's determination was that it was unlawful.

Q. Misbranding?

A. Misbranding.

Q. Did the fact that the agency didn't pursue the

case beyond making them send out the correction letter make it legal?

A. No. It's like if you -- it's like getting a speeding ticket and then speeding. The fact that you don't get another ticket doesn't make that conduct legal.

Q. There was talk about call notes. Let's talk about that for a minute. And you were asked about the fact that in these two boxes there are thousands of call notes representing visits to Texas child and adolescent psychiatrists in which there is no field to enter what happened when they went to the doctor's office.

A. Correct.

Q. When Mr. Jeff Dunham went 96 times to the office of Dr. Valerie Robinson who he knew treated only children, including his own, was there a single time when he made any entry in the message field on his call notes?

A. My recollection is that he did not.

Q. The official company position at the time was that a message should be entered every time to show what happened; is that true?

A. Yes, to -- yes, to the extent there was an opportunity to do so in the -- in the call notes.

Q. Does it raise any questions in your mind,

Mr. Friede, why, in dispatching its sales force to call upon child and adolescent psychiatrists pursuant to company plans and company training, there might be reasons why the company didn't want the sales reps to write down what happened on those sales calls?

MR. McDONALD: Objection, Your Honor. May we approach, please?

THE COURT: Why don't you go ahead and just state the objection.

MR. McDONALD: Speculation and way beyond his scope of his expertise.

THE COURT: Sustained.

Q. (BY MR. JACKS) Except on the subject when there were calls made on child and adolescent psychiatrists, did you see any other call notes in your review where there was not even a field in which the reps could enter information about what happened? Did you see that anywhere else in your review of call notes?

A. I don't recall specifically whether it was limited to child and adolescent or whether it also covered other categories of promotional behavior. I just don't recall.

Q. All right. You were asked about seeding the literature, a phrase we saw in the same business plan that talked about getting label changes. And you were

asked a question about, well, now, the definition we showed was out of a document that came in the 2000s, not in the mid 1990s. Now, as somebody who's been involved in the pharmaceutical industry on both the regulatory side and the industry side for decades, had you ever heard of the term seeding the literature before?

A. Yes.

Q. You saw the definition here from a Janssen document that it referred to articles that had little scientific validity and were mainly for promotional purposes, right?

A. Correct.

Q. Is that what it meant in the mid '90s as well as in the 2000s?

A. It meant sort of planting these promotional messages under the guise of publishing a scientific article.

Q. The last thing I want to ask you about: You were asked questions about, well, now, with respect to the call notes you reviewed, you don't know whether the doctor was a Medicaid doctor, right?

A. Correct.

Q. Was that something you were seeking to determine in your work? You said, well, you don't know if the doctor wrote a prescription unless it's in the

call note itself as a result of the sales call. Was that the focus of your inquiry?

A. No.

Q. Were you trying to find out if the conduct of this company, from the top where the business plans are made to the middle management where the sales training takes place down to the ground level where the sales calls take place, was consistent or inconsistent with federal law?

A. That was my objective, to make that determination.

Q. Now, they said, well, the -- well, you looked at business plans, and just writing the business plan and keeping it inside the company and not doing anything about it, that's not illegal promotion. Did they ask you that?

A. Yes.

Q. And that's true?

A. In and of itself, the business plan is internal to the company, but there are relevant parts of it.

Q. And then you were asked about the training programs. Well, you don't know for sure who all went, and just educating the sales force about the competition, that's not illegal promotion, right?

A. I was asked about that, that's correct.

Q. And that's true?
A. That's true.
Q. And then you were asked about the call notes and what the sales force was doing. And if all you had in this case to look at was call notes and you knew nothing about how the representatives were trained and nothing about the plans pursuant to which they were trained, would you be able to make any judgment about the legality or illegality of the company's conduct based only on what was happening down at the grass roots?
A. It would certainly have a much weaker foundation for making that kind of a -- of a determination.
Q. Is that why you did what you did and how you did it?
A. Yes. I was looking to see what was the company's intention, how did it train its people, and what it did in the field. And so what -- again, we come back to this -- to this whole notion of you look at the entire picture. You don't take each individual piece. It's got to be the entire picture. And so when you see evidence that a company planned to engage in certain behavior, that it trains its people to engage in that behavior, that it actually engaged in that behavior,

then you have a pretty strong foundation for concluding that that behavior, because it is unlawful, you know, violates the federal Food, Drug and Cosmetic Act. So you don't look at anything in isolation; you look at the whole picture. It's as simple as that.

MR. JACKS: No further questions.

RECROSS-EXAMINATION

BY MR. McDONALD:

Q. I'm going to be very brief. I want to talk about these call notes again. So there's over 500,000 of these call notes to Texas doctors, and you've told us that you looked at five to 10,000 of them; is that right?

A. Thousands, yes.

Q. So that's 1 to 2 percent, right?

A. Yes.

Q. Okay. And of that 1 to 2 percent, you yourself just picked out a couple of hundred of them, right?

A. I'm not sure what you mean picked out.

Q. Of the 500 -- of the 1 to 2 percent you looked at, you yourself picked out a couple of hundred from the 500,000?

A. Oh, right.

Q. And the rest were picked out from the lawyers?

A. Correct.

Q. And sitting here today, you can't tell the jury conclusively how many of the 1 to 2 percent you looked at indicate something illegal or a violation of the Food, Drug and Cosmetic Act, correct?

A. That's correct.

Q. Okay. Let's -- I want to look at Exhibit 751. This is the one I stumbled around and couldn't find. This is the FDA's response to Janssen's correction letter, correct? Is that right?

A. Appears to be.

Q. Okay. And it says -- the FDA said, "In light of the aforementioned actions taken by J&J PRD regarding Risperdal's promotional materials, DDMAC considers this matter closed," right?

A. Yes.

MR. McDONALD: Thank you. No further questions.

MR. JACKS: And none here, Your Honor.

THE COURT: Well, why don't we get a good start, and I will see y'all back Tuesday morning. Have a good weekend.

(Jury not present)

THE COURT: Why don't y'all undock Mr. Friede. There's not anything we need to take up before we recess, is there?

MR. JACKS: No, sir.

MR. McDONALD: No, sir.

(Court adjourned)

THE STATE OF TEXAS)

COUNTY OF TRAVIS)

I, Della M. Koehlmoos, Official Court Reporter in and for the 250th District Court of Travis County, State of Texas, do hereby certify that the above and foregoing contains a true and correct transcription of all portions of evidence and other proceedings requested in writing by counsel for the parties to be included in this volume of the Reporter's Record, in the above-styled and numbered cause, all of which occurred in open court or in chambers and were reported by me.

I further certify that this Reporter's Record of the proceedings truly and correctly reflects the exhibits, if any, admitted by the respective parties.

WITNESS MY OFFICIAL HAND this the 13th day of January, 2012.

/s/: Della M. Koehlmoos
DELLA M. KOEHLMOOS, TX CSR 4377
Expiration Date: 12/31/13
Official Court Reporter
250th District Court
Travis County, Texas
P.O. Box 1748
Austin, Texas 78767
(512) 854-9321