

1 SUPERIOR COURT OF CALIFORNIA
 2 COUNTY OF ORANGE
 3 BEVERLY SMITH, on behalf of herself)
 and all others similarly situated)
 4 and on behalf of the general public,))
)Case No.:
 5 Plaintiff,)04 CC 00590
)
 6 vs.)
)
 7 SMITHKLINE BEECHAM)
 CORPORATION, dba GLAXOSMITHKLINE, a)
 8 Pennsylvania Corporation, and DOES)
 1-100, inclusive,)
 9)
 Defendants.)

10 -----
 11 IN THE UNITED STATES DISTRICT COURT
 FOR THE EASTERN DISTRICT OF PENNSYLVANIA

12 -----
 13 PAMELA BLAIN, Individually and as)
 Personal Representative of the Estate)
 14 of TREVOR KYLE BLAIN, II, Deceased, and)
 on Behalf of All Those Similarly)
 15 Situated; TONYA D. Brooks, Individually)
 and on Behalf of ALL of Those Similarly)
 16 Situated; RONALD BLAIN, Individually;)
 LEX BROOKS, Individually; Cheryl Brooks,)
 17 Individually)Case No.:
)06-1247-JD
 18 Plaintiffs,)
 vs.)
 19)
 SMITHKLINE BEECHAM CORPORATION d/b/a/) DEPOSITION OF
 20 GLAXOSMITHKLINE, a Pennsylvania) NEAL RYAN, M.D.
 Corporation,) PITTSBURGH, PENNSYLVANIA
 21 Defendant.) OCTOBER 4, 2006

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STATE OF MINNESOTA
COUNTY OF HENNEPIN

- - -

Leigh Ann Engh, Darcene and Greg)
Lensing, on behalf of the general)
public, themselves and all others)
similarly situated)
Plaintiffs,)

vs.) Court No:
PI-04-012879

SMITHKLINE BEECHAM CORPORATION,)
d/b/a/GLAXOSMITHKLINE, a)
Pennsylvania corporation,)
Defendants.)

Deposition of NEAL RYAN, M.D., taken on
behalf of the Plaintiffs at Professional Suites, US
Steel Tower, Suite 600, 600 Grant Street,
Pittsburgh, Pennsylvania, commencing at 9:00 a.m.,
Thursday, October 4, 2006, before Michele A. Kohar,
Certified Court Reporter.

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A P P E A R A N C E S

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Pittsburgh, Pennsylvania 15260

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EXHIBIT

DEFENDANT'S

2

DESCRIPTION

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(NONE)

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QUESTIONS WITNESS WAS INSTRUCTED NOT TO ANSWER

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(NONE)

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INFORMATION TO BE SUPPLIED:

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1 BY MR. MURGATROYD:

2 Q. Doctor, can you please state your full
3 name for the record.

4 A. Neal David Ryan.

5 Q. Okay. And what is your current address?

6 A. University of Pittsburgh, 3811 O'Hara
7 Street, Pittsburgh, 15213.

8 Q. And you understand that you're under oath?

9 A. Yes.

10 Q. Okay. It's the same oath as you would
11 take as if you were in a court of law, right?

12 A. Yes.

13 Q. Have you been deposed before?

14 A. No.

15 Q. Have you had a chance to talk to your
16 attorney about the ground rules of a deposition?

17 A. Yes.

18 Q. Let me go over them briefly to make sure
19 we're on the same page. Okay?

20 A. Okay.

21 Q. The first thing is -- and what you're
22 doing is great -- it's important that you wait for
23 me to fully ask a question before you answer. Okay?

24 A. Yes.

25 Q. And make sure all your answers are out

1 loud, because the court reporter can't take down
2 shrugs or nods. Okay?

3 A. Okay.

4 Q. Now, at some point in the not too distant
5 future, probably in a few weeks, you'll receive a
6 copy of the transcript of this deposition today, at
7 which time you'll have an opportunity to change or
8 make corrections to your testimony, but I need to
9 caution you now that if you do change your testimony
10 at a later date that fact of changing it can be used
11 at trial. Do you understand that?

12 A. Yes.

13 Q. Okay. The idea today is to give your best
14 testimony. Is there any reason why you can't?

15 A. No.

16 Q. Okay.

17 MR. DAVIS: Since we're talking about
18 ground rules I assume that the deposition -- that
19 we're proceeding in that all objections except for
20 the form of the question or the responsiveness of
21 the answer are reserved until such further use of
22 the deposition or until time of trial?

23 MR. MURGATROYD: That's correct.

24 MR. DAVIS: Also, it's my understanding
25 that when we agreed to this, this is for -- Dr.

1 Ryan's deposition is not only for Beverly Smith and
2 the Blain case, but also the six other cases that
3 have now been consolidated in front of Judge Savage
4 in Federal Court in Pennsylvania as well as your
5 firms other pediatric cases or clients?

6 MR. MURGATROYD: Not cases that are filed.

7 MS. CONNELLY: I don't understand that?

8 MR. MURGATROYD: Well, if it turns out
9 that I have a client that was treated by Dr. Ryan or
10 I have a client that has some other connections or I
11 think I need to come back again we'll have to come
12 back again.

13 MR. DAVIS: Well, we'll agree to disagree
14 on that. If we're here to arrange to have Dr.
15 Ryan's testimony I just don't see how his testimony
16 is going to be different in those cases.

17 MR. MURGATROYD: We can agree to disagree.
18 So the record is clear this deposition is being
19 taken in what is called the ENGH case, E-N-G-H,
20 which is pending in State Court in Minnesota, and
21 normally there would be an attorney here by the name
22 of Chris Coffin for that case. He is in Minnesota
23 so he can't be here, but the transcript and the
24 videotape for this deposition will be used for that
25 case also.

1 MR. DAVIS: And you're here on behalf of
2 the Plaintiffs?

3 MR. MURGATROYD: That's right.

4 MS. CONNELLY: My name is Pam Connelly. I
5 represent Dr. Ryan in this proceeding. I have
6 negotiated with Mr. Brava-Partain through your
7 office --

8 MR. MURGATROYD: Right.

9 MS. CONNELLY: -- orally in the form of
10 letters, and he has agreed that this deposition will
11 be the deposition for Dr. Ryan for the cases in
12 which you represent Plaintiffs relating to the
13 pediatric or adolescent use of Paxil so we can argue
14 about how that'll shake out later, but I wanted to
15 get that on the record.

16 MR. MURGATROYD: That's fine. Also, for
17 the record we have a videographer who is running
18 late and when he gets here we'll take a short break
19 and pick up the deposition at that point.

20 MS. CONNELLY: Not to nit-pick, but it's
21 my understanding that the videographer was not
22 scheduled and that we quickly had to schedule one
23 this morning and he's on his way? Is that right?

24 MR. MURGATROYD: That's my understanding.

25

1 BY MR. MURGATROYD:

2 Q. Now, in preparing for your deposition
3 today, Doctor, did you review any documents?

4 A. Yes.

5 Q. What did you review?

6 A. I reviewed the Keller article about the
7 Paxil study and the three letters to the editor and
8 the three responses, and I reviewed the ANCP article
9 on which I was a coauthor on.

10 Q. And the ANCP paper that you were a
11 coauthor on, do you recall the title of that?

12 A. I do not.

13 Q. Did you read the entire pages?

14 A. Yes.

15 Q. Did you see that the Keller article is
16 referenced in that document?

17 A. Yes.

18 Q. Now, we'll probably get into that
19 tomorrow.

20 Are you aware that the other coauthors of
21 your article have been deposed in this case?

22 A. Yes.

23 Q. Okay. Have you seen or heard any portions
24 of their depositions?

25 A. No.

1 Q. Have you discussed their depositions with
2 any of them, and particularly Martin Keller?

3 MS. CONNELLY: Objection to the extent
4 that it may involve anything that may invade the
5 attorney/client privilege.

6 MR. MURGATROYD: I'm just asking him about
7 discussions with Keller?

8 MS. CONNELLY: No. I think you said, Did
9 you have any discussions relating to it? I'm not
10 sure if that -- to the extent you're talking about
11 discussions with counsel then I would direct him not
12 to answer.

13 MR. MURGATROYD: That's okay. I'm not
14 asking that.

15 BY MR. MURGATROYD:

16 Q. Have you had any discussions with Martin
17 Keller regarding his deposition?

18 A. No.

19 Q. Have you had any discussions with Jim
20 McCafferty about his deposition?

21 A. No.

22 Q. How about Karen Wagner?

23 A. No.

24 Q. Have you had any e-mails or -- by
25 discussions I mean not just phone calls or in-person

1 meetings I'm talking about also e-mails, have you
2 had any e-mails from any of those individuals
3 regarding what happened in their depositions?

4 A. No.

5 Q. Okay. How is it you became aware they
6 were deposed?

7 MS. CONNELLY: Objection to the extent it
8 calls for communications between his lawyer and
9 himself.

10 BY MR. MURGATROYD:

11 Q. Okay. Can you tell me?

12 MS. CONNELLY: Can you rephrase the
13 question to: Other than discussions with counsel
14 have you had any?

15 MR. MURGATROYD: Yes. That's fine.

16 MS. CONNELLY: What's the question you
17 want to ask him now?

18 BY MR. MURGATROYD:

19 Q. Other than any discussions you had with
20 your lawyer, how did you become aware that these
21 other individuals had been deposed?

22 A. I don't know if there's an answer to the
23 question the way you phrased it.

24 Q. Well, let me ask you this: Is the only
25 way that you became aware of those depositions is

1 through your counsel?

2 A. Yes.

3 Q. Okay. Thank you.

4 Now, what is your educational background?

5 A. I have a degree in Computer Science and
6 Electrical Engineering from MIT. I have a medical
7 degree from Yale University. I did my residency in
8 general psychiatry at Columbia and I did my child
9 psychiatry fellowship at the University of
10 Pittsburgh.

11 Q. When did you complete your education?

12 A. My bachelors degree was 1974. My medical
13 degree was 1978. I finished my residency in 1982
14 and I finished my child psychiatry fellowship in --
15 oh, goodness -- I think it was '86.

16 Q. Are you currently employed by the
17 University of Pittsburgh?

18 A. Yes.

19 Q. And what is your position?

20 A. I'm a professor of psychiatry at the
21 University of Pittsburgh.

22 Q. How long have you been there?

23 A. I've been at the University of Pittsburgh
24 since 1984 so it's 22 years now.

25 Q. Now, you have done work for pharmaceutical

1 companies in terms of doing clinical trials,
2 correct?

3 A. Correct.

4 Q. How many?

5 A. Two.

6 Q. Were both of those with GlaxoSmithKline?

7 A. No.

8 Q. Okay. Why don't you tell me about the
9 two?

10 A. The first study was with GlaxoSmithKline.
11 The second study was with Wyeth.

12 Q. And what drug did you test for Wyeth?

13 A. Venlafaxine.

14 Q. Which is also known as Effexor?

15 A. Yes.

16 Q. Okay. And did you test this drug on kids?

17 A. Children and adolescents.

18 Q. When I use the term kids today I mean both
19 kids and adolescents. I'm not going to
20 differentiate. Is that okay?

21 A. Sure.

22 Q. Okay. Great. Now, are you or have you
23 been a member of any drug company's advisory board?

24 A. I am not. I have been.

25 Q. Okay. And what companies?

1 A. I think the only one I was on was the
2 Pediatric Advisory Board. It was for Abbott.

3 Q. And what years?

4 A. Don't remember. A few years ago.

5 Q. For how many years?

6 A. Approximately three years.

7 Q. And do you get paid by the year?

8 A. I got paid. I went to one meeting
9 annually. I got one fee annually.

10 Q. Okay. Now, have you ever been a
11 consultant for GFK -- actually, let me back up a
12 minute -- when I refer to GSK I mean
13 GlaxoSmithKline, do you understand that?

14 A. Yes.

15 Q. Have you ever been a consultant for GSK?

16 A. Yes.

17 Q. Okay. And you currently are a consultant
18 or you currently are not?

19 A. I currently am not.

20 Q. Okay. And when did you first become a
21 consultant for GSK?

22 A. You have the -- each time I was a
23 consultant I was paid, and you have all that
24 information so your information on yours would be
25 more accurate than mine.

1 Q. Okay. And when did you cease being a
2 consultant for GSK?

3 A. A few years ago, and again, I provided you
4 all the 1099's and those are more accurate than my
5 memory.

6 Q. Okay. Are you a member of the Speakers
7 Borough for any drug company?

8 A. No.

9 Q. Have you ever?

10 A. No, not to the best of my knowledge.

11 Q. Okay. Now. You're right. You did
12 provide me some information on payments you received
13 from GlaxoSmithKline. Did that include a -- you did
14 what is called a blinded review of 35 patients?

15 A. That's correct. I did that.

16 Q. Okay. For GlaxoSmithKline?

17 A. Right.

18 Q. Did you get paid for that?

19 A. I don't believe so.

20 Q. And we'll talk about that. That ended
21 up -- that review was part of the process of
22 drafting an article, correct?

23 A. Yes.

24 Q. Okay. In which you were listed as one of
25 the original authors; do you remember that?

1 A. Yes.

2 Q. And that article was published recently,
3 this year, 2006? Is that correct?

4 A. I don't know if that's correct. I did not
5 see the article published.

6 Q. Okay. Well, it has been, and again, I'm
7 just laying a foundation. We'll get into that
8 later.

9 A. You'll need to show me the article then
10 when we get into it.

11 Q. Okay. That's fine.

12 Are you on the editorial boards for any
13 medical journals?

14 A. I am on the editorial board for -- that's
15 a good question -- I have been at various times. I
16 do not actually know whether or not I am right now.
17 I think I am not.

18 Q. And what journals do you recall that you
19 were on?

20 A. For Biological Psychiatry, for the
21 American Academy for Child and Adolescents
22 Psychiatry and for the Journal of Child and
23 Adolescence Psychopharmacology.

24 Q. Okay. And do you consider yourself to be
25 an expert in psychopharmacology?

1 A. In all of psychopharmacology? No.

2 Q. Okay. Is psychopharmacology broken into
3 categories?

4 A. Yes.

5 Q. And do you consider yourself to be an
6 expert in any of those categories?

7 A. Sure. The psychopharmacology in child and
8 adolescent depression and anxiety, basically.

9 Q. Do you consider yourself to be an expert
10 in suicidality?

11 A. No.

12 Q. Do you have a clinical practice?

13 A. Essentially no.

14 Q. So you don't currently treat patients?

15 A. That's not correct.

16 Q. Okay.

17 A. I treat patients in research protocol, but
18 not in clinical practice.

19 Q. Okay. When you say research protocol, are
20 there any current research protocols that you're
21 doing?

22 A. Yes.

23 Q. Does it involve drugs?

24 A. Yes.

25 Q. Which drug?

1 A. It involves fluoxetine, sertraline and
2 paroxetine.

3 Q. And who is financing that research?

4 A. Through the NIH.

5 Q. And what's the hypothesis that you're
6 testing?

7 A. We're testing the -- whether on
8 adolescents who have not responded to first-line
9 Serotonin Reuptake Inhibitors -- whether the best
10 treatment is to switch to a different class of
11 agents or not or just switch to a different agent
12 within class and whether to add psychotherapy or
13 not.

14 Q. And what are the different classes of
15 agents you are testing?

16 A. The two classes we're looking at are
17 Serotonin Reuptake Inhibitors, and specifically
18 fluoxetine and sertraline, and the other class is
19 norepinephrine.

20 Q. And what class is that for? You said
21 SNRI?

22 A. It's not a pure SNRI, but yes.

23 Q. Okay. And what does the public know
24 citalopram as?

25 A. Celexa.

1 Q. And how many patients are enrolled in that
2 research program?

3 A. In the Pittsburgh arm I believe the
4 number's about 80.

5 Q. When -- let me go to -- specifically to
6 the clinical study that you did for GSK that's
7 commonly known as study 329; is that correct?

8 A. Yes.

9 Q. Okay. And were you paid personally for
10 performing your part of that study?

11 MR. DAVIS: Object to the form.

12 MS. CONNELLY: Dr. Ryan, if there's an
13 objection it's generally to preserve the record, and
14 you can answer it unless there's a privilege issue
15 and then I'll instruct you not to answer.

16 THE WITNESS: Okay. Sounds good. Was I
17 paid personally?

18 BY MR. MURGATROYD:

19 Q. Yes.

20 A. It was -- I was paid -- let's see.
21 Basically no.

22 Q. Was your department paid and then your
23 department paid you? Is that how it worked?

24 A. The department was paid.

25 Q. Okay.

1 A. The University was paid.

2 Q. Okay.

3 A. And I was paid two components; one, my
4 salary, which I would get any way although part of
5 that would have been supported by the study, and
6 then our department has the practice of paying
7 additional incentive pay for a wide range of things
8 including doing studies or extra clinical work. So
9 I got a little bit of money from the additional
10 incentive pay for having this particular grant.

11 Q. So the more money you bring into the
12 university for research the more money you get paid?
13 Is that correct?

14 A. Or the more clinical work I get; yes, that
15 is correct.

16 Q. All right. So let me just make sure I
17 have this right. So you got this for GSK and that
18 was completed in 1997? Correct?

19 A. Correct.

20 Q. And the only other clinical trial you've
21 done is the one you're currently doing?

22 A. That's not correct.

23 MS. CONNELLY: Object to form. He's done
24 many, many clinical trials.

25 MR. MURGATROYD: Okay. Then maybe I

1 didn't get the answer.

2 MS. CONNELLY: I believe he did make
3 mention of them.

4 BY MR. MURGATROYD:

5 Q. How many clinical trials have you done?

6 A. I don't know. That's an interesting
7 question.

8 MS. CONNELLY: Funded by NIH? Funded by
9 anyone?

10 BY MR. MURGATROYD:

11 Q. Yes. Clinical trials?

12 A. Funded by anyone?

13 Q. Yes.

14 A. Do you have a copy of my CV? I've done a
15 bunch.

16 Q. It's not on your CV.

17 MS. CONNELLY: It wasn't requested in the
18 Documents Request.

19 THE WITNESS: I've probably done about
20 ten, and only two have been funded by industry and
21 the rest were by NIH.

22 BY MR. MURGATROYD:

23 Q. So that's ten clinical trials since 1984?

24 A. I was involved in one other clinical trial
25 when I was in Europe before 1984.

1 Q. And is the term clinical trial and study,
2 are those synonymous terms?

3 A. Not to my mind.

4 Q. Okay. Well, when I say study 329,
5 clinical trial 329, is there a difference?

6 A. No.

7 Q. I'm sorry?

8 A. No. There would be no difference.

9 Q. Okay. Why do studies have pre-specified
10 outcomes?

11 A. Could you clarify your question, please?

12 Q. Well, do you know an outcome is for a
13 trial?

14 A. Yes.

15 Q. Okay. And are there protocols for trials?

16 A. Yes.

17 Q. Okay. And the protocols normally specify
18 the outcomes for -- well, let me ask you this: The
19 protocols set forth a hypothesis as being tested in
20 the study?

21 A. Yes.

22 Q. And are outcome measures defined so you
23 know what you're looking for?

24 A. Yes.

25 Q. And why are there -- do you consider those

1 to be pre-specified outcomes?

2 A. Yes.

3 Q. And why do you have those?

4 A. There are a numbers of reasons that I --
5 clearly one of the most important reasons is saying
6 to specify clearly which things you're putting the
7 most money on for the outcome, which things you're
8 saying is most important for the outcome, primarily
9 to avoid the problem of testing a bunch of different
10 ways, so doing too many comparisons.

11 Q. And why are there primary outcomes
12 distinguished from secondary outcomes?

13 A. Because, for example -- again, I think the
14 question before was -- the answer before was
15 responsive to that -- but for example, regulatory
16 agencies will require a positive significance on
17 your one or two primary outcomes that you propose
18 rather than a multitude of significant findings on
19 secondary outcome measures, because that's the
20 regulation about approval.

21 Q. Do you have primary outcome measures
22 strictly for regulatory purposes or is it also
23 scientific purposes?

24 A. It has a scientific purpose also, which is
25 what I answered before.

1 Q. Okay. Now, in terms of clinical trials,
2 what does it mean to say that there is a signal for
3 efficacy? What does that mean?

4 A. Sure. Are you asking in this particular
5 study or any?

6 Q. No. In general?

7 A. That a significant amount of the data came
8 out in a way that would suggest that there's
9 efficacy.

10 Q. And is there a difference between that and
11 a safety signal?

12 A. Yes.

13 Q. And what's the difference?

14 A. One is about safety and one is about
15 efficacy.

16 Q. But the same primaries apply?

17 MS. CONNELLY: Object to form.

18 MR. DAVIS: Objection.

19 THE WITNESS: Can you clarify your
20 question, please.

21 BY MR. MURGATROYD:

22 Q. Sure. Now, you said a minute ago -- let's
23 back up a minute -- I asked you what a signal for
24 efficacy is?

25 A. Yes. You did ask that, and I said that --

1 Q. Maybe I'll get you to say your answer
2 again, because I don't want to misquote you.

3 So a signal for efficacy -- and correct me
4 if I'm wrong -- you said a significant amount of
5 data, said a significant amount of that was
6 statistically significant on a number of secondary
7 studies?

8 THE WITNESS: Can you read that back.

9 (Answer read back.)

10 BY MR. MURGATROYD:

11 Q. Okay. A minute ago you said -- and
12 correct me if I'm wrong -- you said a significant
13 amount of data indicated that there was efficacy?

14 A. So let me see if I can -- in the example
15 that you're talking about there was a significant P
16 value. There was statistically significant findings
17 on a number of the secondary measures of efficacy.

18 Q. No. I'm not talking about this. I'm
19 talking about in general. We'll get into 329 a
20 little bit later. I'm talking about a signal for
21 efficacy just in a general form?

22 A. I'm doing my best to answer your question,
23 but I'll try to generalize it.

24 Q. Okay.

25 A. So I think that would be the general case

1 whether it's 329 or another one, that if you say a
2 bunch of the secondary measures came out positive --
3 I think that's what certainly I was referring to in
4 that particular phrase and that is how I would refer
5 to it on another study, and if you said the same
6 thing on side effects or suicidality I think that
7 would be a fair way of saying the signal. If you
8 had significant P values not on side effect data or
9 suicidality you are -- you would increase specified
10 as an hypothesis, but on something you're looking at
11 as a secondary analysis if those came out
12 significantly significant, you know, more than just
13 one thing.

14 Q. Okay. And do you believe that you have to
15 have a statistical significance for signal?

16 A. I was -- the way I was suggesting it is
17 meaning it was not only statistically significant on
18 one examination, but on several different ways we
19 examine them.

20 Q. Okay. Now, there is such a thing known as
21 a randomized placebo controlled trial, correct?

22 A. Yes.

23 Q. And what is that exactly?

24 A. Sure. It's two separate concepts. The
25 first is randomized, which means that you do a

1 computer equivalent of flipping a coin, so that a
2 person is on one of several different treatments.
3 And once you say placebo controlled it means that
4 one of the arms is with the placebo, presumably one
5 or more other arms of treatment are not with placebo
6 or with active compounds and the people are assigned
7 at random and the -- with the placebo the intent is
8 that neither the study subject nor the investigators
9 evaluating the placebo know which the patient's been
10 assigned to.

11 Q. And is that considered the gold standard
12 for determining efficacy of the drug that's being
13 tested?

14 A. By many people it's not the only gold
15 standard.

16 Q. Okay. But it is a gold standard?

17 A. Yes.

18 Q. And it is also the gold standard for
19 determining the safety of the drug?

20 A. No.

21 Q. What is the gold standard for determining
22 the safety of the drug?

23 A. It depends on the safety issue you're
24 trying to address.

25 Q. Okay. What are the different

1 possibilities?

2 A. Sure. The gold standard for determining
3 safety with a drug would be a large number of
4 subjects, and certainly blinded would have some
5 randomized controlled trials where they're blinded
6 and someone on placebo would have significant
7 advantages large enough to -- and then prospective
8 hypothesis during testing of specific side effects.

9 Q. Okay. And what do you mean by
10 prospective?

11 A. That you plan to look for those side
12 effects from the get-go and so you're investigating
13 what you could on those side effects.

14 Q. Okay. And if you want to look for -- you
15 want to look at the safety of the drug regarding
16 adverse events that weren't looked at prospectively,
17 what's the method of doing that?

18 A. A method is to go back and see what you've
19 got.

20 Q. Okay. All right. Now, turning to study
21 329, were you involved in the very beginning of the
22 creation of the protocol for that study?

23 A. Yes.

24 Q. And were you a part of a team of people?

25 A. Yes.

1 Q. And who consisted of them? Who was on the
2 team?

3 A. Yes. The -- it was Michael Strober at
4 UCLA, Martin Keller at Grand University, myself,
5 Boris Birmaher, B-I-R-M-A-H-E-R, at the University
6 of Pittsburgh, and Rachel Gittelman-Klein,
7 G-I-T-T-E-L-M-A-N, K-L-E-I-N, with a hyphen, who is
8 at NYU. I do not believe there were others, but I'm
9 not certain.

10 Q. And how did you all get together?

11 A. We met annually at a meeting called the
12 Child Depression Consortium and the idea came up
13 that we should do a study similar to this in a
14 discussion there.

15 Q. And why was Martin Keller there? He's not
16 a child psychiatrist?

17 A. He's been a member of the Child Depression
18 Consortium for a long time before that, because he
19 studies depression in families.

20 Q. Okay. And the idea was you guys wanted to
21 get together and test any particular drugs on kids?

22 A. I'm sorry. I don't know how to answer
23 your question.

24 Q. Well, you as a team, right, and I think
25 Keller was -- did you have a chairman of the team or

1 was there a captain of the team?

2 A. No.

3 Q. They were all equally distributed?

4 A. Yes.

5 Q. Okay. Who pitched GSK to do the study
6 329?

7 MS. CONNELLY: Object to form. Did you
8 say pitch?

9 BY MR. MURGATROYD:

10 Q. Yes. Who pitched it?

11 A. Okay. This is a different question than
12 you asked me before, right?

13 Q. Yes.

14 A. Fine. When we designed the study --
15 because we were interested in looking at any of the
16 then available serotonin Reuptake inhibitors and
17 wanted to compare it to a tricyclic antidepressant,
18 and in this case Imipramine. We were wondering what
19 SSRI to test imipramine, I-M-I-P-R-A-M-I-N-E, and
20 placebo and we were interested about which of the
21 serotonin Reuptake inhibitors to test.

22 We thought that we would be able to get
23 funding from several different pharmaceutical
24 manufacturers for this study that we designed.
25 Dr. Keller suggested that GSK or SKB at the time

1 might be interested so he negotiated with them to
2 see if they were interested.

3 Q. Okay. Now prior to going to GSK, had you
4 gone to another drug company first?

5 A. Not to my memory.

6 Q. You don't recall going to Lilly?

7 A. I don't recall doing that. We may have.
8 I don't recall whether we did or not.

9 Q. Okay. How about Pfizer?

10 A. Again, I don't recall that we did that. I
11 just don't know the answer to your question.

12 Q. Now, what was your primary
13 responsibilities in regard to study 329?

14 A. I was one of the people that lead the
15 design, wrote it up, and I managed the Pittsburgh
16 team that carried it out and I was also responsible
17 with all the other coauthors for the write up.

18 Q. Now, when the study was completed, who was
19 responsible for analyzing the results?

20 A. GFK did the statistical analysis.

21 Q. Were you wholly dependant upon the results
22 they told you were the results?

23 MR. DAVIS: Object; form, vague and
24 ambiguous.

25

1 BY MR. MURGATROYD:

2 Q. Did you have any way of double checking
3 their work?

4 A. No.

5 Q. Is it a correct statement to say that you
6 were dependant upon GFK to do a correct analysis?

7 MR. DAVIS: Objection to form.

8 THE WITNESS: You mean a statistical
9 analysis?

10 BY MR. MURGATROYD:

11 Q. Yes.

12 A. Yes.

13 Q. Okay. Did you ever have full access to
14 all the raw data for that study?

15 A. No.

16 MR. DAVIS: Object to form.

17 (Ryan Deposition Exhibit No. 1
18 was marked for identification.)

19 BY MR. MURGATROYD:

20 Q. Let me show this to you, Dr. Ryan. Can
21 you identify for the record what that document is,
22 sir?

23 A. The title is "Adolescent Unipolar Major
24 Depression: Multi-Center Pharmacology Study." It
25 says draft, December 5, 1982. It is a document

1 describing the study that we proposed. I don't know
2 who prepared this document.

3 Q. Does it appear to be authentic?

4 MS. CONNELLY: Objection. He just said he
5 doesn't know who prepared it.

6 BY MR. MURGATROYD:

7 Q. I know that's -- you've seen that document
8 before, right?

9 A. I do not know whether I've seen this
10 document or similar documents. It certainly
11 describes our study. I don't know who prepared this
12 document.

13 Q. Okay. It would have been one of the
14 members of your team, right?

15 MS. CONNELLY: Object to form and
16 speculation.

17 THE WITNESS: I don't know the answer to
18 that. I don't know whether this was prepared by
19 someone at GFK based on what we've given them or one
20 of the members of our team.

21 BY MR. MURGATROYD:

22 Q. Okay. Well, does this discuss outcome
23 measures?

24 A. I looked through it briefly. I did not
25 see those in there.

1 Q. Okay. Well, if --

2 A. If you want to give me more time or really
3 want to tell me where they're described I'll review
4 that part specifically.

5 Q. Page 14.

6 A. Where on page 14?

7 Q. Definition of responders.

8 A. I cannot tell whether they're talking here
9 about responders here of the statistical analysis or
10 responders for purposes of going into continuation
11 phase. It could be either one or both -- and where
12 it's on Page 14? I can't tell which purpose it's
13 talking about it for?

14 Q. Okay. So you don't believe that the
15 information on page 14 relates to outcome measures?

16 A. That's not what I said.

17 Q. You're not sure if it is?

18 A. I'm saying by the reference on page 14
19 they talk about responders and non-responders. I
20 can certainly take more time and go through the
21 whole thing. I don't know if they were talking
22 about this for the purposes of the statistical
23 analysis of the primary hypothesis versus secondary
24 ones.

25 Q. Okay. Now, when 329 was completed, were

1 you provided a copy of the final clinical report by
2 GFK?

3 A. I assume that I was, but I don't recall --
4 yes, I'm sure I was.

5 Q. Okay. Prior to that, had you been
6 provided a copy of the protocol that was going to be
7 used for the study?

8 A. Yes.

9 Q. Okay.

10 MS. CONNELLY: Do you want bates number
11 identified for the record or are you all so familiar
12 with these documents that it's not necessary?

13 MR. DAVIS: I'm fine.

14 (Ryan Deposition Exhibit No. 2
15 was marked for identification.)

16 BY MR. MURGATROYD:

17 Q. Have you have a chance to review that
18 document?

19 A. I've looked at it briefly. It's a whole
20 lot of pages. It's about 50 pages. I've not
21 reviewed it.

22 Q. Okay. Can you identify for the record
23 what the document is?

24 A. The document appears to be produced by
25 SmithKline Beecham. Says "Study drug: BRL

1 29060/paroxetine." It appears to describe the Paxil
2 study we did.

3 Q. And does this document contain information
4 on the outcome measures that you were going to look
5 at?

6 MR. DAVIS: Object to form.

7 THE WITNESS: I don't know. It would take
8 me a considerable period of time to go through
9 there. Do you want to tell me which pages it may be
10 on and I can examine those pages in detail?

11 Q. 17.

12 A. Okay. Yes.

13 Q. Okay. And are there primary efficacy
14 variables listed there?

15 A. Yes.

16 Q. As well as secondary efficacy variables?

17 A. Yes.

18 Q. Okay. And with regard to the two primary
19 efficacy variables, were these changed at any time
20 from this protocol to the time the study was
21 finished?

22 A. Not to my memory. I don't believe so.

23 Q. Okay. When the study was complete and the
24 data was analyzed -- well, so the record's clear,
25 there are two primary efficacy variables, correct?

1 A. Yes.

2 Q. When the study was complete and the data
3 was analyzed, how many of these measures or
4 variables did Paxil separate statistically from
5 placebo?

6 MS. CONNELLY: Object to form. Are you
7 talking about primary?

8 MR. MURGATROYD: Yes. Primary.

9 THE WITNESS: Primary? None.

10 BY MR. MURGATROYD:

11 Q. Now, let's look at the secondary variables
12 that are listed in the protocol. Can you state for
13 the record what these are exactly?

14 A. There's five listed: Depression items in
15 K-SAD-P, global impression, autonomic function
16 checklist, self perception profile and sickness
17 impact scale.

18 Q. Okay. And on how many of these measures
19 did Paxil separate statistically from placebo?

20 A. Two I believe.

21 Q. And what two are those?

22 A. The depression item in the K-SAD-L and the
23 global impressions.

24 Q. Now, the global impressions. When the
25 study was completed the mean global compression

1 separated statistically? Paxil separated
2 statistically from placebo?

3 A. Yes.

4 Q. With regard to the mean global
5 impressions?

6 A. This doesn't say mean.

7 Q. Okay. That's not my question.

8 A. Okay. Give me the paper and I'll double
9 check before I answer.

10 Q. Okay.

11 MR. MURGATROYD: Let's go off the record
12 while you look at that.

13 (Ryan Deposition Exhibit No. 3, 4
14 was marked for identification.)

15 (Recess taken.)

16 BY MR. MURGATROYD:

17 Q. Okay. We're now back on the record, and
18 while we were off the record I handed the doctor
19 a -- actually, let's stay off the record for a
20 second because the videographer is here.

21 (Recess Taken.)

22 VIDEOGRAPHER: This is October 4, 2006 at
23 approximately 10:10 a.m. The videotape operator is
24 Martin Murray of Investigative Videography, 121
25 Glenwood Avenue, Pittsburgh, Pennsylvania 15209.

1 We are located at 660, USX Tower,
2 Pittsburgh, Pennsylvania 15219. We are here to
3 videotape the deposition of Neal Ryan, M.D. to
4 be used at time of trial or for any other
5 reason in the Superior Court in the State of
6 California for the County of Orange. Case
7 Number 04-CC-00590. We have Beverly Smith,
8 Plaintiff versus SmithKline Beecham
9 Corporation, et. al.

10 We also have in the United States District
11 Court for the Eastern District of Pennsylvania
12 Case No. 06-1247JD. We have Pamela Blain,
13 Plaintiff versus SmithKline Beecham Corporation
14 et.al.

15 We also have for the State of Minnesota,
16 County of Hennepin, District Court, Fourth
17 Judicial District, Case Number PI-04-012879.
18 Leigh Ann Engh Plaintiff versus SmithKline
19 Beecham Corporation et. al.

20 The witness has already been sworn. Would
21 Counselors please identify themselves and who
22 they represent.

23 MR. MURGATROYD: My name is Skip
24 Murgatroyd and I represent the Plaintiffs in each of
25 the actions.

1 MS. CONNELLY: My name is Pam Connelly. I
2 represent Dr. Neal Ryan.

3 MR. DAVIS: Todd Davis representing
4 GlaxoSmithKline and also here, but not entering an
5 appearance is Thomas Moore with Biddie and Reath.

6 VIDEOGRAPHER: Please continue.

7 BY MR. MURGATROYD:

8 Q. Doctor, when we went off the record we
9 were talking about the secondary outcome measures
10 that were listed in the protocol, which is listed in
11 Exhibit 2, correct?

12 A. Hold on a second. Yes.

13 Q. Okay. And you had a question. A question
14 came up with the secondary efficacy variables listed
15 in the original protocol include global impressions;
16 is that correct?

17 A. That's correct.

18 Q. And that question was whether or not that
19 parameter reached statistical significance in favor
20 of Paxil in study 329; is that correct?

21 A. I believe so.

22 Q. And you asked to look at the actual
23 study -- the article that you had published?

24 A. That's correct.

25 Q. Regarding study 329?

1 A. Yes.

2 Q. To determine whether or not that parameter
3 had reached statistical significance in favor of
4 Paxil; is that correct?

5 A. Right.

6 Q. And were you able to find the answer to
7 that?

8 A. Yes.

9 Q. Okay. And what is the answer?

10 A. The answer is yes by one analysis and no
11 by the other.

12 Q. Okay. Now, I also showed you what is
13 Exhibit 4.

14 A. Yes, you did.

15 Q. Which is the final clinical report,
16 correct?

17 A. Correct.

18 Q. And on the third page of that document it
19 talks about evaluation criteria?

20 A. I see that section.

21 Q. Okay. And in that section it lists the
22 primary and secondary outcome measures, correct, in
23 the second -- in the last paragraph of that page,
24 third page of the document?

25 A. Yes. I have that page. I'm looking at it

1 now.

2 Q. Okay. And if you would, can you read the
3 first two sentences into the record.

4 A. Of which paragraph would you like?

5 Q. That last paragraph.

6 A. "The protocol defined the primary efficacy
7 parameters as the change from baseline in the HAM-D
8 total score, and the proportion of responders
9 defined as patients with a 50 percent reduction in
10 the total HAM-D score or a score of eight or less."

11 Q. Okay. Let me stop you there just for a
12 second. Now, we talked about that earlier. Those
13 are the two primary efficacy variables, correct?

14 A. That's correct.

15 Q. And I believe you stated that with regard
16 to either of those reaching statistical significance
17 in favor of Paxil the answer was none?

18 A. That's correct.

19 Q. Okay. Now, can you read the second
20 sentence, please.

21 A. "Secondary parameters included the change
22 in baseline in the K-SADS-L depression subscale, the
23 mean CGI score and the functional/quality of life
24 instruments."

25 Q. Okay. Now with regard to those secondary

1 parameters, how many of those reached statistical
2 significance in favor of Paxil, if any?

3 A. Of those secondary parameters? One.

4 Q. Okay. And which one was that?

5 A. The K-SADL-L depression subscale.

6 Q. And is that in your paper? Do you have a
7 listing for that?

8 A. Yes.

9 Q. And where is that exactly in your paper?

10 A. It would be table 2.

11 Q. Okay.

12 A. Page 766. The paper you have referenced
13 is -- we don't actually have an exhibit on this one.

14 Q. Actually, there's a number.

15 A. Oh, there is a number? Exhibit 3, and it
16 would be about 40 percent of the way down the table.

17 Q. And what does it say exactly?

18 A. It says K-SADS-L depressed mood item and
19 the P value is .05 of paroxetine compared to
20 placebo.

21 Q. Okay. But this document talks about the
22 K-SADS-L depression subscale?

23 MS. CONNELLY: Object to form. Which
24 document are you referencing? The article?

25 MR. MURGATROYD: No. The evaluation

1 criteria in the final clinical report.

2 THE WITNESS: My apologies. I was reading
3 the wrong one.

4 Q. You were correct?

5 A. I was incorrect. The KSADS-L depression
6 subscale is about 60 percent of the way down and
7 that has a P value of .07.

8 Q. Okay. And so did that reach statistical
9 significance?

10 A. No. The statistical significance for this
11 was set at priority point of .05 so it did not.

12 Q. Okay. So am I correct in stating that
13 none of the secondary parameters that you just
14 discussed reached statistical significance in favor
15 of Paxil?

16 A. None of the secondary parameters that were
17 in this particular document, Plaintiffs Exhibit 4,
18 reached statistical significance.

19 Q. Okay. And in reviewing a study in which a
20 drug failed on both primary outcome measures and all
21 six secondary outcome measures as specified in its
22 protocol, what would you conclude?

23 MR. DAVIS: Object to the form.

24 THE WITNESS: Right. You're saying a
25 hypothetical. Are you saying that I had looked at

1 nothing else or are you saying that I looked at
2 other?

3 BY MR. MURGATROYD:

4 Q. Yes.

5 A. If I had looked at nothing else I wouldn't
6 have done the analysis correctly and I would assume
7 it was negative. If I had looked at other things,
8 which would be the correct thing to do, depends on
9 how the other things come out.

10 Q. Well, let me ask you this. As one of the
11 primary authors of that article and the original
12 protocol in the study, because I think you said you
13 helped design it, correct?

14 A. That's correct.

15 Q. What was your role in deciding from the
16 outcome measures for the study as defined in this
17 protocol?

18 A. Sure. At the time this study was designed
19 we didn't know which were the best measures to look
20 at depression in kids with treatment. There had
21 been essentially no contributory data to that
22 question so we picked, by guess and by golly, what
23 would appear to be reasonable choices on this.

24 Q. And those were the six secondary efficacy
25 variables and the two primary efficacy variables

1 that are listed in the protocol that's before you?

2 MR. DAVIS: Object to form.

3 THE WITNESS: I don't know. I don't know
4 what you just said is correct. I certainly remember
5 the two primary efficacy variables, which we've
6 discussed. On the discussions of the secondary
7 variables, because certainly we reported some
8 more in here, I don't think I would say it the way
9 you said it. I don't think I would agree with your
10 second part of that question on the secondary
11 variables.

12 BY MR. MURGATROYD:

13 Q. Okay. Well, who picked the six secondary
14 variables that you just read into the record?

15 A. I have not reviewed enough of the paper
16 trail to say were those precisely the ones that the
17 group designed and gave to GSK or was this just an
18 internal GSK internal document. I don't know the
19 answer to your question.

20 Q. So with regard to the six secondary
21 variables that are listed in the protocol, three had
22 to do with function scales? What are those?
23 Function scales, is that correct?

24 A. Yes. How people -- that is indeed
25 correct -- about how people perform in the rest of

1 their life, not simply their depressed mood.

2 Q. Okay. And what were those scales?

3 A. It's in here. Let me go back and find
4 them for you, please. I don't know. It's listed in
5 the paper or you can you help me find them and I'll
6 confirm if those are correct.

7 Q. Let me ask you this: What are the three
8 function scales that were used in your study?

9 A. The self-perception profile, the
10 autonomous functioning checklist and the sickness
11 impact profile.

12 Q. Okay. Let's take up those one at a time.
13 What is the autonomous checklist?

14 A. Yes. I think it's autonomous rather than
15 autonomic.

16 Q. Okay.

17 A. I am not -- I did not review those scales
18 before coming here today, and they're not scales
19 I've used in other studies. I know what the purpose
20 of -- I know what domains they're trying to assess,
21 but I don't have more information on the scales than
22 that. They're all trying assess how the children
23 perform in the rest of their life in terms of their
24 performance at school, performance with their family
25 and with their friends and with tasks of everyday

1 living.

2 Q. And who fills out those forms?

3 A. I don't know. That's either self report
4 or interview-rated, and I don't remember on those.

5 Q. Why don't I see if I can refresh your
6 recollection by turning to the fourth page of the
7 final clinical report, which we've marked as Exhibit
8 4.

9 A. Okay. So this says 000403 at the top?
10 That is correct.

11 Okay. So these are just some of the pages
12 from it and not all of the pages from it? Is that
13 correct?

14 Q. That is correct.

15 A. Okay. So these are selected pages, and
16 what's your pages now?

17 Q. Looking at this document, does that
18 refresh your recollection as to who fills out the
19 autonomous functioning checklist?

20 A. It appears to be a self report profile.

21 Q. And what exactly --

22 A. It's the patients's parent. I said that
23 wrong. It's the parent fills this out on the child.

24 Q. Okay. And can you describe to the jury
25 how that works? Is that the parent observing the

1 child, how they're doing in their life to see if
2 they're doing better?

3 A. Yes. It would be the parent reporting on
4 how they done over the interval. So that the parent
5 report would be on an interval, not on how they're
6 doing on that moment on a checklist of different
7 questions.

8 Q. Okay. And how about the sickness impact
9 profile? Who fills out that scale?

10 A. I don't know.

11 Q. Okay. By turning to the fourth page of
12 Exhibit 4, does that help you with that?

13 A. It says the patients rated their present
14 health so that appears to be the adolescent.

15 Q. And with regard to the self perception
16 profile, who fills out that form?

17 A. Presumably it's the adolescent. I don't
18 have detail on it here. I don't remember.

19 Q. Okay. Now, with regard to these three
20 secondary outcome measures, did any of them reach
21 statistical significance in study 329 in favor of
22 Paxil?

23 A. No.

24 Q. Now, I think you stated earlier, and I
25 think it also states in this report on the bottom of

1 the third page of Exhibit 4 under "Evaluation
2 Criteria"?

3 A. Yes.

4 Q. Do you see the last sentence of that
5 paragraph?

6 A. Yes. I see it.

7 Q. Can you read that into the record, please.

8 A. "An analytical plan developed prior to the
9 opening of the blind also described additional
10 outcome measures including patients in quote
11 'remissions', (a score of 8 or less on the HAM-D
12 total), and the mean changes in the depressed mood
13 items from the HAM-D and the K-SADS-L instruments.

14 Q. And is that a correct statement?

15 A. Yes.

16 Q. Okay. So there were changes in the
17 outcome measures as the study progressed?

18 A. I don't know that that's correct.

19 Q. Well, additional outcome measures were
20 added from the original protocol, correct?

21 A. From what you presented me here as the
22 original protocol it didn't outline very much on
23 secondary analyses and this outlines some secondary
24 analyses.

25 Q. Okay. Maybe we're confusing terms. By

1 original protocol I mean the original GSK protocol.

2 A. The original GSK protocol. Give me the
3 page number on that one again. You gave it to me
4 before. Sorry.

5 Q. 17.

6 A. Okay. From this document to this document
7 they've added some secondary analyses.

8 Q. Okay. And that's not they? That's you,
9 right? You as part of the group?

10 A. Presumably. I think that clearly the
11 question on this is in a first study in an area is
12 how broadly to look and what are the interesting
13 domains to look, and so you have a moral and ethical
14 obligation to specify what you're going to look at
15 before you look at it, but I certainly can't tell
16 you from here when the group listed all the
17 different secondary analysis to look at.

18 Q. But you know that some were added after
19 this protocol was finalized?

20 A. Correct. It appears so, yes.

21 Q. And you know that from your paper? From
22 your article?

23 A. The article has some that are not in the
24 protocol that you gave me today.

25 Q. Right.

1 A. Right.

2 Q. And I think we've established that all of
3 the outcome measures, all eight in the primary, in
4 the original protocol failed to reach statistical
5 significance in favor of Paxil, correct?

6 A. Yes.

7 Q. Now, my question is: Did you participate
8 in adding more secondary variables as the study
9 progressed from the original protocol? Your role?

10 A. Right. Presumably so. I don't remember
11 it specifically. It's clear that they were
12 specified before the blind was broken and the
13 analysis was done and I don't remember specifically
14 when they were added. They were certainly extremely
15 reasonable secondary measures that you should have
16 looked at. These were things that would have been
17 wrong not to look at.

18 Q. Okay. And who participated in the
19 decision-making process to add the additional
20 secondary variables -- efficacy variables?

21 A. Yes. Right. I don't know the answer to
22 your question. They were the right things to look
23 at. It was a group process on the things. I just
24 don't remember the conversations for adding these,
25 but it would have -- I mean, it would have been

1 unethically to look broadly at what improved and what
2 didn't. So these were the right things to add.

3 Q. Okay. And a --

4 A. And they were added before it was
5 analysed.

6 Q. Are you sure of that?

7 A. Well, this document was before the
8 analysis. This was a document to plan the analysis,
9 right?

10 Q. I'm sorry. Have you seen the statistical
11 appendix of what was analysed with regard to the
12 secondary variables?

13 MR. DAVIS: Object to the form. No
14 foundation for the question.

15 THE WITNESS: I saw at the meeting
16 presenting the data we were presented with the
17 analysis.

18 BY MR. MURGATROYD:

19 Q. Okay. Let me show you what I'll mark as
20 the next Exhibit.

21 MR. MURGATROYD: Let's go of the record
22 for a second.

23 VIDEOGRAPHER: At this time we're going
24 off the record. The time is 10:28 a.m.

25 (Pause in Proceedings.)

1 VIDEOGRAPHER: We are now going back on
2 the record. The time is approximately 10:31 a.m.

3 (Ryan Deposition Exhibit No. 5
4 was marked for identification.)

5 BY MR. MURGATROYD:

6 Q. Doctor, I want to show you what we've
7 marked as Exhibit 5 -- what I've marked as Exhibit
8 5. It's a document from Rosemary Oakes. Do you
9 know who Rosemary Oakes is?

10 A. No, I do not.

11 Q. Okay. You are not aware that she did the
12 statistical analysis for study 329?

13 A. I don't remember who did it so I don't
14 remember whether it was her or not. I don't
15 remember if I've ever met her.

16 Q. But you recall though or you can tell from
17 your article that she was one of your coauthors,
18 right?

19 MS. CONNELLY: Which exhibit is that?

20 MR. MURGATROYD: Number 5.

21 THE WITNESS: My apologies. I don't
22 remember her name, but I can find out if she was a
23 coauthor on there. She was the next to the last
24 author.

25

1 BY MR. MURGATROYD:

2 Q. Okay. And let me show you what is known
3 as the statistical appendix for 329, and it's a copy
4 that was used with Dr. Keller in his deposition and
5 the part that I'm going to refer you to is the page
6 5. You're perfectly free to look at any part of the
7 document that you want, but I'm going to question
8 you on page 5 regarding the secondary efficacy
9 parameters that were analyzed with regard to study
10 329. Okay?

11 MR. DAVIS: And I want you to be very
12 careful about what you represent to this witness
13 about what that document is or is not given the
14 record in this case and about the timing of what
15 that -- when that document was done, the purpose for
16 which it was done. I'm just putting you on notice.

17

18 MR. MURGATROYD: My gosh, I have no idea
19 what you're talking about -- if you want to object
20 --

21 MR. DAVIS: That's -- as I said --

22 MR. MURGATROYD: If you want to object
23 that's fine.

24 MR. DAVIS: This was covered in Mr.
25 McCafferty's deposition about the purpose for that

1 analysis. I'm just putting you on notice. Be very
2 careful of what you represent it to be.

3 MR. MURGATROYD: I'm not representing --
4 if you have an objection --

5 MR. DAVIS: I'm just putting you on
6 notice.

7 MR. MURGATROYD: You don't need to put me
8 on notice. You have the right to object at a
9 deposition. You don't put people on notice.

10 BY MR. MURGATROYD:

11 Q. Okay. So if you would, please take a look
12 at that first major paragraph of that document.

13 MS. CONNELLY: Can we identify this
14 document for the record?

15 MR. MURGATROYD: Yes. It's the results of
16 GSK's analysis of study 329.

17 MR. DAVIS: Object to the form. That
18 mischaracterizes the document.

19 MR. MURGATROYD: You can't object to the
20 form. It's called "Statistical Appendix." Do you
21 see that?

22 BY MR. MURGATROYD:

23 Q. It's called statistical appendix, do you
24 see that on the top page, Doctor?

25 A. I see that is -- appears to an internal

1 e-mail from one GSK person to multiple other ones.

2 It's entitled "Statistical Appendix." That's all I
3 know about it of what you're representing it to be.

4 Q. Okay. That's fine. And if you would just
5 take a look through the document and you'll see
6 that -- well, let me ask you this: Did GSK not
7 share the results of their analyses?

8 A. GSK shared the results of analyses.

9 Q. All the results?

10 A. How would I answer such a question?

11 Q. Well, this document answers the question.
12 If you would take a look through it and see if
13 you're familiar with all the results that are in
14 that document.

15 A. Okay.

16 Q. Okay. And I'm talking about secondary
17 parameters. We've already discussed the primary
18 parameters.

19 MS. CONNELLY: Just for the record, if the
20 witness is going to be required to review this new
21 document -- just for the record, it is approximately
22 38 pages of apparent statistical analysis so there
23 may be some delay.

24 MR. MURGATROYD: That's fine.

25 THE WITNESS: Okay. I briefly scanned the

1 document. I haven't reviewed it in its entirety.
2 In answer to your question it appears that they did
3 a thoughtful analyses of a lot of the data. We were
4 -- I remember being presented a significant subset
5 of this. I do not think it likely we were presented
6 every number in here. I don't know that that would
7 have been appropriate.

8 Q. That's fine. Well, in regard to the
9 document in front of you, you see the page that
10 you're turned to that lists the secondary
11 parameters?

12 A. Again, remind me on the page. I'm sorry.
13 I lost that one as you did it. Here it is. Page 5.
14 Got it.

15 Q. Do you see the little handwritten numbers
16 on it? That was Dr. Keller's handwriting.

17 MS. CONNELLY: Can I interject that --
18 just -- it assume facts that I don't know to be in
19 evidence. Is that the testimony of Dr. Keller?

20 MR. MURGATROYD: Beyond dispute.

21 MS. CONNELLY: Okay.

22 MR. MURGSTROYD: Those are the 20's that
23 Dr. Keller put on that document.

24 MR. MURGATROYD: Dr. Keller's handwriting
25 on that document? Unless you know?

1 THE WITNESS: No. I don't know Dr.
2 Keller's handwriting well enough to say anything
3 cogent on that one.

4 MR. DAVIS: It's not disputed.

5 BY MR. MURGATROYD:

6 Q. Now, if you would, Doctor, as Dr. Keller
7 did in his deposition, can you count the numbers of
8 secondary efficacy variables that were analyzed by
9 GSK?

10 A. Okay. The count on here was 20. I think
11 that's an accurate count.

12 Q. Okay. Good. Now, can you go to the page
13 that gives the results of the analysis of each of
14 those secondary variables?

15 A. Do you want to help me out on that or?

16 Q. I think it's probably the next page or
17 look for the first chart that has the statistic
18 analyses.

19 A. Okay. I see a page for HAM-D for K-SADS-L
20 depression scale. Do you think actually it would be
21 on separate pages?

22 Q. Yes. But I think you'd get a summary on
23 that first page that said "by investigators" right
24 there. Do you recognize those as being the scales
25 that are listed?

1 A. Those are the scales, but the statistic
2 isn't referring to what you think it is.

3 Q. Okay. What's it referring to?

4 A. It's treatment by site. P values.
5 Whether the sites had a specific interaction term on
6 it is what it appears to be.

7 Q. Okay. Now, let's go to 20 that are
8 marked -- that you look at earlier.

9 A. The P values on this are whether there was
10 a mean difference between sites, not whether the
11 Paxil was better than placebo.

12 Q. Okay. Let's go to down to 20 that are
13 listed --

14 A. Why don't you show me which page you'd
15 like me go to, please?

16 Q. Where you looked at the 20 --

17 A. The 20 before?

18 Q. Yes.

19 MS. CONNELLY: It might have been page 5?

20 THE WITNESS: Page 5. Yes.

21 BY MR. MURGATROYD:

22 Q. And of those 20 secondary efficacy
23 parameters that were listed there, how many of those
24 reached statistical significance in favor of Paxil?

25 A. I don't know. The HAMD depressed mood

1 certainly did. Let's see. I don't know if the
2 other ones did. I would have to go through it.

3 Q. Okay. Why don't you take your time and go
4 through it.

5 A. K-SADS-L subdepression subscale. Let's
6 see. This does not appear to have the correct
7 analysis on some of these because -- no -- I'm
8 sorry -- I'm saying that wrong. No, I would still
9 say that. Some are listed here. I do not find the
10 P values for all of them listed here. You can show
11 me where they are. I'm just not seeing them.

12 Q. No. That's fine. I'm just asking you if
13 they're there?

14 A. I'm sorry. I thought you asked me how
15 many of the 20 had a significant P value, and you
16 gave me a document without most of the P values?

17 Q. Well, I just want -- to that degree you
18 can interpret that document, Doctor, that would be
19 helpful to the jury and me.

20 MS. CONNELLY: Is that a question?

21 MR. DAVIS: What's the question?

22 THE WITNESS: What's the question?

23 BY MR. MURGSTROYD:

24 Q. The question is how many of those --

25 A. I'm sorry. You gave me a document without

1 the data you asked me to report to you?

2 Q. Doctor, you may know it off the top of
3 your head. I don't know whether or not -- what you
4 know or not know. I mean, you can look at those and
5 determine that you know some clearly did not reach
6 statistical significance and --

7 A. I know some didn't, but you asked me a
8 question that I told you I could not answer and
9 isn't in this document.

10 Q. That's fine. Okay. Now, go down the ones
11 and tell me the ones that you can't give me an
12 answer for. Go down the list and find --

13 A. Fine. The ones that I can give you an
14 answer for are the ones in this paper.

15 Q. So you cannot give me an answer --

16 A. For the other ones? No.

17 Q. Okay. That's fine. If you go down them,
18 correct, are there function scales discussed in
19 there?

20 A. The things that we don't report in the
21 paper I don't have in my memory and they're not in
22 this document.

23 Q. Okay. Well, let's look at that list right
24 there of 20. Are there function scales listed in
25 there?

1 A. Right. But what we reported negative is
2 the total function scales in here. I'm not seeing
3 the separate function subscales in here.

4 Q. Okay. So you're saying they're not
5 listed?

6 A. They're listed here. I'm not finding them
7 in the pages you gave me subsequently.

8 Q. Okay.

9 A. So I don't have the data you're asking me.

10 Q. Well, let me ask you this. I think you've
11 established or you stated that the function
12 subscales all failed to reach --

13 A. The overall ones, but that's different
14 than the subscales. I don't know on the subscales.
15 It was the overall scales we put in here that
16 weren't significant.

17 Q. Okay. And have you -- were you -- did you
18 never look at that data before?

19 MR. DAVIS: Object to the form.

20 THE WITNESS: I have no memory of seeing
21 this document before.

22 BY MR. MURGATROYD:

23 Q. Were you ever presented with the results?

24 A. Yes.

25 Q. The subscale results?

1 A. I was presented with the total subscales,
2 because they're in the paper. I don't if I saw the
3 different break out of the subscales.

4 Q. Okay. Do you think you would have seen
5 them if they had reached statistical significance?

6 MS. CONNELLY: Object to form.

7 THE WITNESS: Tell me if I'm supposed to
8 answer if they object to the form. I'm just trying
9 to find out what I'm supposed to do. I'm sorry.

10 MS. CONNELLY: I'm just objecting because
11 it's speculation.

12 THE WITNESS: It seems likely.

13 BY MR. MURGATROYD:

14 Q. Okay. Do you recall? You don't recall?

15 A. I've answered that a whole bunch of
16 different ways. I'm not recalling seeing them. I
17 don't know if I didn't see them.

18 Q. Okay. That's fine. With regard to --
19 well, how many secondary variables did you and your
20 paper find were statistically significant in favor
21 of Paxil?

22 A. Let me refer to the chart. We found four
23 that were significant, but to answer the imputed
24 question there, these are related to the core
25 functions. A lot of these other ones were things

1 that are of interest, but not related to the core of
2 depression so they're not all created equal.

3 Q. Well, I'll move to strike your question,
4 because my question was simply how many --

5 A. Okay.

6 Q. How many of the secondary variables did
7 you find and stated in your paper reached
8 statistically significance in --

9 A. Four.

10 Q. And again, it would be helpful if you
11 would let me finish ask my question before you
12 answer. That way the court reporter and the
13 record is clear.

14 A. Didn't I let you finish asking your
15 question before I answered?

16 Q. No.

17 MS. CONNELLY: Just for the record. To
18 the extent the witness feels he needs to clarify or
19 explain an answer he is free to do so, and you all
20 can fight before the Judge as to whether or not it
21 gets stricken later.

22 MR. MURGATROYD: Okay. That's fine.

23 BY MR. MURGATROYD:

24 Q. Now, in a study in which both primary
25 efficacy variables failed to reach statistical

1 significance in favor of the drug being tested, and
2 16 of the 20 secondary variables failed to reach
3 statistical significance in favor of the drug being
4 tested, would you say that was a successful study
5 for the drug being tested?

6 MR. DAVIS: Object to the form; it's
7 vague, ambiguous and incomplete.

8 THE WITNESS: I think that if you're
9 talking about this particular study, I think
10 strongly that the secondary measures which came out
11 were at the core of the issue and so I think that
12 definitely gave a significant signal, a positive
13 signal for efficacy. I think also that the fact
14 that the two primary outcome measures didn't come
15 out is absolutely the case and was presented
16 clearly.

17 BY MR. MURGATROYD:

18 Q. And you were at some point in the study
19 presented with what were call the top-line results?
20 Do you recall that?

21 A. No, I do not.

22 Q. Do you recall the conference in which the
23 GFK staff got together with the investigators to go
24 over the results of the study?

25 A. Yes.

1 Q. Okay. Do you recall when that occurred?

2 A. It was in the fall, and I don't know, '97.
3 '98, somewhere though there.

4 Q. Okay. Where did that take place?

5 A. Philadelphia.

6 Q. Okay. And do you recall getting a letter
7 discussing the results?

8 A. I don't recall it specifically. Perhaps
9 you could show me the letter.

10 Q. Okay. I'm going to show you a series of
11 three documents which we'll mark as 6, 7, and 8.

12 (Ryan Deposition Exhibit No. 6, 7, 8
13 were marked for identification.)

14 A. Okay.

15 MR. DAVIS: Can I see those for just a
16 minute?

17 MS. CONNELLY: One second. For the
18 record, 6 and 7 are e-mails produced by Dr. Ryan.
19 Number 8 is a document which was produced by some --
20 by a party presumably, not produced with Dr. Ryan's
21 documents.

22 BY MR. MURGATROYD:

23 Q. Okay. Let's take the first exhibit,
24 Exhibit 6, correct?

25 A. Yes.

1 Q. Can you identify for the record what that
2 is?

3 A. That appears to be e-mail from me to Dr.
4 Birmaher, who is my co-investigator on the
5 Pittsburgh site CC'd to my administrative assistant
6 at the time talking about the meeting that SKB was
7 setting up and suggesting that Dr. Birmaher should
8 also be at that meeting.

9 Q. And is this document authentic?

10 A. It appears to be so.

11 Q. Okay. And did you prepare this document?

12 A. It looks like it came from me and it looks
13 like something I would have said.

14 Q. Now, let's go to the next document.

15 A. Huh-uh.

16 Q. Is that document that you describe to --

17 A. That's an e-mail from my administrative at
18 the time to me saying that the meeting is at the
19 Marriott in downtown Philadelphia and that Mr.
20 McCafferty would be mailing out details of the
21 meeting and I sent e-mail back asking her to find
22 out where the hotel was and let Dr. Brent also know
23 who's a consultant to the study and his
24 administrator at the time. She said she would do
25 her best.

1 Q. Okay. And the next document. Do you
2 recognize that document?

3 A. The next document is a document that
4 appears to have a SKB letterhead on it dated 3
5 November 1997. It says, "As a prelude to the
6 meeting we would like to provide you a synopsis of
7 the top line results of the 275 patients." It's
8 typed signed by Jim McCafferty, Katherine Beebe,
9 Ivan Gergel and Colin Broom.

10 Q. Okay. And did you receive this document?

11 A. I don't know.

12 Q. Is that saying you don't recall?

13 A. I don't recall. I'm sorry. Yes. I don't
14 recall.

15 Q. And does this document give an analysis of
16 the results of your study 329?

17 A. It purports to give -- it gives some data
18 from the study. It's certainly not a complete
19 analysis.

20 Q. Okay. And you'll see that one of the --
21 well, the first sentence of the second paragraph,
22 can you read that into the record, please.

23 A. "Briefly, there is support that paroxetine
24 produces benefits in treating adolescents with major
25 depression."

1 Q. Okay. And then the next sentence it talks
2 about "The number of patients who stopped therapy
3 for insufficient effect." Right?

4 A. That's correct.

5 Q. And it shows that it provides clinical and
6 statistical evidence of a P value of 0.05, correct?

7 A. Huh-huh.

8 Q. And that shows superiority of Paxil over
9 placebo?

10 A. That's what this document says.

11 Q. Okay. And that actually is not true,
12 though right? That primary did not reach
13 statistical significance, did it?

14 A. I don't know the answer to your question.

15 Q. Well, is it in your paper?

16 A. It's not in our paper.

17 Q. Okay. If you would, please go to the
18 Exhibit that is the "Final statistical Report."

19 A. What Exhibit is that?

20 MS. CONNELLY: It's Exhibit 4. Here it
21 is.

22 THE WITNESS: Okay.

23 BY MR. MURGATROYD:

24 Q. And if you would, please turn to page 59
25 at the upper right-hand corner.

1 A. Okay.

2 Q. Do you see that table there?

3 A. It says number of number of randomized
4 patients who completed or withdrawn, and paroxetine
5 28 percent, placebo 24 percent, imipramine 40
6 percent. Yes. I see that table.

7 Q. Okay. And how many patients withdrew for
8 lack of effect?

9 A. Well, if this is table is correct it says
10 four withdrew for lack of effect on paroxetine, one
11 on imipramine and six on placebo.

12 Q. Okay. And do you think that it's
13 likely to have been a statistically significant
14 advantage for paroxetine when you have the numbers
15 of four for placebo -- or six for placebo and four
16 for paroxetine?

17 A. I can't do the statistics in my head. I
18 think it's unlikely however.

19 Q. Highly unlikely, correct?

20 A. I think it's unlikely. I don't know how
21 to distinguish the two. I mean, I'm no calculator
22 or statistician. I think it's unlikely that's
23 significant.

24 Q. Okay.

25 A. But you could probably run the numbers and

1 tell me.

2 Q. Okay. I just wanted your opinion. Okay.
3 Now, when you -- let me ask you this: When you
4 prepared the manuscript that ultimately resulted in
5 a published article?

6 A. Huh-huh.

7 Q. Did you ask to review the statistical
8 analyses, the complete analysis that GSK had done
9 for the entire study?

10 A. No. Not to my memory.

11 Q. With regard to the manuscript that
12 ultimately ended up in your article that was
13 published, do you know who prepared the first draft
14 of that manuscript?

15 A. Dr. Keller.

16 Q. Did he tell you that?

17 A. He was the first author. It came from
18 his -- his -- the -- no.

19 Q. Is that just an assumption that you made?

20 A. Yes.

21 Q. Have you ever heard of a woman called
22 Sally Laden? L-A-D-E-N?

23 A. Yes.

24 Q. And did you have dealings with that
25 particular person?

1 A. Yes.

2 Q. And who did she work for?

3 A. She has her own company. I don't know who
4 she was working as an agent for in this particular
5 one.

6 Q. Do you know what her job was?

7 A. She does lots of things. She certainly
8 helps pulls stuff together for papers. She also
9 organizes synopsis for industry. I don't know what
10 else she does for a company.

11 Q. Is she what is known in the pharmaceutical
12 industry as a ghost-writer?

13 MR. DAVIS: Object to the form.

14 BY MR. MURGATROYD:

15 Q. Do you know what a ghost-writer is?

16 A. I think I know what a ghost-writer is. I
17 don't think she was a ghost-writer for this one.

18 Q. Okay. Well, let me have you define what
19 your consider what a ghost-writer is.

20 A. Right. Somebody you dictates your memoirs
21 to and they write up the book. I don't think that
22 she did all the writing and Marty just put his name
23 on here.

24 Q. Okay. Do you know who prepared the first
25 draft? I guess that's the question?

1 A. To the best of my knowledge it was Dr.
2 Keller.

3 Q. Okay. And again, that's an assumption,
4 not something you know from personal experience?
5 Did he tell you that? Did he ever tell you that he
6 prepared the first manuscript?

7 MR. DAVIS: Objection; asked and answered.

8 THE WITNESS: I don't remember him ever
9 telling me that, but that would be -- but I've never
10 had a conversation with another author who said, I
11 prepared this manuscript.

12 BY MR. MURGATROYD:

13 Q. Okay. I mean, did Sally Laden ever tell
14 you that she personally prepared the original
15 manuscript?

16 A. No.

17 Q. Okay. Do you recall that at the end of
18 your meeting in Philadelphia where you went over the
19 results of study 329 there was a consensus statement
20 drafted?

21 A. I don't recall that. It seems possible.
22 I don't recall it specifically, no.

23 Q. Okay. Let me show you the document.

24 (Ryan Deposition Exhibit No. 9
25 was marked for identification.)

1 MS. CONNELLY: For the record Exhibit 9 is
2 a draft consensus statement. It appears to be
3 produced by a party to this case.

4 MR. DAVIS: May I see it before you
5 question Dr. Ryan about it?

6 MR. MURGATROYD: That's okay. No.

7 MR. DAVIS: Thank you very much.

8 BY MR. MURGATROYD:

9 Q. Okay. Have you had a chance to read that
10 document, sir?

11 A. Yes.

12 Q. Okay. And can you read into the record
13 the part that starts with "There was agreement."

14 A. It's the third paragraph down. "There was
15 agreement that the overall results of the study were
16 positive for Paxil in the treatment of this
17 potentially devastating illness, whereas imipramine
18 was no more effective than placebo. Patients
19 treated with Paxil showed greater clinical
20 improvement on several measures compared to placebo.
21 The most common side effect reported in patients
22 treated with Paxil were headache, dry mouth, nausea
23 and dizziness. However, it was the opinion of the
24 study group that Paxil was generally safe and well
25 tolerated." Next paragraph?

1 Q. Okay. That's fine. Let's stop there.
2 Does that paragraph accurately represent your views
3 at the time that draft was issued?

4 A. I don't know that this draft was issued.
5 It does accurately reflect my views at the time.

6 Q. Okay. And on what did you base your views
7 at that time?

8 A. On the data that came out at the meeting
9 that on a meaningful number of the core secondary
10 analysis there was a robust effect of Paxil, and the
11 directionally was correct on the primary ones it
12 just didn't reach significance.

13 Q. And did you, at that time, see the summary
14 tables of the analysis of all parameters?

15 A. It seems like we've gone over this
16 question before. We saw a lot of summary tables. I
17 have no idea whether we saw all the variables or not
18 that were analyzed. It would be unusual to do that.
19 I don't know that I reviewed all the variables in
20 any study I've been involved with on any paper,
21 because the statisticians do a lot of analysis.

22 Q. Well, let's take a look at the next
23 Exhibit. It's actually two pages.

24 (Ryan Deposition Exhibit No. 10
25 was marked for identification.)

1 MS. CONNELLY: Do you want to see this?

2 MR. DAVIS: No. I have it. Thank you.

3 BY MR. MURGATROYD:

4 Q. Okay. All right. Can you identify for
5 the record what that document is, sir?

6 A. It says "Paroxetine Study 329. A
7 Multi-center Double-blind Placebo Controlled Study
8 of Paroxetine and Imipramine in Adolescents with
9 Unipolar Major Depression --

10 MR. MURGATROYD: Slow down a little bit.

11 THE WITNESS: I'm bad. I'm sorry.

12 BY MR. MURGATROYD:

13 Q. You're going to burn those fingers off
14 over there on the court reporter. Why don't we take
15 it from the top and go a little bit slower?

16 A. Sure. My apologies.

17 It says "Paroxetine Study 329, A
18 Multi-center Double-blind Placebo Controlled Study
19 of Paroxetine and Imipramine in Adolescents with
20 Unipolar Major Depression. In the subheading is
21 "Top line Results". It says. "To Kathy from Sylvia
22 two pages." The second part of it is a page of
23 printing that looks like my writing, only some of
24 which I can read.

25 Q. Okay. And at the bottom of the page does

1 that have a Ryan bates number?

2 A. It says Ryan 002264 and 2265.

3 Q. Do you understand what that means?

4 A. No.

5 Q. What it means, and your counsel can
6 clarify that, is that you gave me those documents.

7 A. Good.

8 Q. Okay. So those documents came from your
9 file. Okay. Do you recognize them as coming from
10 your file?

11 A. The first page, I wouldn't be sure that
12 was my scribbling. The top is not my writing. The
13 bottom of the first page could be mine or other
14 peoples. The second page, as I said earlier, looks
15 like my writing.

16 Q. Okay.

17 A. So I'm believing you on this one.

18 Q. Okay. Great. Does that document appear
19 to be authentic?

20 A. I guess so.

21 Q. And did you produce it to me as it was
22 produced to you?

23 MS. CONNELLY: I have to object. He
24 produced documents to me and I produced them to you.

25 MR. MURGATROYD: Right. Through you?

1 THE WITNESS: Right. And I had staff
2 producing them so I didn't look individually at all
3 the documents that were produced.

4 BY MR. MURGATROYD:

5 Q. Okay. But you understand those are
6 authentic documents, right?

7 A. The -- I have no reason to doubt that.

8 Q. Okay. Thank you. And looking at -- well,
9 actually let's take the -- there's a date,
10 handwritten date on the top of the first document,
11 correct?

12 A. Right. I did not write the date. It says
13 1-21-98. It's to Kathy from Sylvia, and that looks
14 like Sylvia Janosky's handwriting.

15 Q. Okay. And who is that Sylvia Janowski?

16 A. She was my administrator at the time.

17 Q. Okay. And -- and do you know what the top
18 line results mean?

19 A. No.

20 Q. Okay. Does that appear to be an analyses
21 of the data from your study 329?

22 A. It appears to be that, yes.

23 Q. Okay. And in that analyses, how many of
24 the four efficacy variables that were found to be
25 statistically significant in favor of Paxil in your

1 paper are listed in that document?

2 A. Okay. I don't know. I'm not sure that
3 it's listing -- it looks like it has the depression
4 item endpoint that was also in the paper. I'm not
5 seeing the other ones. I'm also not sure -- I have
6 no data that would indicate this is complete. I
7 have no data that indicates this is the only table
8 related to it, but I see one there, there may be
9 more, but I only see one.

10 Q. Is there any reference there to the
11 K-SAD-L depression item?

12 A. I'm not seeing it.

13 Q. Is there any reference in the document to
14 the CGI of 1 or 2?

15 A. Global. I'm not seeing it.

16 Q. Is there?

17 A. I mean, if you want to point it out, I'm
18 not deliberately trying to miss something. If you
19 see something I'm not. I just got this.

20 Q. No. You didn't just get that. I got it
21 from you.

22 A. Right. You're absolutely right. I stand
23 corrected.

24 MS. CONNELLY: The witness has testified
25 that his administrator gathered all the documents in

1 response to the subpoena and forwarded them to
2 counsel. Dr. Ryan did not go through these
3 documents, some of which are a decade old
4 page-by-page, prior to this deposition.

5 THE WITNESS: I haven't seen this in a
6 decade.

7 BY MR. MURGATROYD:

8 Q. That's fine. I'm just saying from looking
9 at that document is there any reference in the
10 result section that talks about a CGI of 1 or 2?

11 MS. CONNELLY: Asked and answered.

12 BY MR. MURGATROYD:

13 Q. Okay. The answer's, it's not there,
14 right?

15 MR. DAVIS: Object to form.

16 MS. CONNELLY: It's asked and answered
17 several time.

18 MR. MURGATROYD: Well, he actually
19 questioned me. He asked me whether or not I saw it
20 there and I said --

21 MS. CONNELLY: He said, I don't see it.

22 THE WITNESS: I don't see it here.

23 BY MR. MURGATROYD:

24 Q. Okay. Good. Okay. Fine.

25 A. But I also said I have no way of knowing

1 this is the complete thing.

2 Q. All right. Now, going to the bottom of
3 the document, can you decipher the handwriting at
4 the bottom of the document?

5 A. The handwriting is mine without a doubt.
6 It says: "CGI very much" and it's got -- but it's
7 my handwriting. "It's got worse, much worse." It
8 looks like "very much improved, much improved." I
9 assume that's "no change, minimally improved, no
10 change, worse, and much worse", and it looks like I
11 got percentages. I assume, but do not know for a
12 fact, that I was copying this as this was being
13 presented at the investigators meeting. That would
14 be the most likely thing.

15 Q. Okay. Would it be reasonable to conclude
16 that you were eyeballing the CGI pattern to see if
17 it could be used in support a case for paroxetine?

18 MR. DAVIS: Object to the form.

19 THE WITNESS: Yeah. I think that would
20 not be reasonable to assume.

21 BY MR. MURGATROYD:

22 Q. Okay. And why is that?

23 A. Because I was trying to find out what the
24 data showed with respect to everything so I would
25 not have been copying it for that end. I would have

1 been copying it because I wanted to know the data.

2 Q. And can you go to the second page of that
3 document?

4 A. Yes.

5 Q. And can you decipher as much as you can
6 and please read it into the record.

7 A. Yes. Sure. It says, "Hamilton D
8 subscale." I cannot make out the next line. "For
9 anxiety", it says. I believe that's anxiety on the
10 third line and it says ".18" and then it says
11 "there's a side, regular side for" -- and I can't
12 make out the rest. It says ".10." The next one
13 says "autonomous final checklist 0.148. Sickness
14 impact", and it says home or heme, but it wouldn't
15 say heme, home management or something 0.16 or 0.10
16 and then -- oh, boy, I can't read the next. It's
17 something ".16." and then it has "SAE" and it's
18 got -- there's a table and the heading of the
19 columns are "P I and PI", and it says, "SAE", for
20 sudden adverse events presumably -- I'm sorry. It's
21 "PIS." So the left most column would be P for
22 Paxil. The middle column would be I for Imipramine.
23 The right most column would be PL for placebo. And
24 for as SAE it has --

25 Q. What does SAE stand for?

1 A. Severe adverse event.

2 Q. Okay.

3 A. Presumably. I mean, that's the most
4 likely abbreviation. Obviously abbreviations are
5 multi-used, but that's what I assume it is. I don't
6 know that for a fact. And the numbers under Paxil
7 are 10, Imipramine 5 and Placebo 2. And there's a
8 note with an arrow that says "worsening depression,
9 worsening depression suicide" pointing to the 2
10 under placebo. And then it's got something that is
11 illegible with "in order 12 for Paxil, 30 for
12 imipramine and 6 for placebo, and something
13 that's -- two lines that are completely and totally
14 illegible in the labeling for 9, 8 and 0, and 12, 7
15 and 7 is the best I can make out. And then it says
16 "SAE, colon," oh, boy, "CD", I assume that's conduct
17 disorder. I cannot make out the next word at all.
18 "A rash" and then "increasing depression" and the
19 next word looks like, but I'm not sure on,
20 "agitation" and then one on "chest pain" that's
21 circled and that looks like that's SAE for
22 imipramine.

23 Q. Let's stop there real quick. We have to
24 change the tape.

25 VIDEOGRAPHER: We're now going off the

1 record. The time is 11:12 a.m. End of Tape Number
2 1.

3 (Pause in Proceedings.)

4 VIDEOGRAPHER: This is the beginning of
5 Videotape Number 2 of the deposition of Dr. Neal
6 Ryan. Please proceed.

7 BY MR. MURGATROYD:

8 Q. Okay. I think we were having you decipher
9 your handwriting on the that second page of that
10 exhibit; is that correct?

11 A. That's correct.

12 Q. Let's complete it.

13 A. Fine. The final block on the bottom right
14 of the second page says "SAE" and I cannot make out
15 the next word. It looks like taxes, which makes no
16 sense. And it says -- and the things are up arrow
17 with "TPR, increased depression", an up arrow with
18 "ODD", increased oppositional defiance disorder,
19 "two times" -- it may be fatigue. I'm just not sure
20 what that next word is. And then one says
21 "migraine" and then it looks like "hallucinations"
22 but maybe not. Something that's completely
23 illegible and the last one says "worsening of the
24 DEPR" for worsening depression.

25 Q. Now, those are -- that document has bates

1 stamps on them, right?

2 A. That's correct.

3 Q. Are they consecutive?

4 A. They are consecutive.

5 Q. Now, and the documents does bear a date
6 that you believe was placed on it by your secretary?

7 A. The first document bears a date that was
8 placed on by my secretary. That's her handwriting,
9 not mine.

10 Q. Okay. And do you believe that you had
11 this document at the time you met in Philadelphia to
12 go over the results of the study in November?

13 MS. CONNELLY: Objection. Which document
14 are you talking about? The first page or the second
15 page or both?

16 MR. MURGATROYD: Well, I think they're one
17 document. I got them as one document.

18 MS. CONNELLY: Maybe you could ask him the
19 question. I don't if it was one document or not.

20 MR. MURGATROYD: Okay. Maybe the question
21 will sort itself out. Let's see. Let's ask the
22 question.

23 THE WITNESS: Repeat your question for me,
24 please.

25

1 BY MR. MURGATROYD:

2 Q. When do you believe you first obtained the
3 first page of that document?

4 A. I don't know. It seems quite likely it
5 was at the investigator's meeting, but it could have
6 been subsequently. I simply don't know. It
7 certainly wouldn't have been before that meeting,
8 because I didn't have any results before that
9 meeting.

10 Q. Okay. And but you don't know why that
11 January date is on top of that document?

12 A. It appears that Sylvia was sending them to
13 Cathy with a C. The last name is abbreviated. It
14 could be Cathy Kalis, who is one of the nurses that
15 worked on the project or it could be another Cathy.
16 I just don't know which Cathy she was sending it to
17 and I have no idea why she sent it, and it does say
18 two pages, "2 pgs" at the top of the first page.

19 Q. Okay. And do you have any independent
20 recollection as you sit here today of when you made
21 those notes?

22 A. No, I do not.

23 Q. Okay. That's fine. Now with regard to
24 the -- let me show you what I'm marking as Exhibit
25 11.

1 (Ryan Deposition Exhibit No. 11
2 was marked for identification.)

3 MR. MURGATROYD: Do you know need a paper
4 clip?

5 THE WITNESS: Yes.

6 MR. MURGATROYD: I'll do that during
7 lunch. I'll make sure it doesn't get.

8 MS. CONNELLY: Thanks.

9 MR. MURGATROYD: Sure.

10 MR. DAVIS: Is that the memo sending the
11 skeleton report?

12 MR. MURGATROYD: I don't recall. I just
13 glanced at it before I handed it to him. I'm just
14 trying to find out for my own purposes.

15 MS. CONNELLY: I'll just look at the first
16 page. For the record, the first page of Plaintiffs
17 Exhibit 11 appears to be a letter to Dr. Ryan from
18 someone at SmithKline, James McCafferty and Sarah
19 Wheeler from SmithKline Beecham, March of 1997.

20 THE WITNESS: Does this contain two
21 different documents?

22 BY MR. MURGATROYD:

23 Q. No. This is one continuous document.

24 A. All right. I understand the issue of what
25 it is now.

1 MR. DAVIS: While Dr. Ryan is looking at
2 that I'll just put on the record that that is
3 incomplete. That they've said it doesn't include
4 the complete package that was sent to Dr. Ryan as
5 reflected in the letter.

6 THE WITNESS: Okay. I've looked at this
7 one.

8 BY MR. MURGATROYD:

9 Q. Okay. And do you recall receiving this
10 letter?

11 A. No.

12 Q. Do you recall being asked at any time
13 for -- well, let me have you turn to the last page
14 of the document that's attached, and that you have
15 there.

16 A. Okay.

17 Q. And do you see where it has in bold in the
18 middle of the page, "We need", starting there? Do
19 you see that?

20 A. Yes, I do.

21 Q. Can you read that into the record.

22 A. It's all caps, bold. "We need to decide
23 whether we want to include any other efficacy
24 parameters. Any comments from the investigators
25 whether this would useful or not."

1 Q. Okay. And what is the date of this
2 document?

3 A. The date of the cover letter is 17 March
4 1997.

5 Q. Okay. And do you recall providing anyone
6 with any additional efficacy parameters from that
7 day forward?

8 A. I do not recall either way. I don't
9 recall whether I did or whether I didn't.

10 (Ryan Deposition Exhibit No. 12
11 was marked for identification.)

12 Q. Okay. Let's take a look at the next
13 document.

14 MS. CONNELLY: And this Plaintiff's
15 Exhibit 12 is an e-mail from someone named Linda
16 Dyer to someone at SmithKline -- I guess GSK now
17 employees, produced by a party in this case.

18 MR. DAVIS: Can I see that.

19 MS. CONNELLY: Okay. Just so I know, who
20 is the PAR bates stamp?

21 MR. MURGATROYD: That's GlaxcoSmithKline.

22 MS. CONNELLY: Okay. I guess we probably
23 won't see any documents from Plaintiffs in this case
24 anyway?

25 MR. MURGATROYD: No, you won't.

1 MS. CONNELLY: We won't see medical
2 records?

3 MR. MURGATROYD: Nope.

4 BY MR. MURGATROYD:

5 Q. Okay. Now, that's a chart, correct?

6 A. Yes.

7 Q. Okay. And in the chart does it have a box
8 for adding additional efficacy variables?

9 A. Yes. In the box number 6 "Additional
10 Efficacy Parameters."

11 Q. Okay. What's the date of that document?

12 A. The date -- it looks like it's e-mail from
13 SKB to SKB people dated 4-17-97.

14 Q. Okay. So that's exactly one month after
15 the document that you just looked at requesting
16 additional efficacy variables, correct?

17 A. I don't know. Let me go back. Can you
18 refresh my memory on which document that is?

19 Q. Yes. It's the document you're looking at
20 right there.

21 A. 17 March, 17 April. Exactly one month
22 later. Yes.

23 Q. Okay. And are there -- in the box it says
24 "Additional Efficacy Variables", do you see that?

25 A. Yes.

1 Q. And can you read those efficacy variables
2 into the record.

3 A. Yes. It say: "Suggestions so far: 1.
4 Kaplan-Meir", K-A-P-L-A-N, M-E-I-R. Those are both
5 names. So capital K, capital M. "Survival method
6 to analyze time to sustained response or time to
7 time to first response during acute phase. 2.
8 Percentage of patients who no longer meet
9 DSM-III-R", all caps, dash, Roman numeral III-R, all
10 caps, "criteria for MDD, all caps, at end of the
11 acute phase. 3. Use one or more of instruments
12 listed in Q4 to examine improvement in social
13 functioning, feelings of competence, et cetera."

14 Q. Okay. And did you suggest any of those?

15 A. I have no memory of that.

16 Q. Okay.

17 A. I cannot -- I don't know yes or no to the
18 answer of that.

19 Q. Okay. And are any of those in your
20 paper -- in the article that was ultimately
21 published regarding 329 of which you were one of the
22 coauthors?

23 A. Well, the criteria, no. Social
24 functioning feelings of competence. Certainly the
25 measures that didn't come out positive --

1 significant, but were in there, certainly would
2 capture those, but no, I don't think we included
3 these analyses.

4 Q. Okay. Do you recall -- let me ask you
5 this: Mike Strober, Michael Strober. He was one of
6 the coauthors of your paper and one of the
7 participants in this study, correct?

8 A. Correct.

9 Q. And where is he?

10 A. He's at UCLA, University of California,
11 Los Angeles.

12 Q. Okay. Is he still there today?

13 A. Yes.

14 Q. And is he considered a competent person?

15 A. Yes.

16 Q. Okay. And is he a child psychiatrist?

17 A. No.

18 Q. Is he -- how was it that he became
19 involved in this study if he wasn't a child
20 psychiatrist?

21 A. He's a psychologist and his career's been
22 treating children including depression and eating
23 disorders.

24 Q. Okay. So he is not a psychiatrist
25 obviously, correct?

1 A. That's correct.

2 Q. Okay. And do you recall his suggestions
3 on adding additional efficacy -- secondary efficacy
4 variables for this study?

5 A. I do not. I do not recall any specifics
6 of who added what variables.

7 MR. MURGATROYD: Okay. Let's go off the
8 record for a minute.

9 VIDEOGRAPHER: At this time we're going
10 off the record. The time is approximately 11:30
11 a.m.

12 (Ryan Deposition Exhibit No. 13
13 was marked for identification.)

14 (Recess taken.)

15 VIDEOGRAPHER: We are now back on the
16 record. The time is approximately 11:39 a.m.
17 Please proceed.

18 MS. CONNELLY: We've been handed
19 Plaintiffs Exhibit 13, which has no bates number,
20 but appears to be an internal GSK document.

21 MR. DAVIS: May I see it, please.

22 MR. MURGATROYD: Yes. You might want to
23 see that one, because it has no bates number.

24 BY MR. MURGATROYD:

25 Q. Okay. Have you had a chance to review

1 that document?

2 A. Yes.

3 Q. And the question that I asked prior to our
4 break was, whether or not you were of Dr. Strober
5 asking for additional analysis be performed in the
6 study data regarding 329, correct?

7 A. Correct.

8 Q. Okay. Now that document does discuss Dr.
9 Strober's request for additional analysis, correct?

10 MR. DAVIS: Object to the form.

11 THE WITNESS: This document appears to be
12 internal mail from SKB from Mr. McCafferty to
13 Rosemary Oakes from William Bushnell with a CC to
14 Ivan Gergel that says Michael Strober suggested such
15 and such additional analyses below. Yes.

16 BY MR. MURGATROYD:

17 Q. Okay. Can you read into the record what
18 those additional analysis suggested by Dr. Strober
19 were?

20 MS. CONNELLY: Object to form. He can't
21 testify as to the suggestions. He can only testify
22 as to what the document says the suggestions were.

23 BY MR. MURGATROYD:

24 Q. Right.

25 A. The document from Mr. McCafferty says that

1 the following were suggested by Dr. Strober: 1.
2 Analyzing HAM-D using its four factors,
3 [anxiety/somatization, sleep, cognitive disturbance
4 and psychomotor slowing, and 2, if there's evidence
5 of a treatment effect, analyze responsiveness of
6 individual symptoms of depression via relevant
7 pairwise comparisons of treatment. This amounts to
8 repeated measures Anova to assess the effects of
9 treatment, [Paroxetine versus Placebo, Imipramine
10 versus placebo], Paroxetine versus imipramine, time,
11 and their interaction, thereby illustrating
12 different patterns of improvement across treatment.

13 Q. Okay. Now, taking the first series of
14 analyses that he requested, number one that's listed
15 there, was that included in your paper?

16 A. No.

17 Q. None of them?

18 A. Not to my knowledge, no.

19 Q. How about the second analyses requested by
20 Dr. Strober, was that included in your paper?

21 A. In part, yes; in part, no.

22 Q. Okay. And what --

23 A. And so the pairwise comparisons that he
24 asked for were and the time interactions were not.
25 I don't know whether they were included in the paper

1 or not. I don't know whether they stated -- the
2 question there is, does the time course differ and
3 they were sort of -- they were included in a
4 different format in the paper. I'm sorry -- which I
5 can point out to you -- anyway -- I can tell you
6 what it is. They were effectively included in a
7 time wise graph of the clinical course, and so what
8 his question is -- the poetry of the math on his
9 question is, does the course differ, so that would
10 be figure two in the paper and then if it differs,
11 how do you analyze it? And how you analyze the
12 difference in course depends on the sort of
13 difference. And so he's saying that he wants to
14 look at the time wise things and there's a lot of
15 different methods of looking at it depending on how
16 they vary, but there really wasn't course
17 differences between the treatments so you wouldn't
18 have done -- you wouldn't have put more than that in
19 the paper and the figure clearly shows that.

20 Q. Okay. And what is the date of that e-mail
21 in that exhibit?

22 A. The date on the exhibit is 7-03-96.

23 Q. Okay. So that would be July --

24 A. July 3. My apologies.

25 Q. Okay. And do you know when the blind was

1 broken? Well, actually, so the record's clear and
2 the jury is clear, what does breaking the blind
3 mean?

4 A. Yes. In a double blind study, as we
5 discussed earlier, nobody except the fewest possible
6 people have a link between subject I.D. user names
7 and which medication they were on. At some point
8 after all the people had been enrolled, after you
9 got the last data on the last person there, after
10 you cleaned up the data then you match up the
11 treatment assignments with the individual subjects.
12 That's what breaking the blind would mean.

13 Q. Okay. And at that point the data can then
14 be analysed, correct?

15 A. That's correct.

16 Q. And do you know the date that the blind
17 was broken with regard to study 329?

18 A. I do not.

19 Q. But I think you can state with certainty
20 that it had been broken by the time you met in
21 November in Philadelphia to discuss the results?

22 A. Yes, and almost certainly was broken very
23 shortly before that. I would assume it took them a
24 month to do the analyses so your guess would be
25 something in the few months before that, perhaps a

1 little bit earlier.

2 Q. Okay.

3 A. It would take some to do the analyses that
4 they did, but they obviously wanted to do the
5 investigator's meeting as soon as possible so the
6 blind would have been broken some time before then,
7 not a long time before.

8 Q. All right. Was one of the secondary
9 efficacy variables listed in your paper the K-SADS-L
10 depressed mood item?

11 A. That's correct.

12 Q. And did that one show a statistical
13 significance in favor of Paxil?

14 A. I believe that it did, yes.

15 (Ryan Deposition Exhibit No. 14
16 was marked for identification.)

17 MS. CONNELLY: Exhibit 14. Plaintiffs
18 Exhibit 14 is a four-page document. It looks to be
19 an internal SmithKline document.

20 BY MR. MURGATROYD:

21 Q. Did you by any chance get any clips at the
22 break?

23 A. No, I did not, but I know the documents
24 well enough that I can put them together.

25 MS. CONNELLY: I'm just worried about the

1 witness. He's not seen many of these documents
2 before. I don't want the pages getting intermingled
3 in our big pile that's accumulating over here.

4 MR. MURGATROYD: I will sort it out.
5 Don't worry.

6 BY MR. MURGATROYD:

7 Q. Can you identify for the record what that
8 document is?

9 MR. DAVIS: Object to form. There's no
10 foundation laid. The witness can't identify it.

11 THE WITNESS: The document is what appears
12 to be a computer printout. At the top it's labeled
13 "SmithKline Beecham Pharmaceuticals." It says
14 "Program: S329KSAD1.SAS by R. Oakes Date:
15 25-June-1998 for Jim McCafferty." There is what
16 appears to be two pages of SAS program. That's
17 S-A-S, all caps.

18 BY MR. MURGATROYD:

19 Q. Do you know what that is?

20 A. It's a language to program a statistical
21 analyses package called SAS.

22 Q. Okay.

23 A. It's probably the most widely used for
24 analyses such as this although there are others
25 equally well used, and then there's two pages after

1 that, one page after that are the results table and
2 one page after that is some more SAS programming.
3 It does not appear that the pages are in the order
4 generated by the computer, though perhaps I'm wrong,
5 because the lines for the -- the -- yes, the lines
6 for the title are after the table so I think these
7 are probably not in the right order or not
8 consecutive.

9 Q. Okay. And does it have consecutive baste
10 stamps numbers?

11 A. 31, 32, 33, and 34. Yes, it does.

12 Q. Okay. And what is being analyzed there,
13 is you can tell?

14 MR. DAVIS: Object to form.

15 THE WITNESS: Yes. I don't know the
16 internal database so I can tell you what the table
17 says.

18 BY MR. MURGATROYD:

19 Q. Okay. Do you see the heading at the top
20 of the document though that says what's being
21 analyzed?

22 A. The document says "GLM", general linear
23 model, "Analyses for mean changes from baseline and
24 creation of tables for KSADS Depressed Mood Item."

25 Q. Okay. And the KSADS Depressed Mood Item

1 is one of the secondary variables that's mentioned
2 in your paper?

3 A. That's correct.

4 Q. And that's one of the secondary variables
5 that achieved statistical significance in favor of
6 Paxil, correct?

7 A. That's correct.

8 Q. Okay. And does that document show that
9 statistical significance?

10 A. Yes, it does.

11 Q. Okay. And what's the date of that
12 document?

13 A. The date of this document? The date of
14 the document is 25 June, 1998; however, the date on
15 the table you gave me is 26 June 1998 so I don't
16 quite understand how this is all one document.

17 MS. CONNELLY: And for the record, he's
18 merely reading dates off the document. It's not
19 going to establish that he has any first-hand
20 knowledge as to when any page of this document was
21 provided.

22 MR. MURGATROYD: Okay. That's fine.

23 BY MR. MURGATROYD:

24 Q. My question to you is: Do you know why
25 the statistical analysis for that item, for that

1 secondary efficacy item was done six months after
2 the blind was broken?

3 MR. DAVIS: Object to the form of the
4 question; states facts not in evidence, no
5 foundation.

6 MS. CONNELLY: Same objection. It's not
7 going to establish when that analysis was done.

8 THE WITNESS: Fine. I don't know that it
9 was done six months later so I don't know how to
10 answer your question.

11 BY MR. MURGATROYD:

12 Q. Okay. According to that document it
13 appears to have been --

14 A. This run, I think is likely was done on
15 the date it was said, but I have no first-hand
16 knowledge of that.

17 Q. And what's the date of that run?

18 A. It appears to be 26 June 98. The date of
19 the cover memo appears to be 25 June 98, but if
20 you're saying, why was a particular sub-analysis --
21 if you're implying that this was done for the first
22 time I certainly have no knowledge that would
23 support that assertion.

24 Q. Okay. Does that document support that
25 assertion?

1 A. No.

2 Q. Have you seen an analysis of that item
3 prior to that date?

4 A. I do not know.

5 Q. Well, you know, you mean, you don't know,
6 or you don't recall or you don't?

7 A. I have no knowledge of when I first saw
8 the analysis of this item.

9 Q. Well, let me ask you this, have you --
10 that we've established is an analysis related to
11 your study, right?

12 A. It looks like an analysis related to my
13 study, absolutely.

14 Q. Okay. Have you seen any analyses such as
15 that related to your study that was done by GSK?

16 A. This is the first time I've seen any SAS
17 analyses. So we did end -- it would be -- I mean, I
18 don't look at the SAS or all of the analyses for all
19 of the studies or any of the studies that I do. You
20 look at the results and you ask your statistician to
21 see it so I would not have seen the SAS analyses. I
22 don't remember seeing any. You know, that was a
23 decade ago. I do not know more than that.

24 (Ryan Deposition Exhibit No. 15
25 was marked for identification.)

1 Q. Fine. Let me show you what I've marked as
2 Exhibit 15.

3 MS. CONNELLY: I know you disagree with
4 me, but this is becoming cumbersome for the witness
5 not having --

6 MR. MURGATROYD: Just keep them separated.
7 Just put them all on the other side of the table.

8 MS. CONNELLY: You've represented that you
9 can go outside and get a box of paper clips.

10 MR. MURGATROYD: I intend to do that at
11 lunch.

12 MS. CONNELLY: Can we please do that?

13 MR. MURGATROYD: All right. All right. I
14 didn't want to stall the deposition. Let's go off
15 the record.

16 VIDEOGRAPHER: At this time we're going
17 off the record. The time is 11:54 a.m.

18 (Pause in Proceedings.)

19 VIDEOOPERATOR: We're now back on the
20 record. The time is approximately 11:57 a.m.
21 Please proceed.

22 BY MR. MURGATROYD:

23 Q. While we were off the record, Doctor, I
24 gave you a new exhibit, correct?

25 A. Yes.

1 Q. And what number is that, please.

2 A. 1-5. 15.

3 Q. Okay. And can you identify for the record
4 what that document is?

5 A. The document has at the top a "SmithKline
6 Beecham Pharmaceuticals." Again, it looks like SAS
7 output. "Program: S329CGIR.SAS. By: N.Pugh.
8 Date: 26-June-98. Description: Paroxetine 329
9 CATMOD Model Analysis for Responders Acute Phase
10 Only. CGI Global Improvement of 1 or 2.

11 Q. Okay. And is that one of the secondary
12 parameters that's listed in your article?

13 A. Yes.

14 Q. And was that parameter also statistically
15 significant in favor of Paxil?

16 A. Yes.

17 Q. Okay. And what is the date of that
18 document, sir?

19 A. 26 June 98 is the date on the top page of
20 the first page of SAS. There's three pages of SAS.
21 The document -- but you have another page that says
22 30 June 98, so I have no way of linking that to the
23 SAS at the first.

24 Q. Okay. And does that mean 1998?

25 MS. CONNELLY: Object to form. He has no

1 first-hand knowledge of this document. He can only
2 read what it says.

3 THE WITNESS: You have given me something
4 that is clearly more than one document. It's
5 something that's clearly more than one document.
6 You identified it as one document. It has several
7 different dates. I have no indication that this was
8 -- that the two are linked. I have no indication
9 that this was the first time they ran the analysis.

10 BY MR. MURGATROYD:

11 Q. Well, what is the earliest date on that
12 document?

13 A. The earliest date? This is not one
14 document. It's labeled as one exhibit. It's
15 clearly not one document. The date on the SAS
16 program here, the three pages of it is 26 June 98.
17 So some SAS program was run on 26 June 98. There's
18 a table here labeled 30 June 98, so it's clearly not
19 related to this run, that does appear to have the
20 analysis for the CGI 1 or 2 end point.

21 Q. Okay. And, Doctor, can you explain why
22 this run was not done until after six months after
23 the blind was broken?

24 A. There's absolutely no evidence that it
25 wasn't done until six months after this.

1 Q. I'm sorry. Is there any evidence that
2 shows it was done before this?

3 MS. CONNELLY: Object to the form. Dr.
4 Ryan is not a party to this case and does not have
5 access to the -- I assume -- hundreds of thousands
6 of documents which have been produced. He has asked
7 and answered your question.

8 BY MR. MURGATROYD:

9 Q. My question is: Does that document
10 indicate that analysis of CGI of 1 or 2 was done in
11 June of 1998?

12 MR. DAVIS: Object to the form.

13 THE WITNESS: I don't -- this is two
14 documents. There's no evidence linking the two. I
15 do have a table dated 30 June 98, which is clearly
16 not from these first three pages, that an
17 analysis -- a table showing the analyses of that
18 date. There is no indication here that this is the
19 first time this was done.

20 BY MR. MURGATROYD:

21 Q. Okay. Do you have any evidence in your
22 possession or in your personal knowledge that an
23 analysis of CGI 1 or 2 was done prior to June 1998?

24 A. I do not have in my personal knowledge. I
25 do not remember the first time it was done. I did

1 not review all the documents reproduced for you so I
2 cannot answer the first part of your question.

3 Q. Now, in being a coauthor of a paper such
4 as the one you did for 329, right?

5 A. Huh-huh.

6 Q. Do you agree that it's your responsibility
7 to make sure that the information that's contained
8 in that paper is truthful and accurate?

9 A. I agree that you -- let's see -- authors
10 do not have, in general, the ability to -- that all
11 aspects of a paper so I have to assure that to the
12 best of my knowledge it's truthful and accurate. I
13 certainly did not in this case have the ability to
14 make sure, as you're saying, that it was all
15 truthful and accurate.

16 Q. Well, let me ask you this: You could have
17 asked for the statistical analysis? You only get --
18 there's only a handful of variables that's discussed
19 in your paper, right, eight?

20 MS. CONNELLY: Object to the form of the
21 question. It's sort of -- you started in one
22 sentence and ended in another. For the record, I
23 don't know what your question is.

24 BY MR. MURGATROYD:

25 Q. How many variables are analysed for the

1 analysis of which are presented in your paper total?

2 A. Well, let me look at the paper. This
3 approximately looks like it's something like -- I
4 would say 100 different analyses here.

5 Q. I'm talking about the table? The actual
6 statistical analysis in the table?

7 A. I'm sorry. That's not the question you
8 asked me before. I was trying to be responsive to
9 your question.

10 Q. Okay. The table that you list, right?

11 A. I'm sorry?

12 Q. There's a table in your paper?

13 A. There's several tables in the paper.

14 What's your question?

15 Q. Is there a table in there that lists
16 statistical analysis regarding the primary and
17 secondary end points?

18 A. Yes.

19 Q. And how many are there there?

20 A. There would be -- it looks like about 22.

21 Q. Okay. And -- can I see that paper?

22 A. Sure.

23 Q. Are you stating there's 22 primary and
24 secondary efficacy variables in that table?

25 A. No. That's not the question you asked me.

1 Q. Well, actually that was my question.

2 Maybe it wasn't clear.

3 A. Could you read the question back, please.

4 Q. No. I'll -- we'll make sure it's very
5 clear.

6 How many primary and secondary efficacy
7 variables are in that table?

8 A. 12.

9 Q. Okay. And of those 12, how many reached
10 statistical significance in favor of Paxil?

11 A. One, two, three four. Four. And another
12 two were a strong trend, and they all went in the
13 direction of favoring Paxil.

14 Q. My question was: How many reached
15 statistical significance in favor of Paxil?

16 MS. CONNELLY: Asked and answered.

17 BY MR. MURGATROYD:

18 Q. Okay. Now, you've answered more than my
19 question. My question was very simple and very
20 precise. If I ask a general question you can ask me
21 to make it more precise.

22 My question was: Specifically, how many
23 of the variables reached statistical significance in
24 favor of Paxil? What's the answer?

25 A. I answered that a second ago. I'll answer

1 it again. It looks like one, two, three, four.

2 Q. Four out of 12?

3 MR. DAVIS: Objection to the form.

4 BY MR. MURGATROYD:

5 Q. Correct?

6 A. Yes.

7 Q. And, Doctor, can you state under oath
8 right now that you could not have asked GSK prior to
9 writing that paper for the statistical analyses that
10 it did for 12 variables?

11 A. That's -- no, I could indeed of asked them
12 for 12 variables or I could have asked them for all
13 the important variables in the paper.

14 Q. And did you do that?

15 A. I have never done that on another paper.
16 I did not do it on this one.

17 Q. When you -- strike that --

18 You're aware that there have been
19 allegations made concerning fraud relating to your
20 study, correct?

21 A. I am not aware of that.

22 Q. You are not aware of the lawsuit that was
23 brought by the Attorney General Spitzer in the State
24 of New York?

25 MR. DAVIS: Object to form.

1 BY MR. MURGATROYD:

2 Q. Regarding Paxil use in kids?

3 A. I am aware that Attorney General Spitzer
4 brought a lawsuit, yes. I am not aware that lawsuit
5 alleged fraud in this study.

6 Q. You're aware of an alleged fraud though,
7 correct?

8 A. No. I'm sorry. I'm not aware of alleged
9 fraud.

10 Q. So I want to make sure I understand the
11 process. You produced documents to your lawyer in
12 this case, right?

13 A. Yes.

14 Q. And you're stating under oath you didn't
15 even look at those?

16 A. That's correct.

17 Q. Okay. Do you recall writing an e-mail to
18 Martin Keller in which you attached the Attorney
19 General's statement concerning lawsuit against GSK
20 regarding fraud?

21 A. No, but I'll take your word on it.

22 Q. Okay.

23 A. It's still not my memory that he asserted
24 fraud in this case though, did he?

25 Q. Have you read the various journal articles

1 that have discussed whether or not there was fraud
2 relating to study 329 article?

3 A. I have never seen a journal article
4 asserting fraud in this study.

5 Q. Okay. We'll get into that probably
6 tomorrow.

7 A. Okay.

8 Q. Now, going back to the exhibit -- I think
9 it's 4, the final statistical study report. Do you
10 see that?

11 A. I have the document in front of me, yes.

12 Q. Okay. Now, did you have any role in the
13 preparation of that report?

14 A. Not to my knowledge. I don't think so.

15 Q. Okay. Well, the study was your idea,
16 right? You and your teams's idea?

17 A. That's correct.

18 Q. How do you feel about giving the control
19 of the analyses of the data over to a different
20 entity?

21 A. In retrospect if I was to do another
22 industry study I would put as a clause in there that
23 the university and I had the right to the entire
24 data set for analyses.

25 Q. Okay. Thank you.

1 If you would, please, turn to -- actually,
2 can I see that document real quick? Thanks. Okay.
3 I'm going to hold off on that question until
4 tomorrow.

5 Now, with regard to your work that you
6 have done with GSK you're aware that there were
7 other studies being done that were placebo --
8 randomized placebo controlled trials looking at
9 whether or not Paxil was effective in treating kids
10 with major depressive disorder; is that correct?

11 A. Yes.

12 Q. Do you recall the numbers of those other
13 studies?

14 A. No.

15 Q. Okay. Are you aware of the total number?

16 A. The -- I am aware of two other studies
17 that they did.

18 Q. Okay. And how -- what is the basis of
19 your knowledge of that?

20 A. Yes. I saw it one time a poster
21 presentation for the second study that they did, the
22 study that followed this one, and I saw in one of
23 the FDA things or in one of the articles I read they
24 had done a third study. It was certainly the third
25 study was reported in the -- by the FDA analysis of

1 suicidality.

2 Q. Okay. And --

3 A. And it's been reported in some things
4 subsequent.

5 Q. All right. And have you had a chance to
6 review the synopsis or full study report of either
7 of those other studies?

8 A. I have not reviewed the full study report
9 of either of the studies. I know from the FDA
10 suicidality study and from other articles that both
11 studies were negative. I don't remember the details
12 of negative, you know, I don't remember the
13 details -- you know, I remember the sample sizes
14 were approximately 80 to 100 percel and in both did
15 not find evidence of Paxil to placebo.

16 Q. And those were both, according to your
17 understanding negative studies, correct?

18 A. That's my understanding.

19 Q. When you say a negative study, what's the
20 definition? What definition are you using for a
21 negative study?

22 A. There was indication of efficacy on those
23 two studies.

24 Q. And are you aware that the FDA stated that
25 your study 329 was also a negative study?

1 MR. DAVIS: Object to form.

2 THE WITNESS: I am aware that the FDA did
3 not find it positive by the FDA requirements for
4 what it considers for an-usage indication.

5 BY MR. MURGATROYD:

6 Q. Have you seen the document where it
7 specifically states that your study 329 was
8 negative?

9 MR. DAVIS: Object to form.

10 MS. CONNELLY: Object to form. If you
11 have a document you want to show him. It's assuming
12 facts not in evidence.

13 MR. MURGATROYD: No. I'm just asking him
14 if he has seen the document? That's all. I'm
15 asking him if he's seen it?

16 MS. CONNELLY: So you're saying the
17 document. So you're putting the witness in a
18 position of believing that there's a document.

19 MR. MURGATROYD: Okay. That's fine. I'll
20 correct it.

21 BY MR. MURGATROYD:

22 Q. Have you seen any documents?

23 A. Yes.

24 Q. Okay. And what documents have you seen
25 that listed 329 as being a negative study?

1 A. The Terrick whoever analyses on the
2 suicidality. The analyses of suicidality they did
3 also talked about efficacy to the best of my memory,
4 and that was a FDA document to the best of my memory
5 indicated that the three were negative. I'm not
6 certain that that's correct or it was, but that's
7 the best I can remember right now.

8 Q. Okay. That's fine. Now, are you aware of
9 --

10 A. I gave you an incomplete answer on the one
11 before that though.

12 Q. You can go ahead and correct it.

13 A. I'm just adding to it, which is that the
14 FDA criteria for what it considers positive is a
15 result of a lot of FDA sort of regulatory case law.
16 They've established what they require for a positive
17 indication, which is different than finding evidence
18 that it works. They have a certain thing, you know,
19 that you have to have typically one of two or two of
20 three of the primary indicators positive.

21 Q. Okay. And how do you know that?

22 A. How do I know that? I don't remember how
23 I first learned that. I did for a while serve on
24 the FDA Psychopharm Advisory Committee, but I'm sure
25 I knew that before then.

1 Q. Okay. Now, let me show you a -- and
2 actually we probably should have done this a little
3 bit earlier -- I have shown you today documents that
4 have been stamped confidential by GSK. Do you see
5 that on the bottom of some of those documents?

6 MS. CONNELLY: Mr. Murgatroyd, while we
7 were waiting for the court reporter to arrive.

8 MR. MURGATROYD: Yes.

9 MS. CONNELLY: Dr. Ryan executed the
10 stipulated -- the affidavit in support of the
11 stipulated protective order in the Blain case.

12 MR. MURGATROYD: Excellent.

13 MS. CONNELLY: Because we worked that out
14 with him ahead of time.

15 MR. MURGATROYD: That's absolutely fine.
16 That's just what I was going to get into. I wanted
17 to make sure we had everything properly done here.

18 MS. CONNELLY: Just a facilitator here.

19 MR. MURGATROYD: Absolutely. Why don't we
20 mark that as an exhibit and make it part of the
21 formal record. Is that okay by you?

22 MS. CONNELLY: Fine by me.

23 MR. MURGATROYD: I think we're up to
24 Exhibit 16.

25 MR. DAVIS: We just need the court

1 reporter to execute the notary.

2 MR. MURGATROYD: Okay.

3 (Ryan Deposition Exhibit No. 16
4 was marked for identification.)

5 BY MR. MURGATROYD:

6 Q. This is formality so that nobody gets in
7 trouble. Do you understand that?

8 A. Yes.

9 Q. Okay. And the idea is that you will be
10 shown and have been shown confidential documents
11 today and you're not to share those with other
12 people without the permission from GSK. Do you
13 understand that?

14 A. I understand that.

15 Q. Okay. Great. Let me put that in the
16 pile.

17 MS. CONNELLY: Just to be aware of time.
18 It's about 12:20.

19 MR. MURGATROYD: Okay.

20 MS. CONNELLY: So we'll take a break
21 relatively soon for lunch.

22 MR. MURGATROYD: Moving right along here,
23 aren't we?

24 (Ryan Deposition Exhibit No. 17
25 was marked for identification.)

1 BY MR. MURGATROYD:

2 Q. Let me show you what I've marked as
3 Exhibit 17, sir.

4 A. Okay.

5 MR. DAVIS: May I see that for a second?

6 MS. CONNELLY: Is this one of the
7 documents that you're concerned about
8 confidentiality, Mr. Murgatroyd?

9 MR. MURGATROYD: Well, it's confidential,
10 yes. And you'll see at the bottom it's stamped
11 "Confidential For Sales Force Information Only."

12 MR. DAVIS: Yes. Let me just clarify
13 something here for the record. The cover memo, the
14 first two pages are confidential pursuant to the
15 protective order. The last part, that's the current
16 medical information letter, would not be subject to
17 the protective order.

18 MR. MURGATROYD: Okay.

19 MR. DAVIS: Okay.

20 BY MR. MURGATROYD:

21 Q. It's a rather voluminous document and I'll
22 only be asking you about the documents entitled "use
23 of Paxil CR" or "Paxil in pediatric patients", and
24 I'm going to be referring to the third bullet point
25 on that page. You're absolutely free to review the

1 rest of the document and you may have even seen this
2 document, but we'll discuss that in a second.

3 Q. Okay. Are you ready?

4 A. Huh-huh.

5 Q. Okay. Great. Have you ever seen any part
6 of this document before?

7 A. Not to the best of my knowledge.

8 Q. And you'll see on the cover page -- what
9 is that the date?

10 A. September 10, 2003.

11 Q. Okay. And we're talking about the use of
12 Paxil CR or Paxil in pediatric patients, the part
13 that's attached to that document, do you see that?

14 A. Okay.

15 Q. And do you see the third bullet point?

16 A. Yes.

17 Q. And can you read that bullet point into
18 the -- actually, just the first two sentences of
19 that bullet point?

20 A. Yes. "From an efficacy standpoint, trials
21 in pediatric patients have shown Paxil to be
22 statistically superior to placebo in the treatment
23 of OCD and social anxiety disorders." Is this the
24 one you want?

25 Q. Yes.

1 A. "These studies did not show a benefit for
2 the treatment of MDD in children or adolescents
3 under 18 years of age."

4 Q. And is that your understanding that's a
5 true statement?

6 MR. DAVIS: If the witness can.

7 THE WITNESS: I think that this statement
8 is one -- the best I can tell from this -- is the
9 official position of I guess at the time GSK after
10 the two other studies had reported in this is how
11 either they're evaluating it or how their official
12 legal position for the world is at that time.

13 BY MR. MURGATROYD:

14 Q. Okay. And you'll see that this is a
15 document that was sent out to their sales force,
16 right? Do you see that on the cover page?

17 A. I see it on the cover page, yes.

18 Q. Okay. Well, let me show you the next
19 document and we will discuss it.

20 (Ryan Deposition Exhibit No. 18
21 was marked for identification.)

22 Q. Okay.

23 A. Okay.

24 Q. And this appears to be a series of
25 e-mails, correct?

1 A. It appears to be a series of e-mails.

2 Q. And from the -- from the section of the
3 top of the first page you see Sheila Hood mentioned?

4 A. Sheila Hood is from at the very top of
5 what appears to be a chain of e-mails, yes.

6 Q. And do you know who Sheila Hood is?

7 A. No, I do not.

8 Q. And going down to the first full
9 paragraph, you see where it starts with, "Yes
10 please"? Do you see that?

11 A. I see that.

12 Q. Okay. And can you read that paragraph
13 into the record, please.

14 A. Okay. But this is not from Sheila Hood it
15 appears.

16 Q. Okay.

17 A. Okay. So this looks like it's from -- the
18 best I can tell this one's from a Holly White who I
19 also don't know at YR.com who I also don't know
20 where that's from.

21 Q. That's fine.

22 A. To Sheila Hook.

23 Q. Okay.

24 A. Paragraph says, "Yes, please. Originally
25 we had planned to do extensive media relations

1 surrounding this study until we actually viewed the
2 results. Essentially the study did not show Paxil
3 as effective in treating adolescent depression,
4 which is not something we want to publicize."

5 Q. Okay. Let's stop there.

6 A. Huh-huh.

7 Q. Now, do you agree with this statement?

8 A. No.

9 Q. Were -- have you seen or read about the
10 internal memo that was issued by GSK discussing very
11 similar conclusions to your study such as this?

12 MR. DAVIS: Objection to form.

13 MS. CONNELLY: Object to form; it's facts
14 not in evidence.

15 MR. DAVIS: I mean, I don't even know what
16 document's being discussed.

17 BY MR. MURGATROYD:

18 Q. That's fine. I'm just asking, have you
19 seen any or heard about, read about, any document,
20 GSK document that discuss the results of your study?

21 MS. CONNELLY: Just to be clear, my
22 objection is it is misleading to the witness to
23 frame the question in such a way that it's -- you're
24 talking about the document.

25 MR. MURGATROYD: That's fine. I corrected

1 it. I got it. I got it.

2 MR. DAVIS: I still don't know what
3 document -- if you have a document that you want to
4 show him, but I don't know what --

5 MR. MURGATROYD: I'm asking him a
6 question.

7 THE WITNESS: I don't yet understand your
8 question. Could you state it again for me, please.

9 BY MR. MURGATROYD:

10 Q. I understand. I don't think I've had a
11 chance to ask it fully, but let's take it from the
12 top.

13 Have you read about the existence of any
14 document that GSK created internally that said
15 something similar to this document that your study
16 did not really show Paxil was effective in treating
17 adolescent depression?

18 A. No.

19 Q. Well, we got -- actually, I'm not going to
20 break my promise. I said we're going to break for
21 lunch. We're breaking for lunch.

22 VIDEOGRAPHER: At this time we're going
23 off the record. The time is 12:26 p.m.

24 (Luncheon Recess.)

25 VIDEOGRAPHER: We are now back on the

1 record. The time is approximately 1:33 p.m. please
2 proceed.

3 BY MR. MURGATROYD:

4 Q. Doctor, with regard to study 329 and the
5 article that you wrote following that study, the
6 completion of that study, how many efficacy
7 variables did you find or GSK find or the group of
8 you find reached statistical significance in favor
9 of Paxil?

10 A. Four.

11 Q. Okay. And can you identify for the record
12 which four of those are?

13 A. Yes. They are the Hamilton-D less than
14 eight.

15 Q. Okay. Is it less and equal to or less?

16 A. Less and or equal to. My apologies.
17 You're correct.

18 Q. And is that also the definition of
19 remission?

20 MR. DAVIS: Object to form.

21 THE WITNESS: The -- the -- I think the
22 answer to that is no, right? I'm sorry. Rephrase
23 your question, please.

24 BY MR. MURGATROYD:

25 Q. Is Hamilton-D less and or equal to eight

1 also known as remission as an endpoint in your
2 study?

3 A. I'll have to look up the wording on it.
4 The other ones were -- let me see what we have.
5 Hamilton-D Depressed Mood Item. K-SAD-L Depressed
6 Mood Item --

7 Q. Not too fast. Hamilton-D Depressed?

8 A. Mood Item.

9 Q. Yes.

10 A. K-SADS-L Depressed Mood Item.

11 Q. And the last one is?

12 A. CIG score of 1 or 2.

13 Q. Okay. Now, do you recall Dr. McCafferty
14 asking that the HAMD Mood Item be included as a
15 secondary efficacy variable?

16 A. I don't recall who suggested that item for
17 a secondary efficacy variable.

18 Q. Okay. What was the last number?

19 MS. CONNELLY: I think the last number was
20 18.

21 MR. MURGATROYD: Thanks.

22 (Ryan Deposition Exhibit No. 19
23 was marked for identification.)

24 BY MS. CONNELLY:

25 Q. Exhibit 19 is an unlabeled -- un-bates

1 numbered I should say, apparent e-mail from Jim
2 McCafferty.

3 MR. DAVIS: Can I see that, please?

4 MS. CONNELLY: I'm sorry.

5 MR. MURGATROYD: Actually, it has it on
6 mine, but it's kind of down at the bottom.

7 MR. DAVIS: Yes. Right.

8 MR. MURGATROYD: It didn't quite copy
9 right.

10 MR. DAVIS: The legend that -- the
11 production legend has been -- is not on this copy.

12 MS. CONNELLY: Is this a designated
13 confidential document?

14 MR. DAVIS: It is.

15 BY MR. MURGATROYD:

16 Q. Have you have ever had a chance to look at
17 that?

18 A. I have.

19 Q. And you see that it is an e-mail from
20 James McCafferty to William Bushnell, both GSK
21 employees, correct?

22 A. I don't know Mr. Bushnell. The e-mail
23 address looks consistent with other people I know to
24 be GSK employees.

25 Q. Okay. And what's the date of it?

1 A. 8-28-1997.

2 Q. Okay. So this was a few months before the
3 blind was broken, correct?

4 MS. CONNELLY: Objection.

5 THE WITNESS: I don't know the date of the
6 blind being broken.

7 MR. MURGATROYD: I think we can actually
8 stipulate to that on the record. Do you have any
9 problem with that?

10 MR. DAVIS: I don't.

11 BY MR. MURGATROYD:

12 Q. It's October 22, 1997.

13 A. Okay. So this is before.

14 Q. Okay. Two months before approximately,
15 little less than two months, right?

16 A. Right.

17 Q. Okay. And do you see that Mr.
18 McCafferty -- and so the record's clear and the jury
19 knows -- Mr. McCafferty, who was he? Who is he?

20 A. I don't know what he's doing now. He was
21 an employee of SKB who had significant
22 responsibility for the study. I don't know his
23 reporting line. I can't tell you his official title
24 or official relationship with the study. He
25 certainly was one of the people that did a lot of

1 SKB's interfacing with the investigators on the
2 study.

3 Q. Including yourself?

4 A. Yes.

5 Q. And I take it you met with him on many
6 occasions? Quite a few occasions?

7 A. Quite a few I'll give you. I don't know,
8 how many is.

9 Q. Okay. That's fine. And do you see that
10 in this e-mail he's requesting a tabulation analysis
11 of the HAM-D Mood Item. Do you see that?

12 A. Yes.

13 Q. Okay. And that's consistent with the
14 HAM-D Mood Item that's actually, ultimately shows
15 you up in your paper, correct?

16 A. Yes.

17 Q. Okay. Let me show you what I'm going to
18 mark as Exhibit 20, and for the purposes of this
19 document I'm going to mark -- I hate to be
20 inconsistent so I'm not going to be -- I'm just
21 going to mark the whole document 20, and then we'll
22 discuss it. Okay?

23 (Ryan Deposition Exhibit No. 20
24 was marked for identification.)

25 MS. CONNELLY: Plaintiffs Exhibit 20

1 contains four pages. It appears to be a SmithKline
2 Beecham internal document.

3 BY MR. MURGATROYD:

4 Q. Okay. This is another one of the
5 communication printouts, correct, and table?

6 MS. CONNELLY: Object to form. You
7 haven't established any personal knowledge.

8 BY MR. MURGATROYD:

9 Q. Well, is that what it appears to be?

10 A. This appears to be a computer printout and
11 a table.

12 Q. Okay. And I've shown you two of these
13 earlier, correct?

14 A. You're shown me two earlier exhibits that
15 contained both computer printouts and tables.

16 Q. Right. And I guess that's what I want to
17 clarify, and so it's clear for those earlier
18 documents we may have to go over them again, but the
19 first two pages, correct?

20 A. The first two pages appear to be a SAS
21 computer program.

22 Q. Okay. And you are a computer guy?

23 A. I'm a computer guy. I don't know SAS
24 however.

25 Q. Okay. But do you understand this as

1 requesting a table setup?

2 A. Let me see if I can give you an answer on
3 that one.

4 Q. I think if you look at the very top it
5 says "table."

6 A. Well, I completely understand that it says
7 that. I do not know enough SAS to tell you that
8 this is SAS that generated that table. I don't know
9 enough to say it didn't. I just don't know.

10 Q. Okay. It says on it "table", correct?

11 A. Well, I see a table. I see the word table
12 in a comment.

13 Q. Do you see at the top --

14 A. I'm sorry?

15 Q. Do you see at the top it says --

16 A. Program da, da, da, typed table, yes, but,
17 presumably that's actually a comment, not anything
18 else. So yes, it does indeed say in what appears to
19 be a comment, it says, "Type: Table."

20 Q. And it has to do with the creation of
21 tables, right, for ITT Efficacy Variable HAM-D
22 Depression Item, correct?

23 MS. CONNELLY: Object to the form. It's
24 really vague and confusing, and you haven't
25 established that he has any personal knowledge of

1 what this is requesting.

2 MR. MURGATROYD: That's fine. You can
3 object.

4 BY MR. MURGATROYD:

5 Q. Okay.

6 A. There's -- there's a -- what appears to be
7 a -- again, a comment area.

8 Q. Yes.

9 A. That comments that it's asking for "GLM
10 Analysis of mean changes from baseline and creation
11 of tables for ITT efficacy variable HAM-D Depression
12 Item."

13 Q. Okay. Great.

14 A. Yes. I see that.

15 Q. See that?

16 A. Yes.

17 Q. Okay. Good. Now, do you see the date of
18 this document?

19 A. Well, in the beginning it appears to be
20 two documents.

21 Q. Okay. The --

22 A. The first two pages of SAS says 28 August
23 97.

24 Q. Okay. And now let's look at the exhibit
25 before this one, No. 19.

1 A. Okay.

2 Q. And what's the date of that document
3 again?

4 A. It says 28 August 97.

5 Q. Okay. Same day, right?

6 A. Yes.

7 Q. Okay. And now looking at the last two
8 pages of this document, and again, these documents
9 are in bates stamp order, correct?

10 A. Yes.

11 Q. Okay. And looking at the last two pages
12 of the document, do you see that it's the table that
13 analyze the results of the HAM-D Depression Item,
14 correct?

15 MS. CONNELLY: Object to form.

16 THE WITNESS: This appears --

17 MR. DAVIS: I join in that objection.

18 Sorry, Dr. Ryan.

19 THE WITNESS: No. My apologies for
20 talking first.

21 I believe that actually that's incorrect
22 from the data that I have in front of me.

23 BY MR. MURGATROYD:

24 Q. Okay. What is it?

25 A. Because the dates are different.

1 Q. I understand.

2 A. And so I have absolutely no way of linking
3 this table with the statistical program.

4 Q. Well, does this -- well, that's what we're
5 going to attempt to do here.

6 A. Okay.

7 MS. CONNELLY: I have to object to this.
8 He -- you haven't even asked him if created this
9 document, if he ever saw this document before. So
10 to the extent that you're trying to use this witness
11 to link these two documents.

12 MR. MURGATROYD: Well, let's see if he can
13 do it. He's a computer guy. That's it. If he
14 can't, he can't.

15 MS. CONNELLY: And I object to the phrase
16 computer guy. I don't even know what that means.
17 He's a doctor.

18 MR. MURGATROYD: He has a degree in
19 computer. Didn't you say you have a degree in
20 Computer Science?

21 THE WITNESS: I have a degree in 1974 in
22 Compter Science.

23 BY MR. MURGATROYD:

24 Q. Okay. Great. So that we have the second
25 two pages is a table, right?

1 A. No. The third page is a table. The
2 fourth page is some more SAS program.

3 Q. Okay. Let's take a look at the table,
4 which is the third page, right?

5 A. Yes.

6 Q. What does this table relate to?

7 A. The table is labeled "Baseline and mean
8 changes from baseline at weekly Intervals -- HAMD.
9 Depressed Mood Item. Acute Phase. Intent to Treat
10 Population."

11 Q. Okay.

12 A. It also says "Table 13.35."

13 Q. Okay. And is that similar to the
14 descriptive item on the first page of the document?

15 A. It is similar. Yes.

16 Q. Okay. Now, let's look at the date of this
17 document, of the table.

18 A. Of the table, yes.

19 Q. What is the date of that table?

20 A. It says 30 October 97.

21 Q. Okay. So you would agree that this table
22 was created after the breaking of the blind?

23 MR. DAVIS: Object to the form.

24 THE WITNESS: Again, since I've never seen
25 this before. Since I wasn't involved in the

1 analysis I will agree that the date 30 October 97
2 is -- I'm sorry -- when did we stipulate the blind
3 was broken?

4 Q. October 22, 1997.

5 A. So I will agree that the date on this
6 table is later than the date you told me we've
7 broken the blind, but I don't know when this table
8 was first created. I know the date on this table.

9 Q. That's fine.

10 A. Okay.

11 Q. That's fine. Now, the -- does that help,
12 what we just did, help explain why there are
13 different dates on the other two exhibits that are
14 similar to this exhibit?

15 MR. DAVIS: Objection; no foundation for
16 this witness to answer that question.

17 THE WITNESS: I don't think it explains it
18 at all.

19 BY MR. MURGATROYD:

20 Q. Okay. Well, let's go back to those
21 earlier exhibits.

22 A. What exhibits do you want me to go back
23 to?

24 Q. The two computer runs and tables.

25 MS. CONNELLY: Do you know what numbers

1 those are?

2 MR. MURGATROYD: No, but they're in that
3 pile.

4 THE WITNESS: They have stuff that looks
5 like fixed lines in the beginning.

6 Yes. Okay. So it looks like it's 14 and
7 15. Again, could you restate your question for
8 me?

9 BY MR. MURGATROYD:

10 Q. Yes. Sure. All right. Let's take 14
11 first.

12 A. Okay.

13 Q. Does that have the word "table" in it
14 also?

15 A. Creation of tables, plural, yes.

16 Q. Okay. Does that appear to be a document
17 that's asking the computer to create a table?

18 A. It does, but I don't know the answer to
19 that.

20 Q. Okay. What's the date of that document?

21 A. This again, the date of the SAS program
22 appears to be 25 June 98. The date of the table
23 appears to be 26 June 98.

24 Q. And would you agree, sir, that both of
25 those dates are after the breaking of the blind?

1 A. I'm sorry? The breaking of the blind?
2 Yes. I would agree with that. I mean, given on
3 what you've stipulated to. Sure.

4 Q. Okay. Let's go to the next table, 15.

5 A. Okay.

6 Q. Okay. Now, do you see that that -- our
7 next document 15 -- do you see that also has the
8 word table in the first document, in the
9 computer-generated document?

10 A. I'm not seeing it. I'm not seeing it at
11 all there. Perhaps you want to look and tell me
12 where it is. Okay.

13 Q. Let me take a look at it. Thanks.

14 MR. DAVIS: We're on 20?

15 THE WITNESS: Soon to be on Exhibit 15.

16 MR. DAVIS: Thank you.

17 BY MR. MURGATROYD:

18 Q. Yes. You'll see table number, right here,
19 "Initial set up for commands to create." If you'll
20 take a look at that, please.

21 A. "Initial set up commands to create
22 libnanes and macros for output data set." My
23 apologies. I'm -- oh, table number. Says, "output
24 file, protocol, table number, and population types."

25 Q. Okay. And what is --

1 A. -- and it's clearly in the comment.

2 Q. Okay. And what is the date of that
3 computer-generated document?

4 A. The document says 26 June 98.

5 Q. Okay. And what is the date of the table?

6 A. The table says 30 June 98.

7 Q. Okay. And would you agree, Doctor, that
8 both of those dates were after the breaking of the
9 blind?

10 A. Yes.

11 Q. Okay. Now, I asked you a minute ago how
12 remission was defined in your study 329?

13 A. Yes. I have to just go look through the
14 paper and make sure that I understand the answer to
15 your question. If you want to tell me what you
16 believe it is and I'll see if I can confirm it.
17 That'll save some time. It's up to you?

18 Q. Well, it's my understanding it's HAM-D
19 score of less or equal to eight, but I want you to
20 confirm that for yourself, please.

21 A. Sure. My apologies, but I'm not seeing
22 where the definition -- where that's defined, do you
23 want to show me?

24 Q. I'll print out a document at our next
25 break and show it to you, but I want you to assume

1 for the purposes of this deposition, at this point
2 in time, that that is the definition of remission?
3 Okay?

4 MR. DAVIS: Object to the form; no
5 foundation.

6 THE WITNESS: No.

7 MR. MURGATROYD: No? Okay. Good. Go off
8 the record.

9 VIDEOOPERATOR: At this time we're going
10 off the record. The time is approximately 1:50 p.m.

11 (Pause in Proceedings.)

12 VIDEOGRAPHER: We're now back on the
13 record. The time is approximately 1:58 p.m. Please
14 proceed.

15 (Ryan Deposition Exhibit No. 21
16 was marked for identification.)

17 MS. CONNELLY: Plaintiffs Exhibit 21
18 appears to be one of the documents under the
19 protective order. It appears to be a GSK internal
20 document.

21 MR. DAVIS: Object to the use of that
22 document to this witness, because there's no
23 foundation established that the Doc -- the witness
24 is familiar with it.

25 MR. MURGATROYD: We could say that about

1 half the documents, Todd, that's not an objection.

2 MR. DAVIS: I certainly can agree with you
3 on there, Skip.

4 BY MR. MURGATROYD:

5 Q. Doctor, you can -- you're certainly free
6 to read the whole thing, but what we're going to
7 concentrate on is the last paragraph.

8 A. Okay.

9 Q. Okay. Do you see the word remission in
10 the last paragraph?

11 A. Yes.

12 Q. And how's it defined?

13 A. In this document from GSK folks to GSK
14 folks it states -- let's see. Let me give you
15 enough that you can get the whole thing.

16 To paraphrase it: A Hamilton-D of less
17 than or equal to eight was defined as, quote
18 "remission." It says, although it was, quote,
19 "remission", unquote, was defined in the protocol
20 and remission by itself was a key secondary
21 parameter and Paxil versus Placebo was shown to be
22 statistically significant.

23 Q. Okay. Does that clarify the issue of
24 how --

25 A. No. It does not.

1 Q. Well, less than -- does that say the
2 remission is defined as less than or equal -- HAM-D
3 score of less than or equal to eight?

4 A. That's what this document says.

5 Q. Okay. And is HAM-D less than or equal to
6 eight one of the secondary parameters in your paper?

7 A. Yes, it is.

8 Q. And did it reach statistical significance?

9 A. Yes, it did.

10 Q. Okay. And does that say that it reached
11 statistical significance there?

12 A. Yes, it does.

13 Q. And do you think there's any difference
14 between those?

15 MS. CONNELLY: Object to form. Between
16 what?

17 THE WITNESS: Your question was
18 misleading, and so the answer will be inadvertently
19 misleading because this paper never refers to it as
20 remission.

21 BY MR. MURGATROYD:

22 Q. Okay.

23 A. The fact that an internal GSK document
24 called it remission doesn't mean it was defined as
25 remission by the investigators, and I don't think it

1 would be called remission by the investigators as
2 best I can tell.

3 Q. Okay. Well, fine. So the reason --

4 A. So it's --

5 Q. -- the reason I'm setting that foundation
6 is for the next document. I think it will make
7 sense to you.

8 A. Okay.

9 MR. MURGATROYD: What I'm going to mark as
10 Exhibit 21.

11 (Ryan Deposition Exhibit No. 22
12 was marked for identification.)

13 Q. The next exhibit is a printout with a
14 table and it's a computer printout.

15 A. Okay.

16 Q. Okay. Now you seen GSK's definition of
17 remission in their earlier document I showed you of
18 a Hamilton-D score of less than or equal to eight.
19 Okay. Does this document appear to -- the first
20 three pages, which is the computer printout right,
21 appear to address a tables or table to set up the
22 analysis for remission?

23 MS. CONNELLY: Object to form. We just
24 haven't established that this is one document and I
25 haven't looked at it closely. Based on the other

1 ones that he has been presented, the witness has
2 been presented, they have appeared to be a mixture
3 of different documents and perhaps --

4 THE WITNESS: This is the same document --

5 MR. MURGATROYD: This is the same.

6 THE WITNESS: -- this appears to be the
7 same thing only more so. The first part of this is
8 a SAS program dated 7 May 97. The second part is a
9 table dated 28 October 97.

10 BY MR. MURGATROYD:

11 Q. Right. The same thing as the other ones,
12 right?

13 A. Well, the other ones were off by a date.
14 This is off by half a year so I have no reason to
15 assume there is any substantive linkage between the
16 two.

17 Q. Well, that's -- let's see if you can
18 figure it out. Let's go back to the document that
19 talks about the HAM-D Depressed Item. Go back to
20 that.

21 MS. CONNELLY: Sir, could you please tell
22 us the document number?

23 THE WITNESS: The one we just got,
24 document 21?

25 MR. MURGATROYD: Yes.

1 THE WITNESS: Okay.

2 MR. MURGATROYD: No. The HAM-D --

3 THE WITNESS: My apologies. The HAM-D
4 document. I was wrong on that.

5 MS. CONNELLY: Do you know the Exhibit
6 Number?

7 MR. MURGATROYD: Well, it's one of the
8 last five. You've gone too far if they're in order.

9 THE WITNESS: Is it this one right here?
10 No. I'm sorry.

11 MS. CONNELLY: That's okay. It's not --

12 THE WITNESS: There's not too many there.

13 MS. CONNELLY: It's not well organized.

14 THE WITNESS: This is for the HAM-D.

15 MR. MURGATROYD: Okay.

16 BY MR. MURGATROYD:

17 Q. Now, look at the date on the computer
18 printout sheet?

19 A. Huh-uh.

20 Q. And what is the date again?

21 A. The date on this computer printout is --

22 Q. No. No. Not on the computer printout,
23 not --

24 A. It is 28 August and --

25 Q. Okay. Hang on.

1 A. And 30 August.

2 Q. Okay. Slow down. 28 August, correct?

3 A. On the computer program -- there's several
4 dates -- all of this is obviously computer printout,
5 which part are you asking me about?

6 Q. Okay. What is the -- can I see that
7 document for a second?

8 A. Sure.

9 Q. Okay. You read the dates wrong. I just
10 wanted to make sure that I had it right. The
11 computer printout, right, that discusses a table is
12 the first two pages of that document, correct?

13 A. The first two pages of the document is a
14 computer printout.

15 Q. Okay. Now, what is the date of that?

16 A. Is 28 August 97 is the date printed on
17 there.

18 Q. Right. And we agreed that was the same
19 date that Mr. McCafferty asked Mr. Bushnell to do a
20 tabulation analysis for the HAM-D Mood Item 1,
21 correct?

22 MS. CONNELLY: Objection. We have a
23 printout of a document which you haven't asked him
24 if he had ever seen before. He can't testify as to
25 whether or not that happened. He cannot

1 authenticate that document.

2 MR. MURGATROYD: I'm not asking him to
3 authenticate the document. I asked him a question.

4 MS. CONNELLY: It's not a fair question.

5 BY MR. MURGATROYD:

6 Q. Is it the same date that --

7 A. No. You asked me if that's the date Mr.
8 McCafferty did such and such. I have no information
9 to answer your question.

10 Q. According to the exhibit that you've been
11 presented?

12 A. It's the date he sent him an e-mail
13 related to it, yes.

14 Q. Okay. That's fine. Now, is that date
15 prior to the breaking of the blind?

16 MS. CONNELLY: Object to form.

17 THE WITNESS: I'm sorry? What date again?

18 BY MR. MURGATROYD:

19 Q. The date on the computer run right there
20 in your hand --

21 A. Okay.

22 Q. -- is that date, 28 August 1997, prior to
23 the breaking of the blind?

24 A. The breaking of the blind? Remind me
25 again, please?

1 Q. October 22, 1997.

2 A. The 28 August would be two months ahead of
3 that.

4 Q. Okay. Now, go to the table on that
5 document right there.

6 A. Right.

7 Q. What is the date of that table?

8 A. I have no information that this table is
9 linked to this computer program.

10 Q. I'm sorry. Does the table have a name?

11 A. The names are the same. I have no -- I
12 have nothing to indicate to me that this table is a
13 result of running this program.

14 Q. Fine. What is the date of that table?

15 A. 30 October 97.

16 Q. Would you agree, sir, that that is a date
17 after the breaking of the blind?

18 A. Yes.

19 Q. Okay. Now, let's go to the last -- the
20 document we're talking about now in remission, does
21 the computer run have a date prior -- the computer
22 run document, the first three pages, have a date
23 prior to breaking the blind?

24 A. 7 May 97.

25 Q. You agree that that's prior to breaking

1 the blind?

2 A. Yes.

3 Q. Okay. Now look at the table.

4 A. Right.

5 Q. What is the date of the table?

6 A. 28 October 97.

7 Q. Okay. Would you agree that is after the
8 breaking of the blind?

9 A. Yes.

10 Q. Okay. So would you agree that of the four
11 computer runs and tables that I've shown you in
12 exhibits, two the computer run and table were after
13 the breaking of the blind? Do you agree with that?

14 MS. CONNELLY: Object to form; no
15 foundation.

16 THE WITNESS: Okay. Run it again. Say it
17 again, please. I'm sorry.

18 BY MR. MURGATROYD:

19 Q. Okay. The CGI score of one or two
20 document computer run and table, right, both had
21 dates after the breaking of the blind, correct?

22 MR. DAVIS: Object to the form; no
23 foundation.

24 THE WITNESS: I'm sorry. Give me the CGI
25 again. Let me get it correct then you can ask me.

1 MR. MURGATROYD: No. I agree.

2 MS. CONNELLY: Is this it?

3 THE WITNESS: Hand me the other two of
4 those, if you wouldn't mind. I'm sorry.

5 MS. CONNELLY: Yes. Aren't there six and
6 not four?

7 MR. MURGATROYD: There's four.

8 MS. CONNELLY: Is this it?

9 THE WITNESS: And there should be one
10 more. So this looks like it's a CGI and the --
11 which one is this? K-SAD-L Depressed Mood Item.
12 Okay.

13 BY MR. MURGATROYD:

14 Q. Okay. Now, so you have before you four
15 computer runs and tables, correct?

16 A. Yes. That is correct.

17 Q. Okay. And they relate to the four
18 variables that you found had statistical
19 significance in favor of Paxil in your paper, right?

20 A. They appear to, yes.

21 Q. Okay. Good. Now the CGI -- got that one?

22 A. Yes, I do.

23 Q. There's a computer run and table --

24 A. Right.

25 Q. -- occur after the blind was broken?

1 MR. DAVIS: Object to the form of the
2 question; it's been asked and answered.

3 THE WITNESS: So 26 June 98 and 30 June
4 98, the dates on both of these are later. I do not
5 know how they're late.

6 BY MR. MURGATROYD:

7 Q. That's fine. After the breaking of the
8 blind. That's all I'm asking?

9 A. The dates on these two documents included
10 in one exhibit are later than the dates we've
11 stipulated as the breaking of the blind.

12 Q. Okay. Now, let's go to K-SADS-L Depressed
13 Mood Item.

14 A. Okay. Sorry it takes me a while here.

15 Q. I think it's the one in your hand.

16 A. Okay. Well, that could be. K-SADS-L Mood
17 Depressed Item. Okay.

18 Q. Okay. Now, is the computer run and table
19 dates both after the breaking of the blind?

20 MR. DAVIS: Object to the form; no
21 foundation.

22 THE WITNESS: The computer run and table
23 dates on these documents are both after the date of
24 breaking of the blind.

25 BY MR. MURGATROYD:

1 Q. Now, in your paper, in your article, did
2 you state, you and your coauthors state that the --
3 these four secondary variables had been declared
4 what is known as A priority?

5 A. Show me a page. I -- they were
6 certainly -- do you want to find the document with
7 that statement for me?

8 Q. No. That's your job, sir.

9 A. Okay.

10 MS. CONNELLY: Take your time, Doctor.

11 THE WITNESS: Okay. I'm not seeing it
12 here. I'm not seeing such a statement.

13 BY MR. MURGATROYD:

14 Q. Do you know what the word A priority
15 means?

16 A. Yes.

17 Q. And what does it mean?

18 A. It means before the fact.

19 Q. Okay. And in terms of medical literature,
20 journal articles, such as the one before you, does
21 that mean that the secondary and primary end points
22 were created or agreed upon prior to the breaking of
23 the blind?

24 A. No. It means prior to looking at the data
25 for that question.

1 Q. Okay. Now, do you recall you being
2 questioned on whether or not the -- any of the end
3 points were included in your paper after the blind
4 were broken?

5 A. I don't recall that.

6 Q. Okay. We'll we're going to go through
7 that document tomorrow.

8 A. Okay.

9 Q. Now, in your -- in the abstract of that
10 paper in front of you, right, the article?

11 MS. CONNELLY: Is that a question?

12 BY MR. MURGATROYD:

13 Q. Yes. I want you to look at it.

14 A. I'm sorry?

15 Q. The abstract right there. It's right in
16 front of you. Do you see that?

17 A. Huh-huh.

18 Q. How many efficacy variables are stated in
19 the abstract?

20 A. I think it talks about five plus two.

21 Q. And that gives you a total of what?

22 A. Seven.

23 Q. Okay. And of that number, how many
24 achieved statistical significance?

25 A. Four of the secondary ones.

1 Q. Okay. Would that indicate that the
2 majority of those seven end points reached
3 statistical significance?

4 A. Yes. Although phrasing it that way would
5 be misleading.

6 Q. Okay.

7 A. Because the abstract is -- that's --
8 that's the abstract trying to emphasize what came
9 out in the study, not the presentation of all the
10 things one looked at or all the things one
11 considered.

12 Q. Okay. So if somebody walked away from
13 that paper thinking that the majority of the end
14 points had reached statistical significance they
15 would be misreading that paper, correct?

16 A. Yes, as they would be misreading most
17 papers. Most secondary end points don't -- you
18 know, the majority of secondary end points wouldn't
19 typically come out significant even in a positive
20 study.

21 Q. Right. I'm just asking: If somebody read
22 your paper and walked away with the idea that the
23 majority of the end points had reached statistical
24 significance in favor of Paxil they would have
25 misread your paper, correct?

1 A. Yes. But the answer again is misleading,
2 because there were a lot of end points not related
3 to depression. We were very clear these were the
4 depression related end points.

5 Q. Okay. Again, doctor, if you just listen
6 to my question. I'm just asking: If a person
7 walked away from that paper believing --

8 A. I just answered your question.

9 Q. Okay. Now, there's seven listed in the
10 abstract. We agreed upon that, right?

11 A. Yes.

12 Q. And how many are listed in the table?

13 A. Basically eight.

14 Q. Okay. And how many of those achieved
15 statistical significance?

16 A. Four.

17 Q. So that would be 50 percent, right?

18 A. Huh-huh.

19 Q. So you couldn't say that a majority
20 reached statistical significance from that table,
21 correct?

22 A. From this table? The majority? No, it
23 was 50/50.

24 Q. Okay. Now, you agree, sir, that that
25 table leaves out a number of predefined secondary

1 variables that did not reach statistical
2 significance, correct?

3 A. Yes, but the table is also not -- the
4 label of the table wouldn't indicate that it would
5 include those. This says, the depression related
6 variables.

7 Q. I understand. I'm just saying that table
8 does not, right, include all the secondary variables
9 that were analyzed --

10 A. I just answered your question.

11 MS. CONNELLY: Asked and answered. He
12 gave you a complete answer.

13 MR. MURGATROYD: Okay. He gives me
14 answers that are ...

15 MS. CONNELLY: In all fairness to the
16 witness you have to allow him to give you a complete
17 and accurate answer. He is under oath.

18 MR. MURGATROYD: Great.

19 MS. CONNELLY: The fact that you don't
20 like his answer doesn't necessarily mean it's
21 improper.

22 MR. MURGATROYD: I don't dislike his
23 answer. I think his answer's fine.

24 BY MR. MURGATROYD:

25 Q. My question was: Does the table include

1 other secondary variables that failed to reach
2 statistical significance?

3 MS. CONNELLY: It's asked and answered.

4 MR. DAVIS: I join in that.

5 BY MR. MURGATROYD:

6 Q. Okay. Does it?

7 A. I'm sorry. Say your question again,
8 please?

9 Q. Does the table include other secondary
10 variables that did not reach statistical
11 significance?

12 A. Does the table include secondary variables
13 that didn't reach significance? Yes.

14 Q. Okay. And how many secondary variables
15 that were analysed that did not reach statistical
16 significance are not in that table?

17 A. I don't know the answer to that.

18 Q. Okay. How many do you know from reading
19 your paper that were not included in that table?

20 A. I'm sorry. I still don't know the answer
21 to your question. I'm sorry. The table was
22 concentrating on the depression specific secondary
23 items.

24 Q. I understand.

25 A. Okay. And your question was about

1 secondary items in general?

2 Q. Correct.

3 A. We looked at a lot of things for secondary
4 analyses that weren't strongly related to depression
5 as well as some related to depression.

6 Q. Okay.

7 A. My paper was only for the depression
8 related ones.

9 Q. Okay. I understand. I'm just asking how
10 many total --

11 A. I told you earlier I didn't know the
12 answer to that.

13 Q. But I'm asking, how many do you know the
14 answer for?

15 A. I don't know.

16 Q. Well, your paper talks about some of them,
17 right?

18 A. Undoubtedly, you're correct.

19 Q. Okay. Do you recall which ones?

20 A. No.

21 Q. Okay. How about the functioning items?
22 Do you discuss the functioning items in your paper?

23 A. Yes.

24 Q. Okay. Did they reach statistical
25 significance?

1 A. No.

2 Q. Okay. So if you're counting all the
3 secondary variables we have eight in your table,
4 correct?

5 A. No. We had -- do we have eight in the
6 table?

7 Q. Yes.

8 A. No. The table has the primary ones as
9 well as the secondary ones.

10 Q. Okay. So all efficacy variables?

11 MR. DAVIS: Object to the form.

12 THE WITNESS: You said that wasn't your
13 question, right?

14 BY MR. MURGATROYD:

15 Q. I understand. I'm correcting my question.
16 All efficacies -- how many -- we have a total of
17 eight efficacy variables in the your table, correct?

18 A. Yes.

19 Q. Okay. And now we have other efficacy
20 variables that you discuss in your paper that failed
21 to reach statistical significance such as the
22 functioning scales, correct?

23 A. Correct.

24 Q. And how many of those were there?

25 A. That's what I'm saying. I don't know

1 offhand, but they were not germane to the table.

2 Q. I understand, Doctor. I'm completely
3 understand what you've said. I'm just asking how
4 many of those are there?

5 A. I don't feel like I can give you an answer
6 that reflects the truth if you interrupt me in the
7 middle of it.

8 Q. Well, I'm asking for the functioning
9 scores? You discussed those in your paper, right?

10 A. We discussed three different functional
11 score outcomes.

12 Q. Okay. And those?

13 A. Those were all negative.

14 Q. Okay. So if you take -- and they were
15 variables, right? Outcome measures that you looked
16 at?

17 A. Yes.

18 Q. Okay. So you had eight in the table and
19 three others that you just discussed, right?

20 A. That's correct.

21 Q. A total of 11 that your paper actually
22 talks about?

23 A. Okay.

24 Q. Okay. And would you agree that the
25 minority of these end points achieved statistical

1 significance in favor of Paxil?

2 MR. DAVIS: Object to the form;
3 misconstrues the data.

4 THE WITNESS: 4 out of the 11 things
5 you're talking about 4 are positive so that would be
6 a minority. Yes, I agree.

7 BY MR. MURGATROYD:

8 Q. Okay. Thank you. Now, when you put that
9 paper together, did you rely on GSK to give you
10 accurate information as to when the variables were
11 first analyzed? Did you rely upon that?

12 MR. DAVIS: Object to the form.

13 THE WITNESS: Not to my knowledge.

14 BY MR. MURGATROYD:

15 Q. Okay. So you confirm -- I think we
16 already discussed this -- you confirmed for yourself
17 when these different efficacy variables were
18 analyzed?

19 A. No.

20 Q. Okay. So then you relied upon GSK as to
21 when these efficacy variables were analyzed, right?

22 MR. DAVIS: Object to the form of the
23 question.

24 THE WITNESS: What do you mean relied upon
25 them to do such and such?

1 BY MR. MURGATROYD:

2 Q. Well, the information regarding when the
3 efficacy variables were performed, analyzed by GSK
4 is information that GSK has, right?

5 A. Yes, but I don't know that there's -- I
6 mean, I don't know that there was any reliance on
7 dates of analyses in the paper.

8 Q. Okay.

9 A. Whoever had the information on that, I'm
10 not sure that the paper relies on dates of analyses.

11 Q. Okay. Do you think your paper, your
12 article, included two secondary variables,
13 specifically the HAM-D Depressed -- I'm sorry -- the
14 K-SADS Depressed Mood item -- K-SADS-L Depressed
15 Mood Item and the CGI score of one or two were
16 secondary variables that were decided to be used in
17 the paper after the blind was broken?

18 MR. DAVIS: Object to the form; asked and
19 answered.

20 THE WITNESS: To the best of my knowledge
21 they were decided ahead of time, but I don't have
22 definitive answers -- I don't have a definitive
23 answer for that one.

24 BY MR. MURGATROYD:

25 A. Okay. So to determine the dates on when

1 those were actually analysed you would rely upon
2 GSK?

3 MS. CONNELLY: Object.

4 MR. DAVIS: Object to the form.

5 THE WITNESS: If I was trying to determine
6 the dates I guess I'd rely on all available
7 information including what GSK had, so.

8 BY MR. MURGATROYD:

9 Q. Okay. And if you wanted to you could call
10 up GSK, Jim McCafferty and say, Jim, I want to know
11 when the CGI score of one or two data was analysed,
12 right? You could do that?

13 A. I'm sorry. Are you asking me if I could
14 call him or are you asking me if he'd give me an
15 answer?

16 Q. I'm asking -- you could call him and ask
17 him, correct?

18 A. I could call and ask him.

19 Q. And you can call and ask him for the same
20 thing regarding the K-SAD-L Mood Depressed Item,
21 correct, the analysis for that?

22 A. Right.

23 Q. Have you ever done that?

24 A. No.

25 Q. Now, would you agree, Doctor, that it

1 would be improper to state that a secondary efficacy
2 variable was predefined, meaning before the breaking
3 of the blind, when, in fact, it was analyzed and
4 agreed upon after the breaking of the blind?

5 A. Predefined would not necessarily be before
6 breaking the blind. It means you have a hypothesis
7 that could be different and you went and looked at
8 it. The secondary analysis traditionally -- the
9 primary analysis are the ones that you say, you
10 know, this is for regulatory purposes ahead of time.
11 The secondary analysis are -- you don't look at
12 everything first and then say this was secondary.
13 You have hypothesis that they should be different,
14 but it would not necessarily always before the
15 breaking of the blind that you looked at data like
16 that.

17 Q. Would you state in the paper discussing
18 the results of the study that, in fact, certain
19 efficacy variables were decided to be included in
20 the paper after the blind was broken?

21 A. Not typically.

22 Q. Isn't that called post-hoc?

23 A. No. Post-hoc is you look at 30 things in
24 an unstructured way and then you say this one came
25 out positive.

1 Q. Yes.

2 A. So the answer to your question I think was
3 no.

4 Q. Okay. Did, to your knowledge, GSK decide
5 after the blind was broken which secondary variables
6 would be included in your paper?

7 A. Not to my knowledge. I do not know
8 whether they were decided before or after the blind
9 was broken.

10 Q. Okay. Now, in your paper 329, in the
11 abstract portion there is a part called a
12 conclusion, right?

13 A. Correct.

14 Q. And could you please read the conclusion
15 into the record.

16 A. Let's see.

17 Q. It's the last sentence of the abstract.

18 A. "Conclusions: Paroxetine is generally
19 well tolerated and effective for major depression in
20 adolescents."

21 Q. Okay. Now, are you aware of the different
22 statements by GSK, the FDA, and other regulatory
23 bodies that dispute that finding?

24 MS. CONNELLY: Object to the form.

25 MR. DAVIS: Object to form. Excuse me.

1 Dispute what finding?

2 MR. MURGATROYD: That conclusion. Thank
3 you for correcting me.

4 MR. DAVIS: What conclusion?

5 MR. MURGATROYD: The conclusion he just
6 read into the record.

7 MR. DAVIS: I'm sorry. I didn't hear a
8 conclusion read into the record.

9 MR. MURGATROYD: Do you want him to read
10 it again?

11 MR. DAVIS: Sure.

12 BY MR. MURGATROYD:

13 Q. Doctor, can you read the conclusion again,
14 please?

15 A. "Paroxetine is generally well tolerated
16 and effective for major depression in adolescents."

17 Q. Okay. Now my question is: Are you aware
18 of the various, if any, documents produced, created
19 by GSK and regulatory bodies around the world that
20 dispute that conclusion?

21 A. I'm aware of the GSK document you showed
22 me earlier today. I'm aware of the FDA analyses.

23 Q. Okay.

24 A. That's however not a complete answer.

25 Q. All right.

1 A. Because this was the best available data
2 at the time this was published. Two subsequent
3 negative studies change your assessment of the
4 efficacy of the compound overall.

5 Q. Okay. Let's go to the next document. Let
6 me ask you this: Do you claim that your study 329
7 was conclusively proved that Paxil was effective in
8 the treatment of adolescent depression?

9 A. No.

10 Q. Do you contend that is a signal or
11 suggestive of efficacy?

12 A. Yes. That was the best data on Earth when
13 we published that and it was a signal for efficacy.
14 It was certainly far from conclusively proving it
15 since that requires replication.

16 Q. Okay. Now let's take a look at -- let's
17 take a look at this one.

18 (Ryan Deposition Exhibit No. 23
19 was marked for identification.)

20 MS. CONNELLY: Plaintiffs Exhibit 23
21 appears to be a European "Dear Healthcare
22 professional" document two pages long.

23 BY MR. MURGATROYD:

24 Q. Okay?

25 A. Okay.

1 Q. And do you know what Seroxat is?

2 A. That's a name in parts of Europe for
3 paroxetine.

4 Q. Okay. And are -- you're familiar with
5 "Dear Healthcare Professional" letters are?

6 A. In the general case, yes, in the specific
7 case of how they're used in Europe, no.

8 Q. Generally, you know what -- they're sent
9 to doctors?

10 A. Yes.

11 Q. Okay. And can you read the first -- I'm
12 sorry, the second paragraph into the record?

13 A. "A recently completed programme of
14 clinical trials in children and adolescents under 18
15 years of age failed to demonstrate efficacy in Major
16 Depressive Disorder and there was a doubling of the
17 rate of reporting of adverse events in the
18 paroxetine group compared with placebo, including
19 decreased appetite, tremor, sweating, hyperkinesia,
20 hostility, agitation, emotional lability, (including
21 crying, mood fluctuations, self-harm, suicidal
22 thoughts and attempted suicide)."

23 Q. Okay. Now, do you disagree with the
24 statement that a recently completed program of
25 clinical trials in children and adolescents under 18

1 years of age failed to demonstrate efficacy in major
2 depressive disorder?

3 MR. DAVIS: Object to the form.

4 THE WITNESS: No, I do not disagree.
5 There was in the first trial, as we correctly
6 pointed out, a signal for efficacy. There was two
7 subsequent trials without evidence and so
8 aggregating them up I think that's a fair enough
9 statement.

10 MR. MURGATROYD: Okay.

11 (Ryan Deposition Exhibit No. 24
12 was marked for identification.)

13 MS. CONNELLY: Plaintiffs Exhibit 24
14 appears to be a GKS document subject to the
15 protective order titled "Summary of Product
16 Characteristics."

17 MR. DAVIS: Yes. Thank you.

18 BY MR. MURGATROYD:

19 Q. Doctor, I know it's a longer document. To
20 save you time I'm going to refer you to the -- well,
21 the third page is probably the easiest and it's
22 under the section entitled "Children and
23 Adolescents."

24 A. Okay.

25 Q. Okay. Can you read that into the record,

1 please?

2 MS. CONNELLY: What's the date? Do we
3 have a date on this document just not having seen it
4 before.

5 MR. DAVIS: Maybe at the end.

6 MR. MURGATROYD: No. Actually, the date's
7 not in here. It has a date of the vision, the text.
8 It doesn't have a date.

9 THE WITNESS: I'm not finding a date.

10 BY MR. MURGATROYD:

11 Q. Okay. Now, let's --

12 A. I'm sorry. You had asked me to --

13 Q. Yes. We're going to the third page under
14 Children and Adolescents. Do you see that? Can you
15 read that paragraph into the record, please.

16 A. "Controlled clinical studies failed to
17 demonstrate efficacy and do not support the use of
18 paroxetine in the treatment of children and
19 adolescents with Major Depressive Disorder."

20 Q. Okay. And do you agree with that
21 statement, sir?

22 MR. DAVIS: Object to the form of the
23 question.

24 THE WITNESS: I think that this is the
25 correct interpretation when we aggregate the three

1 studies together that they do not reach the level of
2 proof to support using this compound.

3 BY MR. MURGATROYD:

4 Q. Okay. And the document before you relates
5 to Paxil, right?

6 A. I'm sorry. This document relates to
7 Paxil.

8 Q. Okay. I'll show you the next document.

9 MS. CONNELLY: Does that say 25?

10 MR. MURGATROYD: It should. My
11 handwriting's not that good. I can tell you that.

12 (Ryan Deposition Exhibit No. 25
13 was marked for identification.)

14 MS. CONNELLY: Plaintiffs Exhibit 25
15 appears to be an internal GSK document subject to
16 the protective order labeled as "Appendix 1." I
17 didn't check for a date on it.

18 THE WITNESS: November '03.

19 BY MR. MURGATROYD:

20 Q. Okay. And, Doctor, if you would turn to
21 the fourth page of the document under "Special
22 Warnings" and particularly "Precautions for use."
23 Do you see that?

24 A. "Special Warnings" and "Precautions for
25 use." Yes, I see that.

1 Q. Okay. And do you see the second paragraph
2 "in addition", Do you see that?

3 A. Yes.

4 Q. And can you read that into the record.

5 A. "In addition, during three clinical trials
6 carried out on children and adolescents", and then
7 the first bullet: "Paroxetine was not more
8 effective than the placebo in the treatment for the
9 major depressive episodes."

10 Q. Okay. let's stop there.

11 A. Okay.

12 Q. Do you agree with that statement?

13 A. No.

14 Q. Do you think GSK is not providing a
15 truthful statement in this document?

16 MR. DAVIS: Object to the form. He can't
17 characterize the intent or the nature of the
18 document or the statement from GlaxoSmithKline.

19 BY MR. MURGATROYD:

20 Q. Well, do you think that statement is
21 incorrect?

22 A. I think that that statement would be the
23 negotiation of a company with a regulatory body
24 saying did it meet -- for example, did it meet the
25 FDA's criteria for efficacy? It did it not. Does

1 it have an indication of efficacy? It does. So
2 saying that it wasn't more effective by the
3 regulatory definitions would be correct. Saying it
4 was not more effective by how I would define it and
5 how he described it would be incorrect.

6 Q. Okay. I'm going to strike your answer as
7 nonresponsive to my question. My questions was
8 simply --

9 MS. CONNELLY: He asked and answered your
10 question fully.

11 MR. MURGATROYD: No, he didn't fully
12 answer the question.

13 MS. CONNELLY: You have to allow the
14 witness an opportunity to testify truthfully. He
15 gave you a complete answer to that question.

16 MR. MURGATROYD: I understand. If you
17 think that's true I disagree and I move to strike
18 and we'll let the court decide. That's why we have
19 judges.

20 MR. DAVIS: But here's the problem. You
21 don't get to go and ask the question again. I mean,
22 you don't get to go back multiple times and get
23 multiple attacks at him when he's giving you a full
24 response. I don't think that's fair to the witness.
25 That's not part of the process.

1 MR. MURGATROYD: It's simple, Todd. I
2 move to strike it. If you want to use this
3 statement at trial you can see if you can get my
4 objection overridden. That's all. It's not a
5 complicated fact.

6 MR. DAVIS: Fine. And then you can move
7 on to another question, because that's the answer.

8 MR. MURGATROYD: I will do what I want to
9 do as you know I always do.

10 MS. CONNELLY: Well, I represent Dr. Ryan
11 and that's not necessarily going to be the case in
12 this deposition.

13 MR. MURGATROYD: Well, you can certainly
14 state your objections for the record and the court
15 will certainly rule on them. I can tell you that.

16 MS. CONNELLY: I understand that the judge
17 in Philadelphia is used to your phones calls, but I
18 except that he would side with the witness in being
19 allowed an opportunity for a fair and complete
20 answer.

21 MR. MURGATROYD: We'll let the court
22 decide. That's why we have judges.

23 MR. DAVIS: Can I see that last document?

24 THE WITNESS: Here it is.

25 MR. DAVIS: Thanks, Dr. Ryan.

1 MR. MURGATROYD: Okay. Let's take a look
2 at this next document. Let me keep my copy. I
3 think there's one page that belongs to me on that.

4 MS. CONNELLY: This has two pages.

5 MR. MURGATROYD: Oh, actually, add these.
6 That's the whole document. I don't want to give him
7 an incomplete document.

8 (Ryan Deposition Exhibit No. 26
9 was marked for identification.)

10 MS. CONNELLY: Plaintiffs Exhibit 26 looks
11 like another GSK document subject to the protective
12 order. It's entitled the "Department of Health
13 Press Release. June 10, 2003."

14 BY MR. MURGATROYD:

15 Q. Okay. And can I see that document for one
16 second, sir?

17 A. Okay.

18 Q. Can you please read the second paragraph
19 into the record, please.

20 A. Yes: New expert advise recommends that
21 the drug Seroxat (paroxetine) is not to be used to
22 treat children and teenagers under the age of 18
23 years for depressive illness, said Professor
24 A-L-A-S-D-A-I-R, Alasdair Breckenridge, Chairman of
25 the Medicines and Healthcare Products Regulatory

1 Agency.

2 Q. Okay. Keep reading.

3 A. I'm sorry. New paragraph. "New data
4 received within the last two weeks, has been
5 evaluated and considered by the Committee on Safety
6 of Medicines, (csm), and its Expert Working Group on
7 SSRIs. It shows that there is an increase in the
8 rate of self harm and potentially suicidal behaviour
9 in this age group when Seroxat is used for
10 depressive illness. It has become clear that the
11 benefits of Seroxat in children, for the treatment
12 of depressive illness, do not outweigh these risks."

13 Q. Okay. Do you agree with that statement,
14 sir?

15 A. I think the data is insufficient to say
16 that the statement's correct.

17 Q. Okay. Well, do you agree that the risks
18 of Paxil in the use of kids with major depressive
19 disorder -- strike that -- let me start again.

20 Do you agree that the risks outweigh the
21 benefit for kids who take Paxil for the treatment of
22 depressive disorder?

23 A. By kids, you mean what group?

24 Q. Less than 18.

25 MR. DAVIS: Object to the form.

1 THE WITNESS: Okay. I think there's
2 insufficient data to say that. I do not agree.

3 BY MR. MURGATROYD:

4 Q. So you disagree with that statement in
5 that document, correct?

6 A. That's correct.

7 Q. Okay. And so you think health agencies
8 have access to more data than you do concerning a
9 drug?

10 A. That's a sneaky question. I think that
11 they have access to more data, but not
12 necessarily -- I don't think that necessarily makes
13 them right and my opinion wrong. I think that
14 there's a lot more thing to weigh and there's also
15 more data since this came out that was included in
16 my answer about whether this statement was correct.
17 You asked, is this statement correct now, right?

18 Q. I just asked.

19 A. There's a lot more data that's come out
20 since they made this statement.

21 MR. MURGATROYD: Okay. Let's look at the
22 next document.

23 (Ryan Deposition Exhibit No. 27
24 was marked for identification.).

25 MS. CONNELLY: Plaintiffs Exhibit No. 27

1 is another document subject to the protective order
2 titled: "FDA Talk Paper" dated June 19, 2003.

3 BY MR. MURGATROYD:

4 Q. Okay. Have you seen this document before
5 today?

6 A. Can you tell me whose document this is? I
7 don't know that I've seen it. I don't know that I
8 haven't. Is this a FDA document? Is this a SKB
9 document?

10 Q. That is a FDA document with an SKB stamp
11 across it.

12 A. Okay. So this was an FDA statement of
13 June 2003. I don't remember this specifically, but
14 I certainly knew that the FDA was looking at this
15 question so quite possibly I saw it before. I can't
16 recall specifically.

17 MR. MURGATROYD: Okay. Can I see the
18 document briefly?

19 THE WITNESS: Yes.

20 VIDEOGRAPHER: Can we go off the record to
21 change tapes?

22 MR. MURGATROYD: Yes, please.

23 VIDEOGRAPHER: At this time we're going
24 off the record. The time is 2:41 p.m.

25 (Recess taken.)

1 VIDEOOPERATOR: We are now back on the
2 record. This is the beginning of Tape No. 4 of the
3 deposition of Dr. Neal Ryan. The time is 2:48 p.m.
4 Please proceed.

5 (Ryan Deposition Exhibit No. 28
6 was marked for identification.)

7 MR. MURGATROYD: Okay. Let's take a look
8 at the next exhibit, please.

9 MS. CONNELLY: Exhibit 27 does not have a
10 bates number. It's a Questions and Answers document
11 three or four pages long.

12 MR. DAVIS: I thought 27 was the FDA
13 document. Are we not?

14 MS. CONNELLY: Let's double check.

15 MR. MURGATROYD: Oh, I'm sorry. Wait.
16 You're right. That was.

17 MS. CONNELLY: Wait. Where'd that go?

18 MR. MURGATROYD: It's right here. I
19 thought that I had not used that one yet. So that's
20 27. Can you mark that one 28 or I will?

21 MS. CONNELLY: Sure.

22 MR. MURGATROYD: Great. Thanks. So let's
23 put that in the pile.

24 MS. CONNELLY: Here's 28 for you.

25 BY MR. MURGATROYD:

1 Q. And this document is entitled "Questions
2 and Answers, New advise on Seroxat", and I think
3 we've agreed that that is Paxil, right?

4 A. Yes.

5 Q. From the Committee on Safety of Medicines.
6 Do you see that at the top?

7 A. Yes, I do.

8 Q. And do you see the question 1? What is
9 the new advise?

10 A. Yes.

11 Q. And can you please read that into the
12 record.

13 A. "New advise from the government's
14 independent scientific advisory committee. The
15 Committee on Safety of Medicines (CSM) is that
16 Seroxat should not be used in children and
17 adolescents under the age of 18 for the treatment of
18 depressive illness. This new advise follows the
19 receipt of new data in children under 18, which
20 shows no benefit in the treatment of depressive
21 illness and suggests an increase in the rate of
22 reporting of suicidal thoughts and behaviours in
23 this age group when treated with Seroxat."

24 Q. And you'll see the part that says no
25 evidence of -- shows no benefit in the treatment of

1 depressive illness? Did I say that right? Did I
2 quote that right?

3 MS. CONNELLY: Can you restate that? I
4 think the record might be messy.

5 MR. MURGATROYD: Okay. That's fine.

6 BY MR. MURGATROYD:

7 Q. Do you see it says "No benefit in the
8 treatment of depressive illness." Did I read that
9 right?

10 A. Yes, you did.

11 Q. Okay. And do you contend that this
12 Committee on Safety and Medicine has got that wrong?

13 MR. DAVIS: Object to form.

14 THE WITNESS: I disagree with that
15 conclusion, yes.

16 (Ryan Deposition Exhibit No. 29
17 was marked for identification.)

18 MR. MURGATROYD: Okay. Let me show you
19 what I've marked as Exhibit 29.

20 MS. CONNELLY: Plaintiffs Exhibit 29 is a
21 voluminous document subject to the protective order
22 produced by GSK entitled "Pediatric Advisory Panel
23 Meeting June 10, 2003."

24 BY MR. MURGATROYD:

25 Q. Okay. Now, do you want to take the time

1 to look through that document?

2 MS. CONNELLY: Would you like the witness
3 to read the whole thing?

4 MR. MURGATROYD: I just want to see if he
5 has any familiarity with it, and I think --

6 BY MR. MURGATROYD:

7 Q. Were you present at that presentation?

8 A. No.

9 Q. Okay. Were you aware of that meeting?

10 A. Yes.

11 Q. Okay. And what is the date of that
12 meeting?

13 A. June 10, 2003.

14 Q. Okay. And how were you aware of it?

15 A. Because I was on the FDA
16 psychopharmacology Advisory Committee at the time
17 and the FDA decided I was in conflict for this
18 meeting.

19 Q. I think you have them confused.

20 MR. DAVIS: I agree.

21 THE WITNESS: Okay. Sorry.

22 MR. DAVIS: No. There's a lot for --

23 THE WITNESS: Which meeting is this?

24 BY MR. MURGATROYD:

25 Q. Well, that's what we're going to try and

1 sort out. What's the date of the document?

2 A. June 10, 2003.

3 Q. And what's the title of the document?

4 A. Pediatric Advisory Panel Meeting.

5 Q. Okay. And that, I will tell you, and I
6 think Counsel will agree is a GSK document
7 concerning a GSK meeting.

8 A. So this was an internal GSK meeting with
9 Pediatric Advisory?

10 Q. Okay.

11 A. My apologies for being confused.

12 Q. No problem.

13 A. Okay.

14 Q. My question is: Did you attend that
15 meeting?

16 A. I do not know.

17 Q. Does that mean you don't recall or?

18 A. I don't recall.

19 Q. Okay. Can you turn to the last page of
20 that document? I'm sorry, on the second to last
21 page, and can you read the last sentence in the last
22 paragraph into the record.

23 A. "Controlled clinical trials did not
24 provide evidence of efficacy and do not support the
25 use of Paxil in the treatment of pediatric patients

1 with major depressive disorder."

2 Q. Okay. And do you agree with GSK's
3 statement there?

4 A. Not in -- no.

5 Q. Okay.

6 A. Well, I'm sorry. That's an incomplete
7 answer. I agree with the part that they do not
8 support for regulatory purposes use of compounds in
9 adolescents and children, because they didn't meet
10 the threshold for that. I do not agree with the
11 portion that it did not provide evidence for
12 efficacy. It provided some.

13 Q. Okay. Let's take a look at the next
14 document

15 (Ryan Deposition Exhibit No. 30
16 was marked for identification.)

17 Q. Okay. Let's look at the next one.

18 MS. CONNELLY: Plaintiffs Exhibit 30 is a
19 GSK produced document subject to the protective
20 order titled "Statistical Review."

21 MR. DAVIS: Yes. That's a publicly
22 available document. That was inadvertently stamped.
23 That's publicly available so that's not subject to
24 the protective order.

25 MS. CONNELLY: Okay.

1 BY MR. MURGATROYD:

2 Q. Have you had a chance to review that
3 document?

4 A. I scanned briefly the front page.

5 Q. Okay. You may want to look through the
6 whole thing. Well, actually maybe you don't. Are
7 you familiar with that document?

8 A. No, I'm not.

9 Q. Okay. You've never seen it before?

10 A. Not to my memory.

11 Q. Okay. I think you might want to take the
12 time to read the portion on study 329.

13 THE WITNESS: Do you happen to know the
14 page it's on otherwise it'll take --

15 MR. MURGATROYD: I think it's the fourth
16 page, but it might be the third.

17 THE WITNESS: Okay.

18 MR. MURGATROYD: Why don't we go off the
19 record and give the Doctor a chance to read this.

20 VIDEOGRAPHER: At this time we're going
21 off the record. The time is approximately 2:56 p.m.

22 (Pause in Proceedings.)

23 VIDEOOPERATOR: We are now back on the
24 record. The time is now approximately 2:58 p.m.
25 Please proceed.

1 BY MR. MURGATROYD:

2 Q. Doctor, when we were off the record, did
3 you get a chance to look at that document?

4 A. Yes.

5 Q. Okay. Can you identify for the record
6 what that document is, please.

7 A. This document says confidential to --
8 let's see -- produced by -- no -- I'm sorry. So it
9 says "Pediatric Exclusivity Supplement". It's a
10 report that appears to be by Andy Mosholder, an
11 M.P.H.D, an employee of the FDA. It looks like a
12 ruling on a pediatric exclusivity supplement for
13 Paxil.

14 Q. Okay.

15 MS. CONNELLY: Excuse me. Do you want --
16 to take a break?

17 MR. MURGATROYD: Do you want to take a
18 minute off to get some drinks?

19 THE WITNESS: Yes.

20 VIDEOGRAPHER: We're now going off the
21 record.

22 (Pause in Proceedings.)

23 VIDEOGRAPHER: We're now back on the
24 record. The time is approximately 3:00 p.m. Please
25 proceed.

1 BY MR. MURGATROYD:

2 Q. Okay. How are you doing?

3 A. Good. Thank you.

4 Q. Okay. Good. Now, you were identifying
5 that document for the record, correct?

6 A. That's correct.

7 Q. And does it have a date?

8 A. The date is -- well, it's got three dates.
9 It says, date submitted 4-11-02, PDUFA due date
10 10-11-02 and review completion date 10-7-02. I
11 assume this is -- I assume the date this was
12 produced was the completion date.

13 Q. Okay. And, again, that was in 2002?

14 A. Yes.

15 Q. And do you know who Andrew Mosholder is?

16 A. I know Dr. Mosholder.

17 Q. Okay. And who is he?

18 A. He is an FDA employee. I don't know his
19 official title or position. He had worked in the
20 psychopharmacology group.

21 Q. Okay. Is he a competent person, to your
22 knowledge?

23 A. To the best of my knowledge.

24 Q. Okay. And he has a section of the paper
25 that discusses study 329, correct?

1 A. Yes.

2 Q. And he has a conclusion regarding his
3 review of 329?

4 A. Yes.

5 Q. And can you read that into the record,
6 please.

7 A. "Although there was some evidence of
8 activity of paroxetine on the secondary outcome
9 measures, the paroxetine treatment group did not
10 separate statistically from placebo on the a priori
11 primary efficacy measures in this trial. There was
12 not evidence that imipramine was more effective than
13 placebo in this trial. On balance, this trial
14 should be considered as a failed trial, in that
15 neither active treatment group showed superior over
16 placebo over by a statistically significant margin".

17 Q. Okay. And do you agree with Dr.
18 Mosholder's analyses?

19 A. In parts yes; in parts no.

20 Q. Now, in -- with regard to the adverse
21 events that occurred during the statistical trial
22 329?

23 A. Yes.

24 Q. Whose responsibility was it to analyze the
25 data of those adverse events?

1 A. The first analyses was done by GSK and
2 presented to the investigators. Subsequent analyses
3 were done by the FDA in the past couple of years
4 done by Columbia University so they've been done
5 twice.

6 Q. Okay. Buy my question was: With regard
7 to the study?

8 A. GSK.

9 Q. Okay. Yes. The answer is?

10 A. The answer was GSK.

11 Q. Okay. Great. Could you, as an individual
12 investigator, do a complete analyses of all the
13 serious adverse events that occurred during the
14 clinical trial?

15 MR. DAVIS: Object to the form.

16 THE WITNESS: I did not have the data set
17 for the entire thing so I separately would not have
18 been able to do that.

19 BY MR. MURGATROYD:

20 Q. Okay. And would that be the same for each
21 of your fellow investigators?

22 A. To the best of my knowledge.

23 Q. Okay. Would you agree that you relied
24 upon GSK to do a proper analyses of the safety data
25 regarding 329?

1 A. Yes.

2 Q. And with regard to your particular study,
3 you're aware that there was a risk ratio of 5.9 with
4 regard to possible suicide events related to kids
5 taking Paxil versus those kids taking the placebo,
6 correct?

7 A. There were a number of analysis and
8 questions similar to that one. Can you show me the
9 data that showed you the 5.9?

10 Q. Yes.

11 A. Because there's a whole bunch of different
12 analyses of that equation.

13 MR. MURGATROYD: Let's go off the record.

14 VIDEOGRAPHER: We're going off the record.
15 The time is approximately 3:04 p.m.

16 (Pause in Proceedings.)

17 VIDEOGRAPHER: We are now back on the
18 record. The time is approximately 3:08 p.m. Please
19 proceed.

20 (Ryan Deposition Exhibit No. 31
21 was marked for identification.)

22 BY MR. MURGATROYD:

23 Q. Doctor, do you see the document that I
24 presented you with is a series of e-mails between
25 GSK and the FDA?

1 A. Yes.

2 Q. Okay. And do you see the reference to the
3 329 trial?

4 A. Yes.

5 Q. Okay. And do you see the section that
6 talks about "Possibly Suicide Related"?

7 A. Yes.

8 Q. Okay. And what is the risk ratio of Paxil
9 versus placebo with regard to possibly suicide
10 related events?

11 A. What it says here is 5.9.

12 Q. And can you explain to the jury what a
13 risk ratio is?

14 A. Yes. A risk ratio would be the -- the --
15 the ratio. The division of one risk by the other
16 express a percentage.

17 Q. Okay. How does that relate to people?

18 A. It says that the one number's higher than
19 one, suggests there's more risk with the course on
20 the numerator and less than one -- or less than one
21 to suggest that there's more risk with a course on
22 the denominator, but without a confidence interval
23 you don't know whether that's significantly
24 different than the rest.

25 Q. I understand. If you had to explain this

1 term to a lay person, what would you tell them a
2 risk ratio means?

3 MS. CONNELLY: Asked and answered.

4 BY MR. MURGATROYD:

5 Q. Put into term, but do you think a lay
6 person could just understand your statement?

7 A. I will try again. It's the raw number
8 that gives you the single estimate of the ratio of
9 the -- I mean, you know, the product of division.
10 If one can't understand that it's hard to explain
11 the entirety of the two numbers; obviously, the risk
12 ratio presented as a number alone you have no idea
13 whether it's statistically significant or not.

14 Q. I understand that. But just as a risk
15 ratio? I'm just trying to?

16 A. I think I've answered that one before.

17 Q. Well, let me ask you this: Does it mean
18 that a child who took Paxil in your study 329 was
19 five times more likely than a child who took placebo
20 in your study to experience a possible suicide
21 related event?

22 MR. DAVIS: Object to the form.

23 THE WITNESS: Not necessarily. This means
24 on one analyses on the way that the FDA was looking
25 at it they were saying it was that many more times

1 likely.

2 BY MR. MURGATROYD:

3 Q. Okay.

4 A. But there's a question of whether that was
5 statistically significant, and there's a question
6 of -- this as analyzed a whole bunch of ways and I
7 cannot tell you which analyses this particular one
8 was.

9 Q. Okay. Again, that wasn't my question. My
10 question was -- I'm just trying to understand, and I
11 want the jury to understand what a risk ratio is.
12 That's the only purpose of my question.

13 THE WITNESS: Could you read back the
14 question again because there seemed like there was
15 more in there and I was trying to answer the whole
16 question. It seems like you're asking me about the
17 specific one and not the ratio.

18 MR. MURGATROYD: Let's see if she can read
19 it back.

20 (Record read.)

21 BY MR. MURGATROYD:

22 Q. Let's goes down to the next section that
23 talks about suicide attempts. Do you see that?

24 A. Yes.

25 Q. And what percentage of the kids taking

1 Paxil in study 329 experienced a suicide attempt?

2 A. That's a different question than anything
3 related to this document.

4 Q. Okay. Well, what does -- where it says
5 drug 5.4 percent, what does that mean?

6 A. Right. There -- you're going to have to
7 refer me -- I mean, this document doesn't explain
8 about which group they're including in suicide
9 attempts, from later data and analyses that turned
10 out to be a really hard question and so this --

11 Q. I'm just asking --

12 A. No. I'm sorry. You asked me what --

13 Q. I'm just trying to figure out what the 5.4
14 means? What does it mean?

15 MS. CONNELLY: Object to form; he didn't
16 create this document.

17 BY MR. MURGATROYD:

18 Q. All right. If you know? If you don't
19 know that's fine, you can say so.

20 A. I was -- there were a number of different
21 analyses so you asked me what the 5.4 percent meant
22 in this study, not in this document, and I was
23 trying to answer your question. Do you want to ask
24 me a new question?

25 Q. What does in this document -- do you

1 understand the percentage of 5.4 for people -- kids
2 taking Paxil with regard to suicide attempts?

3 A. Yes. By some method of looking at suicide
4 attempts my understanding in this document is that
5 by measures of looking at suicide attempts, and
6 there were many in the analyses that were done
7 subsequent to this and during this time, there was
8 5.4 percent of these subjects it says on drugs, and
9 I assume that's just on Paxil, but that could be
10 Paxil plus imipramine.

11 MS. CONNELLY: I'm very late on this, but
12 I just wanted to object to kids. I think the study
13 was just on adolescents.

14 MR. MURGATROYD: I think we made it clear
15 in the beginning when I say the terms kids I mean
16 children and adolescents.

17 THE WITNESS: Yeah, though.

18 MR. MURGATROYD: Anybody under 17. That's
19 how I'm using kids.

20 THE WITNESS: No. It's a good point. So
21 adolescents on this one. This study didn't include
22 children. So this was an adolescent study and it's
23 looking like that by some analyses there was a 5.4
24 percent rate, and it says drugs, and I do not know
25 whether that's in the imipramine group, the Paxil

1 group or both combined. The placebo group had zero
2 percent. It says risk ratio, hyphen, meaning you
3 couldn't calculate it.

4 BY MR. MURGATROYD:

5 Q. And what does that -- that's the next
6 question. What does it mean you can't calculate it?

7 A. Because you would be dividing by zero.

8 Q. Okay. So there's no way of -- if you have
9 hypothetically a trial of 100 people and it's a
10 placebo controlled trial, 100 in each arm, right?
11 100 people on Paxil, 100 people on placebo, and 50
12 of the people in the Paxil group tried attempt
13 suicide and zero in the placebo group attempted to
14 commit suicide, can you not create a risk ratio
15 because of the fact of that zero?

16 MR. DAVIS: Object to the form.

17 THE WITNESS: That's correct. That's
18 correct. You would not have a value for the risk
19 value simply mathematically.

20 BY MR. MURGATROYD:

21 Q. So, but if you had one person on placebo
22 who did try attempted suicide, you would be able to
23 create a risk ratio based on the 50 versus one,
24 correct?

25 A. That's correct.

1 Q. Now, you personally have looked into the
2 issue of Paxil's association with suicidality in
3 kids taking the drug, correct?

4 A. We did that in the paper and we did that
5 in one of the letters to the editor following it.

6 Q. Okay. Now, I understand that, but you
7 personally have investigated the issue of kids and
8 the percentage of kids, and the risk ratio of Paxil
9 kids experiencing a suicide event versus placebo
10 kids experiencing a suicide event, right?

11 A. What I have done, to the best of my
12 knowledge, is published in the original article plus
13 the responses to the letters.

14 Q. Well, what about the research you did with
15 regard to what is now known as the Apter article?

16 A. Give me the article and let me look at it.
17 I can tell you, please.

18 VIDEOGRAPHER: Go off the record?

19 MR. MURGATROYD: Yes. Go off and I can
20 print it out.

21 VIDEOOPERATOR: At this time we're going
22 off the record. The time is 3:16 p.m.

23 (Recess taken.)

24 VIDEOGRAPHER: We're now back on the
25 record. The time is approximately 3:35 p.m. Please

1 proceed.

2 (Ryan Deposition Exhibit No. 32
3 was marked for identification.)

4 BY MR. MURGATROYD:

5 Q. Doctor, while we were off the record I
6 handed you what I've marked as Exhibit 32, correct?

7 A. Yes.

8 Q. Can you identify for the record what that
9 document is?

10 A. It's e-mail correspondence and then a
11 draft manuscript of a manuscript entitled
12 "Paroxetine Pediatric Suicidality Manuscript."

13 Q. Okay. And were you part of that e-mail
14 chain?

15 A. I was.

16 Q. Okay. Do you recognize that document?

17 A. Yes.

18 Q. And does it appear to be authentic?

19 A. As far as I can tell.

20 Q. Okay. And did you receive it in the
21 ordinary course of your business?

22 A. I'm sorry?

23 Q. Did you receive it in the ordinary course
24 of your business?

25 A. I apologize. I have no idea what you

1 mean.

2 Q. Okay. You received it, right?

3 A. It came to my e-mail at work, yes.

4 Q. Okay. Great. And attached to that
5 document is a manuscript, correct?

6 A. Yes.

7 Q. And what is the title of that manuscript?

8 A. "Evaluation of Suicidal Thoughts and
9 Behaviors in Children and Adolescents taking
10 Paroxetine."

11 Q. Okay. And who are the listed authors?

12 A. The listed authors are Karen
13 Dineen-Wagner, Neal Ryan, David Shaffer, Regan Fong,
14 David Carpenter, Erica Wetherhold, Philip Perera,
15 John Davies and Alan Lipschitz.

16 Q. Okay. And of all those authors you just
17 read, how many would be considered external to GSK?

18 A. Three to my knowledge; myself, Dr. Wagner
19 and Dr. Shaffer.

20 Q. Okay. And Dr. Wagner also was involved in
21 study 329, correct?

22 A. That's correct.

23 Q. She had a site in Texas?

24 A. Yes.

25 Q. Okay. And Dr. Shaffer? Who is Dr.

1 Shaffer?

2 A. He's a child psychiatrist and director of
3 the division of child psychiatry at Columbia
4 University.

5 Q. Okay. And who prepared that manuscript
6 that you're looking at right now?

7 A. It was one of the GSK authors. I'm not
8 sure who lead the preparation.

9 Q. Okay.

10 A. To the best of my knowledge.

11 Q. And when, if you recall, were you asked to
12 participate in drafting up and publishing this
13 article?

14 A. I was asked to participate in a blinded
15 evaluation of the GSK suicide data maybe about a
16 year before this draft.

17 Q. Okay. And what's the date of that draft
18 again, I'm sorry?

19 A. The date is September 25, 2003.

20 Q. Okay. So you believe you were asked to
21 participate in September of 2002?

22 A. Approximately a year. I couldn't say. I
23 don't know. Approximately a year is the best I can
24 do.

25 Q. Okay. Sometime in 2002?

1 A. My best guess.

2 Q. Okay. I don't want you to guess. I want
3 an estimate. Is that a best estimate?

4 MR. DAVIS: Object to form.

5 THE WITNESS: I thought I said that
6 before.

7 BY MR. MURGATROYD:

8 Q. Okay. Well, there's a difference between
9 a guess and an estimate.

10 A. Well, it's my best estimate. I thought I
11 said that.

12 Q. Okay. That's fine. And who contacted you
13 to get involved in this -- is this a project that
14 you were involved in? Is that how you would
15 describe it?

16 A. Sure. That would be a fine description.

17 Q. Okay.

18 A. I believe it was Dr. Kong or Dr.
19 Carpenter. Probably Dr. Carpenter.

20 Q. Okay. And how was it presented to you?

21 A. That they wanted to -- that they knew that
22 the FDA was doing a blinded analysis and they wanted
23 to do the right analysis of their suicidality data.
24 In all of these studies there --

25 Q. Let me stop you there just for one second.

1 Suicide data just related to kids, right?

2 MR. DAVIS: Object to form.

3 THE WITNESS: To children and adolescents
4 yes, and the problem was that in all of the studies
5 that industry had done and certainly the ones, to
6 the best of my knowledge, that GSK done and
7 certainty in the study 329 there were not a lot of
8 systematic questions on suicidality, and so there
9 were some questions on suicidality in the
10 instruments and those didn't come out significantly
11 different or even a trend in difference between the
12 two groups. What they had was some -- the adverse
13 events, which were coded ambiguously and they were
14 hard to decode which were related to suicide and
15 which weren't.

16 BY MR. MURGATROYD:

17 Q. Okay.

18 A. So they wanted to do a blinded review to
19 see which were fair and square suicide and which
20 were something else to see whether or not there was
21 more suicidality with the Paxil.

22 Q. Okay. And it turns out that there was --
23 we're going to get into that in more detail, but
24 there was more suicidality with Paxil after you
25 completed that review, correct?

1 MR. DAVIS: Object to form.

2 THE WITNESS: I didn't actually complete
3 this because the FDA analysis came out before -- the
4 FDA analysis came out and so I wasn't involved in
5 completing this, because I thought the FDA analysis
6 was more complete than what GSK had done.

7 Q. Okay. And --

8 A. And on the FDA analysis there wasn't more
9 with Paxil.

10 Q. There was not?

11 A. Was not statistically significantly more
12 with Paxil is my memory, but I hope we'll go over
13 that.

14 Q. We will go over that.

15 A. Good. Okay.

16 Q. Okay. And who's responsible for coding
17 the adverse -- serious adverse events that occurred
18 during the statistical trials?

19 A. Yes. It was consensus conferences with
20 Dr. Wagner, myself and Dr. Apter on blinded --

21 Q. No. No. I'm sorry. Let me stop you. I
22 think you're going the wrong way.

23 During the clinical trial?

24 A. During the clinical trial that was
25 typically the nurse who would see the patient.

1 Q. Okay. Who would code --

2 A. No. I'm sorry. I gave you the wrong
3 answer invertedly.

4 Q. Okay.

5 A. The nurse wrote down words to describe it.

6 Q. Right.

7 A. It was GSK staff who would do the coding
8 into the different categories and the categories
9 were predefined and used standard by pharmaceutical
10 industry, and the categories are too broad.

11 Q. Okay.

12 A. Standings in the category with suicidality
13 were other things unrelated to suicidality.

14 Q. Such as?

15 A. Aggression, irritability.

16 Q. And how did GSK code those events?

17 A. They were all coded together.

18 Q. And what were they called?

19 A. The FDA document has the note for that. I
20 don't remember.

21 Q. If I give you a term, do you think that
22 may refresh your recollection?

23 A. That would be super.

24 Q. How about emotional lability?

25 A. I don't know that that's the code. I

1 mean, if you -- if that's the correct code we can
2 treat that. I don't have data in front of me to
3 tell me that code. It's not a code that
4 investigators -- it's not a code that university
5 folks work with and I'm not remembering it.

6 Q. Okay. And it's a code that lumped
7 different serious adverse effects together, correct?

8 A. Yes, but not all. Just a group of them
9 together. Yes, that's correct.

10 Q. Right. If you looked at the term, whether
11 it's emotionable lability or any other term you
12 could not tell by looking at it how many suicide
13 events were in that term?

14 A. That's correct.

15 Q. And so you were asked to try to separate
16 that out?

17 A. That's correct.

18 Q. And what was the process that was
19 developed for you to do that?

20 A. Sure. The process was that GSK sent the
21 cases to two other child psychiatrists uninvolved
22 with any of the studies or anything prior or
23 subsequent for redacting.

24 Q. Okay.

25 A. So that they redacted the minimum amount

1 that would blind a reviewer to medication.

2 Q. So you wouldn't know what drug the kid was
3 taking?

4 A. So you would have -- not just that it
5 wouldn't list which drug, but you'd take out other
6 information which would give you clues to the drug.

7 Q. Right. Which would be typical side
8 effects of the imipramine, which would be
9 cardiovascular problems?

10 A. Yes. That would be a good example.

11 Q. Okay.

12 A. And then the case summaries were sent to
13 Dr. Apter, Dr. Wagner and myself, and we then gave a
14 consensus blind rating on whether these were
15 definitely suicide related, probably suicide
16 related, possibly suicide related, or not.

17 Q. Okay. And who -- when you said it was
18 sent to outside people who weren't involved in
19 anything to make sure the data was not discernible
20 as to what kid -- what kid the drug was taking?

21 A. Yes.

22 Q. Who were those two people?

23 A. It was two child psychiatrists. One was
24 at the University of Pittsburgh. His name will come
25 to me in a minute. He just moved to San Antonio,

1 and the other one I don't remember. The first one I
2 do remember I'm just not getting his name. I'll get
3 it for you in a few minutes or we can look it up or
4 it would be in other documents.

5 Q. Okay. But it's one of your colleagues
6 here at the University?

7 A. Well, no longer here, and it's
8 embarrassing that I'm forgetting his name, but yes.

9 Q. Okay. Was it a man or a woman?

10 A. Man.

11 Q. Brent?

12 A. No. It wasn't David Brent.

13 Q. Okay.

14 A. I can certainly get you that information
15 by tomorrow. It'll probably come to me in a few
16 minutes.

17 Q. Okay. And those two psychiatrists, were
18 they considered experts in suicidality?

19 A. They were both child psychiatrists and so
20 would have reasonable expertise at that. Neither
21 one of them were major child psychiatrists
22 researchers in suicide, but there's only, you know,
23 David Shaffer and David Brent, there's very few
24 people in that category.

25 Q. Okay. And how were you presented the data

1 after those two child psychiatrists did what --

2 A. We were presented in text form for the
3 details they had around the suicidal thing. We were
4 presented the data on the rating scales they'd done,
5 you know, in that interval.

6 Q. Okay. And do you still have those
7 documents?

8 A. No.

9 Q. Okay. What happened to them?

10 A. I threw them away when we were done.

11 Q. Okay. And so you were asked to try to
12 determine which -- no -- how many events were you --
13 what was the universe? How many events, that's if
14 you recall?

15 A. Don't remember. Sorry.

16 Q. Okay. Was it events relating to just the
17 depression trials or all the pediatric trials
18 conducted by GSK?

19 A. I don't remember. I thought it was all
20 the trials. I'm not sure.

21 Q. Okay. Does the number of 35 sound --

22 A. That sounds approximately correct.

23 Q. Okay. And what exactly were you asked to
24 do?

25 A. We were asked to look at them ahead and

1 then be on joint conference phone calls where we
2 discussed the cases and reached a best estimate on,
3 you know, which level of suicidality that was;
4 again, blind to which medication or placebo that
5 they were on.

6 Q. Okay. And how many conference calls --
7 was this conference calls just between the three --
8 let me -- did this include Dr. Shaffer too? Did he
9 participate in this?

10 A. I don't remember whether he did or not.
11 That's a good question. I don't -- I don't -- I'm
12 not remembering that Dr. Shaffer was on those phone
13 calls. I certainly remember -- I don't know the
14 answer to that. I apologize. I should remember. I
15 don't remember that.

16 Q. Okay. Who do you recall being part --

17 A. Dr. Wagner and Dr. Apter and myself.

18 Q. Anybody from GSK?

19 A. I also should know the answer to that. I
20 believe that there was to record what we said a GSK
21 person on there. They certainly did not take part
22 in the discussions.

23 Q. Okay. Didn't have a vote?

24 A. Well, but just not didn't have a vote,
25 didn't talk.

1 Q. Okay. And do you recall who that person
2 was?

3 A. No.

4 Q. Do you have any record that could refresh
5 your recollection?

6 A. No.

7 Q. And how many conference calls did you
8 have?

9 A. My best estimate is on the order of say
10 six.

11 Q. And did GSK set up those conference calls
12 for you?

13 A. Yes.

14 Q. Okay. And the purpose of the calls was to
15 rate the number of -- the different patients whose
16 records you were reviewing?

17 A. That's correct.

18 Q. Okay. And did you complete that process?

19 A. Yes.

20 Q. Okay. And do you recall approximately
21 when you completed that process?

22 A. No.

23 Q. And did you do it to the best of your
24 ability?

25 A. Yes.

1 Q. And do you believe that was done also to
2 the best abilities of Drs. Apter and Wagner?

3 MS. CONNELLY: Object to the form.

4 MR. DAVIS: Object to form.

5 THE WITNESS: Yes.

6 BY MR. MURGATROYD:

7 Q. Okay. And have you seen those results?

8 A. I have seen this draft here. I didn't see
9 drafts after that point.

10 Q. Okay. At which point did you no longer
11 become involved in the project?

12 A. When the FDA -- when the HAMD analyses
13 went up on the FDA web site I thought that this was
14 redundant and no longer contained separate
15 information because they'd done the same methodology
16 only they done it on the universe of data about all
17 the SSRI's rather than just on Paxil. So I thought
18 this was no longer -- I mean, this was just scoop
19 basically. This would have been valuable if we had
20 gotten it out of there ahead of time, because it was
21 the best data we had. When it didn't get out of
22 there ahead of time there was no additional value to
23 this one in my opinion.

24 Q. Okay. Well, actually, the analysis you
25 did on the data was actually different than the

1 analysis the FDA did, correct?

2 A. That's correct. Now, we didn't have
3 assess to their partial -- you know, we didn't have
4 assess to their work product until they released the
5 whole analysis. We used similar methodology what
6 they used. Once they published it using similar
7 methodology by very good people, it was lead by Dr.
8 Shaffer this one was redundant .

9 Q. Okay. Did you drop out of the project
10 because you thought it would interfere with your
11 ability to sit on the advisory committee that looked
12 into the issue of suicidality in antidepressants in
13 February of 2004?

14 A. No.

15 Q. And I think we've established that GSK
16 never sent you the published article?

17 A. They did not.

18 Q. Okay. So as you sit here today you have
19 not read the published article?

20 A. That is true.

21 Q. And you don't know the conclusions of the
22 published article?

23 A. That's true.

24 MR. MURGATROYD: I think that -- let's go
25 off the record for just a second.

1 VIDEOOPERATOR: We're going off the record.
2 The time is approximately 3:40 p.m.

3 (Recess taken.)

4 VIDEOGRAPHER: We are back on the record.
5 The time is approximately 3:47 p.m. Please proceed.

6 (Ryan Deposition Exhibit No. 33
7 was marked for identification.)

8 BY MR. MURGATROYD:

9 Q. Okay. While we were off the record,
10 Doctor, did you get a chance to review that article
11 that's in your hand?

12 A. Yes.

13 Q. And can you identify for the record what
14 that article is?

15 A. It's an article published in 2006 in the
16 Journal of Child and Adolescent Psychopharmacology
17 entitled Evaluation of Suicidal Thoughts and
18 Behaviors in Children and Adolescents Taking
19 Paroxetine.

20 Q. Okay. And is that the same title of the
21 manuscript that you looked at in the proceeding
22 exhibit?

23 A. It's approximately the same, and in a
24 second I'll tell you if it's identical. It's
25 identical.

1 Q. Okay. And this published version -- and
2 it's in the Journal of Child and Adolescent
3 Psychopharmacology, right?

4 A. That's correct.

5 Q. Is that one of the publications that you
6 said you were once upon a time a --

7 A. That's correct. I was a -- on the
8 editorial board of that journal some time ago.

9 Q. Okay. And is that a reputable journal?

10 A. Yes.

11 Q. And does it submit its articles to peer
12 review so the jury knows?

13 A. Sure. The purpose of peer review is to
14 weed out scientific flaws and prioritize how
15 important a paper is to the field compared to other
16 ones so the editor can make decisions about
17 competing things and published.

18 Q. Okay. Now, with regard to the published
19 article, you are no longer listed as an author,
20 correct?

21 A. That's correct.

22 Q. And Karen Wagner is now longer listed as
23 an author, correct?

24 A. That's correct.

25 Q. And the sole external author to GSK is now

1 Alan Apter according to this author; is that
2 correct?

3 A. I don't know everybody on there, but I
4 will take your word for it. I don't know anybody
5 else who is external. On the list I don't know all
6 the people on the list.

7 Q. Okay. And you can look at the bottom and
8 you can see that's there's little --

9 A. GSK on everybody.

10 Q. I'm sorry?

11 A. It looks like everybody else is GSK.

12 Q. Okay. So it's Alan Apter and everybody
13 else is GSK, correct?

14 A. Yes.

15 Q. Who is Alan Apter?

16 A. Alan Apter is an Israeli child
17 psychiatrist who has done a lot of work in suicide.

18 Q. Okay. Is he a competent doctor to your
19 knowledge?

20 A. Yes.

21 Q. Okay. And you read the statistical part,
22 the statistical analysis of the suicide events that
23 you helped rate?

24 A. I didn't help write the draft.

25 Q. No. Rate. Rate. Help rate?

1 A. Oh, rate? I did. I did.

2 Q. And is there an odds ratio mentioned or
3 discussed in this paper regarding Paxil versus
4 placebo?

5 A. There's several odd ratios discussed. It
6 looks like -- I mean, the odds ratio -- the sort of
7 the one that's in the abstract and discussed again
8 in the discussion in most detail is suicide related
9 events occurring more often in paroxetine with an
10 odds ratio of 3.86.

11 Q. Okay. And did that odds ratio reach
12 statistical significance?

13 A. That was significantly different then one
14 with a P value of .003 in this analysis.

15 Q. And what does that mean to a lay person
16 that it's is statistically different -- or
17 significant -- I'm sorry?

18 A. It doesn't have an easy lay explanation.
19 What it means is there's less than one chance in --
20 it really doesn't have an easy lay explanation.

21 Q. Does it try to take the randomness out of
22 the equation?

23 MS. CONNELLY: Object to form.

24 BY MR. MURGATROYD:

25 Q. Do you understand what that means?

1 A. Yes. I understand what that means.

2 Q. Different events can occur randomly,
3 correct?

4 A. That's correct.

5 Q. And a P value, when you reach a P value of
6 05 that statistically is supposed to take out the
7 random factor? Correct?

8 A. That's not correct.

9 Q. Okay. Why don't you explain it to the
10 jury?

11 A. Sure. Any odd thing could happen by
12 happenstance.

13 Q. Right.

14 A. You could flip a coin 20 times in a row
15 and it can come up heads even though it was a fair
16 coin. You could win the lottery. So it --
17 requiring a P value less .5 decreases, but doesn't
18 eliminate the chance that the finding is by
19 happenstance.

20 Q. Okay.

21 A. And you have to simply have a conventional
22 level of where you say, well, we'll say it's
23 probably not happenstance. We can never be certain.

24 Q. Okay. Because there are no absolutes?

25 A. I'll agree with that. There are no

1 absolutes. I would agree with that. It was the
2 clausal implication in there that I wasn't agreeing
3 with.

4 Q. Okay. Now, it says that the odds ratio is
5 3.86. Round it off would be 3.9, correct?

6 A. Yes.

7 Q. Okay. Now, with regard to the pediatric
8 studies done by GSK, does that mean that a child who
9 was placed on -- or a kid, because I don't want to
10 mix up adults and children -- a kid who was placed
11 on Paxil versus a kid who was placed on placebo was
12 3.9 times more likely to experience a possible
13 suicide event?

14 A. No.

15 Q. Okay. What does it mean?

16 A. The odds ratio is a different number than
17 the risk ratio. So what it means -- and there's no
18 particularly easy way to do this one -- is it means
19 the odds of having the event over not having the
20 event are 3.9 times as great. The math is different
21 than what you described.

22 Q. Okay. So how would you explain that in a
23 lay term, in a lay person's term the kids taking
24 Paxil versus the kids taking placebo?

25 A. Someone more skilled than I may have an

1 explanation. I do not for an odds ratio. It's not
2 an easy lay explanation.

3 Q. Okay. Is it the same as gambling odds?

4 A. Yes, actually, but an odds ratio is
5 different than gambling. So if you say the odds of
6 something are two to one --

7 Q. Right.

8 A. -- it means you'd have a 66 percent chance
9 of getting it.

10 Q. Okay.

11 A. If you said an odds ratio was one to two
12 it would be a 33 percent chance. If you looked at
13 the odds ratio on those that would be four to one
14 odds ratio.

15 Q. Okay. So in terms of the odds ratio with
16 regard to the clinical trials conducted by GSK on
17 kids taking Paxil showed that the kids taking Paxil
18 were more likely to experience a suicide event than
19 a kid taking placebo?

20 MR. DAVIS: Object to the form; suicide
21 event, that's not what's described in the paper.

22 THE WITNESS: Possible suicide.

23 MR. DAVIS: No. That's wrong too.

24 THE WITNESS: Yes. I think to give you a
25 complete answer on that one there's sort of a couple

1 of problems, which is that there were, thankfully,
2 no completed suicides in any of these studies and we
3 do not know the relationship between a suicidal
4 gesture or suicidal ideation and completed suicide.
5 What we do know is that there's something like 1000
6 kids who think about suicide -- actually there's
7 something like 2000 kids who think about suicide and
8 something on the order of 1000 kids who make an
9 attempt for each one who completes it, and so the
10 relationship between this number and the risk of
11 completing suicide is completely unknown. This
12 second problem with saying -- with agreeing with
13 your assertion is that as I look through here
14 relatively briefly they look at two different
15 things, one of which was the cryptic description and
16 the adverse event form and they also looked at the
17 data from the systematically collected data about
18 suicidality.

19 BY MR. MURGATROYD:

20 Q. Okay. Doctor, let me just stop you for a
21 second. I think we're kinda going down the wrong
22 path.

23 A. I was trying to answer your question.

24 Q. Well, I think maybe you misunderstood my
25 question. I'm going to try to shortcut it.

1 The first sentence of the results, do you
2 see that?

3 A. Yes.

4 Q. Can you read that first sentence into the
5 record, please.

6 A. Suicide-related events occurred more often
7 in paroxetine (22 of 642, 3.4 percent) than in
8 placebo groups (5 of 549 0.9 percent); odds ratio
9 OR) 3.86 (95 percent confidence interval 1.45,
10 10.26; P equals 0.0003.

11 Q. Now, my question is and I think it's right
12 here: More kids on Paxil experience a suicidal
13 event than kids on placebo?

14 MS. CONNELLY: That's not a question.
15 That's a statement.

16 BY MR. MURGATROYD:

17 Q. Is that correct? I'm just asking, is that
18 correct?

19 MS. CONNELLY: You didn't ask, is that
20 correct? You just made a statement.

21 BY MR. MURGATROYD:

22 Q. Okay. Is that correct?

23 A. The -- by their suicide attempt -- I'm
24 sorry, suicide related events in here, by the
25 definitions they used, by the way they did it; yes,

1 that's correct.

2 Q. Okay. And according to this article, and
3 again, it was based on the information you did with
4 regard to the blinded analysis, correct?

5 A. That's correct.

6 Q. According to this article 22 or 3.4
7 percent of the kids taking Paxil experienced a
8 suicide related event, correct?

9 A. That's correct.

10 Q. And that is opposed to 5 of 549 kids or
11 0.9 percent of the kids taking placebo who
12 experience a suicide related event; is that correct?

13

14 A. Yes.

15 Q. Okay. Now, does that appear to be about a
16 four times difference?

17 MR. DAVIS: Object to the form.

18 BY MR. MURGATROYD:

19 Q. Approximately a four times difference?yes.

20 A. Little bit less than four.

21 Q. Okay.

22 A. Percent. Four times different, yes.

23 Q. Okay. Now, going back to study 329, did
24 that article separate out the individual studies for
25 analysis?

1 A. It would take me a long time to be
2 competent -- I mean, it would certainly take me a
3 couple of hours to review this enough to answer all
4 your questions like that. If you want to tell me
5 where to look at them I'll look at them. I didn't
6 see in the scan that it separated out the separate
7 studies. One would not necessarily -- I didn't see
8 that it did that.

9 Q. And did you in your analysis with
10 Drs. Wagners and Apter separate -- did you know
11 which study the kids were in when you were
12 analyzing?

13 A. No. We never knew which study the were in
14 and I didn't do any analysis. I pulled out at the
15 end of sort of doing all the blind, whatever, and
16 seeing the one manuscript so I was not responsible
17 for any analysis and I did not in detail review the
18 analysis in the prior exhibit, in the draft
19 manuscript.

20 Q. Have you ever seen a distribution of how
21 the suicide related events were distributed among
22 the different sites in study 329?

23 A. In the different sites? No, I've not.

24 Q. Okay.

25 A. To the best of my knowledge.

1 Q. Okay. But you were aware that you in your
2 suit had multiple suicide related events, correct?

3 MR. DAVIS: Object to the form.

4 THE WITNESS: Yes.

5 BY MR. MURGATROYD:

6 Q. Okay. And how many?

7 A. Don't know.

8 Q. You just know that there was more than
9 one?

10 A. Yes.

11 Q. And with regard to your participation in
12 study 329, was that a hands job where you actually
13 interviewed the kids and provided them with the
14 drugs?

15 A. No. That was Dr. Birmaher.

16 Q. And with regard to 329 after your site had
17 been approved and appointed for here in Pittsburgh,
18 what did you do -- what was your exact role in
19 conducting the study?

20 A. Yes. My role was supervisory in
21 conducting the study.

22 Q. Let me ask you this: Where did you get
23 the kids?

24 A. Advertising and from self referral to the
25 child psychiatric clinic.

1 MS. CONNELLY: Also, object to form. I
2 don't think there was any children. I think it was
3 were adolescents.

4 BY MR. MURGATROYD: Again, I think I've said this
5 four or five times. I'm referring to --

6 MS. CONNELLY: That may be what you're
7 referring to because it's vague, because my
8 understanding of this particular study about what
9 you were questioning is that it was not all kids.
10 It was adolescents.

11 MR. DAVIS: That's a big difference
12 between a seven year old and a 18 year old.

13 BY MR. MURGATROYD:

14 Q. Well, let me ask you this: What were the
15 age ranges of the kids in the study?

16 A. 12 to 18.

17 Q. Okay. Now, in terms of advertising, was
18 that radio or newspaper?

19 A. My memory is radio and newspaper. I can't
20 tell you definitely that that's all we used.

21 Q. And how many kids did you end up getting in
22 the study?

23 MS. CONNELLY: Object to form on kids.

24 THE WITNESS: Fine. Adolescents in the
25 study I don't know. I don't remember the exact

1 number.

2 BY MR. MURGATROYD:

3 Q. Do you know if it was more than 10 or less
4 than 10?

5 A. Yes. It was more than 10.

6 Q. Was it more than 20?

7 A. Yes. It was more than 20.

8 Q. Okay. More than 30?

9 A. Do you know the number and could I verify
10 it?

11 Q. I don't know the number off the top of my
12 head. I'm just asking you, for your knowledge?

13 MS. CONNELLY: If you don't recall you
14 don't recall. You're under oath.

15 THE WITNESS: Right. My best guess is
16 more than 30. I don't recall the exact number. My
17 apologies.

18 BY MR. MURGATROYD:

19 Q. And do you recall what percentage of
20 adolescents in your site experienced a
21 suicidal-related event?

22 A. No.

23 Q. Okay. And prior to you publishing your
24 article on 329, had GSK to your knowledge, analyzed
25 the suicide events and determined what the risk

1 ratio was?

2 A. They had given us the data as it is in the
3 paper on that whole category, and they had analyzed
4 whether any -- any -- in the investigator's meeting
5 they presented the side effect categories that they
6 had including that category, and we reported the
7 only side effect that came out different and
8 statistically significant, which was not the
9 category related to suicide events in this study.

10 Q. Okay. But from the information that GSK
11 provided you, could you determine how many suicide
12 events there were?

13 A. You can get close in the suicide events,
14 and so it's -- with the degree here no, but yes, and
15 I believe in the paper we report that, you know, the
16 best data we had at the time.

17 Q. Okay.

18 A. It included -- it clearly could include
19 things other than the suicide event. That was the
20 trouble with that scale. No, they did not separate
21 out the suicide from the other things that got in
22 that adverse event category if that better answers
23 your question.

24 Q. Okay. Thank you. Were you aware that
25 there was a study being conducted in Europe at the

1 same time your study was being done called 511?

2 A. I was aware that there was a study being
3 conducted in Europe. I don't know that I knew the
4 particular number for it.

5 Q. You have since reviewed the data regarding
6 study 511, correct?

7 A. I did review it at one point in my career,
8 yes. I haven't reviewed it recently. I haven't
9 reviewed it in a decade.

10 MR. DAVIS: I still don't believe the
11 witness understands what study you're talking about.
12 There were two studies in Europe.

13 BY MR. MURGATROYD:

14 Q. Okay. Do you know what I mean by 511? Di
15 you know what I'm talking about?

16 A. No.

17 MS. CONNELLY: Thank you. I didn't know
18 there was two studies in Europe.

19 BY MR. MURGATROYD:

20 Q. Well, there was 377 and 511. Do you
21 recall the study in Europe that did not use a
22 placebo control?

23 A. No, I did not know about that one.

24 Q. But you did at some later time, right?

25 A. I knew from something that I saw published

1 something that there was a later one. I hadn't
2 known about it before.

3 Q. Okay.

4 A. And I've never seen that data on the one
5 without a placebo control. I've never seen the data
6

7 Q. But you've seen the data since your
8 article's been published, right?

9 A. That's not -- no I haven't. What I have
10 seen is that the FDA said that there was no
11 significant effect on that and with that I would --
12 I probably saw the same size, but I'm not certain.
13 I've not seen more data on that study to the best of
14 my knowledge.

15 Q. Do you recall the number of suicide acts
16 that occurred during that study?

17 A. No.

18 MR. MURGATROYD: Okay. Let's go off the
19 record for a minute.

20 VIDEOGRAPHER: We're going off the record.
21 The time is 4:11 p.m.

22 (Pause in Proceedings.)

23 VIDEOGRAPHER: We are back on the record.
24 This is Tape No. 5 of the deposition of Dr. Neal
25 Ryan. The time is approximately 4:28 p.m. Please

1 proceed.

2 MR. MURGATROYD: Pamela, what's our next
3 Exhibit?

4 MS. CONNELLY: Next will be 34.

5 MR. MURGATROYD: 34. Thanks.

6 (Ryan Deposition Exhibit No. 34
7 was marked for identification.)

8 BY MR. MURGATROYD:

9 Q. Can you identify for the record what
10 Exhibit 34 is, please.

11 A. Yes. Exhibit 34 is a printout of an
12 e-mail from myself to Dr. Martin Keller entitled
13 "RE: Paxil data on the web," and it references or it
14 contains in its body another e-mail from myself to
15 Dr. Keller, Dr. Strober, Dr. Wagner and Dr. Graham
16 Emslie on a press release from the Wall Street
17 Journal dated June 16, 2004 related -- announcing
18 the New York Attorney General Eliot Spitzer's
19 accusations of fraud and secrecy against GSK.

20 Q. Okay. And I think we talked about whether
21 or no you were aware of Attorney General Spitzer's
22 action?

23 A. Yes.

24 Q. And did you get a chance to read that?

25 A. Yes, I do.

1 Q. Does that refresh your recollection as to
2 what Attorney General --

3 A. Yes.

4 Q. Okay. Do you know what had happened in
5 that case?

6 A. No.

7 Q. Okay. Now the first part of that e-mail
8 to Dr. Keller at the top part?

9 A. Yes.

10 Q. What does that say? Can you read it into
11 the record?

12 A. It says in entirety, "Did we know about
13 study 551 before today? See web site," and then I
14 give a link to a GSK web site detailing stuff on
15 presumedly on that study.

16 Q. And did you look at that web site and look
17 at that study on that date?

18 A. At the time I looked at the web site. I
19 don't remember the details of that study.

20 Q. Okay. Was it a concern to you?

21 MR. DAVIS: Object to form.

22 THE WITNESS: I do not remember that the
23 results of the study were a concern. What my
24 comment here to Dr. Keller was, is to the best of my
25 knowledge this was the first I had heard about that

1 study.

2 BY MR. MURGATROYD:

3 Q. Okay. And we talked about the two other
4 depression studies, and so I'm going to use the
5 numbers so 701 and 377 were the other two depression
6 studies. Okay?

7 A. Yes.

8 Q. 377 was in Europe. 701 was not.

9 A. I'm sorry. 701 was -- I'm sorry. I'm
10 sorry. I'm getting confused.

11 Q. Yes. I want to make sure you -- you may
12 want to write it down because I'll be asking you
13 different questions --

14 A. This is about study 511?

15 Q. That's 511. Correct.

16 A. Do you have anything that would refresh my
17 data on the details of this if you want me to answer
18 on the details?

19 Q. Yes. I'm going to give that to you in a
20 minute, but I want to make sure

21 A. The other studies that -- does anybody
22 have a writing utensil I can share, as we say? So
23 329, 511, 701.

24 Q. And 377.

25 A. Okay. Now I have those numbers. Can you

1 detail 701 and 377 if I'm to answer any questions on
2 them?

3 Q. Yes. Let me get show you some documents
4 on them so you're not getting it from me you're
5 getting it from the documents.

6 A. Okay.

7 Q. I'll show you what I'm going to mark as
8 Exhibit 35, which is the study synopsis for 377, and
9 I'll mark as Exhibit 36 the study synapsis for study
10 301 and just so the record's complete I'll mark as
11 Exhibit 37 a study synopsis for your study 329.

12 (Ryan Deposition Exhibit No. 35, 36, 37
13 was marked for identification.)

14 The questions I'll be asking you about
15 these studies really have to do with the dates. I
16 think we've already talked about the results, but we
17 may briefly talk about the results. Then just to
18 round it out I'm going to show you 38. We can go
19 off the record. It may take the doctor some time to
20 go through these.

21 (Ryan Deposition Exhibit No. 38
22 was marked for identification.)

23 VIDEOOPERATOR: We're going off the record.
24 The time is 4:35 p.m.

25 (Pause in Proceedings.)

1 VIDEOGRAPHER: We're back on the record.
2 The time is approximately 4:38 p.m. Please proceed.

3 BY MR. MURGATROYD:

4 Q. And, Doctor, while we were off the record
5 you reviewed a number of documents to either inform
6 you or refresh your recollection as to which numbers
7 are which trials, correct?

8 A. Yes.

9 Q. And let's take 377 first.

10 A. That's Exhibit 35.

11 Q. I have it here. Okay. And that was a
12 study of Paxil in kids with just depressive
13 disorder, correct?

14 A. In the time allowed I scanned it briefly.
15 That appears correct. Actually, I'm sorry. Is this
16 children or adolescents or both? This is
17 adolescents only.

18 Q. Okay. And I think you've stated earlier
19 that that study achieve statistical significance in
20 regards to any of its end points, correct?

21 A. That was the best knowledge I had before
22 looking at this. This is an internal GSK document,
23 and what I had only before was basically from the
24 FDA web site so I stated it didn't have significance
25 on it, as far as I knew, and --

1 Q. Well, we didn't get the conclusion. Does
2 it have a conclusion?

3 A. I don't know. Let me -- probably go to
4 the back -- it'd probably more likely be there.

5 It looks like this one had a nearly
6 significant, but not significant trend on one
7 analysis if they did age groups greater than 16
8 years old and --

9 Q. Again, just looking for statistical
10 significance.

11 MR. DAVIS: Object to the extent that
12 these synopses are not the complete study reports so
13 it's difficult for the witness to answer the
14 questions.

15 THE WITNESS: It -- the conclusions state
16 that they didn't show superiority of paroxetine over
17 placebo in the treatment of adolescents depression.
18 In the analysis presented here none reached the .05
19 level of statistical significance that I see.

20 BY MR. MURGATROYD:

21 Q. Okay. And that would fit into a category
22 of a failed or a negative trial, correct?

23 MR. DAVIS: Object to the form.

24 THE WITNESS: Not as it was used earlier
25 today, no.

1 BY MR. MURGATROYD:

2 Q. Okay. What category would you put that
3 in?

4 A. A negative trial. A failed trial has a
5 different meaning than what we've seen today.

6 Q. And by negative trial, you mean failed in
7 all regards?

8 MR. DAVIS: Object to the form.

9 THE WITNESS: No.

10 BY MR. MURGATROYD:

11 Q. Okay. What do you mean?

12 A. Primary outcomes measures not
13 significantly different between the medication and
14 placebo.

15 Q. Okay. And let's go to 701.

16 A. Okay.

17 Q. And actually before you do that, 377, look
18 at the -- I think it's the first two pages that give
19 you the study dates? Do you see these?

20 A. Yes.

21 Q. And what were the study dates for that
22 study?

23 A. The study dates for this study reported in
24 this document is 26 April 1995 until 15 May 1998.

25 Q. Almost contemporaneous with your study 329,

1 correct?

2 A. Yes.

3 Q. Okay. And let's go to 701. When --
4 actually one more question, 'm sorry. I hate to
5 make you jump around. When that study was
6 concluded, did GSK provide you the results of that
7 study?

8 A. In a poster format only. Yes, they did.
9 This is the -- the trouble is that they have two and
10 they provided me one of the two in a poster format.
11 I assume it's this one. I'm not certain it's this
12 one versus the other one.

13 Q. When you say they provided it to you in a
14 poster format --

15 A. Sorry. Power Point attachment to e-mail
16 point at some point in my life.

17 Q. Oh, okay. And you don't know if it was
18 701 or 377?

19 A. I don't know. Presumably they indicated
20 it at the time. I don't remember.

21 Q. Okay. But it represented a failed study?

22 MR. DAVIS: Object to the form.

23 THE WITNESS: You -- A failed study has a
24 different meaning than the question you're asking
25 me.

1 BY MR. MURGATROYD:

2 Q. Okay. A negative study? I'm sorry.

3 A. Yes.

4 Q. Okay. Good. Let's go down to

5 A. A failed study does have a meaning, but
6 it's different than that.

7 Q. Okay. Let's go to 701.

8 A. Okay. 701 is No. 36. Okay.

9 Q. And is that the report synopsis for that
10 study?

11 A. Looks to be.

12 Q. Okay. And is that also -- is the third
13 study in which Paxil was been tested on kids with
14 major depression?

15 MS. CONNELLY: Object to form; on kids,
16 again,

17 THE WITNESS: This one's in children and
18 adolescents both. It appears to be the first study
19 in both, and let me look at the dates on this to see
20 if it would make it as the third one. Yes. From
21 the dates on the other one this looks to be the
22 third one done.

23 BY MR. MURGATROYD:

24 Q. Okay. And, again, you don't know whether
25 you received the results of that one or 377?

1 A. No. I believe I received the results of
2 the other one. I hadn't looked in detail enough at
3 701. So I received at one point of 377 not 701 by
4 the dates here.

5 Q. Okay. That's great. Now, we were talking
6 about -- and that was also, 701 was also a negative
7 study in that Paxil did not separate from placebo in
8 a statistically significant manner, correct?

9 A. Yes, though, this one was more interesting
10 in that it sort of looked like the trend was for
11 Paxil to be better, not statistically significant,
12 if I was reading this right earlier. Was I reading
13 that right?

14 Q. Actually, it was the other -- one where
15 the where placebo was better.

16 A. Or was the trend -- was that where it was?
17 Favor of placebo. You're right.

18 Q. So placebo was doing better than Paxil
19 with regard to some efficacy points in that study,
20 correct?

21 A. Age by group. No. So let's see. It's s
22 children 7 to 11, but not the whole group did better
23 in one on the placebo.

24 Q. Okay. And so now we have the three
25 depression studies?

1 A. That's correct.

2 Q. We have a number for all three of them,
3 correct?

4 A. Yes.

5 Q. Okay. Good. And now we have 511?

6 A. 511. Yes.

7 Q. Which was presented to you in a article,
8 and article -- an journal article format, correct?

9 A. That's correct.

10 Q. Okay. And have you read that study before
11 today?

12 A. No, I have not.

13 Q. But you were aware that it existed
14 according to your e-mail?

15 A. I was aware -- my e-mail indicates that I
16 learned first of it from the Wall Street Journal and
17 was surprised.

18 Q. And that date was that?

19 A. The date on that was Wednesday, June 16,
20 2004, which embarrassingly enough was after the
21 publication date on this paper.

22 Q. Okay.

23 A. So I should have seen it, but did not.

24 Q. Okay. That's fine. It's also several
25 years after your article was published though,

1 right?

2 A. Yes.

3 Q. Okay. And there's a table on page 27 of
4 that journal article.

5 A. Okay.

6 Q. Okay. And do you see in that table an
7 entry for suicidal acts?

8 A. Yes.

9 Q. Okay. And what percentage of the kids who
10 were taking Paxil experienced a suicidal act?

11 A. Obviously that's assuming that -- I don't
12 know the answer to that. This list under the
13 "Suicidal Act" line 10.1 percent on clomipramine and
14 12.1 percent on paroxetine, on Paxil

15 Q. Okay. So to answer my question: I asked,
16 how many kids experienced a suicidal act on Paxil.
17 The answer is?

18 A. Well, I was not just trying to be
19 difficult. I had not had time to review the paper
20 to say what they're including in what they call a
21 suicidal act and they assessed it.

22 Q. I'm just asking you to look at the table
23 and tell me what the number is?

24 A. That seems different than your question to
25 me.

1 Q. Okay. What is the number?

2 A. The number on the paper is 12.7 on
3 paroxetine and 10.1 on clomipramine.

4 Q. Okay. And they're listed as suicidal
5 acts, correct, on that table?

6 A. Yes.

7 Q. Now, in your paper, right? Did you have a
8 similar number that broke out the number of kids or
9 adolescents, so you don't object, that experienced a
10 suicidal act?

11 MR. DAVIS: Object to the form.

12 THE WITNESS: No.

13 BY MR. MURGATROYD:

14 Q. Okay. Did GSK participate in the drafting
15 of your article?

16 A. Not to my knowledge.

17 Q. The GSK authors did not participate?

18 A. You said in the drafting of the article?

19 Q. Yes.

20 A. Would you explain to me what you mean by
21 drafting?

22 Q. Well, the -- was the article that was
23 eventually published regarding 329 a collaborative
24 effort between all the authors?

25 A. Yes.

1 Q. And that includes the GSK?

2 A. Yes.

3 Q. Okay. And were aware that that article
4 had to be approved by GSK's legal before it was
5 allowed to go out to be published?

6 MS. CONNELLY: Objection; form.

7 MR. DAVIS: Objection; no foundation.

8 MS. CONNELLY: Yes. There's not facts in
9 evidence that that's true.

10 MR. MURGATROYD: Okay. He can answer.

11 MS. CONNELLY: I think you have to
12 rephrase the question, because to answer that he has
13 to assume that fact that you just stated that there
14 was a required approval by legal. I have no reason
15 to think that there was or wasn't, neither does this
16 witness.

17 BY MR. MURGATROYD:

18 Q. Do you know whether or not the article
19 that you were the coauthor of on study 329 required
20 approval by the legal department at GSK before it
21 would be allowed to be published?

22 A. I have no knowledge on that.

23 Q. Okay. Have you ever seen any e-mails from
24 GSK employees -- strike that -- we'll come back to
25 that later.

1 Now, in study 329, do you know what the
2 ultimate number after the final review was done,
3 which you were part of which resulted in the Apter
4 article, what the final number was for the suicide
5 acts -- actually let be rephrase it -- possible
6 suicide-related events was for study 329?

7 A. No.

8 Q. Okay. Do you know what percentage of the
9 kids on Paxil experienced such an event?

10 MS. CONNELLY: Object to form; it's vague
11 as to what study and you're saying kids again.

12 MR. MURGATROYD: Okay.

13 BY MR. MURGATROYD:

14 Q. 329. Okay. Adolescents. That's fine.

15 A. 329 adolescents I do not know. I mean, w.
16 I don't know, you know, the number in the paper for
17 the whole number, but the number of -- but I don't
18 know precisely -- or one, we presumably could find
19 it from the papers here.

20 Q. Okay. Now, would you agree that if --
21 that if in fact Paxil -- that with regard to Paxil
22 there is a definite risk of increased suicidality in
23 adolescents that Paxil would not be considered a
24 safe drug?

25 MS. CONNELLY: Object; it's compound.

1 MR. DAVIS: Object to the form.

2 THE WITNESS: Let me split it out for you.
3 It -- I think there is at present no data to suggest
4 that Paxil is different from other compounds in the
5 class. There is some data to suggests that there
6 may be an increase in suicidal events in primarily
7 adolescents. There's little data on children
8 separately in with acute treatment with these
9 compounds. This is some data to suggest that there
10 may be overall fewer completed suicide in treated
11 adolescents with this class of compounds then in a
12 untreated adolescents. And so I think the data is
13 mixed, and I thinks it's certainly premature to say
14 that the compounds increase completed suicides.
15 There is data on these things categorized as
16 suicidal acts and there is meaningful data. It's
17 certainly not -- it's certainly a little bit mixed,
18 but there's certainly is data suggesting there's
19 more of these suicidal events in this group.

20 Q. Okay.

21 A. And there was a compound bit that forget
22 by the end. Do you want me to answer that second
23 part?

24 Q. No, we'll came back to it.

25 Do you agree that adolescents treated with

1 paroxetine, there is a definite risk of increased
2 suicidality?

3 MS. CONNELLY: Objection; he just answered
4 that question.

5 MR. DAVIS: It is asked and answered.

6 THE WITNESS: I think my prior answer --
7 okay. Say your question again, please.

8 BY MR. MURGATROYD:

9 Q. Do you agree -- let me ask you this. I'll
10 make it easier. Do you agree with the following
11 statement: In adolescents treated with paroxetine
12 there is a definite risk of increased suicidality?

13 A. No.

14 Q. Okay. Have you seen any documents -- do
15 you know what the Global Safety Board is within GSK.

16 A. No.

17 Q. Do you think GSK as a corporation has more
18 knowledge about the drug Paxil than you personally
19 do?

20 MR. DAVIS: Object to the form.

21 THE WITNESS: They have knowledge that I
22 do not have. They also have constraints I don't
23 have to follow. So if the corollary of that is
24 their statements -- would I accept their statements
25 as truth without the data? No.

1 BY MR. MURGATROYD:

2 Q. Okay. Would --

3 A. Would a reasonable person accept a
4 statement in their's opposed to my conclusion? I
5 don't think that would be a correct conclusion from
6 that.

7 Q. How many kids were treated with Paxil in
8 the Paxil studies?

9 A. In all the studies put together I -- it
10 was in one of the documents here. It's looking like
11 it's -- I don't know 4 or 500 kids on Paxil, but,
12 you'll -- I mean, you'll have to give me some time
13 to wade through here if want a better number than
14 that.

15 Q. Well, it's hundreds, hundreds, right?

16 A. Yes.

17 Q. And how many did you adolescents did you
18 give Paxil?

19 MS. CONNELLY: Object to form.

20 THE WITNESS: As part as this study on the
21 order of 15 or 20, but since we didn't see our data
22 unlighted separately and since I'm not remembering
23 our total site enrollment that's as close as I can
24 do, and as part of this study plus certainly some
25 other children at the same time and before treated

1 with Paxil.

2 BY MR. MURGATROYD:

3 Q. Well, how many children have you
4 personally given the drug Paxil?

5 A. Probably 20 or 30.

6 Q. And do you think GSK has more information
7 than that, the effects of Paxil on 20 or 30 kids?

8 MS. CONNELLY: Object to the form.

9 MR. DAVIS: Joined.

10 MS. CONNELLY: It was vague and confusing.

11 BY MR. MURGATROYD:

12 Q. Did you understand the question?

13 A. Not entirely, but.

14 Q. Okay. Well, do you think GSK as a
15 corporation has more knowledge than what the effects
16 were on 20 or 20 kids?

17 MS. CONNELLY: Same objection. They have
18 more knowledge than what the effects were? You mean
19 what the effects were? I don't understand your
20 question. Can you rephrase it?

21 MR. DAVIS: Objection, form.

22 THE WITNESS: Do you saying -- if you're
23 question is, at one time did they have data related
24 to the effects that were not publicly available so I
25 couldn't evaluate? Yes.

1 If you're saying, do they have meaningful
2 amounts of data on this question that hasn't
3 been released so I cannot even include it in my
4 evaluation I have no knowledge on that one.

5 BY MR. MURGATROYD:

6 Q. Okay. Were you aware that GSK has access
7 to adverse event reports that are submitted to the
8 FDA?

9 A. Yes.

10 Q. And you don't have access to that, do you?

11 A. Well, I don't look at that. I have no
12 idea whether the public -- whether we have access to
13 those. I don't know the answer to your question.

14 Q. You have not looked at that information,
15 have you?

16 A. I have not looked at that.

17 Q. And you are aware obviously that adverse
18 event reports get submitted direct to GSK, correct?

19 A. That's correct. Those are however
20 non-contributory to the question of if there's an
21 increased hazard for suicide. We could discuss in
22 detail the reason that the adverse reports just
23 don't tell you anything, but they don't. So that
24 certainly doesn't support a contention that I'm less
25 qualified to make any evaluation of this than

1 somebody internal to GSK.

2 Q. So you think that you -- you can state
3 under oath -- that you having given Paxil to 20 or
4 30 kids have comparable or greater knowledge of the
5 effects, the safety effects that Paxil has on
6 children and adolescents given Paxil than GSK?

7 A. I think your question was worded to
8 inadvertently to put words in my mouth.

9 Q. Well, you can answer it.

10 A. So the number of children that I've given
11 Paxil to is immaterial to the question of assessing
12 the available data on hazard of suicidality, because
13 if personal experience was the measure we'd never
14 have a reasonable assessment of the risks of these
15 compounds.

16 Q. Well, you agree that GSK obviously has a
17 lot more information than you have?

18 MR. DAVIS: Object to the form.

19 BY MR. MURGATROYD:

20 Q. About the affects of Paxil -- the serious
21 adverse effects of Paxil on children and adolescents
22 given the drug? Do you agree with that?

23 A. GSK has more data than I have. I do not
24 know if there is material that hasn't been released
25 yet. Lots more data rather its material -- whether

1 I can make a better answer than GSK I cannot, but
2 they have different constraints in the decisions
3 that they make. Whether my evaluation of this is
4 separately inferior to theirs so not worth making
5 seems to be what you're getting at and certainly I
6 see no data that my -- my evaluation of this
7 question is, is because of the things you are trying
8 to raise inferior to theirs and so it shouldn't be
9 made.

10 Q. I just asked u a simple question, Doctor.
11 You didn't have to put anything into it.

12 MS. CONNELLY: Objection; you're trying to
13 argue with the witness.

14 MR. MURGATROYD: I'm not trying --

15 MS. CONNELLY: Do you have a question for
16 him?

17 BY MR. MURGATROYD:

18 Q. I'm just trying to make the record clear.
19 The statement that in adolescents treated with
20 paroxetine there is a definite risk of increased
21 suicidality made by a GSK employee who is a member
22 of the Global Safety Committee, bears no weight with
23 you?

24 MR. DAVIS: Object to the form; There's no
25 foundation. How's the witness supposed to answer

1 that question?

2 MR. MURGATROYD: Well, let me show you the
3 document.

4 MS. CONNELLY: What a novel idea.

5 (Ryan Deposition Exhibit No. 39
6 was marked for identification.)

7 BY MR. MURGATROYD:

8 Q. Let's take a look at 39.

9 MR. DAVIS: May I see that when you get a
10 chance?

11 MS. CONNELLY: You can go first.

12 MR. DAVIS: Thank you.

13 MS. CONNELLY: Okay. Plaintiffs Exhibit
14 39 appears to be a GSK produced document subject to
15 the protective order. It appears to be an internal
16 e-mail between GSK people.

17 BY MR. MURGATROYD:

18 Q. Have you had a chance to look at that
19 document?

20 A. Yes.

21 Q. Okay. Can you read the first paragraph
22 and the first three bullet points into the record,
23 please.

24 MR. DAVIS: Yes. And let me just object
25 to the use of this document with this witness.

1 There's no foundation laid that this witness knows
2 anything about the document, the context of the
3 document or the contest of the discussion.

4 THE WITNESS: Okay. This is a document
5 that's from Ronald L. Krall at GSK. I do not know
6 him and do not believe I met him, to Trevor G. Gibbs.

7 BY MR. MURGATROYD:

8 Q. Actually, that's Colin Dollery to Ronald
9 Krall, right?

10 A. It doesn't appear to be the case.

11 Q. What's the left-hand side say?

12 A. Oh, you're right. My apologies. You're
13 absolutely right. It's from Colin Dollery to Ronald
14 Krall and Trevor Gibbs and Alan Metz. I don't know
15 any of the individuals, and the subject line is
16 entitled "GSB Discussion."

17 Q. Okay.

18 A. It says: Dear Ron, I have been reflecting
19 on the three presentations the Global Safety Board
20 has received in relation to the safety of
21 paroxetine. I thought it might be helpful if I list
22 my provisional conclusions prior to our discussion
23 this afternoon. The first bullet point. The
24 presentations (adolescents, adults, epidemiology)
25 were of high quality and well balanced.

1 Second bullet point: In adolescents
2 treated with paroxetine there's a definite risk of
3 increased suicidality.

4 Third bullet point: We have little or no
5 evidence of efficacy in major depressive illness at
6 this age group.

7 Q. Okay. Now, you see that it says the
8 Global Safety Board? Do you see that?

9 A. Yes.

10 Q. Okay. And have you ever, to your
11 knowledge, been presented with presentations that
12 have been presented to the Global Safety Board?

13 A. Not to my knowledge.

14 Q. Have you ever been presented any
15 epidemiologic studies that were done by GSK that
16 were presented to the Global Safety Board concerning
17 the safety of Paxil and the treatment of adolescents
18 with major depressive disorder?

19 A. I have no information about such studies
20 being done. I don't remember seeing such. I don't
21 know that they occurred.

22 MS. CONNELLY: If you have documents
23 showing such studies --

24 MR. MURGSTROYD: I just asking if he's
25 ever seen it?

1 MS. CONNELLY: It's one of those questions
2 where it makes it a fact not in evidence.

3 MR. MURGATROYD: Well, it is a fact in
4 evidence. It's says right here. "The
5 presentations, (adolescents, adults, epidemiology)
6 were of high quality and well balanced." I just
7 wanted to know.

8 THE WITNESS: I'm sorry. It does not
9 indicate that there were any child or adolescent
10 epidemiology studies here.

11 MR. DAVIS: Join in the objection.

12 BY MR. MURGATROYD:

13 Q. My question was simple: Have you ever
14 been presented with any epidemiology studies that
15 were ever presented to GSK's Global Safety Board?
16 That's all I want to know?

17 A. All right. I thought I answered that.
18 No.

19 Q. Okay. Great. In determining whether or
20 not Paxil is causing suicidality in kids -- meaning
21 adolescents -- who take the drug for depressive
22 disorder, is an epidemiologic study something you
23 would want to see in order to determine that if, in
24 fact, that --

25 A. To the best of my knowledge no

1 epidemiologic studies had been done at this point in
2 children.

3 Q. And what's the date of this document?

4 A. This document is 11-4-2004.

5 Q. And you don't content to know everything
6 that GSK has done, do you?

7 A. No.

8 Q. Okay. Now, this document also says "We
9 have little or no evidence of efficacy in major
10 depressive illness in this age group." Do you see
11 that?

12 A. Huh-uh.

13 Q. And do you agree or disagree with that
14 statement?

15 A. We've discussed that before. I think
16 there's a little bit of evidence, so it's above no,
17 but for me when you aggregate it all it's in the
18 little category.

19 Q. Okay. Now, with regard to Paxil and its
20 use in children and adolescents, you have given
21 different presentations on that subject, correct?

22 A. I have given presentations on that
23 subject; that's correct.

24 Q. Okay. How many presentations?

25 A. I remember one at the APA, American

1 Psychiatric Association.

2 Q. Okay. What was the date? Let's take one
3 at a time and go through the details of each of
4 these.

5 A. Okay. I don't know the date.

6 Q. Okay. So we have one with the APA?

7 A. Right.

8 Q. And do you know what year?

9 A. No.

10 Q. Okay. And who was your audience?

11 A. It was -- would in general be members of
12 the APA, but it wouldn't have been restricted to
13 that. Anybody can register for the meeting, but
14 largely psychiatrists, largely from North America,
15 but not exclusivity. They could be lay people. It
16 could be other professionals in the audience.

17 Q. And what type of presentation did you put

18 A. It was a discussion of the study we're
19 calling 329, and the findings in that study.

20 Q. And what kind of presentation was it?

21 A. It was a presentation before an audience
22 with power point slides.

23 Q. And who prepared those slides?

24 A. I prepared the slides. GSK then put them
25 in their uniform slide logo without changing the

1 content, just changing the decoration about them.

2 Q. Okay. And where are those slides today?

3 A. I don't know.

4 Q. You didn't keep them?

5 A. I can check tonight. I don't remember
6 that, but I'll double check.

7 Q. Okay. Where would you look for them?

8 A. I'll look for them on my computer work. I
9 tried to look through the things relevant, and if I
10 didn't produce them -- I don't know if I have them
11 or not, but I will double check.

12 Q. Okay. How long was this presentation, if
13 you recall?

14 A. 45 minutes-ish.

15 Q. And that was 45 minutes of just you
16 talking?

17 A. Yes. Plus the -- approximately 45
18 minutes, 50 minutes with me, and then a discussion.

19 Q. Okay. And during your presentation, did
20 you state that Paxil was effective in treating
21 adolescents with major depressive disorder?

22 A. I don't know.

23 Q. I take it your slides would help refresh
24 your recollection on that regard?

25 A. Yes.

1 Q. Okay. Is that something that you've ever
2 stated publicly?

3 A. I've stated that -- that there was an
4 indication for efficacy, yes.

5 Q. Have you stated definitively that Paxil is
6 effective for the treatment of adolescents with
7 major depressive disorder?

8 A. I don't know. I think that the trouble --
9 I mean, that we got a signal in that direction, but
10 exactly how I stated it I don't know.

11 Q. Okay. That's one presentation, correct?

12 A. Huh-uh.

13 Q. Any others?

14 A. Not to my memory.

15 Q. Okay. Was this presentation recorded by
16 anybody to your knowledge?

17 A. There was a crew from England, a
18 television crew that recorded some of the
19 presentations that morning, I believe, including
20 mine.

21 Q. Okay. And do you know who -- do you know
22 any of the names of these people?

23 A. No.

24 Q. And did GSK ask you to present this
25 information at the APA?

1 A. It was a symposium organized by GSK, yes.

2 Q. And did you get paid either directly or
3 indirectly by GSK for doing this?

4 A. I got an honorarium from the APA that was
5 provided by GSK, you know, an unrestricted
6 educational grant to the APA. They paid me a
7 combination of honorary and then travel fees.

8 Q. Okay. Let me make sure I got that right.
9 GSK pays the APA and the APA pays you?

10 A. That's correct.

11 Q. Okay. And why is that? Why doesn't GSK
12 just pay you directly? Same difference, right?

13 MR. DAVIS: Object to form.

14 THE WITNESS: It's not the same
15 difference, because the APA reviews the content and
16 presentation of those. So you're responsible to the
17 APA for balance and fairness in the presentations,
18 as well as they let the presentations be done.

19 BY MR. MURGATROYD:

20 Q. So if your presentation is unbalanced or
21 unfair, would that make you susceptible to some kind
22 of rules within the APA?

23 A. Yes. Though, I don't -- but I can't tell
24 you offhand the details of it, but yes.

25 Q. Okay. And do you agree that one of the

1 ways that GSK promotes its drug Paxil is by giving
2 presentations at symposium?

3 MR. DAVIS: Object to the form.

4 THE WITNESS: I think that helps them
5 promote their compound, yes.

6 BY MR. MURGATROYD:

7 Q. Okay. Now, another way of promoting their
8 compound is what are known as posters, correct?

9 A. Here -- the way you word your question --
10 posters are done by investigators to present the
11 data. They would have a secondary effect of
12 promoting the compound, yes.

13 Q. Okay. And you personally were involved in
14 how many posters regarding Paxil and its use by
15 adolescents for the treatment of depressive
16 disorder?

17 A. Two or three to my memory.

18 Q. And let's take up each of those at a time,
19 and actually before I do that, have you produced any
20 of those to me?

21 A. No. I don't have those. I wasn't
22 primarily responsible for the posters, and I don't
23 have copies of those.

24 Q. Okay. You don't have copies anywhere?

25 A. No. I produced everything I had, and I

1 have to check on the slides. That may have been an
2 oversight on my part, not deliberately have been,
3 but I will definitely check tonight and I will get
4 them back to you by the morning.

5 Q. That's fine. And so there's two or three
6 posters, correct?

7 A. That's the best I can guess.

8 Q. Okay. Again, that's an estimate not a
9 guess.

10 A. My apologies. It's an estimate.

11 Q. Okay. There's a great analogy on the
12 difference between a guess and an estimate?

13 A. No. No. No. I'm not.

14 Q. You got the difference between the two?

15 A. No. Not up. What's the difference?

16 Q. All right. If I were to ask you what kind
17 of car do I drive you would have no information upon
18 which to base that, correct, so you would have to
19 guess.

20 A. Okay.

21 Q. But if I were to ask you to tell me the
22 length of this table either in inches, feet or
23 yards, you could give some sort of estimate,
24 correct?

25 A. Works for me. So it was an estimate.

1 Q. Okay.

2 A. Could not guess a BMW. See? Your point's
3 well taken then.

4 Q. No. Much faster. I don't drive slow
5 cars. Two or three posters. Let's go over each one
6 of those.

7 A. Right. I don't know. I don't remember
8 where they were presented. As I remember there was
9 a poster with the results of the study before the
10 publication. It was -- and so this is a guess as
11 opposed to an estimation -- my guess is it was
12 presented at the APA or the NCDEU or a meeting like
13 that, but I don't know where it was presented.

14 Q. Okay.

15 A. And I remember that --

16 Q. Wait a minute. I'm going to ask you?

17 A. My apologies.

18 Q. We're going to confuse the jury as well as
19 the court reporter. NCDEU?

20 A. New statistical -- NCDEU. It's a meeting
21 that's always known by those initials and never by
22 more of a name. It's a meeting sponsored by the
23 NIMH that's held annually typically in Florida.

24 Q. And what kind of people attend such a
25 meeting?

1 A. Adult and child psychiatry. Primarily
2 pharmacology, but not exclusivity.

3 Q. Okay. And did we get what those initials
4 stand for?

5 A. The initials stand for a part of the NIMH
6 that existed 20 years ago that hasn't existed since
7 then called the New statistical Drug Evaluation
8 Unit, but what it stood for has been come
9 disassociated with the name. The name is now the
10 NCDEU meeting.

11 Q. Okay. But that part of the NIMH doesn't
12 exist anymore?

13 A. That's correct. It's now just --

14 Q. Carried on its name?

15 A. It's like USX. It used to be US Steel.

16 Q. Okay. Great. Now, the posters -- well,
17 maybe you can explain to the jury, how does a poster
18 work? What is a poster and what is its purpose and?

19 A. The poster is a presentation of selling a
20 data from a study on a -- on a bulletin board that
21 you carry up a rolled up piece of paper to the
22 meeting that's got the details on it. You put it up
23 on the bulletin board. Colleagues come by and
24 discuss it with you for a couple of hours and you
25 take it back down.

1 Q. Okay. So -- and who prepares the poster?

2 A. The investigator or the pharmaceutical
3 industry in collaboration with the investigator
4 depending on the studies.

5 Q. Okay. And with regard to the two posters
6 you did, did you create either of those posters?

7 A. No. I didn't. I was a coauthor on two
8 posters. I wasn't the primary author, and no I did
9 not.

10 Q. Okay. And were you present when your
11 posters were presented to the people who gathered
12 for the meeting?

13 A. I was not for either one.

14 Q. Okay. And with a poster, does one of the
15 coauthors or authors of the poster stand next to the
16 poster?

17 A. Typically the first author stands next to
18 the poster, typically other authors would not.

19 Q. Okay. And what are their job? To field
20 any questions?

21 A. Yes.

22 Q. Do they also give a lecture or do they
23 just --

24 A. No.

25 Q. Okay. And how is it set up? Are they in

1 a meeting hall room where?

2 A. It would be set up in a meeting hall room
3 with 50 to 150 other posters in long lines. You can
4 sort of see, you know, long lines of the poster
5 boards just in aisles down four or five rows of
6 those perhaps.

7 Q. That's so the doctors or whoever's
8 attending the meetings view each poster and if the
9 have a question they can talk to the presenter?

10 A. That's correct.

11 Q. And have you seen recently the poster that
12 was presented that had you as a coauthor?

13 A. I have no idea which poster you're talking
14 about so I can't answer your question.

15 Q. Well, maybe, can you differentiate between
16 the posters that you coauthored?

17 A. The one's I'm remembering now are two.

18 Q. Okay.

19 A. One was a poster on the overall results of
20 the study before the paper came out, and there was a
21 second poster where the lead author was Dr. Boris
22 Birmaher. B-I-R-M-A-H-E-R.

23 Q. Okay.

24 A. Presented at the American Academy of Child
25 and Adolescent Psychiatry doing a sub analysis

1 of saying whether the kids with conduct disorder
2 problems or oppositional defiant disorder responded
3 differently?

4 Q. Okay.

5 A. Those are the two that I can remember.

6 Q. And to your knowledge, was your name stuck
7 on other posters by GSK?

8 A. There was one other poster that I was a
9 coauthor on.

10 MR. DAVIS: Excuse me. Object to the
11 form.

12 Sorry, Doctor.

13 MS. CONNELLY: Yes. I don't know what
14 stuck means? Using glue or?

15 THE WITNESS: There was one other poster
16 that I was a coauthor on for study -- help me get
17 this study right now. I suppose it's -- which was
18 the second study completed?

19 MR. MURGATROYD: 377.

20 THE WITNESS: For study 377. That I was a
21 coauthor on that poster. I did see it before it was
22 presented.

23 BY MR. MURGATROYD:

24 Q. And why would you be a coauthor on 377
25 when it was an European study?

1 A. Right. They were two issued involved in
2 that. One, they needed a member of a particular
3 organization to present at that study, and I felt it
4 was -- they did show me the data on that. I had
5 been a participate in the design of that study and I
6 had done training for the raters in that study. So
7 it was -- I made a modest, but real scientific
8 contribution to the study.

9 Q. Okay. When you say you participated in
10 the designed of that study, can you --

11 A. That's correct.

12 Q. Can you explain that please.

13 A. Sure. SKB, GSK had called a design
14 meeting with a relatively small number of people to
15 talk about the design parameters in the study, so,
16 for example, which assessment instruments to use.
17 Whether to use a run-in placebo period or not, how
18 long a study to do, how to titrate the medication.

19 Q. Okay. Where did that meeting take place?

20 A. I don't remember.

21 Q. Okay. And who else was present other than
22 yourself?

23 A. Don't remember. I'm certain that -- or it
24 seems very -- my memory is that Dr. Graham Emslie
25 was. I don't remember the other participates.

1 Q. Okay. Now, let me pull out one of the
2 posters. Well, other the three that you now
3 described, are you aware of any others?

4 A. I'm not remembering any others right now.

5 Q. Did GSK ever say your name was included on
6 the poster -- well, let me ask you this: Is it
7 proper for GSK to obtain your permission to put your
8 name on a poster before they do it?

9 A. Yes. It would -- yes, it would be proper
10 to obtain -- not only to obtain my permission,
11 but -- yes, it would be proper to obtain my
12 permission before they put my name on a poster, yes.

13 Q. Were you ever made aware that you were
14 named in what's called poster 69 on the safety of
15 Paroxetine and imipramine in the treatment of
16 adolescent depression?

17 A. Show me the poster and it'll refresh my
18 memory, please.

19 MR. DAVIS: Can I see that first?

20 MS. CONNELLY: Yes. Sure.

21 (RYAN Deposition Exhibit No. 40
22 was marked for identification.)

23 THE WITNESS: Okay. I'm ready whenever
24 you want to discuss it.

25

1 BY MR. MURGATROYD:

2 Q. Absolutely. First of all, why don't you
3 identify it for the record what this is.

4 A. Sure. This says, "Poster No. 69." The
5 title is "Safety of paroxetine and Imipramine in the
6 Treatment of Adolescent Depression." It does not
7 indicate a date. It does not indicate which meeting
8 it was presented at.

9 The authors are the physicians outside of
10 GSK and other professionals, you know, Dr.
11 Gittleman-Klein is a Ph.D outside of GSK that
12 participated in the study. There are no GSK
13 coauthors on this study so it does to appear to --
14 it appears to be a poster done very early, because
15 it simply reiterates what is going to be in the
16 paper so it wouldn't have been appropriate to submit
17 it after the paper was published just because it's
18 redundant. The paper is redundant with this and
19 contains basically the side effect data that's
20 presented in the paper.

21 Q. Okay. And your name is on this poster?

22 A. My name is on this.

23 Q. And were you presented with this poster
24 prior to it being presented at the meeting?

25 A. The first author is Dr. Wagner. I assume

1 I would. I certainly would have signed off on this
2 poster. It appears perfectly fair and fine.

3 Q. Do you recall signing off on this poster?

4 A. No.

5 Q. Do you have a copy of this poster in your
6 possession?

7 A. I gave you everything I had. No.

8 Q. Do you recall before today ever seeing
9 this poster?

10 A. Right now I don't recall seeing this
11 before --

12 Q. Okay.

13 A. -- but it's certainly is something that I
14 would have signed off on. It's a very reasonable
15 poster and it also gives no indication of being
16 prepared by GSK. I mean, this is -- this is typed
17 up and ugly so it's not the way that pharmaceutical
18 companies prepare posters.

19 Q. My question was -- do you recall my
20 question?

21 A. Why don't you refresh my memory, please?

22 Q. I reask you.

23 A. This was, what? About a decade ago?

24 Q. There's no question pending. Just be
25 patient.

1 Do you know who prepared this poster?

2 A. It seems overwhelmingly likely that Dr.
3 Wagner did it, but I have no direct knowledge of
4 that.

5 Q. Okay.

6 A. It would be most usual for the first
7 author to prepare the poster. Almost always done
8 that way.

9 Q. Okay. Now, assuming the FDA's analysis:
10 That in your study Paxil had a risk factor of 5.19
11 with regard to possible suicide events, would you
12 state that Paxil is a safe drug?

13 MR. DAVIS: Object to the form of the
14 question.

15 THE WITNESS: Right. The 5.9 was not
16 statistically significant in that study and so one
17 can never state that something's a safe drug. All
18 you can state, you know, from a statistical
19 standpoint, all you can state is that it's not safe.
20 There were not indications in that study that it was
21 not safe.

22 Q. Well, in this poster it's affirmatively
23 stating that the drug is safe, right?

24 A. Okay. Says, "Demonstrates the safety of
25 paroxetine in the treatment of adolescent

1 depression."

2 Q. Do you believe that your study 329
3 demonstrated the safety of paroxetine in the
4 treatment of adolescent depression considering the
5 number of suicidal events that occurred during that
6 trial?

7 MR. DAVIS: Object to the form.

8 THE WITNESS: That was the best available
9 data at the time. I do believe the analysis was
10 correct of it, that it wasn't statistically
11 significant different. It wasn't close to being
12 statistically significant different. So I think
13 that this is a condensed, but fair enough way of
14 saying what is obviously a long statistical
15 argument.

16 Q. Well, my question was -- maybe I can make
17 it clear: Do you contend that Paxil is safe in the
18 treatment of adolescent depression?

19 A. I'm sorry. Are you asking me about the
20 data available to the world now or the data
21 available --

22 Q. Yes. Right now. Yes. To the world now?

23 A. I think there is meaningful data that it
24 may not be safe.

25 Q. Now, and do you agree that it was up to

1 GSK to present you with data that could show the
2 drug was unsafe?

3 MS. CONNELLY: Object to form.

4 THE WITNESS: Do you mean they had an
5 obligation to present data to me after this study
6 was ended or related to this study?

7 BY MR. MURGATROYD:

8 Q. Related to the study?

9 A. I believe they had an obligation, and I
10 believe they did it.

11 Q. Okay. Do you feel that you have to defend
12 GSK at this deposition?

13 A. No.

14 Q. Okay. If GSK failed to give you vital
15 information regarding the safety of the drug, is
16 that something that would bother you?

17 MR. DAVIS: Object to the form; no
18 foundation; that that's a fact of case.

19 THE WITNESS: Yes. If they failed to give
20 me important data related to it that would bother
21 me.

22 BY MR. MURGATROYD:

23 Q. Okay. And it says in this poster that
24 side effects were modest with paroxetine?

25 A. Huh-huh.

1 Q. That's not a true statement, is it?

2 A. That's a completely true statement.

3 Q. Really? How many serious adverse events
4 were in in 329?

5 A. Were there six?

6 Q. That's all you recall? How many do you
7 say in your paper?

8 A. Let me go look. When you say serious
9 adverse events. Oh, 11 in the paper -- sorry -- in
10 the paroxetine group. Two in imipramine and two in
11 placebo.

12 Q. And serious adverse event actually has a
13 technical definition, doesn't it?

14 A. Yes, it does.

15 Q. And what is that definition?

16 A. I can't get it exactly, but basically
17 things requiring hospitalization, significant
18 worsening in the condition, a change of treatment.

19 Q. Life threatening?

20 A. That would be included, but almost none of
21 the statistical -- almost no SAE in any study I've
22 ever been involved with was -- very few was life
23 threatening.

24 Q. Well, you had kids in study 329 who tried
25 to kill themselves, right?

1 MR. DAVIS: Object to the form; no
2 foundation.

3 MS. CONNELLY: I'm going to object to the
4 kids once again. This is an adolescent study.

5 MR. MURGATROYD: Okay. That's fine.

6 BY MR. MURGATROYD:

7 Q. You had adolescents in your study 329 who
8 tried to kill themselves?

9 MR. DAVIS: Object to the form; no
10 foundation.

11 THE WITNESS: Right. There were
12 adolescents in 329 who made suicide gestures and
13 suicide attempts. That's different from them being
14 life threatening.

15 BY MR. MURGATROYD:

16 Q. How many of the adolescents in 329 had to
17 be hospitalized because of the serious adverse
18 affect?

19 A. Let me find out. Two with worsening
20 depression, two with emotional lability, two with
21 conduct problems and one with euphoria.

22 Q. They were all put in the hospital?

23 A. That's what it says here.

24 Q. Okay. Do you consider a side effect
25 modest if it requires hospitalization?

1 A. Modest or more so, but it's -- obviously
2 you have the problem -- these kids had serious
3 depression before they started.

4 Q. Well, that's not quite true. Let's sort
5 that one out right now. For a HAM-D score of 12,
6 what type of depression is that? Mild, moderate or
7 severe?

8 MR. DAVIS: Excuse me. I will move to
9 strike Counsel's comment about that not being true.

10 MS. CONNELLY: And by agreement of the
11 parties just so everyone knows we're to stop in
12 about two minutes.

13 MR. MURGATROYD: That's fine. We'll
14 finish this question and then we'll stop.

15 THE WITNESS: Right.

16 BY MR. MURGATROYD:

17 Q. All right. Hamilton-D score of 12?

18 A. Mild.

19 Q. Okay. You agree that because you had a
20 recruiter problem with 329 you reduced that Hamilton
21 score to 9 to get more patients, right?

22 MR. DAVIS: Object to the form.

23 THE WITNESS: Yes, but what you're saying
24 is misleading in that many of the kids in this study
25 had some more severe depressions so that the -- the

1 threshold for the study was relatively low, doesn't
2 at all indicate that there weren't severe kids in
3 this study and that worsening of a depression from
4 somebody even with a Hamilton-D of 12 was clearly a
5 result of the medication.

6 Q. Let me ask you this: How many of the kids
7 who tried to kill themselves, had a suicide attempt,
8 entered the study with a Hamilton-D score of 12?

9 A. I don't know.

10 Q. How many had the Hamilton-D score of 15?

11 A. I don't know the correlation between the
12 Hamilton-D score at entries of the study and
13 attempting suicide. When the analysis of what
14 predicted suicidality was largely negative, because
15 I remember suggesting that that's not probably a
16 strong predictor across these studies. I don't know
17 that we ever looked at that in this particular
18 study.

19 MR. MURGATROYD: Okay. That's fine.
20 We'll stop here. Thank you.

21 VIDEOGRAPHER: That's the end of the
22 deposition for today. The time is 5:27 p.m.

23 (Ending time: 5:27 p.m.)

24

25

1 REPORTER'S CERTIFICATION

2 I, Michele Kohar, Court Reporter certify;
3 that the foregoing proceedings were taken by
4 me at the time and place therein set forth;at
5 which time the witness was put under oath by me;

6 That the testimony of the witness, the
7 questions propounded, and all the objections
8 and statements made at the time of the examination
9 were recorded stenographically by
10 me and were thereafter transcribed;

11 That the foregoing is a true and correct
12 transcript of my shorthand notes so taken.

13 I further certify that I am not a relative
14 or employee of any of the attorneys of the parties,
15 nor financially interested in the
16 action.

17 I declare under penalty of perjury under the
18 laws of Pennsylvania that the foregoing is
19 true and accurate.

20 Dated this 1st day of November, 2006.

21

22

23

24

MICHELE A. KOHAR, COURT REPORTER.

25

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