IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF INDIANA (HAMMOND)
CIVIL No. 2:07-CV-174-PPS-APR

CHERYL J. CUNNINGHAM, Individually and as Personal Representative of the Estate of Scott Randall Cunningham, Deceased, JOHN J. CUNNINGHAM, Individually, and KEVIN CUNNINGHAM, Individually,	:
Plaintiffs,	:
vs.	:
SMITHKLINE BEECHAM CORPORATION d/b/a GLAXO SMITHKLINE, a Pennsylvania Corporation,	:
Defendants.	:
----------	:
IN RE: PAXIL	:COURT OF COMMON PLEAS :PHILADELPHIA COUNTY :OCTOBER TERM, 2004 :NO. 1503

- - -

September 28, 2007

- - -

Oral Videotape deposition of Dr. Ronald Krall, taken pursuant to notice, was held at the Law Offices of DRINKER BIDDLE, 1 Logan Square, Philadelphia, Pennsylvania, commencing at 9:00 a.m., on the above captioned date, before Kathleen Ruccolo, Professional Reporter and Notary Public in and for the Commonwealth of Pennsylvania.

A P P E A R A N C E S:

BAUM, HEDLUND, ARISTEI, GOLDMAN & MENZIES
BY: GEORGE W. MURGATROYD, ESQUIRE
12100 Wilshire Boulevard, Suite 950
Los Angeles, California 90025

POGUST BRASLOW
BY: ANDREW J. SCIOLLA, ESQUIRE
161 Washington Street, Suite 1520
Conshohocken, Pennsylvania 19428
ON BEHALF OF GLAXOSMITHKLINE:
KING & SPALDING
BY: TODD P. DAVIS, ESQUIRE
BY: ERIC M. WACHTER, ESQUIRE
1180 Peachtree Street, N.E.
Atlanta, Georgia 30309
and
ANDREA L. PARRY, ESQUIRE
One Franklin Plaza
Philadelphia, Pennsylvania 19101
PHILLIPS LYTLE
BY: ROBERT E. GLANVILLE, ESQUIRE
3400 HSBC Center
Buffalo, NY 14203

A L S O P R E S E N T:
Michael J. Kutys, Jr., Videotape Technician

MAGNA LEGAL SERVICES
Two Penn Center
1500 John F. Kennedy Boulevard
Suite 910
Philadelphia, PA 19102

- - -

I N D E X

- - -

- - -

E X H I B I T S

- - -

- - -

E X H I B I T S

- - -

- - -

E X H I B I T S

- - -

- - -

DEPOSITION SUPPORT INDEX

- - -

Direction to Witness Not to Answer

Page	Line	Page	Line	Page	Line
None					

Request for Production of Documents

Page	Line	Page	Line	Page	Line
13	23				

Questions Marked

Page	Line	Page	Line	Page	Line
None					

(By agreement of counsel, the sealing, filing and certification of the transcript has been waived; and all objections, except as to the form of the question, have been reserved until the time of trial.)

DR. RONALD KRALL, after having been duly sworn, was examined and testified as follows:

PROCEEDINGS

THE VIDEOGRAPHER: We are now on the record. My name is Mike Kutys. I am a videographer retained by Magna Legal Services. Today's date is September 28th, 2007, and the video time is 9:09 a.m. This deposition is being held at One Logan Square, Philadelphia, Pennsylvania. This is a video deposition for the Court of Common Pleas, Philadelphia County, October Term, 2004, Number 1503, In Re of Paxil, and for the United States District Court for the Northern District of Indiana, Civil Action Number 2:07-CV174-PPS-APR, in the matter of Cheryl J. Cunningham, et al, versus SmithKline

Beecham.

The deponent is Ronald Krall. This deposition is being taken on behalf of the plaintiff. All counsel will be noted on the stenographic record. The court reporter is Kathy Ruccolo, and she will now swear in the witness.

DR. RONALD KRALL, after having been duly sworn, was examined and testified as follows:

EXAMINATION

BY MR. MURGATROYD:

Q. Doctor, can you please state and spell your full name?

A. Ronald Lee Krall, R-0-N-A-L-D, L-E-E, K-R-A-L-L.

MR. DAVIS: Sorry. Skip, I'm not trying to interrupt you. I want to put a couple additional logistical things on the record. We can agree to relieve the court reporter of her responsibilities, such that the errata sheet can be exchanged between counsel, as opposed to providing it to the court reporter. Is that acceptable to both

of you all?

MR. MURGATROYD: That's fine.

MR. DAVIS: And then the court reporter can send the transcript to me, as opposed to witness, and I will forward the transcript and the errata sheet to the witness. And we've agreed that this deposition, like the others, can be used in the Baum Hedlund suicidality matters, so we don't have to redo the deposition. Is that acceptable?

MR. MURGATROYD: That's fine. What about the other case?

MR. DAVIS: I don't believe they have any outside the States.

MR. MURGATROYD: All right. Good enough.

BY MR. MURGATROYD:

Q. Okay. Now, have you had a chance to go over the ground rules of a deposition?

A. We reviewed ground rules of a deposition yesterday.

Q. You understand you are under oath?

A. Yes.

Q. It is the same oath you would take as if you were sitting for a judge and jury?

A. Yes.

Q. Now, the court reporter is here to take everything down, and at a later date you will get a chance to review your testimony today, at which time you can make changes, but I need to caution you now that if you do make changes later the fact of a later change can be commented upon at the time of trial. Do you understand that?

A. Yes.

Q. The idea is to give your best testimony today. Okay?

A. Thank you.

Q. And the other thing is the court

reporter can't take down nods or shrugs. All your answers have to be out loud.

A. I understand.

Q. Great. Have you ever been deposed before?

A. Once, many years ago in a civil matter.

Q. Okay. Not involving the drug Paxil, obviously?

A. No.

Q. Okay. Did you review any e-mails or correspondence between GSK and FDA regarding the current label changes?

A. I did.

Q. Okay. And were those new to you or had you seen those before?

A. I'm sure I had seen them at the time they were written as e-mail correspondence. I hadn't seen them since.

Q. Any other documents, any other e-mails?

A. I know that I looked at several other documents. I can't recall exactly which ones.

Q. Okay. Now, did you read any depositions or any parts of any depositions?

A. No.

Q. Now, beginning with your medical training, can you give us your background, please?

A. I did my medical school training at the University of Pittsburgh. Subsequently went to

Los Angeles County Harbor General Hospital and did a general medicine internship. I then spent three years at the National Institute of Health doing research in epilepsy. I then did a neurology residency and a clinical pharmacology residency at the University of Rochester in Rochester, New York. And I joined the faculty of the Department of Neurology and Departments of Clinical Pharmacology at the University of Rochester.

In 1983 I joined the pharmaceutical industry working for a company called Lorex Pharmaceuticals. In, I believe it was 1989, I moved to Abbot Laboratories, and in 1992 to Zeneca Pharmaceuticals. I stayed at Zeneca through the merger with Astra and stayed at Astra Zeneca until 2003, when I joined Glaxo SmithKline.

Q. Okay. So, I take it you do have special training in neurology?

A. That's true.

Q. And do you have special training in psychiatry?

A. I don't have credential training in psychiatry. I have some experience taking care of psychiatric patients, but not formal post-graduate

training in psychiatry.

Q. You don't consider yourself a psychiatrist?

A. I do not.

Q. You have special training in psychopharmacology?

A. I don't have special training in psychopharmacology. I have worked on the development of a number of psychotropic drugs, drugs for anxiety, for depression, for schizophrenia in the past.

Q. Okay. That was actually going to be my next question. Do you have experience in clinical trials?

A. I do.

Q. Okay. And what type of experience do you have?

A. I have certainly participated in the design and conduct of clinical trials in many therapeutic areas over the career that I've had in the pharmaceutical industry, and much of my current responsibilities, and responsibilities for many years have been the interpretation of the results of the clinical trials.

Q. Were you also involved in the safety

aspects of clinical trials?

A. Yes.

Q. Let me ask you this, in clinical trials when you are looking for treatment, emergent signs and symptoms, are you familiar with that?

A. Yes.

Q. DESS?

A. Yes.

Q. Is that a common term in the clinical trial business?

A. It is.

Q. Okay. And when you are looking for treatment of emergent signs and symptoms did you count event that occur during the placebo run-in period?

A. This depends on the trial, and the purpose for which the events are being collected, and the design of the trial.

Q. You are looking for treatment in emergent signs and symptoms. Are you saying in some instances you count placebo run-in events?

A. Key.

Q. And what does a treatment emergent event mean?

A. It generally means events seen in the

period of randomized treatment but not in the period of either entry or placebo run-in.

Q. Okay. Thank you. Now, you agree that important safety information can be gleaned from clinical trials?

A. Yes.

Q. And that information makes its way into the label of the drug when it is ultimately approved?

A. The information on the safety of a medicine that comes from clinical trials is always part of the label of a medicine, yeah.

Q. Okay. And doctors rely upon labels in prescribing drugs to patients, correct?

MR. DAVIS: Objection to the form.

BY MR. MURGATROYD:

Q. Well, do they?

A. I'm sorry. Can you repeat the question?

Q. Do doctors -- at some point in time you were a practicing physician, correct?

A. That's true.

Q. At that time and to your knowledge now do doctors rely upon the accuracy of labels in

deciding what drugs to prescribe to their patients?

A. Doctors rely on many sources of information to understand the safety profile and the benefit profile of the drugs, one of which is the label.

Q. Okay. But then there are others, such as Dear Doctor Letters, correct?

A. Dear Doctor Letters, scientific publications, other kinds of reports and scientific meetings, abstracts. So, many sources of -- yes.

Q. Posters presented at symposiums would also be another source?

A. Yes.

Q. Okay. Now, am I correct in stating that the label is important because that allows the physician who is going to prescribe the drug to do what is called a risk/benefit analysis?

A. The label is one of the sources of information in order to do a risk/benefit. To make a risk/benefit decision for a given patient, yes.

Q. And can you tell the jury what a risk/benefit analysis is for a physician who is going to prescribe a drug?

A. A risk/benefit analysis -- first I

think we should be careful in using the term risk/benefit analysis because there are many methods that are used to understand and compare the benefits of a medicine and the adverse events experienced with the medicine. But essentially what we are talking about is some way to understand what might be the benefits that a patient would receive, and what might be the risks that that patient might experience.

Q. And that's because drugs cause side effects, correct?

A. Yes.

Q. Okay. And all drugs cause side effects?

A. Cause is a strong word. Drugs are associated with adverse events, and in some cases they may cause them.

Q. Okay. And you agree that Paxil can cause some side effects to some patients who take the drug?

A. Paxil is associated with a number of adverse events.

Q. Okay. That is not my question. I move to strike your answer as non-responsive. My question was cause. Do you agree, sir, that Paxil can

cause certain side effects in some patients who take the drug?

A. The best answer to that question that I can give is, not being close to the data and an expert in Paxil's adverse-event profile I am not prepared to agree that is causes adverse events.

Q. Not a single one?

A. I am not prepared to be -- to say today that I can tell you one that it causes.

Q. Well, you knew you were going to be here today to discuss Paxil?

A. Yes.

Q. And do you have experience with that drug?

A. I have some experience with that drug, yes.

Q. And you have people who work for you who have a lot of experience?

A. That's right.

Q. Well, what about those that are actually caused -- do you have a hard time admitting that -- you admitted that all drugs cause side effects, and now you won't admit that Paxil causes side effects?

A. You'll remember that I added --

MR. DAVIS: Excuse me. I'll object to the form of the question, but you may answer the question.

BY MR. MURGATROYD:

Q. Go ahead.

A. You'll remember that I added quite quickly after I made that statement that not -- that there are many things -- many adverse events that are associated with drugs, very few that are clearly caused by them.

Q. So, do you want to state here, under oath, that you are not familiar with a single -- this is to the jury, by the way. The jury right there.

Q. Okay. Now, in terms of the question I asked, the question I asked, are you willing to tell the jury under oath that you are not aware of a single side effect that is caused by Paxil?

A. I am prepared to say to the jury that I am not sufficiently familiar with all of the data for all of the adverse events to tell you that there is an adverse event that is caused by Paxil.

Q. Now, you said you were familiar with the Paxil side-effect profile?

MR. DAVIS: Object to the form.

BY MR. MURGATROYD:

Q. And you agree that with regard to children and adolescents Paxil is associated with suicidality?

A. In the short-term trials of Paxil in pediatric patients there was an increase in the incidents of suicidal behavior of thinking in patients that took Paxil compared to those that took placebo.

Q. I move to strike your answer because it does not respond to my question.

MR. MURGATROYD: Can you read my

question back, please?

(At this time the court reporter read back from the record as was requested.)

THE WITNESS: Yes, I can agree with that question.

BY MR. MURGATROYD:

Q. Okay. I think you said that you came to Glaxo in 2003?

A. That's correct.

Q. Okay. I think I actually saw the

announcement of that. Let me see if I can find that.

MR. MURGATROYD: Can I get a bunch of exhibit stickers from you? I probably need about 40. Thanks.

(At this time a document was marked for identification as Exhibit No. 1.)

BY MR. MURGATROYD:

Q. Okay. Let me show you what I'm marking as the first exhibit, which came from a website called PharmaBiz. P-H-A-R-M-A-B-I-Z, dot com. Let me have you take a look at that, sir.

A. Thank you.

Q. Okay?

A. Yup.

Q. And does this talk about your appointment to GSK?

A. It does.

Q. And does it appear to be accurate?

A. It does.

Q. Okay. So, it says that your employment began effective February 19th, 2003. Is that a correct date?

A. I think it is correct.

Q. Okay. And then it says, Krall,

obviously Dr. Krall, will have global responsibility at GSK for clinical development, medical affairs, and regulatory affairs; is that correct?

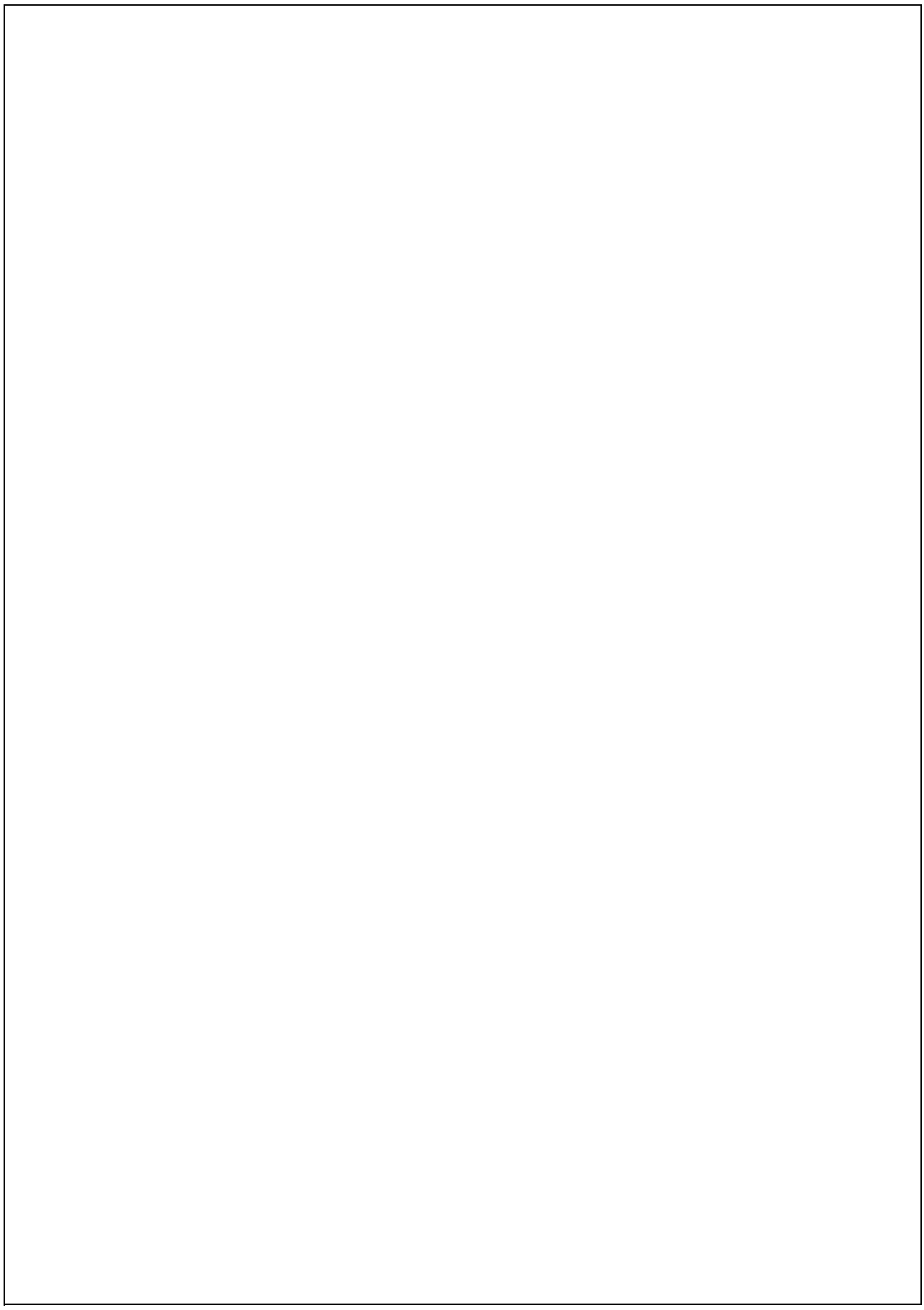
A. That's correct.

Q. Okay. And your title, according to this, is Senior Vice President World Wide Development, Research and Development; is that correct?

A. That was my title when I joined the company, that is correct.

Q. And we are going to talk more about any changes in your title in a minute.

A. Okay.



Q. Okay. Now, are you considered an executive of the company?

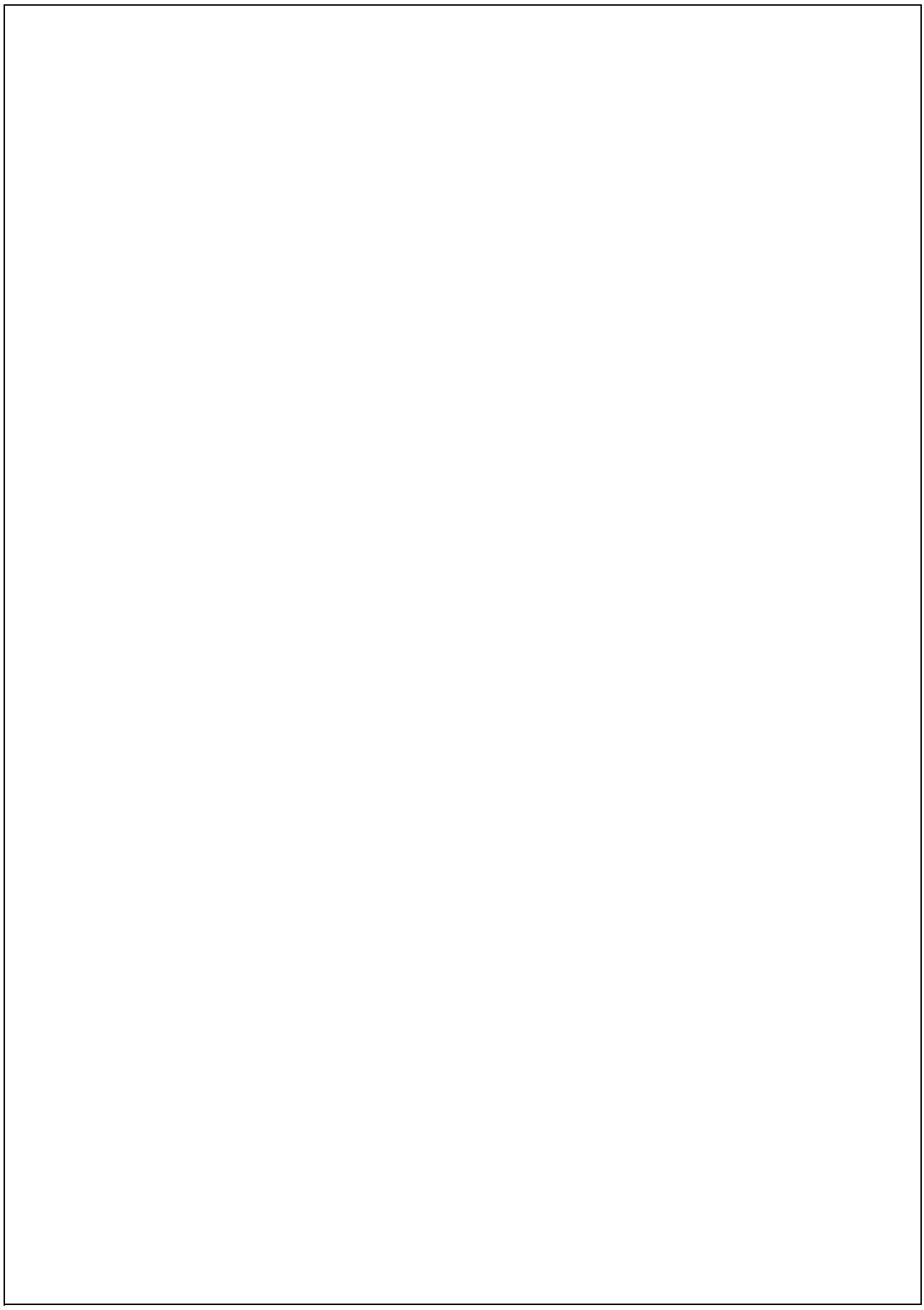
MR. DAVIS: Object to the form.

BY MR. MURGATROYD:

Q. Do you know?

A. I'm not sure what you mean by executive. So, I don't how to answer that question.

Q. Okay. That is fine. If you don't know, you don't know.



Q. Okay. And when did he leave the company?

A. I believe about a year ago. I'm not sure. It is actually more recent than that that he left. Maybe six months.

Q. Do you know where he went?

A. He retired. I don't know whether he stayed under employment.

Q. Okay. And is he in the UK?

A. Yes.

Q. Do you know what city he lives in?

A. I do not.

Q. Okay. And is Trevor Gibbs still with GSK?

A. He is.

Q. Okay. And where is he physically located?

A. He works in the United Kingdom.
Q. And do you know where he lives?
A. No, I don't.
Q. Have you ever physically met him?
A. Oh, yes.
Q. Okay. And does he come to the United States?
A. From time to time.
Q. Okay. And do you know when the next time he plans to come here?
A. Not offhand.
Q. Okay. But I take it those are scheduled, those trips are scheduled?
A. They are.
Q. Okay.
MR. DAVIS: You mean scheduled when they occur, as opposed to scheduling it is going to happen or he is coming to the United States.
BY MR. MURGATROYD:
Q. Are his trips --
A. What I meant by my answer was he always plans his trips --
Q. Okay.

A. -- because it is otherwise impossible to fly here.

Q. Do you know where he lives?

A. He is also a resident in the United Kingdom. I don't know exactly where he lives.

Q. Okay. And Dr. Yamada, he is no longer with GSK?

A. That is correct.

Q. But he was a member of the Board of Directors?

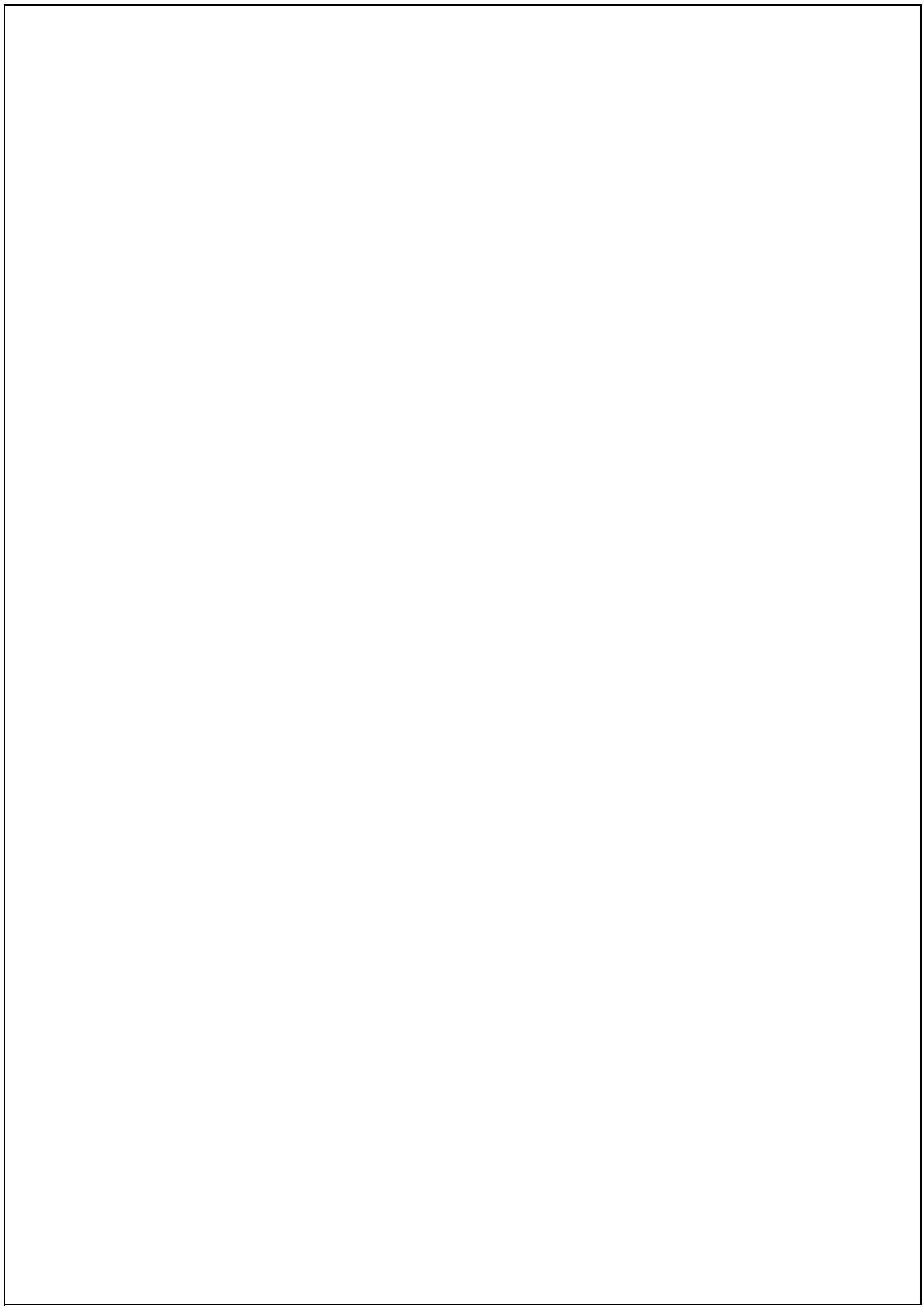
MR. DAVIS: Object to the form.

THE WITNESS: At that time I do not think he was.

BY MR. MURGATROYD:

Q. Okay. Do you know his position was?

A. He was Chairman of R&D, Chairman of Research and Development.



Q. Actually, I realized I need to show you one other document before we talk about that. Let me show you what I'll mark as Exhibit 4, which is a

portion of the deposition I took of a woman by the name of Pamela Barrett, Pam Barrett. Do you know who she is?

A. I do.

Q. Okay. And did you work with her or she worked for you?

A. Yes, she did. Not directly for me, but in the group that I manage.

Q. Okay. And let me just show you a portion of the deposition that I excerpted for today.

(At this time a document was marked for identification as Exhibit No. 4.)

THE WITNESS: Okay.

BY MR. MURGATROYD:

Q. Okay. So, you see that I was asking her in her deposition about studies 057 and 106, correct?

A. Correct.

Q. And I asked her whether or not these

two studies were different from all the others that were performed regarding Paxil?

MR. DAVIS: Object to the form.

BY MR. MURGATROYD:

Q. Do you see that?

A. I see that.

Q. I specifically stated?

MR. MURGATROYD: What is the problem with form? What are you saying is wrong with the form?

MR. DAVIS: You said they were two that were different than all the others that had been preformed. It is different in what context?

MR. MURGATROYD: What does that have to do with form?

BY MR. MURGATROYD:

Q. I asked her, there were two that were different from all the others performed regarding Paxil, right? Is that correct, Doctor?

A. That's true.

Q. And she said yes, correct?

A. (Indicating.)

Q. And she --

A. That's true.

Q. Okay. And she said that -- thank you. That was self contracted. Very good. Did the court reporter kick you?

All right. And she said what the study numbers are, 057 and 106, correct?

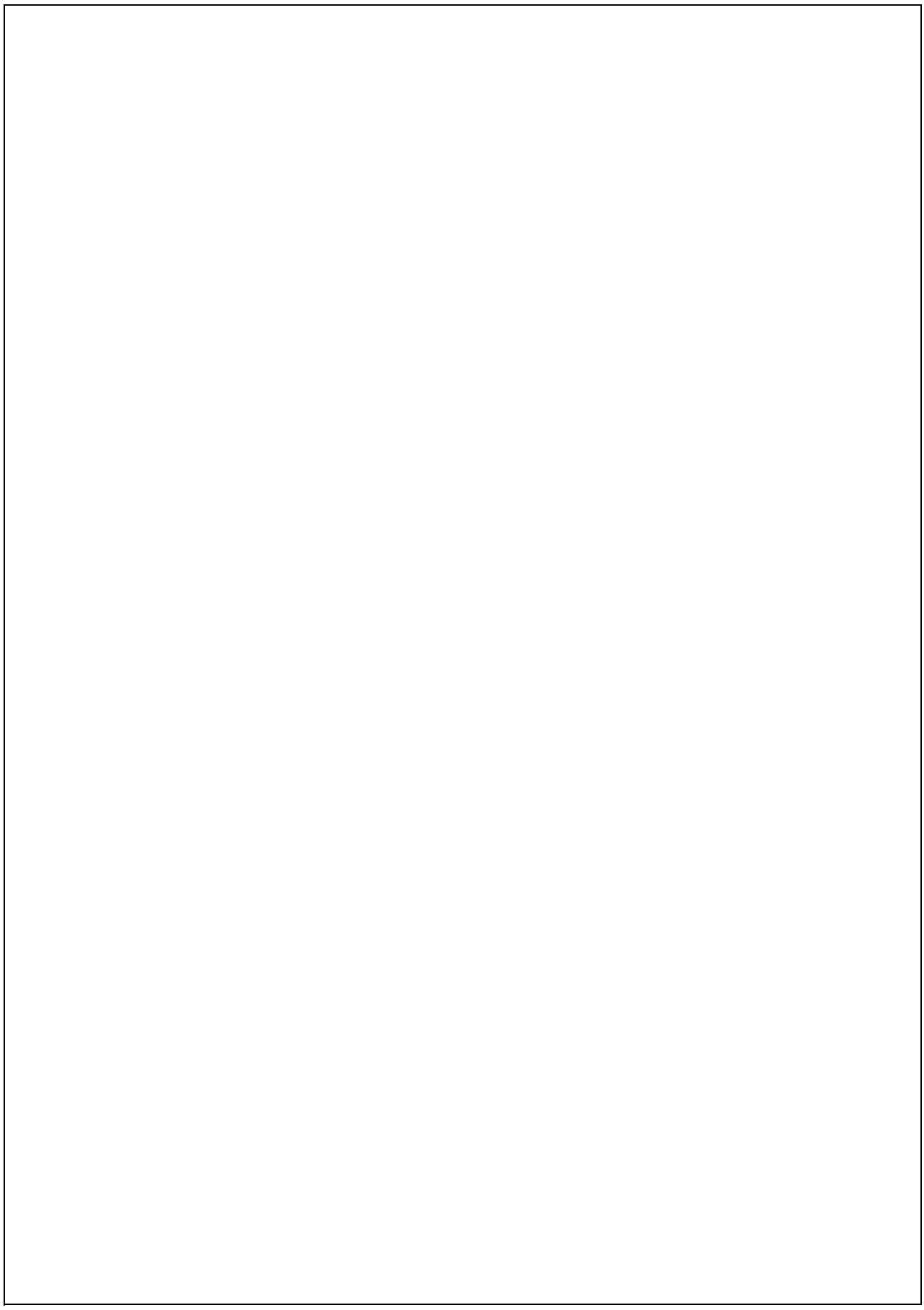
A. Correct.

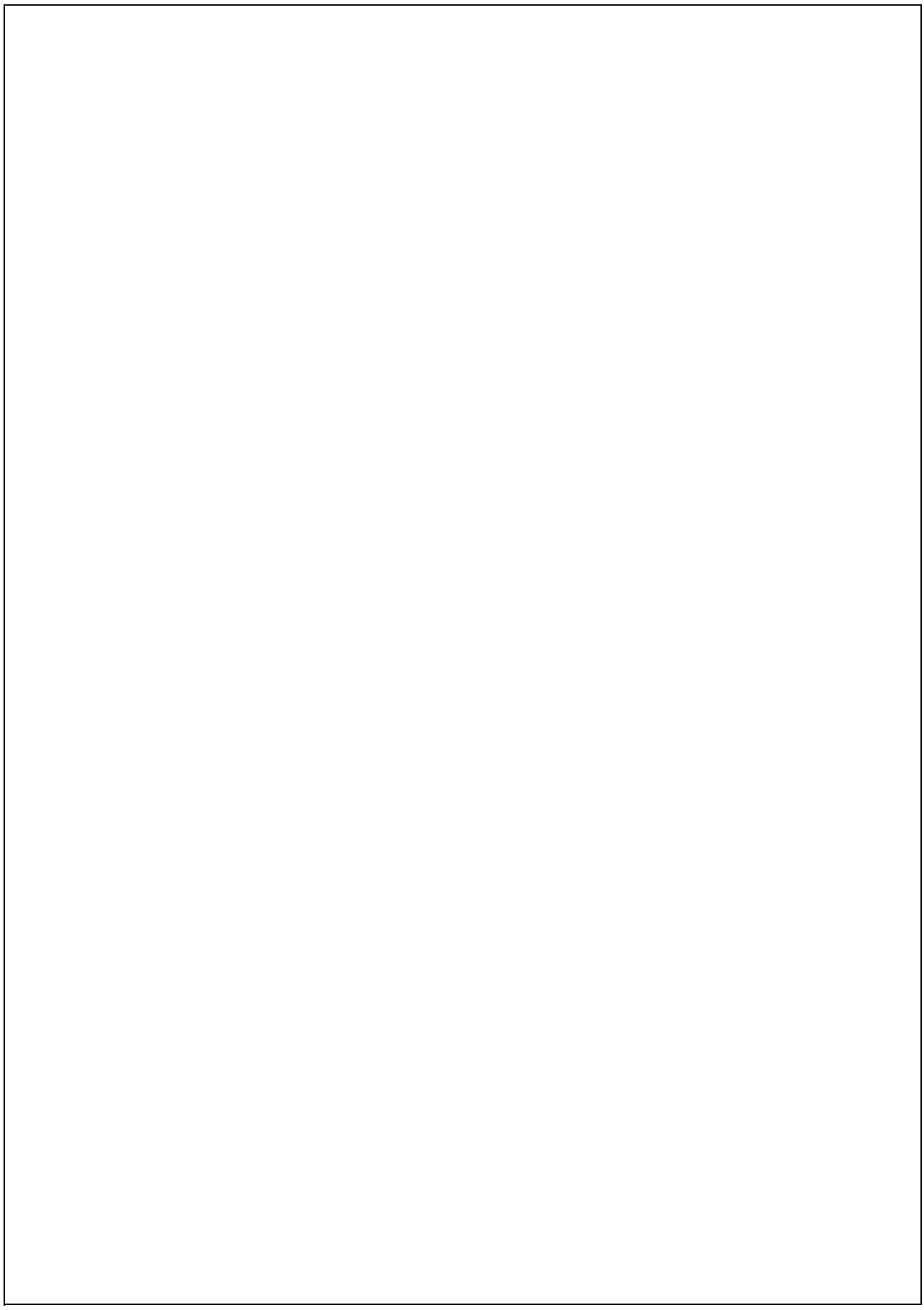
Q. Okay. And then she explains why they are different, correct?

A. Correct.

Q. And is that your understanding, what of her explanation -- does that comport with your understanding of why 057 and 106 were different than the other studies?

A. I would have been a little bit more -- I would have described the difference more thoroughly, but otherwise what she has said I agree with.





Q. Okay. And one data set was going to be based on the original question, MDD only, less than 17 weeks, at least 30 patients?

A. I believe that is right.

Q. Okay. And then there is a second data set that was later submitted to the FDA of all indications, actually all lengths of trial?

A. What I don't remember about that second submission is whether it was all durations or all studies independent of duration, or whether it was just other indications.

Q. Okay.

MR. DAVIS: Are we done with this document?

MR. MURGATROYD: Yes.

MR. DAVIS: Do you mind if we take a break? We have been going about ninety minutes.

THE VIDEOGRAPHER: 10:39. Off the record.

(At this time a short break was taken.)

THE VIDEOGRAPHER: 10:48. On the record.

BY MR. MURGATROYD:

Q. Doctor, I think before we took the break we were determining whether or not the second data set that GSK submitted to the FDA included studies of all lengths. Do you recall that?

A. That's right.

Q. Working our way through that?

A. Yes.

Q. Okay. That's fine. Now, so as you sit here today you do not know whether or not the second data set submitted by GSK to the FDA to analyze contained events that occurred in 057 and 106?

A. I believe that it did, but I'm not certain about that.

THE VIDEOGRAPHER: 10:58. Off the record.

(At this time, a discussion was held off the record.)

THE VIDEOGRAPHER: 11:02. On the record.

Q. Do you know who John Mann is?

A. I know of him. I don't know him personally.

Q. Is his opinion respected?

A. It is.

Q. And do you know who Dr. Thase is?

A. Yes.

Q. And is his opinion also respected?

A. Yes.

MR. MURGATROYD: We are going to go off the record to change the tapes for just a second.

THE VIDEOGRAPHER: This concludes video tape number one. The time is 11:17 a.m. We are off the record.

(At this time, a discussion was held off the record.)

THE VIDEOGRAPHER: Stand by, please. This begins videotape number two. The time is 11:18 a.m. We are on the record.

Q. Okay. Have you heard the term break point being used, in terms of when the risk of Paxil outweighs its benefits in terms of people who take the

drug?

A. I don't think I've heard the term break point used.

Q. Okay. Have you heard a term used where -- or have you heard an age expressed where it was determined that the risks of Paxil outweighed the benefits, at a certain age cutoff, below, obviously?

MR. DAVIS: Object to the form.

THE WITNESS: I think I have heard and participated in discussions where we talked about the effective age on the incidents of suicide-related adverse events.

BY MR. MURGATROYD:

Q. Okay. My question went more to the risk/benefit analysis, at what age does the risk of Paxil outweigh its benefits?

A. I don't think I can recall specific discussions about break points or age cutoffs or anything like that in reference to risk/benefit analysis, except in the pediatric population where there has been demonstrated evidence of efficacy in Major Depressive Disorder based on primary end points in clinical trials.

BY MR. MURGATROYD:

Q. Okay. Now, the first analysis had to do with what is called the MDD data set, right?

A. That's right.

Q. And that would be an analysis that excluded the data from study 057 and 106?

A. That's right.

Q. Okay. And such an analysis was performed by GSK?

A. Correct.

Q. Okay. And can you tell the jury what that means to a -- what does that mean to a layperson, odds ratio of 6.7 with regard to incidents of definitive suicidal behavior?

MR. DAVIS: Object to the form. You mean to a layperson?

MR. MURGATROYD: Yeah. Didn't I say that?

MR. DAVIS: Yeah. Object to the form.

BY MR. MURGATROYD:

Q. Do you understand what an odds ratio is? Can you explain to it to the jury?

A. I'm not a statistician, so my explanation would not be statistically correct.

Q. Can you tell us what your understanding is?

A. Yeah. It expresses the likelihood of an event occurring in one group compared to another group.

Q. Okay.

A. And it's a ratio of events that did occur.

Q. Okay. And in this instance 6 -- there is an odds ratio of 6.7, meaning the odds of a Paxil patient experiencing definitive suicidal behavior were 6.7 of that of a person taking a placebo pill?

A. I believe that is correct.

Q. Okay. But actually I think you will find, and we'll go over a document in a moment, it was statistically significant pursuant the protocol that was devised for this analysis, correct?

A. I accept that. I don't have it in front me.

Q. But do you recall that being correct?

A. I think so.

Q. Okay. But we are going to -- I don't want to jump too far ahead, but we'll see that GSK did find it to be statistically significant in a minute, okay?

A. Okay.

or that GSK did send out a Dear Healthcare Provider Letter to doctors regarding the data that was found by these analyses?

A. Yes, but I don't recall whether it was after this analysis or after the subsequent analysis.

Q. Okay.

A. And I don't recall the exact timing or the content of that letter.

Q. Okay. And we are going to get into that letter because that is where it talks about statistical significance, also.

Q. Okay. Well, do you recall that GSK did write to the FDA and tell the FDA about that particular analysis?

A. My recollection is that we submitted these results to the FDA, yes.

Q. Okay. And asked for a label change, correct?

A. My memory, unfortunately, is not good enough to know whether it was based on this data set or the next data set.

Q. Okay. Well, let's take a look at the next document I'll mark as Exhibit 13, which is a letter to Tom Laughren at the FDA dated March 8th, 2006, and attached to it is a document entitled: Briefing Document. And let's take a look at this, sir.

(At this time a document was marked for identification as Exhibit No. 13.)

THE WITNESS: Okay. Thank you.
BY MR. MURGATROYD:
Q. Okay. And did I identify this document correctly, sir?
A. It is a correspondence to the FDA, Division of Psychiatry Director, Thomas Laughren, from us.
Q. Okay. Does it appear to be authentic?
A. It does.
Q. Okay. This was created during the ordinary course of GSK's business?
A. Yes.

Q. Okay. And then turning to the second page of this document, there is a heading that says: Summary of Results of GSK Adult MDD Suicidality Analysis and Interpretation, correct?

A. Correct.
Q. Okay. And then what we were talking about earlier was definitive suicidal behavior, which is discussed in the second bullet point, right?
A. Correct.
Q. And this talks about -- actually it says, quote: The results provide evidence of an increased suicide attempts in adults with MDD treated with paroxetine compared to placebo. Did I read that correctly?
A. Correct.
Q. And that is what the results did show?
A. Correct.
Q. Okay. And then it talks about the odds ratio being 6.7, which we've already talked about, correct?
A. It also points out the number of events are small, and that these data should be interpreted with caution --
Q. Okay.
A. -- because of that.
Q. I understand. And it concludes down at the bottom of this page that, based on these recent

findings -- this is a quote: In the adult patient set GSK conclude that some statements in the approved prescribing information will need to be amended to reflect the results from this analysis following the completion of the entire analysis, correct?

A. Correct.

Q. Okay. So, GSK in this sentence is telling the FDA that they are going to want -- GSK is going to want to amend the label?

A. Correct.

Q. Okay. And in the next paragraph it talks about GSK also wants, not only to amend the -- to revise the label, but also provide the information directly to healthcare professionals through a Dear Doctor Letter, correct?

A. Correct.

Q. Okay.

A. After completion of the entire analysis.

Q. Correct. And, in fact, GSK did amend its label to reflect this data, correct?

A. Yes.

(At this time a document was marked

for identification as Exhibit No. 15.)

BY MR. MURGATROYD:

Q. Okay. Thank you, sir. And so the record is clear, what you are looking at, this is the Paxil label, correct, the Document 15?

A. It is.

Q. And you'll see on the last page it is dated June 2006, correct?

A. Correct.

Q. Okay. So, that is after the request by GSK to the FDA to amend its label?

A. Correct.

Q. Okay. And the sentence in adults with MDD (all ages) there was a statistically significant increase in the frequency of suicidal behavior in patients treated with paroxetine compared to placebo, in this actual label, correct?

A. Yes.

Q. And, sir, would you agree that this new change to the warning section of the Paxil label GSK thought was important to get to prescribing physicians?

A. Yes.

Q. Okay. Now, in fact, the importance was such that GSK believed that it should notify physicians immediately through what we've described or what we've called the Dear Healthcare Professional Letter?

A. Correct.

Q. Okay. So, let's take a look at that actual letter, which I'll mark as Exhibit 16.

(At this time a document was marked for identification as Exhibit No. 16.)

MR. DAVIS: Thanks.

THE WITNESS: Thank you.

BY MR. MURGATROYD:

Q. Okay. So, this is a Dear Healthcare Professional Letter dated May 2006, correct?

A. Correct.

Q. And it is entitled important prescribing information, correct?

A. Correct.

Q. And it does tell prescribing doctors or healthcare professionals about the results of GSK's analyses that we have been discussing, correct?

A. Correct.

Q. Okay. And if you go to the one, two, three, four, fifth paragraph, it says: Further in the analysis of adults with MDD (all ages) the frequency of suicidal behavior was higher in patients treated with paroxetine as compared with placebo. Did I read that correctly, sir?

A. You did.

Q. And that is consistent with the label change, correct?

A. It is.

Q. Okay. And do you believe the information contained within the letter is accurate and correct?

A. I do.

Q. Okay. Now, on --

MR. MURGATROYD: What time is it?

MR. DAVIS: It is almost 12:00.

MR. MURGATROYD: This is a good chance, I think, to break for lunch. Is that okay for you?

THE WITNESS: It's fine by me.

MR. MURGATROYD: Let's go off the record. Let's take a lunch break, and, actually, I have a meeting, so I'll probably be gone an hour.

THE VIDEOGRAPHER: 12:01. Off the record.

(At this time, a discussion was held off the record.)

THE VIDEOGRAPHER: 1:17. On the record.

BY MR. MURGATROYD:

Q. Okay. Did you have a good lunch?

A. I did.

Q. Great. I see you looking at your watch. We won't be long.

A. I'm just checking my watch against his time.

Q. Okay. I think we ended off, before lunch we talked about the changes to the label in 2006 and the Dear Doctor Letter that was issued, correct? Do you remember that?

A. Correct.

Q. Okay. And then after that, after both of those events occurred the FDA held a meeting where it reported its analysis of the adult suicidality data, correct?

A. Correct.

Q. Were you present at that meeting?

A. No, I was not.

Q. Okay. Were you provided the results

of that meeting?

A. A summary of the results of that meeting.

Q. Okay.

A. And I don't think I was provided anything in writing, or if it was it was just an e-mail --

Q. Okay.

A. -- summary.

Q. Were you aware that there was report issued by two individuals by the name of Stone and Jones?

A. I do not remember that.

Q. Okay. Well, let me show you -- well, are you aware that the results that the FDA issued came from a pooled analysis of antidepressant data?

A. Yes.

Q. Okay. And were you aware that some of the analyses actually separated the analyses out by drug?

A. Yes.

Q. Okay. Have you seen those results with regard to Paxil?

A. I have.

Q. Okay. So, let's -- I just want to show you one particular chart from that meeting, which I'll mark as Exhibit 17, which consists of the cover page, entitled, Clinical Review: Relationship Between Antidepressant Drugs and Suicidality in Adults. And I attached table 16, because this is the one I want to discuss with you.

(At this time a document was marked for identification as Exhibit No. 17.)

BY MR. MURGATROYD:

Q. Does it look familiar to you, sir?

A. Yes.

Q. Okay. You've seen this before?

A. I have.

Q. Okay. And this table is entitled: Suicidal Behavior Risk for Active Drug Related to Placebo - Preparation or Worse - Adults with Psychiatric Disorders - By Drug and Drug Class, correct?

A. Correct.

Q. Okay. And under the -- in the box that has an analysis for what are called the SSRI drugs, correct?

A. Yes.

Q. And Paxil is an SSRI drug?
A. It is.
Q. Okay. And do you see the data for Paxil in this table?
A. Yes.
Q. And do you see it lists an odds ratio?
A. Yes.
Q. Okay. And what is that odds ratio?
A. 2.76.
Q. Okay. And does it appear to be statistically significant?
A. It does appear to be statistically significant, with the caveat that there are multiple statistical analyses done in this analysis, no corrections for multiple comparisons, and my recollection the FDA's interpretation here was to be very cautious about findings with individual drugs.
Q. Okay. But there weren't any multiple comparisons in this table concerning Paxil, right?
MR. DAVIS: Object to the form.
THE WITNESS: No, not compared to Paxil, but there are multiple statistical analyses done even on this table alone, let

alone the other analyses that were done as part of this analysis.

BY MR. MURGATROYD:

Q. Correct, but with regard to this table there is just one analysis for Paxil?

MR. DAVIS: Object to the form.

BY MR. MURGATROYD:

Q. I'm sorry. Just one analysis for Paxil?

A. Yes.

Q. Okay. Thank you. Now -- and this analysis is not for -- for Paxil is not inconsistent with the analysis that was done by GSK internally, correct?

A. It is not inconsistent with.

Q. Okay. Now, based on the results of the analyses, these FDA analyses, the FDA asked drug manufacturers to change their label, correct?

A. Correct.

Q. Do you recall that?

A. Yes.

Q. And the label requested is what is known as a generic class-wide label?

A. A class label.

Q. A class label?
A. Yes.
Q. And that -- so the jury understands, what is a class label?
A. It is labeling that applies equally to a group of products all defined to be in the same, quote, class.
Q. And the class here is antidepressants?
A. Yes.
Q. So, basically, the FDA asked that all the drug manufacturers conform to one warning regarding the issue of suicidality in adults?
A. Right.
Q. Okay. Now, GSK asked the FDA if it, meaning GSK, could include in the label its Paxil-specific language that it had just put in its label, as we discussed, in 2006. Do you recall that?
A. Yes.

Q. Okay. Now, let me show you what I'll mark as Exhibit 18. And this is a letter dated

May 11, 2007 to Thomas Laughren from GSK?

A. Hold on just a second. Okay. Thank you.

Q. Sure.

A. Yes, this is a letter.

Q. It's dated May 11, 2007, from GSK to Thomas Laughren, regarding the proposed label change.

A. Okay.

Q. Okay. And this letter actually reflects what we are just talking about, right? I think in the second full paragraph it says, and I quote, this is in the middle of the paragraph: The specific information on incident rates in young adults, specific data on patients with MDD and the age ranges given, could help physicians to make a more informed decision regarding the use of paroxetine in the adult patient population. We therefore propose maintaining the paragraph within the new class labeling. Did I read that correctly, sir?

A. You did.

Q. Okay. And it is talking about the

A. Yes.
Q. And that's that paragraph, correct?
A. It is.
Q. Okay. And do you recall that the FDA responded to this letter?
A. It did.
Q. Okay.
A. Yes.
Q. And how were you made aware of the response?
A. I don't remember how I was made aware of the response.
Q. Okay. Did you actually see the e-mail to GSK that contained the response?
A. I think I did, and it may have even been sent to me in an e-mail.
Q. Okay. Well, let's take a look at it.
A. My recollection is there were several communications between GSK and the FDA on this matter, and in each case the FDA was very clear that it did not want us to incorporate this Paxil-specific paragraph.

Q. All right. Let's take a look at what the FDA actually said in this e-mail, and I marked it as Exhibit 19. And just so the record is clear, with regard to Exhibit 18, sir, would you agree that document is authentic?

A. Yes.

Q. And it was prepared during the ordinary course of GSK's business?

A. Yes.

Q. Okay. Thank you.

MR. DAVIS: Do you have the other correspondence?

MR. MURGATROYD: Do I?

MR. DAVIS: Yes.

MR. MURGATROYD: I don't know. I have the documents that I chose to show to the doctor.

MR. DAVIS: Okay.

THE WITNESS: Okay.

(At this time documents were marked for identification as Exhibit Nos. 18 and 19.)

BY MR. MURGATROYD:

Q. Okay. And this is an e-mail from the

FDA to GSK, correct?

A. It is.

Q. And this is the one you recall you think you saw?

A. I actually think I've seen another one, as well, which occurred before this one. I think this was the second of two communications between the FDA and us.

Q. Okay. But, again, you recall seeing this?

A. Yes.

Q. Okay. And can you read the first sentence of the second paragraph, beginning with as, into the record slowly, please?

A. Yes. As for your first question, the agency has reviewed your proposed changes and we do not believe that your product-specific analysis should be included in the class labeling revisions, since the labeling is targeted at the class of drugs.

Q. Okay. And that's your understanding of what the FDA said, correct?

A. Yes.

Q. Okay. And now can you please read the next sentence into record?

A. If you would like to discuss this matter further, please submit a formal meeting request.

Q. Okay. So, the FDA didn't put a complete bar to GSK including the Paxil-specific language? It said that if it wanted to include it, it would have to be requested in a meeting, correct?

MR. DAVIS: Object to the form.

MR. MURGATROYD: What is wrong with the form?

MR. DAVIS: There is an improper foundation that has been laid to ask that question, and it is also a compound question. It is more of a statement than a question.

BY MR. MURGATROYD:

Q. Well, Doctor, is it true that the FDA gave -- in this e-mail gives GSK an opportunity to request a meeting to discuss further the addition of the Paxil-specific language in the label?

A. This e-mail leaves open the opportunity to submit a formal meeting request. From experience in regulatory matters, especially with this division, the fact that the division had already declined to agree to our inclusion of the

Paxil-specific labeling twice told us that it would take a long time to schedule such a meeting, and the outcome would not lead to a different result.

Q. Well, you speculated that?

A. Of course it is a speculation.

Q. Okay.

A. But it's based on lots of experience with this division.

Q. All right. Well, let me ask you this, so you agree that the option was there to ask for a meeting?

A. Yes.

Q. Okay. Now --
A. And I believe that the FDA had given us a very clear answer to your request to include the Paxil-specific labeling.
Q. Okay. Well, I have to move to strike your answer, simply because there wasn't a question pending.
MR. DAVIS: I'll disagree. Someone else brought that out.
BY MR. MURGATROYD:
Q. Now, let's take a look at the -- well, let me just take the next document in order.

Q. Okay. And that's referenced in what I'm going to mark as Exhibit 20. Actually, I marked the wrong one. Let's see.
(At this time a document was marked for identification as Exhibit No. 20.)
BY MR. MURGATROYD:
Q. And this is a letter dated July 3,

2007 to Tom Laughren from GSK. And so the record is complete, let me show you what I'm marking as Exhibit 21, and we can discuss these two documents in conjunction with each other.

(At this time a document was marked for identification as Exhibit No. 21.)

BY MR. MURGATROYD:

Q. So, the record is clear -- actually, Doctor, let me just interrupt for a second. I think I forgot to authenticate that last Document 19. Does that document appear to be authentic?

A. It does.

Q. And did GSK receive that during the ordinary course of its business?

A. I believe so.

Q. Okay. Great. So, let's take a look at the next two exhibits. And the next one is dated June 25, 2007, an e-mail between GSK and the FDA. And the second is a letter dated July 3, 2007, from GSK to Tom Laughren of the FDA. And we'll see how they relate to each other as soon as you've had a chance to read them.

A. Yeah.

Q. Okay. So, according to this first

document, the e-mail, does this appear to be authentic?

A. It does.

Q. And received by GSK in the ordinary course of its business --

A. Yes.

Q. -- or written? Actually, this was written, right?

A. Yes.

Q. Okay. And it confirms that GSK -- it says, confirm the intention of GSK to comply basically with the generic label, am I reading that correctly?

A. Class label.

Q. I'm sorry. The class label?

A. Yes.

Q. And then going to the next document, Exhibit 21, it is a formal letter that was written to the FDA, to Tom Laughren, and in it GSK announces, on the second page, top sentence, that the paroxetine-specific language originally included in the warning section is now deleted, correct?

A. Correct.

Q. Okay. And then can you read the next sentence into the record, please?

A. GSK still believes that the paroxetine-specific language that has been in effect for the past year would be useful for prescribers. Nevertheless, we understand the FDA's reasons for keeping the language generic to the class and will implement the labeling as attached after receiving your approval letter.

Q. And you agreed that GSK believes it is important to provide the Paxil-specific language, though it was going to not request a meeting and go forward with the class one labeling?

A. We believed that the language would be useful for prescribers, but we understood the strength of the FDA's view for keeping the language generic to the class, as the letter states, and felt that that underscored the FDA's view about the caution that should be applied to the analysis for specific

drugs.

Q. Okay. Now, let me go to the next document, instead of asking to you speculate. Let's look at the current label for Paxil and the Paxil CR label, which I'll mark as Exhibit 22.

(At this time a document was marked for identification as Exhibit No. 22.)

BY MR. MURGATROYD:

Q. Well, just so I have it clear, when you sent the Dear Doctor Letter in 2006 with the results of the MDD analysis and the other analyses that GSK did, that was entitled Important Prescribing Information, correct, as a title?

A. I believe so.

Q. So, that information regarding the 2006 analysis GSK thought was important, correct?

A. Correct.

Q. Okay. And now it is being taken out of the current label, correct?

A. Well, it is being substituted by labeling that is consistent across all of the SSRIs.

Q. And the Paxil-specific language is deleted, gone?

A. Yes.

Q. As you'll see from Exhibit 22, let's just confirm that, in fact, this Paxil-specific language from the current label has, in fact, been deleted?

A. Yes, the Paxil-specific language has been deleted.

Q. Okay. And, in fact, turning to page nine of this document where it has a table one.

A. Yes.

Q. Okay. And it talks about the risk decreasing by age. Do you see that, 25 to 64?

A. Yes.

Q. Okay. Now, would you agree, sir, that that information is inconsistent with the Paxil-specific language that we looked at in the earlier label that was amended in June 2006?

MR. DAVIS: Object to the form.

THE WITNESS: No, I would not agree. It is not inconsistent. It is additional information.

BY MR. MURGATROYD:

Q. Well, let's take a look at --

MR. MURGATROYD: Todd, will you pull up PL42? Can I see that for a second,

please? Actually, I have a copy.

BY MR. MURGATROYD:

Q. Doctor, let's take a look at that. Give me one second to pull up my copy.

Okay. So, turning to the warning section it says: PXL42, which is the June 2006 label, correct, which you have in front of you?

A. I think so.

Q. See it at the top right-hand corner?

A. Yes, I believe you are right. Yes.

Q. Okay. Good. And then turning to page 11 -- I'm sorry, page 12. There you have Paxil-specific language, correct, in the second full paragraph, starting with young adults?

A. Correct.

Q. And within that paragraph you have the data, in adults with MDD, all ages, there was a statistically significant increase in frequency of suicidal behavior of patients treated with paroxetine compared with placebo, correct?

A. That is correct, but in the sentence before there is a very specific statement, in the older age groups, age 25 for 64 ages, and above 65 years, no such increase was observed.

Q. Yes. But that's not true for patients treated with MDD?

MR. DAVIS: Object to the form. I withdraw the objection. Go ahead and answer the question, if you understand it.

THE WITNESS: No, that is true for patients treated with MDD.

BY MR. MURGATROYD:

Q. Well, it says in the next sentence, in adults with MDD, all ages, there was a statistically significant increase in the frequency of suicidal behavior in patients treated with paroxetine compared with placebo?

A. Allow me to read the sentence again to make sure I answer it correctly.

Q. Absolutely.

A. You are right. I misspoke. The sentence I wanted to emphasize was the sentence after that, or the sentence after it. It pointed out that the majority of the attempts for paroxetine, eight of eleven, were in younger adults, age 18 to 30 years.

Q. Okay. That's fine. But, again, this sentence also says all ages, correct? I read that correctly?

A. It does say that.
Q. And that information, you agree, sir, is no longer in the current Paxil label?
A. That's right. But I don't think that the new label is inconsistent with the one in June of 2006, because, in fact, what was conveyed in the June 2006 label was that the majority of events were in the younger age population, and that the risk would not necessarily extend to all ages.
Q. Well, according to your 2006 label it extended to all ages?
A. It says if you include all patients of all ages there is an increase, but that increase, in fact, was largely confined to the 18- to 30-year-old age group.
Q. All right. And you don't see that in the current label, do you?
A. In the current label, in fact, it goes further. This is based on the overall analysis all SSRIs, and says from 25 for 64 there is one fewer case, and above the age 65 there is six fewer cases.
Q. So less risk?
A. Right.
Q. Okay. And that only -- and the

increase risk is only to 24?

A. Correct.

Q. And your 2006 letter, which goes to 30?

A. Correct.

Q. So, it is inconsistent in that regard?

A. Yes.

Q. Okay. Does GSK ever have meetings with the FDA?

A. Yes.

Q. Okay. And that is something that is part of the activities of GSK in terms of its drugs?

A. Yes.

Q. Okay. Now, have you participated in such meetings?

A. In some, yes.

Q. Where you have met face-to-face with

the FDA?

A. Yes.

Q. And have you met face-to-face with Dr. Laughren?

A. Yes.

Q. Have you discussed the issue of Paxil and its association with suicidality with him at any time?

A. To my knowledge, no.

Q. Okay. Is that something you could have brought up if you wanted to, but you just didn't?

A. I don't believe I have been present at a meeting with Dr. Laughren where Paxil was the subject.

Q. Okay. Other drugs?

A. Yes.

Q. Okay. And how many occasions have you met with Dr. Laughren?

A. You know, I can't give you an exact answer to that because it goes back over 20, 25 years. It could be a half a dozen formal meetings, maybe even ten that I've had with him.

Q. Okay. And how about is it also possible to have an informal meeting with the FDA?

A. Yes. It is possible to have informal meetings.

Q. And have you participated in such meetings?

A. Yes.

Q. How many --

A. It is very difficult to have informal meetings that have any effect, any regulatory effect.

Q. Okay. It is better to have a formal meeting?

A. Yes.

Q. Okay. And what is the process of having a formal meeting? You have to make a written request?

A. Yes, for a formal meeting you have to make a written request. You have to file a briefing document for that meeting.

Q. Okay. And that is something GSK has done in the past?

A. Certainly.

Q. Okay. Great. Now, let's clean those exhibits up there. I think I authenticated all of the documents, didn't I?

MR. MURGATROYD: Todd, are all of

those authentic? Do you have any problem with authenticating any of those documents we went through?

MR. DAVIS: You mean, 22, 21, 20?

MR. MURGATROYD: Yup.

MR. DAVIS: 19?

MR. MURGATROYD: Yup.

MR. DAVIS: And 18?

MR. MURGATROYD: Yes.

MR. DAVIS: Yes, no question on authenticity.

BY MR. MURGATROYD:

Q. Those were all created during the ordinary course of GSK's business?

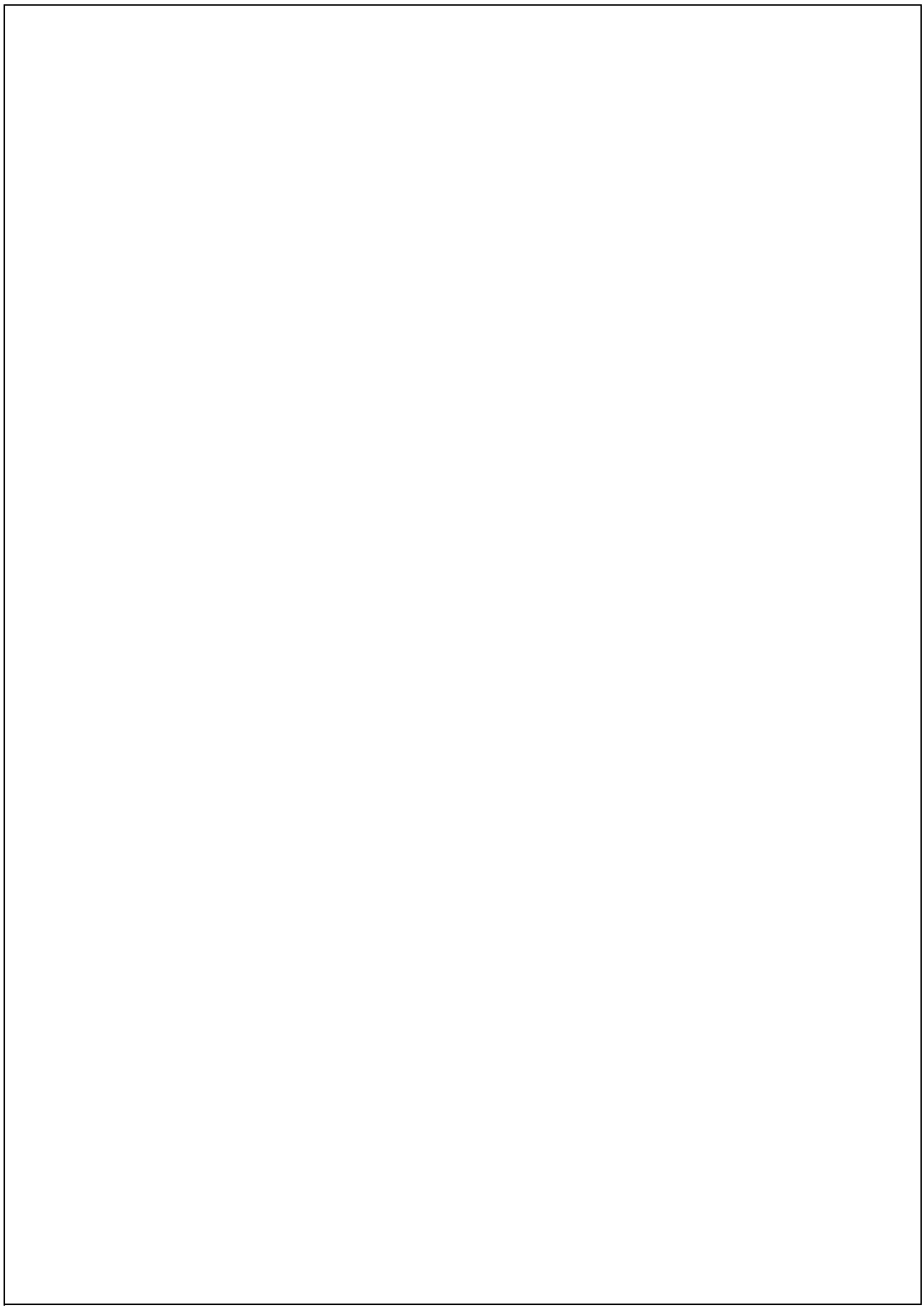
A. Yes, some of them were received.

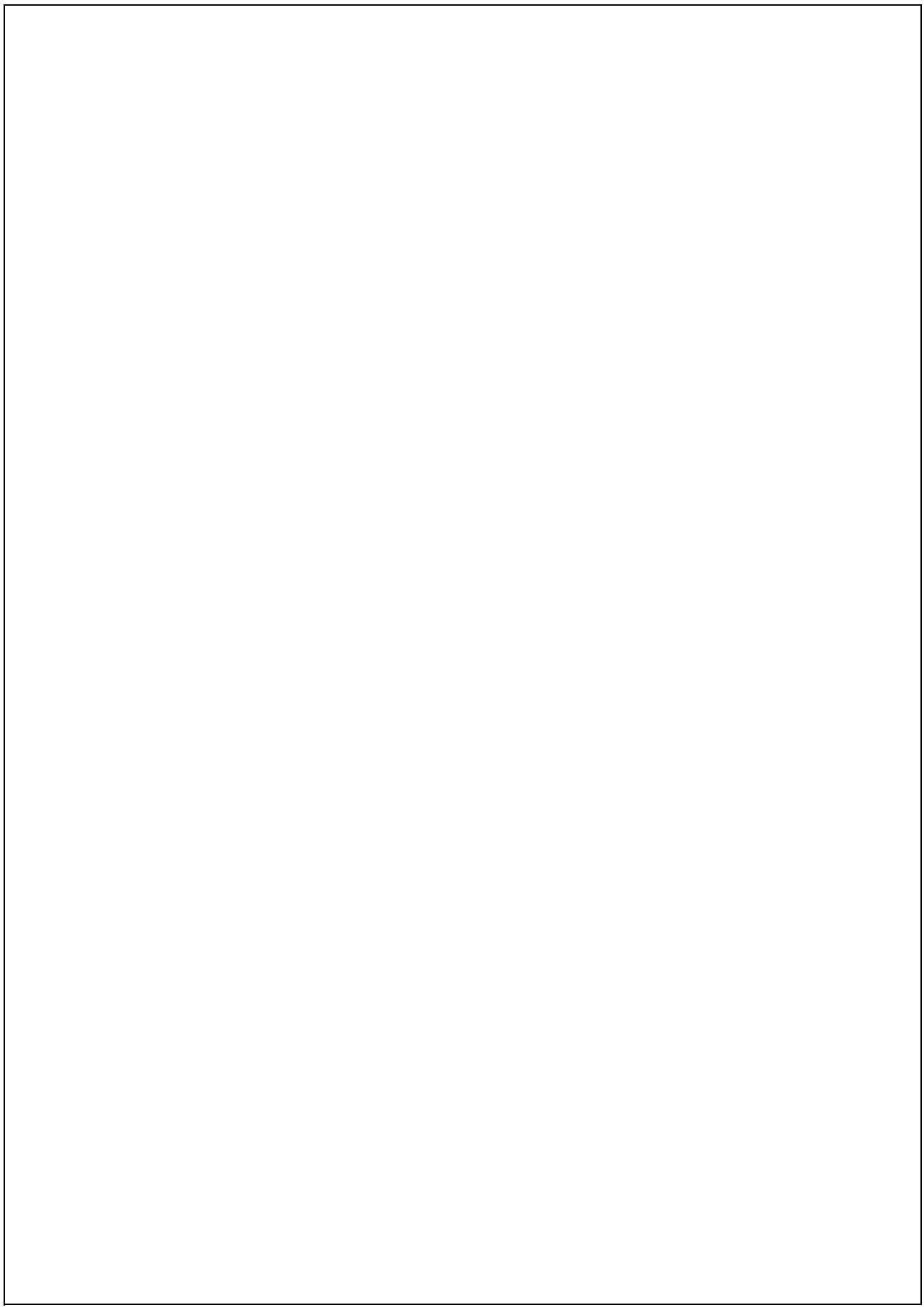
Q. Right. Some were received?

A. And some were created.

Q. Now I'm going to turn to a different topic. You've met a gentleman by the name of Robert Gibbons, correct?

A. I believe I have met Robert Gibbons, yes.





Q. Okay. You know there is an upcoming

trial in these cases set for next month? Are you aware of that?

A. No, I was not aware it was next month.

Q. It is actually set for November 7th.

MR. DAVIS: It is a setting that says we are to be prepared by November 7th. There is not a special setting in the case.

MR. MURGATROYD: Okay. I'm sure somebody can sort that out other than me. I got what you are saying.

BY MR. MURGATROYD:

Q. Okay. That's fine.

MR. MURGATROYD: Now, let's take a five-minute break. I just have to make a quick phone call.

THE VIDEOGRAPHER: 1:58. Off the record.

(At this time, a discussion was held off the record.)

THE VIDEOGRAPHER: 2:08. On the record.

EXAMINATION

BY MR. SCIOLLA:

Q. Doctor, I'm Andrew Sciolla. We met earlier. I just have a few more questions. My colleague was just starting to go into suicidality in adolescents and pediatrics.

MR. DAVIS: And before you start, Andrew, I just want to put on the record that Mr. Murgatroyd left. He informed us that he was finished with his questioning and he was handing the questioning over to Mr. Sciolla, and that we are proceeding accordingly and hopefully to get done today.

MR. SCIOLLA: I'll do my best.

MR. DAVIS: Thanks.

BY MR. SCIOLLA:

Q. So, we are getting in to the subject of suicidality in adolescents and pediatrics taking Paxil. I'm going to continue along with that line of questioning. When did GSK change the label to warn about suicidality in kids or adolescents taking Paxil?

MR. DAVIS: Object to the form.

THE WITNESS: I'm not certain about the -- I'm sorry. You asked about when we changed the label.

BY MR. SCIOLLA:

Q. Are you aware at some point --

A. Actually, could you repeat your question? Make sure I understood.

Q. Are you aware at some point GSK

changed the label on Paxil to warn about suicidality in children and adolescents?

A. Yes.

Q. When did that occur?

A. I am not certain I can remember exactly when it occurred. It might -- it was sometime in 2003 to my recollection, but I'm not sure when.

Q. Was it before or after you arrived at GSK or began your employment at GSK?

A. I believe it was after.

Q. Okay. And in that changing of the label what language did GSK change at that time?

MR. DAVIS: Object to the form.

THE WITNESS: I would have to see the labels to be able to answer that for you.

BY MR. SCIOLLA:

Q. Are you aware of when the black box -- are you aware that a black box warning was put on the label for Paxil at some point?

A. Yes.

Q. When did that occur?

A. Again, I'm not certain of the exact timing of the black box warning. So, I wouldn't want to give you a date without actually looking at the

progression of the labels.

Q. Okay. Do you think that it was towards the beginning of your employment or do you think it was more --

A. No, it was some time later.

Q. Does early 2005 sound correct?

A. It sounds correct, but I only want to say that it sounds correct.

Q. And what is MHRA, sir?

A. I think -- it is the UK regulatory authority, the equivalent of the FDA.

Q. Sir, are you aware that at some point the UK put a contraindication on Paxil for children and adolescents?

A. Yes.

Q. Was that during the time that you were working for GSK?

A. Yes.

MR. SCIOLLA: I'm going to mark this as Exhibit 25.

(At this time a document was marked for identification as Exhibit No. 25.)

MR. DAVIS: You done with this document?

MR. SCIOLLA: Yes.

BY MR. SCIOLLA:

Q. Take a moment and look that over.

A. Okay.

Q. Have you ever seen this document before?
A. I don't believe I have.
Q. Does it look authentic?
A. Yes.
Q. Do you believe that you would not have received this during the ordinary course of your business at GSK?
A. I could have received it during the ordinary course of my business at GSK, but I don't recall that I did.
Q. Okay. The top of the exhibit says, Department of Health Press Release, correct?
A. Correct.
Q. It's dated Tuesday, June 10th, 2003?
A. Correct.
Q. And the opening line of the body of this document says: Seroxat must not be used for treatment of children?
A. Correct.
Q. What is seroxat?
A. Seroxat is the trade name for paroxetine in Europe.
Q. What is a contraindication, Doctor?

A. A contraindication is -- means that something should not happen.

Q. Would you consider that statement that seroxat must not be used for treatment of children to be a contraindication?

A. It could be interpreted that way, but it is interesting that this document has a number of statements in it that suggest that it actually is not a contraindication, including the statement right below there that says, it is essential that patients taking seroxat do not suddenly discontinue use of the drug, and further statements that suggest that patients seek advice from their physician.

Q. You would agree that neither of those statements that you just pointed out specifically draws attention to children and adolescents, correct?

A. Sorry. I don't -- I don't understand your question.

Q. In neither of the statements that you just read to me does it mention children or adolescents specifically, correct?

A. The first statement which I read to you, was one I actually read to you. I didn't actually read any other statements, and it does not

specifically refer to children, but surely it must refer to children since the letter is about treatment of children.

Q. So --

A. The press release is about the treatment of children.

Q. So, the answer to my question is that neither of those two following statements mentions children or adolescents specifically?

A. That's true.

Q. Okay. But that first sentence that seroxat must not be used for treatment of children, obviously, does mention children specifically?

A. Yes.

Q. Are you aware that -- did you become aware that the contraindication was changed by the British regulatory authority?

A. I'm sorry. Would you repeat the question?

Q. Sure.

A. I was reading another sentence here.

Q. That's fine. You can take your time if you need to.

A. That's fine.

Q. Are you aware that the regulatory authorities in the UK eventually changed the contraindication?

A. Yes.

Q. Okay. And from your understanding what did they change the contraindication to?

A. I don't have the exact language in my mind, so I would have to see it, but it was a removal of the contraindication. It also, to my recollection, brought the UK language in line with the rest of the European union labeling for seroxat.

Q. Did that include a warning instead of contraindication?

A. I would have to see it in order to answer that question.

Q. Okay.

MR. SCIOLLA: I'm marking Exhibit 26.

(At this time a document was marked for identification as Exhibit No. 26.)

MR. DAVIS: Thank you.

THE WITNESS: Thank you.

BY MR. SCIOLLA:

Q. Doctor, have you ever seen this document before?

A. I do not believe I have.
Q. This seems to be a press statement, correct?
A. If you give me just a minute to look at it --
Q. Sure. Take your time.
A. -- I will be glad to tell you. Yes, this seems to be a press statement.
Q. Okay. Now, in this press statement it seems to indicate that the contraindication was replaced, if you look in the second paragraph, by a warning against the use of seroxat in the age group of under 18, correct?
A. Correct.
Q. If I could draw your attention back to Exhibit 25 quickly. One second. Could I just see that real quickly? Drawing your attention to that third paragraph that begins new data.
A. Uh-huh.
Q. Could you read that into the record?
A. New data received within the last two weeks has been evaluated and considered by the Committee on Safety of Medicines (CSM) and its expert working group on SSRIs.

Q. If you could continue?
A. It shows that there is an increase in the rate of self harm and potentially suicidal behavior in this age group when seroxat is used for depressive illness. It has become clear that the benefits of seroxat in children for the treatment of depressive illness do not outweigh these risks.
Q. Is there anything in that statement that you disagree with?
A. This statement reaches a conclusion about risk and benefit, which I personally would not agree with.
Q. You don't agree with the risk/benefit analysis?
A. Correct.
Q. Okay. Why?
A. Because I believe that there is evidence that some children receive great benefit from seroxat and other SSRIs, and in those children it's not clear to me that the benefit is outweighed by the risk.
Q. But, obviously, in this contraindication the British regulatory authorities did find that the risk did not out -- I'm sorry -- the

risk outweighed the benefit, correct?

A. That is what this statement says.

Q. Okay. If I could draw your attention back to Exhibit 26. I am done with 25. You can put that to the side. Now, this warning in Exhibit 26 was for use of paroxetine in the under-18 age group, correct?

A. Correct.

Q. Now, in this country did the FDA call a meeting to look at this decision?

MR. DAVIS: Object to the form.

THE WITNESS: Sorry. In the United States?

BY MR. SCIOLLA:

Q. Yes.

A. Did the FDA call a meeting to look at the decision of the MHRA?

Q. Yes. Are you aware of that?

A. Not to -- I am not aware of that.

Q. Do you know what a PDAC is, or P-D-A-C?

A. Pediatric Drug Advisory Committee to the FDA.

Q. I think it is actually

Pharmacological Drug Advisory Committee?

A. Is it the Psychopharmacology Drugs Advisory Committee?

Q. Could be it as well.

A. I guess the answer is no.

Q. Okay.

MR. SCIOLLA: We are going to go ahead and change the tapes.

THE VIDEOGRAPHER: This concludes videotape number two. The time is 2:34 p.m. We are off the record.

(At this time, a discussion was held off the record.)

THE VIDEOGRAPHER: This begins videotape number three. The time is 2:36 p.m. We are on the record.

BY MR. SCIOLLA:

Q. Okay. So, going back to what we were discussing, have you ever heard of the Psychopharmacologic Drugs Advisory Committee?

A. Yes.

Q. Okay. And what is that?

A. That is an advisory committee to the Food and Drug Administration's division of

psychopharmacology.

Q. Are you aware that they had two meetings to discuss the use of paroxetine or Paxil in the pediatric population?

A. Yes.

Q. Do you know when those meetings were?

A. I won't have the dates exactly right, but it seems to me they were in the first part of 2004.

Q. Do you know who is on that committee or on the panel on that committee?

A. I couldn't name the members, no.

Q. Do you know what types of doctors?

A. They are -- routinely that committee has experts in psychiatry and neurology on it.

Q. In you said that you believe that the meetings took place in early 2004? Is that what you said?

A. That is my recollection, but I wouldn't want to be held to that.

Q. Does February of 2004 sound correct?

A. It sounds correct.

Q. Okay. Do you remember, did the FDA announce that they were going to analyze this

pediatric suicidality data more carefully and then have another meeting, which would be the second meeting later that year?

A. Yes. They were going to complete the analysis of the suicidality data that they had requested from and received from manufacturers.

Q. And they did actually complete that analysis, correct?

A. Correct.

Q. And that is when they held the second meeting, sometime in late 2004?

A. Later in 2004. I don't believe it was late. I think it might have been April.

Q. Okay. And do you agree that the panel in that second meeting found that there was a causal link between antidepressants and suicidality in children and adolescents who took the drugs?

MR. DAVIS: Object to the form.

THE WITNESS: I don't have in front of me the minutes from that meeting, and, therefore, can't really speak to what the committee concluded.

(At this time documents were marked for identification as Exhibit Nos. 27 and

28.)

BY MR. SCIOLLA:

Q. Okay. I'm handing you what has been marked as Exhibit 27. If you'll take a look at this exhibit, Doctor. You can feel free to take a look at the whole thing, but I only want to draw your attention to one line on the second page.

A. Okay. Okay.

Q. Okay. Real quickly this is an article entitled: The FDA Pediatric Advisories and Changes in Diagnosis and Treatment of Pediatric Depression.

A. It is an editorial.

Q. Correct. It is an editorial. And the author of the editorial, if you'll look on the last page, is Cynthia Pheffer?

A. Correct.

Q. Okay. I'm going to use this document in conjunction with the next one, which is marked as 28.

A. Okay.

Q. And if you'll look, 28 is the summary minutes of the CDER Psychopharmacologic Drugs Advisory Committee and the FDA Pediatric Advisory Committee.

Do you see that?

A. I do.

Q. And this is dated September 13th through 14th, 2004?

A. It is.

Q. Do you think that this could have been the second meeting that we are talking about occurred on September of 2004?

A. Yes.

Q. Okay. And if you'll look under where it says consultants, second paragraph down almost, you'll see that Cynthia Pheffer is included as a consultant to the Psychopharmacologic Drugs Advisory Committee?

A. Yes.

Q. And she's also a voting member?

A. Yes.

Q. Okay. Now, going back to Exhibit 27, turning your attention to the second page.

A. If you don't mind, I would like to finish looking at Exhibit 28.

Q. Oh, sure. Take your time.

A. Okay.

Q. Okay. So, now we are looking at 27

again.

A. Okay.

Q. If you'll look on the second page, in the second full paragraph, about halfway down the paragraph the sentence starts, At a second advisory meeting. Do you see that?

A. Uh-huh. I do.

Q. Okay. It says, At a second advisory meeting conducted September 13th through 14th, 2004, FDA researchers presented statistical reanalyses of suicidality data indicating an increased risk of drug-induced suicidal behavior. And then it goes into the relative risk equals 1.95, 95 percent CI equals 1.28 minus 2.98. So, increased risk of drug-induced suicidal behavior from the combined database of the clinical trials. Did I read that correctly?

A. You did.

Q. If you skip the next sentence, going on to where it begins, The committee, do you see that?

A. Yes.

Q. It says, The committee concluded that a causal link exists between antidepressant treatment and pediatric suicidality and advised that policies be implemented for pediatric use of antidepressants. Did

I read that correctly?

A. You did.

Q. Do you agree with the statement that a causal link exists between antidepressant treatment and pediatric suicidality?

A. No, I do not.

Q. So, do you think --

A. And I don't believe that I could say that this statement in the editorial accurately reflects the question that was asked of the advisory committee.

Q. We are going to come back to that document in a second. I'm not avoiding that. But this statement right here is from a woman who was on that committee or was a consultant to the committee, correct?

A. Correct.

Q. And she says that the committee concluded that a causal link existed between antidepressant treatment and pediatric suicidality, correct?

A. That's what it says.

Q. And you said that you disagree with this statement?

A. Yes.

Q. So, do you believe this woman who was a consultant to the committee got it wrong?

A. I just don't agree with that conclusion.

Q. Okay.

A. And bluntly, I don't believe that a causal relationship between antidepressant treatment pediatric suicidality has been shown. There is an association, but many of the elements that would be expected to prove a causal link do not exist.

Q. Okay. If we go back to Exhibit 28, and we'll go right to the section that has the votes on it, which you were pointing out before.

A. Yes.

Q. If you could read number two, the question to the committee?

A. Do the suicidality data from these trials support the conclusion that any or all of the these drugs increase the risk of suicidality in pediatric patients.

Q. So, that was the question, correct?

A. Correct.

Q. And there was a vote?

A. There was.

Q. And the vote count was, 25 yes; no one; and abstain one?

A. Correct.

Q. So, 25 members of this panel voted that the data that they reviewed supported the conclusion that any or all of the antidepressant drugs increased the risk of suicidality in pediatric patients, correct?

A. Correct.

Q. And someone who was a voting member of this panel, as we looked at her editorial on Exhibit 27, as we read earlier, did say that the committee concluded that there was a causal link, correct?

MR. DAVIS: Object to the form.
THE WITNESS: That's what the sentence in Exhibit 27 says.
BY MR. SCIOLLA:
Q. And she was a voting member of this committee, correct?
A. Correct.
Q. You can put that to the side.
A. Thank you.
Q. We've talked about Thomas Laughren, correct, today?
A. I believe we have.
Q. You know who he is?
A. Yes, I do.
(At this time a document was marked for identification as Exhibit No. 30.)
BY MR. SCIOLLA:
Q. I'm handing you what has been marked as Exhibit 30. Exhibit 30 is a memorandum which says that it's from Thomas P. Laughren, M.D., correct?
A. Correct.
Q. It's dated November 16th, 2006?
A. Correct.
Q. If you need a minute to look over the

document, Doctor, feel free.

A. Thank you.

Q. But actually the portion that I'm going to draw your attention to is on the second page. There is actually brackets next to it.

A. Okay.

Q. That is unintended.

A. Okay.

MR. DAVIS: While he is reading that, what is your timetable?

MR. SCIOLLA: I'd say probably 20, 25 minutes.

MR. DAVIS: Okay.

MR. SCIOLLA: I'll try to go quick.

BY MR. SCIOLLA:

Q. Doctor, I don't mean to interrupt, but I'm actually going to refer you to a citation which -- in this article, which somewhat makes the rest of the article not necessarily the most important.

A. Okay.

Q. If you'll look on that second page in the bracketed, do you see that?

A. Yes.

Q. It reads: The pediatric data presented at the September, 2004 PDAC meeting represented the first systematic demonstration of a causal link, citing to Hammad, et al, 2006?

A. Correct.

Q. Okay. So, this article that is being cited to also used the terminology of demonstrating a causal link, or that a causal link existed?

MR. DAVIS: Object to the form.

THE WITNESS: It specifically says: The first systematic demonstration of a causal link.

BY MR. SCIOLLA:

Q. Okay. And that's similar language that Dr. Pfeffer used in her editorial, correct?

A. Correct.

Q. Okay. Now, after the PDAC voted, and we looked at the vote, the FDA requested that GSK change its label, correct?

A. Correct.

Q. Okay. That is fair. Now, at the bottom of that first page it says, Alert for healthcare professionals on paroxetine hydrochloride, and that's Paxil, correct?

A. Correct.

Q. Do you see the section that says, Pediatrics?

A. I do.

Q. Do you see the second sentence underneath that paragraph that begins with, Increases in suicidal?

A. Yes.

Q. Okay. Could you read that into the

record?

A. I would like to read the first sentence, as well.

Q. Sure.

A. FDA has concluded that suicidal thinking or behavior may increase in pediatric patients treated with any type of antidepressant, especially early in treatment. Increases in suicidal thinking or behavior due to drug can be expected in about 1 out of 50 treated pediatric patients.

Q. Okay. Now, thank you for reading that first sentence, and I understand your stress on may increase, but that second sentence says can be expected, correct?

A. Correct.

Q. So, that is more than just may? It's can be expected, correct?

MR. DAVIS: Object to the form.

THE WITNESS: Two sentences say two different things.

BY MR. SCIOLLA:

Q. Okay. Well, turning your attention to the second sentence about how often suicidal thinking and behavior can be expected, do you agree

with that statement?

MR. DAVIS: Object to the form. Are you saying do you agree that it is written or do you agree with the substance?

BY MR. SCIOLLA:

Q. Do you agree with the substance of the statement?

A. No, I do not.

Q. So, this FDA alert you disagree with the substance of what the FDA is saying?

A. It is more definitive than I would have been. It is also quantitative, and I don't have the data with me today to be comfortable with that quantitative statement.

Q. Okay. But this -- the language that we just read does reflect the FDA's thinking on the subject, correct?

MR. DAVIS: Object to the form.

THE WITNESS: You are asking if it reflects the FDA's thinking. All I can say is this is a statement that appears to have been issued by the FDA.

BY MR. SCIOLLA:

Q. Okay. Well, we'll show you.

MR. SCIOLLA: Let's mark this 36. Did I skip 35?

MR. DAVIS: Yeah, you don't have 35.

MR. SCIOLLA: If you could hand that one back to me?

(At this time a document was marked for identification as Exhibit No. 35.)

BY MR. SCIOLLA:

Q. There you go. That is what I meant to give you. Have you ever seen this document before?

A. Yes, I have.

Q. Okay. When did you receive this document?

A. I'm not sure of the first time I saw this document.

Q. Okay. The heading of this document says: Evaluation of Suicidal Thoughts and Behaviors in Children and Adolescents Taking Paroxetine,

correct?

A. Correct.

Q. And the first author listed underneath that is Alan Apter?

A. Correct.

Q. Okay. I'm sorry -- give me one second.

MR. SCIOLLA: Can we go off the record one second?

THE VIDEOGRAPHER: 3:22. Off the record.

(At this time, a discussion was held off the record.)

THE VIDEOGRAPHER: 3:25. On the record.

BY MR. SCIOLLA:

Q. Okay, Doctor, I handed you what has been marked as Exhibit 36 and you said that you recognize this, correct?

A. I'm sorry, you handed me --

Q. 35. 35.

A. Yes, I want to make sure we are talking about the same one.

Q. I'm sorry.

A. That is okay.
Q. If you look in the abstract of this article, which was -- I'm sorry, this article was published in the Journal of Child and Adolescent Psychopharmacology, correct?
A. That's right.
Q. And it says, Volume 16, 2006?
A. Correct.
Q. And the author is Alan Apter?
A. That is the lead author, yes.
Q. Some of the other authors are Alan Lipschitz, who we mentioned before?
A. Correct.
Q. And are some of these authors some of your colleagues at GSK?
A. They are.
Q. Now, in your abstract, if you look in the results section. The first sentence of the results section says: Suicide-related events occurred more often in paroxetine than placebo groups, correct?
A. Correct.
Q. And if you look in the conclusion section it says: Adolescents treated with paroxetine showed an increased risk of suicide-related events?

A. Correct.

Q. Okay. Is this language consistent with the other language that we have been looking at in these exhibits regarding a causal link or causal relationship?

MR. DAVIS: Object to the form.

THE WITNESS: This --

BY MR. SCIOLLA:

Q. In your opinion?

A. This language is quite specific and does not say anything about a causal link. It reports a fact.

Q. Okay. Correct. Thank you. So, considering all the documents that we just looked at, specifically the ones mentioning the committee's conclusions of the causal link, you are still not comfortable saying at that point that there is a

causal link between suicidality and pediatric patients taking Paxil?

A. I do not believe it has been demonstrated that there is a causal link.

Q. But you are comfortable saying, at the very least, there is an association?

A. Correct.

Q. Okay.

MR. SCIOLLA: All right. I don't have any further questions.

MR. DAVIS: Okay.

THE VIDEOGRAPHER: This concludes --

MR. DAVIS: Give me a chance. All right. I'm going to switch sides over here, if I could, with Andrew.

MR. SCIOLLA: Thanks, Doctor.

THE WITNESS: You're welcome.

EXAMINATION

BY MR. DAVIS:

Q. Are you ready?

A. I'm ready.

Q. Well said, Doctor. Dr. Krall, I'm going to ask you some follow-up questions based upon what plaintiffs' counsel asked you. If at any time

you don't understand one of my questions, will you please let me know?

A. I will.

Q. Thank you, sir. Now, we have been talking -- the plaintiffs' lawyers have been questioning you all day about questions concerning whether there is an association between Paxil and suicidal thinking or behavior in either pediatric or adult patients. With respect to those questions I would like for you to tell us how you would characterize the strength of that association between Paxil and suicidal thinking and behavior enter pediatric or adult patients?

MR. SCIOLLA: Object to the form.

THE WITNESS: I characterize the association as a weak association. It lacks a number of characteristics that would -- I would want to see for it to be both stronger or causal.

First, only some of character -- some of the measures of suicide, and suicide behavior, and suicidal thinking have been shown to be increased in patients treated with Paxil, or have been found to be

increased in patients treated with Paxil, and for a stronger association I would have expected all of those measures to go in the same direction and to show stronger statistical significance.

Second, the measures of suicidality in the depression rating scales of Hamilton and MADRS rating scales do not show any evidence changing in the direction of an increase of suicidal thinking or behavior, and leave me uncertain about the inconsistency between the sensitive measures and the adverse experiences that lead to the one positive finding that exists.

It's not clear to me that there is any biological plausibility between an association between SSRIs and suicidal thinking and behavior. And these are just some of the reasons that, for me, mean the association is weak and falls far short of a causal link.

BY MR. DAVIS:

Q. Now, with respect to what you mentioned as the HAM-D and the MADRS rating scales,

would you describe those, just briefly, for the jury so they can understand what those are?

A. Yes. The HAM-D is a rating scale. It is a Hamilton Depression Rating Scale, that kind of rates the severity of depression overall with a series of questions that kind of ask for the severity of different symptoms of depression.

The MADRS is a Montgomery-Asberg Depression Rating Scale. It is a different scale, but it achieves the same purpose.

So, patients who have significant depression have high scores on those rating scales. One of the items in each of those rating scales is a question about suicidality, and in the case of the studies for Paxil neither of those items has shown evidence of an increase in Paxil-treated patients.

Q. Now, you were asked some questions about one of the statistical analyses that was completed by GSK in the early part of 2006, dealing with the adult clinical trials for Major Depressive Disorder. And I'm going to refer you back, and I want to ask you some follow-up questions about that.

I want to hand you what has been marked as Plaintiff's Exhibit 13, which is the

March 8th, 2006 correspondence with FDA submitting the briefing document you were asked some questions about. With respect to the findings in the adult -- what's called the Adult MDD Analyses, on the primary end point, which included suicidal ideation and behavior, was there a statistically significant increased risk between Paxil and suicidal ideation and behavior?

A. No, there was not.

Q. Now, with respect to the -- what has been described as -- there is a secondary end point that included suicidal behavior?

A. Yes.

Q. Now, and that finding, what were the vast majority -- what were the age ranges of the majority of the patients?

A. Eight of the eleven patients who had suicide attempts or suicide behavior were under the age of 30 or 30 years old. In the last paragraph of this sentence or letter -- next to last paragraph of the clinical summary it says, There were proportionally slightly more events in young adults between 18 and 24 years of age, but the vast majority were under 30.

Q. With respect to the analyses on the

adult MDD studies, did GSK find an increased risk with completed suicides in the use of Paxil?

A. No.

Q. And with respect to the other data set, what has been referred to as the non-MDD data set, do GSK find in its analyses increased risk of completed suicide with the use of Paxil?

A. No.

Q. Now, were there any completed suicides in any of the Paxil pediatric studies that were submitted and then ultimately analyzed by FDA?

A. No.

Q. With respect to the one finding of an association between use of Paxil and suicide attempts in the MDD analyses, were there any other analyses that were part of GSK's 2006 analysis of the data using either the primary or secondary end point that showed a statistically significant increased risk for the use of Paxil in either suicidal behavior?

A. No.

Q. Okay. Let me ask it just a little bit clearer way, because that was a long question. In any of the analyses done by GSK in the beginning of 2006 on the MDD data set and non-MDD data set, when

one was looking at the primary and the secondary end points, was there any statistically significant increased risk shown in those analyses, other than the one finding with respect to adult with pediatric MDD?

A. To my knowledge, no.

Q. So, and just so the jury can understand, how many analyses did GSK run on the MDD data set and the non-MDD data set?

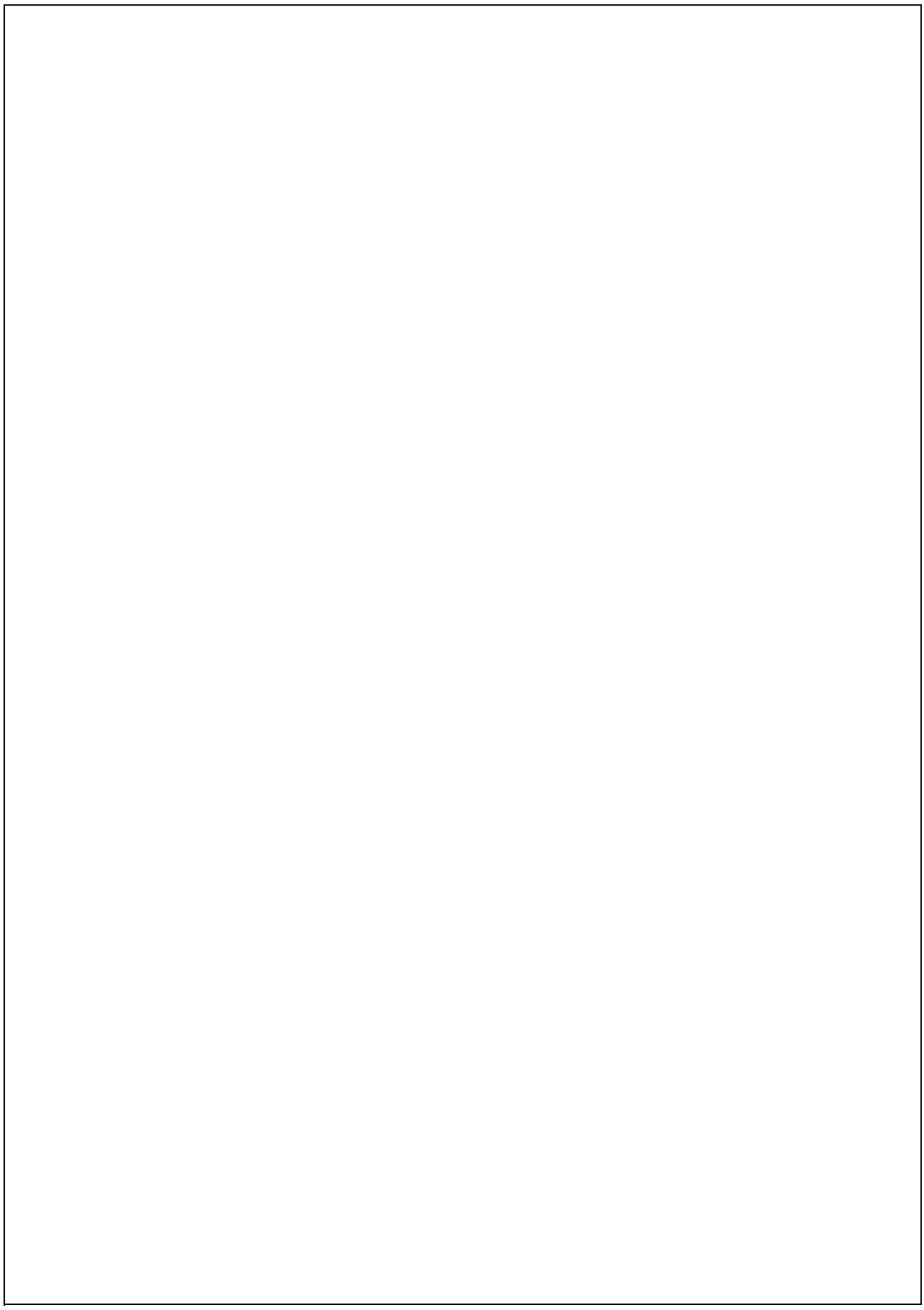
A. Many, but I don't know the number.

Q. All right. Fair enough. Now, was the only statistically significant association found, was a single statistically significant association when looking at the primary or the secondary end point?

A. Yes.

MR. SCIOLLA: Object to the form.

BY MR. DAVIS:



Q. Let me hand you what has been marked as Plaintiff's Exhibit 17, which is the excerpt of a clinical review that the FDA did. You got some questions asked of you of that?

A. Yes.

Q. All right. Now, you were asked questions about the statistical association between Paxil and suicidality risk that is reflected the table 15, is that right?

A. Table 16, yes.

Q. Table 16, yes. And let me hand you what's marked -- what's page 23 of the FDA analysis, and if you could look at the paragraph that is below the table. I'm going to ask you some questions about that.

Dr. Krall, does that table have any discussion about the FDA's views about the significance of the findings in table 16 that you were asked questions about?

A. It does.

Q. Okay. And what does it say?

A. The middle sentence in the paragraph says, Although the values for some individual drugs

are statistically significant at the 0.05 level, the significance of those findings must be discounted for the large number of comparisons being made.

Q. And do you agree with that assessment?

A. I do.

Q. So, even though that there is a statistical significant association reflected for the paroxetine data in Table 16 of the FDA's clinical review, do you believe that that establishes that there is a causal relationship between use of Paxil and suicidal thoughts or behavior?

A. I do not.

Q. Let me turn your attention to -- let me hand you Plaintiff's Exhibit 28. This is the summary minutes of the Psychopharmacologic Drugs Advisory Committee that you got asked a number of questions about by plaintiffs' counsel?

A. Yes.

Q. And you were asked questions about the conclusions of the committee; is that right?

A. That's correct.

Q. And the committee we are talking about is the Pediatric Advisory Committee that took

place in September of 2004?

A. Correct.

Q. Now, and you were asked -- if you recall, you were asked questions about whether or not the committee concluded that a causal link had been established between the use of antidepressants and suicidal thoughts or behavior?

A. Correct.

Q. Now, look at each of the questions that were put to the committee by the FDA that are reflected the summary of that meeting. Do you see those questions?

A. Yes.

Q. How many questions there?

A. Five.

Q. Do any of those questions put to the committee -- are any of the questions that the FDA put to the committee, ask the committee whether or not a causal link has been established between the use of antidepressants and suicidal thoughts or behavior in pediatric patients?

A. None of the questions ask that.

Q. Do any of the questions contain a reference or language concerning a causal link?

A. No.

Q. Okay. And so, in terms of what the committee voted on, based upon the questions put to them, did the committee conclude anything about a causal relationship between use of -- strike that.

Did the committee -- based upon the questions put to the committee, did the committee ever vote on the question of whether or not a causal relationship had been established between the use of antidepressants and suicidal thoughts or behavior in pediatric patients?

A. Under the assumption this is an accurate accounting of what the committee voted on, no.

Q. You were asked some questions about the FDA's analyses with respect to Paxil in the pediatric suicidality analyses. I'm going to hand you an article entitled: Suicidality in Pediatric Patients, that is authored by Dr. Tarek Hammad, Dr.

Thomas Laughren, and Dr. Judith Rancosin. Okay. Are you familiar that the authors are members of the FDA?

A. Yes.

Q. Now, let me turn your attention to the highlighted portion of the article, and do you understand that this article is a reflection of the FDA's analysis on the pediatric data for all antidepressants manufacturers concerning possible risk of suicidal thoughts or behaviors?

MR. SCIOLLA: Object to the form.

THE WITNESS: It is.

BY MR. DAVIS:

Q. Now, let's turn back to the highlighted portion. Can you, based upon FDA's analysis of the paroxetine or Paxil data for possible suicidal thoughts or behavior, did the FDA find a statistically significant increased risk in the Paxil data?

A. You asked me to look at the highlighted section?

Q. Yes.

A. Give me just a minute to look at this, because -- I do not see in the figure or in the text any evidence that the paroxetine data alone were

found statistically significant.

Q. Okay. And finally, to wrap this up. You've been asked a host of questions about FDA's position about whether or not a causal link has been established between use of Paxil and suicidal thoughts or behavior. Let me hand you a copy of the prescribing information for Paxil that's been marked as Plaintiff's Exhibit 22, which is the current prescribing information, and I call your attention to page nine of that prescribing information in the paragraph that begins, The follow symptoms. Doctor, based upon the FDA's recent approval of that prescribing information for Paxil, does it contain any language showing that there -- that the FDA believes that a causal link has been shown between use of Paxil and suicidal thoughts or behavior?

MR. SCIOLLA: Object to the form.

THE WITNESS: No.

BY MR. DAVIS:

Q. And what language does it contain instead?

A. I'm not sure about what you mean.

Q. If you look at the language part that begins, Although?

A. So, the language here is: Although a causal link between did emergence of such symptoms -- and it refers here to a series of symptoms earlier in the paragraph -- and either the worsening of depression and/or the emergence of suicidal impulses has been established there is concerns that such symptoms may represent precursors to emerging suicidality.

Q. That is all the questions I have. Thank you, Doctor.

THE VIDEOGRAPHER: This concludes today's videotape deposition. The time is 3:54 p.m. We are off the record.

- - -

(Witness excused.)

(Deposition concluded at 3:54 p.m.)

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

I, Kathleen Ruccolo, Professional Reporter and Notary Public, do hereby certify that the foregoing is a true and accurate transcript of the stenographic notes taken by me in the aforementioned matter.

- - -

DATE: _____

KATHLEEN RUCCOLO

INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it.

You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

- - -

E R R A T A S H E E T

- - -

PAGE	LINE	CHANGE
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

ACKNOWLEDGMENT OF DEPONENT

I, _____ , do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached errata sheet.

_____ _____

DATE SIGNATURE

Subscribed and sworn to before me.

My commission expires: _____

_____

Notary Public