

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT  
OF PENNSYLVANIA  
C.A. NO.: 06-3022-TJS

CHERYL J. CUNNINGHAM, Individually )  
and as Personal Representative of )  
the Estate of SCOTT RANDALL )  
CUNNINGHAM, Deceased, JOHN J. )  
CUNNINGHAM, Individually, and KEVIN )  
CUNNINGHAM, Individually, )  
Plaintiffs, )

VS. )

SMITHKINE BEECHAM CORPORATION d/b/a )  
GLAXOSMITHKLINE, a Pennsylvania )  
Corporation, )  
Defendant. )

-----)

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA  
CASE NO.: C-06-03186 MJJ

-----)  
WILLIAM P. WILLIAMS, individually )  
and as Guardian Ad Litem for )  
KEVIN J. WILLIAMS, )  
Plaintiffs, )

VS. )

SMITHKLINE BEECHAM CORPORATION, )  
d/b/a GLAXOSMITHKLINE, a )  
Pennsylvania Corporation; )  
McKesson Corporation, A California )  
Corporation; and DOES 1-50 )  
Defendants. )

-----)

DEPOSITION OF SALLY K. LADEN

NEW HAVEN, CONNECTICUT  
MARCH 15, 2007

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FILE NO.: A00851B

1 COURT OF COMMON PLEAS  
 2 PHILADELPHIA COUNTY  
 3 C.A. NO.: 1503  
 -----)  
 4 )  
 IN RE: PAXIL )  
 5 )  
 -----)  
 6  
 7 IN THE UNITED STATES DISTRICT COURT  
 FOR THE WESTERN DISTRICT OF WASHINGTON  
 8 AT SEATTLE  
 9 C.A. NO.: 06-CV-0170 (RSM)  
 10 CHRISTOPHER SHIBLEY, )  
 Plaintiff, )  
 11 )  
 VS. )  
 12 )  
 SMITHKLINE BEECHAM, d/b/a )  
 13 GLAXOSMITHKLINE )  
 Defendant. )  
 -----)  
 14 DEPOSITION OF  
 15 SALLY K. LADEN  
 16 NEW HAVEN, CONNECTICUT  
 17 MARCH 15, 2007  
 18  
 19  
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 23 REPORTED BY: DENISE D. HARPER-FORDE  
 CRS NO. 0133  
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 25 FILE NO.: A00851B

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 Defendant. )  
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 14  
 15 Deposition of SALLY K. LADEN, taken  
 16 on behalf of Plaintiff, at NEW HAVEN  
 17 HOTEL, 229 George Street, New Haven,  
 18 Connecticut at 10:00 A.M., Thursday,  
 19 March 15, 2007, before Denise D.  
 20 Harper-Forde, CSR No. 0133.  
 21  
 22  
 23  
 24  
 25

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 21 Corporation; and DOES 1-50 )  
 Defendants. )  
 22 -----)  
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Page 11	Page 13
<p>1 VIDEOGRAPHER: We are on the 2 record. This is the video operator 3 speaking, Shawn Budd. Today's date is 4 March 15, 2007. The time is five minutes 5 after 10:00. We are here at the New 6 Haven Hotel located in New Haven, 7 Connecticut to take the videotaped 8 deposition of Sally Laden. 9 In the matter of Cheryl J. 10 Cunningham et al versus SmithKline 11 Beecham Corporation d/b/a 12 GlaxoSmithKline. 13 And William P. Williams versus 14 SmithKline Beecham Corporation d/b/a 15 GlaxoSmithKline et al. 16 And In Re: Paxil. 17 And Christopher Shibley versus 18 SmithKline Beecham d/b/a GlaxoSmithKline. 19 Would counsel please introduce 20 themselves. 21 MR. MURGATROYD: My name is Skip 22 Murgatroyd. And I represent the 23 Plaintiffs in the Cunningham and Williams 24 cases. 25 MR. BRASLOW: My name is Derek</p>	<p>1 DIRECT EXAMINATION 2 3 BY MR. MURGATROYD: 4 Q. Can you please state and spell 5 your full name for the record? 6 A. <b>Sally K. Laden. S-A-L-L-Y, K.,</b> 7 <b>L-A-D-E-N.</b> 8 Q. Okay. And what is your current 9 address? 10 A. <b>898 Cahill Court. Cheshire,</b> 11 <b>Connecticut.</b> 12 Q. Okay. And you're represented by 13 counsel today; correct? 14 A. <b>Yes.</b> 15 Q. Okay. Now, have you ever been 16 deposed before? 17 A. <b>No.</b> 18 Q. Okay. Did you get a chance to go 19 over the ground rules of a deposition? 20 A. <b>Yes.</b> 21 22 MR. MURGATROYD: Okay. Most 23 importantly, you understand that you're 24 under oath. And it's the same oath that 25 you take as if you were sitting before a</p>

1 Judge and Jury. You understand that?  
 2 THE WITNESS: Yes.  
 3 MR. MURGATROYD: Okay. Now, the  
 4 Court Reporter here is here to take down  
 5 everything that is said. And some time  
 6 after this deposition is completed you  
 7 will get a transcript. Which will  
 8 contain the testimony that you have given  
 9 today.  
 10 At the time you receive that, you  
 11 can review it and make any changes you  
 12 want to make. But I must caution you now  
 13 that any changes you do make can be  
 14 commented upon at the time of trial. Do  
 15 you understand that?  
 16 THE WITNESS: Yes.  
 17 MR. MURGATROYD: The idea is to  
 18 give your best testimony today. Okay?  
 19 THE WITNESS: Okay.  
 20 MR. MURGATROYD: Okay. Great.  
 21 One of last rules is that you have to  
 22 give answers that are out loud. The  
 23 Court Reporter can't take down shrugs  
 24 nods or gestures.  
 25 And also if you would, please

1 too should that case get re-launched.  
 2 MR. DAVIS: If the stay is lifted  
 3 and those cases proceed.  
 4 MR. MURGATROYD: Okay. Great.  
 5 All right.  
 6  
 7 (BY MR. MURGATROYD):  
 8 Q. Now, you understand that you're  
 9 here today in connection with lawsuits  
 10 involving the drug Paxil?  
 11 A. Yes.  
 12 Q. Okay. Are you familiar with what  
 13 the allegations are in any of the  
 14 complaints?  
 15 A. Yes, I am.  
 16 Q. Okay. And what is your  
 17 understanding of what they are?  
 18 A. Well, my understanding is that  
 19 the Plaintiff's children took their own  
 20 lives while taking Paroxetine.  
 21 Q. Okay.  
 22 A. And that is the basis for the  
 23 lawsuit.  
 24 Q. Okay. Are you also aware that  
 25 there are other actions involving

1 wait for me to completely ask a question  
 2 before you begin to answering. So that  
 3 the Court Reporter can get down a clean  
 4 record. Is that okay?  
 5 THE WITNESS: Yes.  
 6  
 7 (BY MR. MURGATROYD):  
 8 Q. Okay. Is there any reason why  
 9 you can't give your best testimony  
 10 today?  
 11 A. No.  
 12 Q. Okay.  
 13  
 14 MR. DAVIS: Skip, just for  
 15 logistical issues. I understand that  
 16 Ms. Laden's deposition is also being  
 17 taken -- or the Plaintiffs want to use  
 18 Ms. Laden's deposition in other Baum  
 19 Hedlund pediatric cases. And that this  
 20 deposition will serve as that function as  
 21 well.  
 22 MR. MURGATROYD: That is correct.  
 23 MR. DAVIS: Okay. Thanks.  
 24 MR. MURGATROYD: And I guess for  
 25 that matter, it would be the Smith case

1 allegations of fraud?  
 2  
 3 MR. DAVIS: Object to form.  
 4 THE WITNESS: Yes.  
 5  
 6 (BY MR. MURGATROYD):  
 7 Q. Okay. Were you aware of a  
 8 lawsuit of the Attorney General Spitzer  
 9 of the State of New York brought?  
 10 A. Yes, I am. I am not familiar  
 11 with the details.  
 12 Q. Okay. Were you aware that it had  
 13 to do with fraud?  
 14 A. No. Not specifically.  
 15 Q. Okay --  
 16  
 17 MR. DAVIS: Excuse me, Derek.  
 18 Just so we have got the ground rules here  
 19 too straightened out. I'm sorry I didn't  
 20 mention this earlier.  
 21 But I assume that all objections  
 22 except as to the form of the question for  
 23 the responsiveness of the answer are  
 24 reserved until such further use of the  
 25 deposition or until time of trial?

1 MR. BRASLOW: That's correct.  
 2 MR. DAVIS: Is that right?  
 3 MR. MURGATROYD: I'm agreed.  
 4 MR. DAVIS: Okay.  
 5 MR. BRASLOW: But we are not  
 6 necessarily agreeable to that. There may  
 7 be certain questions that are  
 8 objectionable. But we would have to  
 9 discuss at that time as to whether I'm  
 10 going to direct her to answer.

11 MR. DAVIS: Oh, I certainly  
 12 didn't mean to imply that if there is  
 13 something that impinged upon privileged  
 14 communication or something of that  
 15 nature, that that would cut off your  
 16 right to objection. I just meant the  
 17 party's objections would be subject to  
 18 those limitations.

19 MR. MURGATROYD: Absolutely.

20 MR. DAVIS: Thank you.

21 (BY MR. MURGATROYD):

22 Q. Have you had any contact with  
 23 anyone from GlaxoSmithKline regarding  
 24 your deposition today?  
 25

1 Q. Okay. What does that consist  
 2 of?

3 **A. It was continuing education  
 4 required to maintain my pharmacy  
 5 license.**

6 Q. Okay. Is that something you do  
 7 on a yearly basis?

8 **A. When I maintained my license, yes  
 9 it was.**

10 Q. Okay. So I take it you no longer  
 11 have your license?

12 **A. No. I haven't worked as a  
 13 pharmacist for many years.**

14 Q. Okay. Now going back to earlier  
 15 questions. Are you currently employed?

16 **A. Yes.**

17 Q. Okay. And where are you  
 18 employed?

19 **A. I'm self-employed, and I work  
 20 from my home.**

21 Q. And do you have a corporation?

22 **A. Yes.**

23 Q. What is it called?

24 **A. MSE. "M" as in "Mary". "S" as  
 25 in "Sam", "E" -- Communications. MSE**

1 **A. No.**

2 Q. Okay. Are you aware that other  
 3 people who are involved in what is known  
 4 as Study 329 have been deposed?

5 **A. I'm not aware of that.**

6 Q. Okay. So I take it you haven't  
 7 obviously read or heard of any of their  
 8 depositions; correct?

9 **A. Correct.**

10 Q. Okay. Now, are you currently  
 11 employed?

12 **A. Yes.**

13 Q. Actually, before I get into that.  
 14 Can you briefly take me through your  
 15 educational background beginning with  
 16 college?

17 **A. Yes. I graduated in 1981 from  
 18 the University of Connecticut with a  
 19 Bachelors degree in Pharmacy. And in  
 20 1983 from the University of Kansas -- or  
 21 let me say Kansas University, with a  
 22 Masters degree in Hospital Pharmacy.**

23 Q. Have you had any continuing  
 24 education training since then?

25 **A. Yes.**

1 **Communications.**

2 Q. Does MSE stand for anything in  
 3 particular?

4 **A. Family initials.**

5 Q. Now, what does that business  
 6 do?

7 **A. I'm a freelance writer.**

8 Q. And what kind of writing do you  
 9 do?

10 **A. A wide variety of different  
 11 science and medical writing.**

12 Q. Okay. And do you do that for  
 13 pharmaceutical companies?

14 **A. Pharmaceutical companies makeup  
 15 part of my client base. Not entirely.**

16 Q. Okay. Whose the rest?

17 **A. Individuals who need help editing  
 18 their papers. Patient advocacy groups,  
 19 agencies.**

20 Q. Okay. And do you currently work  
 21 for any particular pharmaceutical  
 22 companies?

23 **A. Yes.**

24 Q. Which ones?

25 **A. Myriad Pharmaceuticals. That's**

1 it.

2 Q. So I take it you're the founder  
3 of MSE Communications; correct?

4 A. Yes.

5 Q. Okay. And prior to starting that  
6 company, did you work with a company  
7 called STI?

8 A. Yes.

9 Q. Did you go right from STI to  
10 starting your corporation?

11 A. Yes.

12 Q. What does STI stand for?

13 A. **Scientific Therapeutics**  
14 **Information.**

15 Q. And where is it located?

16 A. **Springfield, New Jersey.**

17 Q. What kind of business is it? Is  
18 it still in existence?

19 A. Yes.

20 Q. Okay. What kind of business does  
21 it do?

22 A. **Well when I worked for STI it was**  
23 **considered a medical communications. Or**  
24 **sometimes called medical education**  
25 **company.**

1 for STI for four years.

2 MR. MURGATROYD: Okay.

3 THE WITNESS: So it very  
4 similarly resembles what it was four  
5 years ago.

6 MR. MURGATROYD: Okay.

7 THE WITNESS: You know, how they  
8 have changed in the last four years, I  
9 can't tell you.

10 MR. MURGATROYD: I'm only  
11 interested in when you were there.

12 (BY MR. MURGATROYD):

13 Q. Okay. So it does accurately  
14 describe the activities of that business  
15 while you were there?

16 A. **I cannot say that there are**  
17 **things on here that might be new.**

18 Q. Okay.

19 A. **Because there could very well be**  
20 **things that are new.**

21 Q. Okay. Well it appears on the  
22 second page of this document that there  
23 are three main areas of activities. Do  
24 you see that?  
25

1 MR. MURGATROYD: Okay. Now,  
2 let's see. I pulled a -- let me see if I  
3 can get a copy of this. I looked STI up  
4 on the Web, and copied or downloaded what  
5 appears to be Company profile. Let me  
6 show this to you. I will mark it as  
7 Exhibit one.  
8  
9

10 (Plaintiff's Exhibit 1, marked)

11 (BY MR. MURGATROYD):

12 Q. Did you get a chance to review  
13 that?  
14

15 A. Yes.

16 Q. Okay. And does it accurately  
17 describe the business of STI?  
18

19 MR. DAVIS: Object to the form.

20 THE WITNESS: What does that  
21 mean?  
22

23 MR. MURGATROYD: You can answer.  
24 He says that a lot. Don't worry about  
25 that.

THE WITNESS: I have not worked

1 A. Yes.

2 Q. First is medical writing. Do you  
3 see that?  
4

5 A. Yes.

6 Q. Okay. And was that activity part  
7 of the business when you were there?  
8

9 A. Yes, it was.

10 Q. Okay. And it that an activity  
11 that you were personally involved in?  
12

13 A. Yes.

14 Q. Okay. And the second area it  
15 says "meetings". Do you see that?  
16

17 A. Yes.

18 Q. Okay. And some of the  
19 subcategories are advisory board  
20 meetings. Those type of meetings. Did  
21 you participate in those types of  
22 activities when you worked at STI?  
23

24 A. Yes.

25 Q. Okay. And the last section or  
major heading on this page is "Consulting  
Services". Do you see that?  
26

A. Yes.

Q. And it talks about pre-launch and  
launch programs; is that correct?

1 **A. Yes.**

2 Q. Okay. What is a launch  
3 program?

4 **A. To the best of my understanding,**  
5 **a launch program is planning the**  
6 **pharmaceutical company does prior to you**  
7 **know making a new drug available for the**  
8 **market or launching. Launching it onto**  
9 **the market.**

10 Q. Does it have to be a new drug or  
11 can it be a new indication for an older  
12 drug?

13 **A. I guess it can be both.**

14 Q. Okay. Now did you participate in  
15 any types of those activities while you  
16 were with STI?

17 **A. Yes.**

18 Q. Okay. Now, is the purpose of STI  
19 to help pharmaceutical -- when they work  
20 for a pharmaceutical company. Obviously  
21 they have other -- let me ask that  
22 question.

23 Does STI have other clients than  
24 pharmaceutical companies while you were  
25 there?

1 **A. I don't recall. There could very**  
2 **well have been, but I don't recall.**

3 Q. Okay. Did you work for any  
4 company other than a pharmaceutical  
5 company while you were at STI?

6 **A. I cannot say that I did not, but**  
7 **it was primarily pharmaceutical**  
8 **companies.**

9 Q. Okay. And was the purpose of  
10 that work to help pharmaceutical  
11 companies get their products well known?  
12

13 MR. DAVIS: Object to the form.

14 THE WITNESS: Can you repeat the  
15 question.

16 MR. MURGATROYD: Yes, sure.  
17

18 (BY MR. MURGATROYD):

19 Q. Was part of that business --  
20 STI's business was to help  
21 pharmaceuticals getting the products of  
22 drug companies well known?  
23

24 MR. DAVIS: Same objection.

25 THE WITNESS: It's hard for me to

1 answer that question. I don't know if  
2 that was -- it's hard to button hole a  
3 purpose.  
4

5 (BY MR. MURGATROYD):

6 Q. Okay. Well did STI have any  
7 activities regarding promotion of drugs?  
8

9 **A. No.**

10 Q. Okay. Well have you ever seen  
11 business plans of pharmaceutical  
12 companies on how they are going to  
13 promote their drugs? Different ways they  
14 promote drugs?  
15

16 **A. I may have.**

17 Q. Okay. Is having articles  
18 published in peer review medical journals  
19 one way in which a drug company can  
20 promote it's drug to prescribing  
21 physicians?  
22

23 MR. DAVIS: Object to the form.

24 THE WITNESS: No. I don't  
25 consider that promotion.

(BY MR. MURGATROYD):

1 Q. Okay. Is that a way of  
2 communicating to the medical field about  
3 a drug?  
4

5 **A. Yes.**

6 Q. Okay. And would you agree that  
7 the purpose of that communication is so  
8 the person reading it will think -- will  
9 learn about the drug?  
10

11 MR. DAVIS: Object to the form.

12 THE WITNESS: Will learn about  
13 the drug?  
14

15 MR. MURGATROYD: Right.

16 THE WITNESS: As far as reading  
17 any peer review journal helps you learn  
18 about the topic, then I would say  
19 "yes".  
20

21 (BY MR. MURGATROYD):

22 Q. Okay. Well as a medical writer,  
23 would you agree -- you are a medical  
24 writing; correct?  
25

**A. Yes.**

Q. Okay. Would you agree that your  
purpose for your clients is to bring

<p style="text-align: right;">Page 30</p> <p>1 information out about whoever you're 2 working for?</p> <p>3</p> <p>4 MR. DAVIS: Object to form. 5 THE WITNESS: No.</p> <p>6</p> <p>7 (BY MR. MURGATROYD): 8 Q. Okay. You don't do that? 9 <b>A. Repeat the question, please.</b> 10 Q. Okay. Well let's take -- let me 11 ask you this. Do you agree that one of 12 the ways that GSK promotes the drug 13 Paxil --</p> <p>14</p> <p>15 MR. MURGATROYD: And whenever I 16 say "GSK", that means "GlaxoSmithKline". 17 But I'm not going to say that every time. 18 I will say "GSK". Do you understand 19 that?</p> <p>20 THE WITNESS: Yes. 21 MR. MURGATROYD: Okay. Great.</p> <p>22</p> <p>23 (BY MR. MURGATROYD): 24 Q. Now, do agree that one of the 25 ways that GSK promotes it's drug Paxil is</p>	<p style="text-align: right;">Page 32</p> <p>1</p> <p>2 MR. DAVIS: Objection. 3 THE WITNESS: No.</p> <p>4</p> <p>5 (BY MR. MURGATROYD): 6 Q. What is the purpose? 7 <b>A. The purpose is to further 8 scientific discourse. Which is why you 9 would publish something in a peer review 10 journal.</b> 11 Q. Okay. And do you think that one 12 of the subsidiary premises is to promote 13 the drug and have doctors prescribe it?</p> <p>14</p> <p>15 MR. DAVIS: Object to form. 16 THE WITNESS: I can't answer 17 that, because I don't know.</p> <p>18</p> <p>19 (BY MR. MURGATROYD): 20 Q. Okay. Now, you were paid when 21 you were at STI to write medical journal 22 articles? 23 <b>A. I was an employee of STI, and I 24 was paid to do whatever project STI threw 25 my way.</b></p>
<p style="text-align: right;">Page 31</p> <p>1 by publishing articles in peer review 2 journals?</p> <p>3</p> <p>4 MR. DAVIS: Object to the form. 5 Also asked and answered. 6 MR. MURGATROYD: It's a specific 7 question. 8 THE WITNESS: You ask if it 9 promotes Paxil? 10 MR. MURGATROYD: Yes.</p> <p>11</p> <p>12 (BY MR. MURGATROYD): 13 Q. One of the ways it promotes Paxil 14 is by having articles published in peer 15 review journals?</p> <p>16</p> <p>17 MR. DAVIS: Same objection. 18 THE WITNESS: I agree that it 19 provides clinicians with information 20 about a study using Paxil.</p> <p>21</p> <p>22 (BY MR. MURGATROYD): 23 Q. Okay. And would you agree that 24 the purpose of that is to get the 25 clinician to prescribe the drug?</p>	<p style="text-align: right;">Page 33</p> <p>1 Q. Okay. And was one of the 2 projects to write medical journal 3 articles? 4 <b>A. Yes.</b> 5 Q. Okay. And how many medical 6 journal articles did you write while you 7 were with STI? 8 <b>A. I do not know. I cannot 9 remember.</b> 10 Q. Okay. Do you have any idea? Any 11 estimate? 12 <b>A. I worked for John Romankowitz for 13 20 years. It's hard for me to say you 14 know how many individual projects of any 15 of these kinds that I did. I don't 16 remember.</b> 17 Q. Okay. I'm sorry. You mentioned 18 a person's name, John? 19 <b>A. John Romankowitz is the President 20 of STI.</b> 21 Q. Okay. What was your position at 22 STI? 23 <b>A. I think when I left I was 24 Associate Editorial Director.</b> 25 Q. Okay. And when I asked how many</p>

1 medical journal articles you may have  
2 written. Would it be more than ten?

3 **A. Yes.**

4 **Q. Okay. More than 20?**

5 **A. Yes.**

6 **Q. Okay. I think you said you were**  
7 **there 20 years?**

8 **A. I worked for him for 20 years. I**  
9 **was with STI 18 years.**

10 **Q. Okay. Did you write on average**  
11 **more than one article per year?**

12 **A. Yes.**

13 **Q. Okay. So obviously that takes us**  
14 **over 18; correct?**

15 **A. Yes.**

16 **Q. Okay. Would it be two articles a**  
17 **year?**

18 **A. It could have been, yes.**

19 **Q. Okay. And STI would charge --**  
20 **when a pharmaceutical company such as GSK**  
21 **was the client, STI would charge your**  
22 **services to that company; correct?**

23 **A. It was not just my services. It**  
24 **was the services of the entire company.**

25 **Q. Including your services?**

1 **A. Including myself.**

2 **Q. Okay. And would you agree that a**  
3 **journal article that you wrote that was**  
4 **positive in terms of the drug's efficacy**  
5 **and safety would help the drug company**  
6 **with the sale of its drugs?**

7  
8 **MR. DAVIS: Object to the form.**

9 **THE WITNESS: No, I can't agree.**  
10 **I don't agree with that.**

11 **MR. MURGATROYD: Okay. Let me**  
12 **ask you this.**

13  
14 **(BY MR. MURGATROYD):**

15 **Q. How many medical journal articles**  
16 **did you write where in the article you**  
17 **stated the drug was not effective or not**  
18 **safe?**

19  
20 **MR. DAVIS: Object to the form.**  
21 **Vague and ambiguous.**

22 **THE WITNESS: Again I can't**  
23 **answer that, because it's not always --**  
24 **these aren't glowing advertisements. So**  
25 **I don't know. I mean our objective was**

1 to be as balanced as possible. And if  
2 that meant bringing out some negative  
3 aspects if they were there, that is what  
4 we did.

5  
6 **(BY MR. MURGATROYD):**

7 **Q. Okay. My question is how many**  
8 **medical journal articles -- let me break**  
9 **it out. Did you state conclude -- there**  
10 **are abstracts to medical journal**  
11 **articles; right?**

12 **A. Yes.**

13 **Q. Okay. And they have**  
14 **conclusions?**

15 **A. Yes.**

16 **Q. And how many times did you**  
17 **conclude in a medical journal article**  
18 **that you were involved in writing, that**  
19 **the drug that was being discussed in the**  
20 **article was not effective?**

21  
22 **MR. DAVIS: Object to the form.**

23 **THE WITNESS: I don't know. I**  
24 **don't know. Each project is different.**  
25 **So I really can't answer that.**

1  
2 **(BY MR. MURGATROYD):**

3 **Q. Okay. Would you recall ever**  
4 **concluding that a drug was not**  
5 **effective?**

6 **A. Perhaps for a given purpose.**  
7 **Again I can't remember. I cannot give**  
8 **you -- we did a lot of work. A lot of**  
9 **different projects, and it's hard for me**  
10 **to remember specifics.**

11 **Q. Okay. Well that would be**  
12 **something that would stand out in your**  
13 **mind. If you actually wrote an article**  
14 **where somebody is paying you to write it,**  
15 **and you're saying their drug is not**  
16 **effective. Wouldn't that stand out in**  
17 **your mind?**

18  
19 **MR. DAVIS: Object to the form.**

20 **THE WITNESS: I believe that we**  
21 **were paid to give good advice. And if**  
22 **that good advice wasn't always what**  
23 **people wanted to hear, we gave it anyway;**  
24 **so.**

25 **MR. MURGATROYD: Okay. I move to**

1 strike your answer. It doesn't answer  
2 the question that I --

3 THE WITNESS: Okay. I'm sorry.

4  
5 (BY MR. MURGATROYD):

6 Q. Do you recall a specific  
7 incidence in which you concluded that the  
8 drug you were writing about was not  
9 effective?

10 **A. I do not recall.**

11 Q. Okay. Do you recall ever writing  
12 an article in which you concluded that a  
13 drug was not safe?

14  
15 MR. DAVIS: Object to the form.

16 THE WITNESS: Could you define,  
17 "not safe".

18  
19 (BY MR. MURGATROYD):

20 Q. Sure. The risks outweigh the  
21 benefits?

22 **A. That is a pretty broad  
23 definition, and I would say "no".**

24 Q. Okay. No, you don't recall or no  
25 you didn't conclude that?

1 **A. I don't specifically recall. I  
2 don't.**

3 Q. Okay. Well other than medical  
4 writing you said you were also involved  
5 in the business of setting up meetings?

6 **A. Yes.**

7 Q. Okay. And what type of  
8 meetings -- well let's stick with  
9 GlaxoSmithKline. What type of meetings  
10 did you set up for GlaxoSmithKline?

11 **A. Advisory boards. Large CME,  
12 Continuing Medical Education symposia at  
13 national meetings. Such as the American  
14 Psychiatric Association.**

15 Q. Okay.

16 **A. American Academy of Family  
17 Physicians. You know, major national  
18 groups.**

19 Q. Okay.

20 **A. Consulting meetings.**

21 Q. Okay. And this is all for GSK?

22 **A. Yes. And consensus conference  
23 programs.**

24 Q. Okay. Let's take the first one,  
25 Advisory Board meetings. What is the

1 purpose of an Advisory Board meeting?

2 **A. The purpose of an Advisory Board  
3 meeting is for the pharmaceutical company  
4 to pick the brains of medical experts in  
5 the field.**

6 Q. Do they pick their brains with  
7 regards to different uses for the drug?

8  
9 MR. DAVIS: Object to the form.  
10 Calls for speculation.

11 MR. MURGATROYD: Well if you  
12 know.

13 THE WITNESS: I'm sorry.

14  
15 (BY MR. MURGATROYD):

16 Q. Well, let me ask you this. What  
17 do they pick the brains for? What are  
18 they looking for?

19  
20 MR. DAVIS: Object to the form.  
21 I don't think this witness can answer on  
22 behalf of GSK, but you may ask the  
23 question or rephrase it.

24 THE WITNESS: What are they  
25 looking for?

1 MR. MURGATROYD: Yes?

2 THE WITNESS: Every advisory  
3 board meeting is different. So it's hard  
4 to answer that given a blanket statement.

5  
6 (BY MR. MURGATROYD):

7 Q. Okay. Well would you agree that  
8 the Advisory Board meetings -- one of the  
9 purposes is to promote the drug to the  
10 people who sit on the board?

11  
12 MR. DAVIS: Object to the form.

13 THE WITNESS: No.

14  
15 (BY MR. MURGATROYD):

16 Q. And would you agree that -- or  
17 let me ask you this. Was part of the  
18 Advisory Board meetings for GSK, was to  
19 pick the brains of the people on the  
20 board regarding how to best promote  
21 Paxil?

22 **A. No.**

23 Q. You have never written anything  
24 that said that?

25 **A. Most of the -- if anyone puts**

1 **together a good advisory board, those**  
 2 **people don't care about promotion. They**  
 3 **care about science. They care about**  
 4 **furthering the field. That is my**  
 5 **experience.**

6 Q. Do you recall specifically  
 7 setting up an Advisory Board meeting in  
 8 September of 1993 for GlaxoSmithKline?

9 **A. I could very well have. I don't**  
 10 **recall that exact date.**

11  
 12 MR. MURGATROYD: Well let me  
 13 refresh your recollection by showing you  
 14 the next document.

15  
 16 (Plaintiff's Exhibit 2, marked)

17  
 18 MR. MURGATROYD: I will give you  
 19 my copy while I look for another copy. I  
 20 will mark this as Exhibit 2. And for the  
 21 record, it is a letter from Sally Laden  
 22 to Bonnie Rossello at GlaxoSmithKline  
 23 regarding psychiatric advisory board.  
 24 Dated September 29, 1993.

25 Attached to it is a second

1 letter -- this is one continuing  
 2 document. Also by Ms. Laden to David  
 3 Wheadon. Attached to that is an agenda.  
 4 Tentative agenda and discussion points.

5 MR. DAVIS: Skip I see this  
 6 document is subject to protective order  
 7 in the case. Just for your reference,  
 8 Ms. Laden and her counsel have signed a  
 9 protective order in the case.

10 MR. MURGATROYD: I know. I have  
 11 a copy of it.

12 MR. DAVIS: You do?

13 MR. MURGATROYD: Yes.

14 MR. DAVIS: Okay. GSK would  
 15 designate of course this document and  
 16 discussions related thereto subject to  
 17 the protective order.

18 (BY MR. MURGATROYD):

19 Q. You had a chance to review those  
 20 documents?

21 **A. Yes.**

22 Q. Okay. It's a series of  
 23 documents; correct?

24 **A. Yes.**  
 25

1 Q. Okay. Let's take the first one.  
 2 Can you identify for the record what that  
 3 is, please?

4 **A. That's a letter to Bonnie**  
 5 **Rossello from myself.**

6 Q. Okay. And does it appear to be  
 7 an authentic document?

8 **A. Yes.**

9 Q. Is it a document that you  
 10 prepared in the ordinary course of your  
 11 business at STI?

12 **A. Yes.**

13 Q. Okay. Now, Bonnie Rossello works  
 14 for GSK; correct?

15 **A. At the time she did.**

16 Q. Okay. And she was in the  
 17 marketing department?

18 **A. Yes.**

19 Q. Okay. And what was the purpose  
 20 of that letter?

21 **A. It was basically a status report.**  
 22 **Letting her know where we were and how we**  
 23 **were coming along with the project, with**  
 24 **the Advisory Board.**

25 Q. Okay. And what type of Advisory

1 Board were you setting up? A psychiatric  
 2 Advisory Board?

3 **A. Yes. It's a Psychiatrist**  
 4 **Advisory Board. This was a very large**  
 5 **one. I think it included family**  
 6 **physicians. People other than**  
 7 **psychiatrists. If I remember**  
 8 **correctly.**

9 Q. Okay. That is fine. And do you  
 10 recall where that meeting took place?

11 **A. According to the letter or one of**  
 12 **the subsequent letters?**

13 Q. Yes?

14 **A. It was in Florida.**

15 Q. Okay. Did you attend it also?

16 **A. Yes.**

17 Q. Okay. And how many people were  
 18 there, to your knowledge?

19 **A. Possibly -- I don't know**  
 20 **precisely how many people were there. It**  
 21 **could have been 30.**

22 Q. Okay.

23 **A. It was a large Advisory Board**  
 24 **meeting.**

25 Q. Okay. And did that include

1 people that are known in the industry as  
2 key opinion leaders?

3 **A. Yes.**

4 Q. Okay. And what is your  
5 understanding of what a key opinion  
6 leader is?

7 **A. My understanding is that a key  
8 opinion leader in any field is an expert  
9 in the given field. Someone who speaks  
10 nationally. And people know that person  
11 because they have heard that person speak  
12 at say the American Heart Association,  
13 and know him or her. That person has  
14 published widely in the literature on  
15 that subject, and that's my  
16 understanding.**

17 Q. Okay. And was part of your job  
18 with regard to this meeting to line up  
19 key opinion leaders to attend?

20 **A. With regard to this meeting?**

21 Q. Yes?

22 **A. Yes. In addition to people who  
23 are not key opinion leaders. Just  
24 regular physicians.**

25 Q. Okay. And would you agree that

1 if a key opinion leader states I believe  
2 patients should given Paxil, that is  
3 something that other physicians will  
4 listen to?

5  
6 MR. DAVIS: Object to the form.

7 THE WITNESS: I don't believe  
8 that, no.

9  
10 (BY MR. MURGATROYD):

11 Q. You don't think their opinion has  
12 any weight at all?

13 **A. Well, I think people aren't  
14 stupid, and they will hear that and then  
15 hopefully look at the data and make their  
16 own decision.**

17 Q. Okay. And where do you think  
18 they would look for data?

19 **A. Published literature, major  
20 meetings.**

21  
22 MR. MURGATROYD: Okay. And let's  
23 go to the next part of that document.

24 THE WITNESS: Sure.  
25

1 (BY MR. MURGATROYD):

2 Q. What is the next part of the  
3 document?

4 **A. This is a memo from myself to  
5 Bonnie Rossello.**

6 Q. Okay. And what are your stating  
7 there?

8 **A. "Enclosed please find the  
9 suggestions for the Advisory Board  
10 agenda." This looks like I am sending --  
11 attaching to this a draft of an agenda.**

12 Q. Okay. And is there a draft of a  
13 tentative agenda attached to that  
14 document later on?

15 **A. Yes.**

16 Q. Okay. And are all the documents  
17 that are in the makeup of that Exhibit  
18 authentic?

19 **A. They have been out of my control  
20 but they look authentic to me.**

21 Q. Okay. Is there any reason to  
22 think they aren't?

23 **A. No.**

24 Q. Okay. Were they all prepared by  
25 you during the ordinary course of your

1 business at STI?

2 **A. Yes.**

3 Q. Okay. Now let's go to the  
4 agenda. If you look -- again, this is  
5 for the SmithKline Beecham Psychiatrist  
6 Advisory Board meeting for the dates  
7 November 5th through 7th, 1993, according  
8 to this tentative agenda; correct?

9 **A. Yes.**

10 Q. Okay. And it's to start on a  
11 Saturday morning; correct?

12 **A. Yes.**

13 Q. Okay. And this is an agenda that  
14 you helped put together?

15 **A. Yes.**

16 Q. Okay.

17 Q. And one of the first people to  
18 speak was a gentleman by the name of  
19 Charles Nemeroff; correct?

20 **A. Yes.**

21 Q. And is he considered a key  
22 opinion leader in the psychiatric  
23 field?

24 **A. Yes, he is.**

25 Q. Okay. And can you read into the

1 record the various bullet points that you  
2 have underneath Charles Nemeroff for him  
3 to talk about?

4 **A. Sure. "Strengthen Paxil profile.  
5 Identify competitor deficits/strengths.  
6 Identify clinical research/promotional  
7 programs. Generate information for use  
8 in promotion/education. Reach primary  
9 care physicians".**

10 Q. Okay. I think you actually  
11 misspoke. I think the third one says,  
12 "Evaluate clinical research/promotional  
13 programs"; correct?

14 **A. What did I say?**

15 Q. I think you said "identify".

16 **A. Oh, sorry. I don't remember.  
17 Yes. I may have miss-spoken. I don't  
18 know.**

19 Q. Okay. This specifically talks  
20 about promotional activities; correct?

21 **A. Yes, it does.**

22 Q. And I asked you before whether or  
23 not these meeting had to do with  
24 promoting the drug Paxil?

25 **A. Yes.**

1 Q. And what did you say then?

2 **A. I said that I didn't recall that  
3 they did. However, I have to say this  
4 was a number of years ago. And if I  
5 remember correctly, the promotional  
6 discussions did not go over well. These  
7 people did not want to talk about  
8 promotion. Which perhaps was why -- what  
9 colored my recollection of that.**

10 Q. Okay. This specifically talks  
11 about promotion?

12 **A. Yes, it does.**

13 Q. Okay. And not in just this one  
14 part you read. Throughout this document;  
15 correct?

16 **A. Yes.**

17 Q. Okay. And would you agree now  
18 having read this, that one of the  
19 purposes of Advisory key opinion Advisory  
20 Board meetings is to promote the drug  
21 Paxil. The ones that you were involved  
22 in in creating for GSK?

23  
24 MR. DAVIS: Object to form of the  
25 question.

1 THE WITNESS: This was one  
2 Advisory Board. There were a number of  
3 different Advisory Board meetings. This  
4 was a very unusual Advisory Board  
5 meeting.

6  
7 (BY MR. MURGATROYD):

8 Q. Okay. Would you agree with  
9 regard to this specific meeting that one  
10 of the purposes of it was to promote the  
11 drug Paxil?

12  
13 MR. DAVIS: Object to the form.

14 THE WITNESS: From looking at  
15 these documents, yes I would agree.

16  
17 (BY MR. MURGATROYD):

18 Q. Okay. Now, as a matter of fact  
19 if you look at the second page at 11:30  
20 on Saturday. Brian Lortie, L-O-R-T-I-E,  
21 the Paxil Product Manager was to review  
22 Paxil promotion; correct?

23  
24 MR. DAVIS: Object to the form.

25 THE WITNESS: Yes.

1  
2 (BY MR. MURGATROYD):

3 Q. Okay. And the purpose of that  
4 was to get feedback from the Advisory  
5 Board members on the promotional  
6 programs; correct?

7 **A. Yes. However sometimes the  
8 planned purpose didn't always pan out.  
9 And again I have to say these people did  
10 not want to talk about promotion.**

11 Q. Okay. Though that was the agenda  
12 that you helped create?

13  
14 MR. DAVIS: Object to the form.

15 THE WITNESS: Yes.

16  
17 (BY MR. MURGATROYD):

18 Q. Okay. And actually it says --  
19 talks about assessment of competitors  
20 promotion; is that correct?

21  
22 MR. DAVIS: Object to the form.

23 THE WITNESS: That is what it  
24 says.

25 MR. MURGATROYD: Okay. Can you

1 read the last bullet point under 12:00  
2 o'clock into the record, please.

3 THE WITNESS: "Suggestions for  
4 additional programs, future directions."

5  
6 (BY MR. MURGATROYD):

7 Q. Okay. And that has to do with  
8 promotional programs; right?

9  
10 MR. DAVIS: Object to the form.

11 THE WITNESS: I believe that  
12 there were a number of other things that  
13 were discussed here other than promotion.  
14 Including clinical trial programs, and  
15 the design of clinical studies.

16 It would be my recollection that  
17 that was -- suggestions for additional  
18 programs encompassed the whole scope of  
19 what was talked about in the meeting.

20  
21 (BY MR. MURGATROYD):

22 Q. Including promotional programs?

23 **A. Including promotional programs.**

24 Q. Okay. Now, if you go to the  
25 third page of the document, it talks

1 about workshops on the second day of the  
2 meeting for Sunday?

3 **A. Yes.**

4 Q. Okay. And do you see workshop  
5 number three? Can you read that first  
6 sentence into the record, please?  
7 "Reaching"?

8 **A. "Reaching the primary care  
9 physician".**

10 Q. Okay. And was that one of the  
11 objectives of this program? Was how to  
12 reach the primary care physicians with  
13 regard to getting them to prescribe  
14 Paxil?

15 **A. It was my recollection that the  
16 purpose of this -- primary care  
17 physicians were included. Which is  
18 unusual for a scientific Advisory Board.  
19 There maybe a primary care Advisory  
20 Board. But the psychiatrist Advisory  
21 Board typically are the top academics in  
22 the area.**

23 **And so we did include primary  
24 care doctors in this. So it may have  
25 been also to gain their input on what**

1 **studies should be done that would help  
2 them take care of their patients.**

3 Q. Well it's also to get them to  
4 prescribe the drug Paxil; right?

5 **A. I can't answer that. I don't  
6 know.**

7 Q. Well, you can't tell from reading  
8 this document? What does it say?  
9 "Goals".

10 MR. DAVIS: Object to the form.

11 MR. MURGATROYD: What is the  
12 goals? Read that into the record,  
13 please.

14 THE WITNESS: "Generate  
15 recommendations for educating primary  
16 care physicians about depression,  
17 appropriate treatment, and use of Paxil."  
18

19  
20 (BY MR. MURGATROYD):

21 Q. It specifically states use of  
22 Paxil?

23 **A. Correct.**

24 Q. Would you agree that part of this  
25 Advisory Board meeting was to get primary

1 care physicians to use Paxil?

2  
3 MR. DAVIS: Object to the form.

4 THE WITNESS: I guess my  
5 recollection is that definitely it was an  
6 effort to reach out to primary care  
7 physicians. It's hard to say, because I  
8 don't remember.

9  
10 (BY MR. MURGATROYD):

11 Q. Does this document help refresh  
12 your recollection?

13 **A. It doesn't. Because often what  
14 goes on in an agenda really doesn't  
15 happen in the actual meeting.**

16 Q. Well wouldn't you agree that the  
17 whole purpose of the meeting was to  
18 promote Paxil?

19 **A. No.**

20 Q. You can sit here under oath and  
21 say --

22 **A. The "whole" purpose?**

23 Q. No, "a" purpose.

24  
25 MR. DAVIS: Excuse me. Excuse

1 me. That is a different question that  
2 you asked her, and you are also being  
3 argumentative with her.

4 MR. MURGATROYD: You can  
5 object.

6 THE WITNESS: I'm sorry.

7 MR. MURGATROYD: "A" purpose.

8 THE WITNESS: Can you repeat the  
9 question, please.

10 MR. MURGATROYD: Sure.

11 (BY MR. MURGATROYD):

12 Q. A purpose of this meeting was to  
13 promote the use of Paxil?

14 MR. DAVIS: Object to the form.

15 THE WITNESS: Yes. "A" purpose  
16 was to promote the use of Paxil,  
17 according to these documents.

18 (BY MR. MURGATROYD):

19 Q. Okay. Would you agree that a  
20 purpose of publishing medical journal  
21 articles is to promote drug use?  
22  
23  
24  
25

1 I also object because it's not a  
2 complete document. So I object to the  
3 use by the witness because it's not a  
4 complete document.

5 MR. MARGOLIS: Did you give a  
6 time frame on this slide?

7 MR. MURGATROYD: No, I did not.  
8 It's just a general topic. That's all  
9 I'm going to talk about is a general  
10 topic.

11 MR. MARGOLIS: So at some point  
12 in history this slide was provided by  
13 GSK?

14 MR. MURGATROYD: Correct. That's  
15 correct.

16 (BY MR. MURGATROYD):

17 Q. Did you get a chance to read  
18 that?

19 A. Yes.

20 Q. Can you read it into the record,  
21 please?  
22  
23

24 MR. DAVIS: Excuse me. I will  
25 object to the use of this document with

1 MR. DAVIS: Object to the form.  
2 Asked and answered three times now.

3 THE WITNESS: That's very hard  
4 for me to say.

5 MR. MURGATROYD: Well let me show  
6 you a document. I don't want you to  
7 struggle with this. I will show you a  
8 GSK document. A slide that they  
9 prepared. Which I will mark as Exhibit  
10 three.

11 (Plaintiff's Exhibit 3, marked)

12 MR. MURGATROYD: For the record,  
13 I will state that that is a slide that  
14 was produced by GSK in this litigation.

15 MR. MARGOLIS: What do you mean  
16 by "slide"?

17 MR. MURGATROYD: Slide. That's a  
18 slide presentation. It's part of a slide  
19 presentation.  
20  
21

22 MR. DAVIS: May I see that. GSK  
23 designates Plaintiff's Exhibit three  
24 subject to the protective order. As well  
25 as all discussions surrounding it.

1 --

2 MR. MURGATROYD: You already  
3 have. That's fine.

4 MR. DAVIS: Excuse me. Let me  
5 finish. There is no foundation that Ms.  
6 Laden can lay with respect to this  
7 document to know the context, the  
8 circumstances, or the time period for  
9 which it was generated.

10 So I think it's inappropriate to  
11 ask her questions about it. But it's  
12 your nickel. You spend your time how you  
13 want.

14 MR. MURGATROYD: Can you read the  
15 content of that slide into the record,  
16 please.

17 THE WITNESS: The entire thing?

18 MR. MURGATROYD: Yes, please.

19 THE WITNESS: "Paxil CAT. CAT  
20 Program Objective. To support key  
21 commercial strategic and tactical  
22 objectives via broad based medical  
23 communication (publications, posters,  
24 symposia, CME courses)."  
25

(BY MR. MURGATROYD):

Q. Okay. Now that lists a number of activities; correct? What is the first one?

**A. You mean the material in parenthesis?**

Q. Yes?

**A. Publications.**

Q. Okay. And that is one of several items that are under what heading?

**A. Broad based medical communication.**

Q. Okay. And is the purpose is this has commercial objectives?

**A. Yes.**

Q. Okay. And my question is, would you agree that publications that you did for GSK had commercial objectives?

MR. DAVIS: Object to the form.

THE WITNESS: No.

(BY MR. MURGATROYD):

Q. Okay. Would you agree that the meetings that you set up for GSK had

MR. MARGOLIS: Right. So the commercial objectives --

MR. MURGATROYD: For GSK.

MR. MARGOLIS: For GSK?

MR. MURGATROYD: Correct.

MR. MARGOLIS: As if she can answer for GSK?

MR. DAVIS: That is what -- again, I'm having a problem with that part of the question too. You're asking the witness to speak on behalf of someone whose mind set she doesn't know. So I will object to the form.

MR. MURGATROYD: Well, let me ask you this. The Jury is going to see this. So let's make sure we got it really straight.

(BY MR. MURGATROYD):

Q. You knew when you set up meetings for GSK that part of the reason for those meetings was to meet GSK's commercial objectives; correct?

MR. DAVIS: Object to the form.

commercial objectives?

MR. DAVIS: Object to the form.

MR. MARGOLIS: Are you saying that by educating people in the field, that that has indirect commercial objective or what have you?

MR. MURGATROYD: Indirect or direct. I'm just asking her.

THE WITNESS: There is a difference between being direct and indirect. That is why I'm struggling to answer your question.

(BY MR. MURGATROYD):

Q. Okay. Well let's take indirect first. Did setting up the meetings for GSK have indirect commercial objectives?

MR. DAVIS: Object to the form. Vague and ambiguous.

MR. MARGOLIS: Are you saying on behalf of GSK?

MR. MURGATROYD: Yes. The meetings she set up on behalf of GSK.

THE WITNESS: STI was not privy to the strategic plan and strategic -- whatever they call it in marketing. We viewed our job as providing an educational experience for a CME program or a publication that balanced the literature.

(BY MR. MURGATROYD):

Q. What were you educating the doctors about?

**A. About the underutilization of treatment in the elderly. Or the special needs of the elderly or you know.**

Q. How about the use of Paxil?

MR. DAVIS: Object to the form.

THE WITNESS: I would agree with the use of antidepressants.

(BY MR. MURGATROYD):

Q. How about the ones you did for GSK? It didn't have to do with all antidepressants, did it?

**A. Most of the time they certainly**

1 **did.**  
2 Q. Did they have to do with the drug  
3 Paxil?

4 **A. Yes, they did.**

5 Q. Okay. Would you agree that part  
6 of the objective of the meetings was to  
7 get doctors to prescribe Paxil?

8  
9 MR. DAVIS: Object to the form.  
10 Asked and answered.

11 THE WITNESS: That was not the  
12 objective we were tasked with. So I  
13 cannot answer that to GSK's objective.  
14 STI's objective was to -- in a broad  
15 sense, was to educate physicians.

16 (BY MR. MURGATROYD):

17 Q. And part of the education had to  
18 do specifically with the use of Paxil;  
19 correct?

20 **A. Yes.**

21 Q. Okay. So that would meet any  
22 commercial objective that GSK would have  
23 with regard to the meeting; correct?  
24  
25

1 from a study.

2  
3 (BY MR. MURGATROYD):

4 Q. Okay. Is part of the purpose  
5 also to promote the use of the drug that  
6 is being discussed in the poster? That  
7 is all I'm asking.

8  
9 MR. DAVIS: Objection. Asked and  
10 answered.

11 THE WITNESS: I'm struggling  
12 because I don't consider a poster as  
13 promotional material when it's presented  
14 at a scientific meeting.

15 (BY MR. MURGATROYD):

16 Q. Does it have a promotional  
17 effect?  
18  
19

20 MR. DAVIS: Object to the form.

21 THE WITNESS: I don't know.

22 (BY MR. MURGATROYD):

23 Q. Have you personally prepared  
24 posters ?  
25

1 MR. DAVIS: Object to the form.  
2 Asked and answered.

3 THE WITNESS: I guess, yes.

4 MR. MURGATROYD: Okay.

5  
6 (BY MR. MURGATROYD):

7 Q. Now, are you familiar with  
8 posters? What posters are?

9 **A. Yes.**

10 Q. What are posters?

11 **A. Posters are what they say they**  
12 **are. Big large document like this that**  
13 **generally -- posters are presented at**  
14 **scientific meetings showing new data.**  
15 **Studies recently completed or perhaps not**  
16 **yet completed prior to submission for**  
17 **publication.**

18 Q. Okay. And would you agree that  
19 part of the purpose of a poster is to  
20 promote the use of the drug that's being  
21 discussed in the poster?  
22

23 MR. DAVIS: Object to the form.

24 THE WITNESS: Part of -- the  
25 purpose of a poster is presenting data

1 **A. Yes.**

2 Q. Have you done it for GSK?

3 **A. Yes.**

4 Q. Have you done it for the drug  
5 Paxil?

6 **A. Yes.**

7 Q. And how many times?

8 **A. Perhaps once or twice, to my**  
9 **recollection.**

10 Q. Why don't you tell me about the  
11 one or two times that you recall?

12 **A. The one poster that I can**  
13 **remember was a study in the elderly.**

14 Q. Okay. And the second?

15 **A. I don't remember.**

16 Q. Did you prepare any of the  
17 posters for the use of Paxil in the  
18 pediatric population?

19 **A. I do not think so, no.**

20 Q. Okay. And when you prepared the  
21 poster for a study in the elderly, was  
22 that under the supervision with GSK?

23 **A. Yes.**

24 Q. Okay. And did it find that the  
25 use of Paxil is helpful for elderly

1 people?

2 **A. I don't recall specifically. It**  
3 **could have been a safety analysis.**

4 Q. Okay. Did it say that Paxil is  
5 safe for elderly people?

6 **A. I don't remember the specifics of**  
7 **the poster.**

8 Q. Well did it say that Paxil was  
9 unsafe for the elderly?

10 **A. I don't remember the specifics**  
11 **the poster.**

12 Q. You don't think that would stand  
13 out in your mind?

14 **A. I would think so, yes it would.**  
15 **But I don't recall the exact specifics of**  
16 **that poster on the elderly.**

17 Q. Okay. Would you agree that the  
18 purpose of that -- one of the purposes of  
19 that poster was to provide information to  
20 physicians so that they could prescribe  
21 the drug Paxil?

22  
23 MR. DAVIS: Object to the form.  
24 Asked and answered.

25 THE WITNESS: I would agree that

1 it provided information on that study to  
2 physicians attending that scientific  
3 meeting.

4  
5 (BY MR. MURGATROYD):

6 Q. Okay. And the purpose is --  
7 would you agree that the underlying  
8 purpose is so that the drug gets  
9 prescribed?

10  
11 MR. DAVIS: Object to the form.

12 THE WITNESS: That was not --  
13 promotion was not part of my job, so it's  
14 very hard for me to answer that  
15 question.

16  
17 (BY MR. MURGATROYD):

18 Q. Well you're a human being;  
19 right?

20 **A. Yes.**

21 Q. Would you agree as a human being  
22 that part of the purpose of those posters  
23 is to get the drug Paxil prescribed?

24  
25 MR. DAVIS: Object to the form.

1 You have asked this six different ways.

2 She has given you the same response every  
3 time. Let's move on to a different  
4 topic. I object to the form.

5 MR. MURGATROYD: You can answer  
6 the question.

7 THE WITNESS: Then please repeat  
8 it. I'm sorry.

9 MR. MURGATROYD: I understand.  
10 Can you read the question back, please.

11  
12 (Question read back)

13  
14 MR. MURGATROYD: Thank you.

15 THE WITNESS: I suppose.

16 MR. MURGATROYD: Okay. Thank  
17 you.

18  
19 (BY MR. MURGATROYD):

20 Q. Now, when you worked at STI, did  
21 your company have a policy that prohibits  
22 discussing writings that you produced  
23 with the media?

24 **A. Did STI have a policy?**

25 Q. Yes?

1 **A. I do not recall.**

2 Q. Okay. Do you have a policy with  
3 your corporation now? Such a policy?

4 **A. No.**

5 Q. Okay. Did STI have a company  
6 policy that prohibited discussing the  
7 writings you produced with other  
8 pharmaceutical companies.

9 Like if you prepared a paper for  
10 one pharmaceutical company, were you  
11 allowed to discuss that with another  
12 pharmaceutical company?

13 **A. There were no specific**  
14 **guidelines, if I recall that STI had.**  
15 **That was just standard client**  
16 **confidentiality that we respected.**

17 Q. Okay. Now, did any part of the  
18 STI functions relate to public  
19 relations?

20 **A. No. I don't believe so, no.**

21 Q. You are aware that GSK had a  
22 separate public relations firm that you  
23 dealt with; correct?

24 **A. Yes.**

25 Q. What was the name of that

1 company?

2 **A. At one point there was a company**  
3 **by the name of -- the name Cohn Wolfe**  
4 **comes to mind. That may have been an**  
5 **advertising agency and not a PR firm. I**  
6 **don't recall.**

7 Q. Is it C-O-H-N, W-O-L-F?

8 **A. It may have been W-O-L-F-E.**

9 Q. Okay.

10 **A. Again, I don't recall which of**  
11 **the two it was.**

12 Q. Okay. At the time you were with  
13 STI, was STI a medical education  
14 company?

15 **A. I'm sorry. I didn't hear you.**

16 Q. Was STI a medical education  
17 company?

18 **A. Yes.**

19 Q. Are you familiar the distinction  
20 between data driven pursuit and message  
21 driven model in the medical  
22 communications strategy?

24 MR. DAVIS: Object to the form.

25 THE WITNESS: Am I familiar with

1 a GSK launch program for Paxil for the  
2 treatment of children and adolescents?

3 **A. I don't know.**

4 Q. Now, have you ever heard of the  
5 business of STI referred to as "ghost  
6 writing"?

8 MR. DAVIS: Object to the form.

9 THE WITNESS: Can you be more  
10 specific? I am not sure I exactly  
11 understand your question.

13 (BY MR. MURGATROYD):

14 Q. Okay. Do you know what the term  
15 "ghost writing" means?

16 **A. Yes.**

17 Q. Okay. What does it mean?

18 **A. Ghost writing in my mind is an**  
19 **individual writing a document with the**  
20 **intent of another individual stamping**  
21 **their name on it and then publishing**  
22 **it.**

23 Q. Okay. Does ghost writing also  
24 have any other definition that you're  
25 aware of?

1 it?

2 MR. MURGATROYD: Yes. Are you  
3 familiar with those terms?

4 THE WITNESS: I don't recall  
5 hearing them.

6 MR. MURGATROYD: Okay.

7 THE WITNESS: Those specific  
8 terms.

10 (BY MR. MURGATROYD):

11 Q. We talked earlier that one of the  
12 activities involved in -- that STI was  
13 involved in was launching -- preparing  
14 launch programs for drugs, new drugs or  
15 drugs for a new indications; correct?

16 **A. Yes.**

17 Q. Okay. And again we have  
18 established I believe that you were  
19 involved in Study 329. Do you recall  
20 that?

21 **A. Yes.**

22 Q. 329 had to do with adolescents;  
23 correct?

24 **A. Yes.**

25 Q. Was Study 329 in any way part of

1 **A. No. I'm not aware of any others.**  
2 **I am not aware of a definition for ghost**  
3 **writing.**

4 Q. Okay. Have you ever read any of  
5 the journal articles that talk about  
6 ghost writing?

7 **A. Yes.**

8 Q. Okay. Have you heard the term  
9 industry sponsored ghost writing?

10 **A. Yes.**

11 Q. What does that mean?

12 **A. It's my understanding that that**  
13 **would mean pharmaceutical company hiring**  
14 **a medical writer to help them prepare a**  
15 **document for publication.**

16 Q. Okay. And was part of the  
17 business of STI industry sponsored ghost  
18 writing?

20 MR. DAVIS: Object to the form.

21 THE WITNESS: Part of the  
22 business of STI was working with  
23 pharmaceutical clients who hired us to  
24 help them prepare a document, and work  
25 with the authors for publication.

1  
2 (BY MR. MURGATROYD):  
3 Q. That's fall under the category of  
4 industry sponsored ghost writing?  
5 **A. I don't know what industry**  
6 **sponsored ghost writing is. It sounds**  
7 **like it would.**  
8 Q. Okay. Now, what are the  
9 responsibilities of a medical writer?  
10 **A. The responsibilities of a medical**  
11 **writer? I'm not aware of any formal**  
12 **definition. Although I'm sure there is.**  
13 **There is an association that I am not**  
14 **involved with. Are to present data**  
15 **fairly and accurately, in the best**  
16 **possible format.**  
17 Q. Okay. And is a medical writer  
18 such as yourself merely a typist?  
19 **A. No.**  
20 Q. Okay. Are there conferences, and  
21 seminars and workshops for medical  
22 writers?  
23 **A. Yes.**  
24 Q. And have you attended any of  
25 those?

1 Q. Okay. With regard to the medical  
2 journal articles that you have personally  
3 been responsible for for any drug  
4 company. Has your name ever been listed  
5 as an author?  
6 **A. Yes.**  
7 Q. Okay. For any publications you  
8 have done for GSK, has your name ever  
9 been listed as an author?  
10 **A. Yes.**  
11 Q. Okay. With regard to the drug  
12 Paxil and medical articles which you have  
13 Written regarding that drug. Has your  
14 name ever been listed as an author?  
15 **A. I do not believe so.**  
16 Q. Okay. With regard to Paxil and  
17 the use by kids, meaning children and  
18 adolescents. How many articles did you  
19 personally write?  
20  
21 MR. DAVIS: Object to the form.  
22 THE WITNESS: I recall the study  
23 in question. That is what can I  
24 recall.  
25

1 **A. I attended one probably in 1985,**  
2 **1986.**  
3 Q. Okay. Are you aware of an  
4 organization called the World Association  
5 of Medical Editors?  
6 **A. No.**  
7 Q. How about the International  
8 Committee of Medical Journal Editors?  
9 **A. No.**  
10 Q. Are you aware that guidelines  
11 exist regarding authorship of medical  
12 literature?  
13 **A. Yes.**  
14 Q. And are you familiar with  
15 those?  
16 **A. I have read them, yes.**  
17 Q. Is that something that you  
18 follow?  
19 **A. I try to.**  
20 Q. Okay.  
21 **A. I don't know the exact guidelines**  
22 **you're talking about.**  
23 Q. Okay. But you are aware that  
24 there are guidelines?  
25 **A. Yes.**

1 (BY MR. MURGATROYD):  
2 Q. Study 329?  
3 **A. Yes.**  
4 Q. That is the only one?  
5 **A. That is what I remember.**  
6 Q. Okay. Have you ever heard of a  
7 launch company by the name of Torre  
8 Lazur? T-O-R-R-E, L-A-Z-U-R? Two words.  
9 **A. I remember the name Torre**  
10 **Lazur.**  
11 Q. Okay. Torre Lazur? That is how  
12 it's pronounced?  
13 **A. Yes.**  
14 Q. Okay. Do you recall attending a  
15 brainstorming agenda -- a Paxil tactical  
16 brainstorming session in 1998 that was  
17 put on by Torre Lazur?  
18 **A. I recall attending one session**  
19 **like that. I don't know if it was in**  
20 **1998.**  
21 Q. Okay. The document I'm looking  
22 at, which I'm about to give you. It says  
23 "Torre Lazur, The Launch Agency". Is  
24 that your understanding of what that  
25 company did?

1 **A. My understanding was that they**  
2 **were an ad agency.**

3 Q. Okay. Do you recall attending a  
4 meeting that was put on by them on behalf  
5 of GSK?

6 **A. Yes.**

7 Q. Okay. And do you recall that  
8 part of that meeting was to educate  
9 school nurses about the use of Paxil?

10  
11 MR. DAVIS: Object to the form.

12 THE WITNESS: I don't recall  
13 that.

14 MR. MURGATROYD: Let the record  
15 reflect that I am marking a document that  
16 was produced by GSK in this litigation.  
17 At the top it says, "Torre Lazur, the  
18 Launch Agency. Paxil Tactical  
19 Brainstorming". Dated August 10, 1998.

20  
21 (Plaintiff's Exhibit 4, marked)

22  
23 MR. MURGATROYD: And please feel  
24 free to look through the entire document.  
25 The only portions I'm going to talk to

1 you about are the ones that start with  
2 the yellow tabs. Do you see that?

3 THE WITNESS: Yes.

4 MR. MURGATROYD: Todd you want to  
5 see this?

6 MR. DAVIS: Please. Skip, this  
7 has some of your highlighting on it. I  
8 don't know if you want that or not.

9 MR. MURGATROYD: That is fine.

10 MR. DAVIS: GSK designates  
11 Exhibit four as subject to the protective  
12 order. As well as all discussions  
13 related thereto. May I see Exhibit two,  
14 please.

15 MR. MURGATROYD: We will go off  
16 the record and switch the tape real  
17 quick.

18 VIDEOGRAPHER: This is the end of  
19 tape number one. The time is 11:22. We  
20 are off the record.

21  
22 (Off the record)

23  
24 (Back on the record)

1 VIDEOGRAPHER: We are back on the  
2 record. This is tape number two. The  
3 time is 11:45.

4  
5 (BY MR. MURGATROYD):

6 Q. Have you had a chance to review  
7 that document?

8 **A. Yes, I have.**

9 Q. Do you recall attending that  
10 session?

11 **A. Yes.**

12 Q. What was the purpose of that  
13 session?

14 **A. This was a meeting called by the**  
15 **marketing team that was coordinated by**  
16 **Torre Lazur.**

17 Q. Is that the Paxil marketing  
18 team?

19 **A. Yes.**

20 Q. Okay.

21 **A. The specific purpose, I don't**  
22 **remember. I mean I could guess by**  
23 **looking at the contents, but I don't**  
24 **remember.**

25 Q. But does the contents help

1 refresh your recollection?

2 **A. A little bit, yes.**

3 Q. Okay. And when you say the Paxil  
4 marketing team, does that list the  
5 members who were in that group on that  
6 document?

7 **A. Yes.**

8 Q. And can you read those names into  
9 the record, please?

10 **A. Some of the members. There may**  
11 **have been others. I don't remember. On**  
12 **this document it states Barry Brand, Tom**  
13 **Gibbs, Chris Hanson, and Scott Sproull.**

14 Q. Okay. And it's your  
15 understanding each of those individuals  
16 were part of the Paxil marketing team?

17 **A. Yes.**

18 Q. Okay. And did you work with each  
19 of those individuals at GSK?

20 **A. Yes.**

21 Q. Okay. And would you agree that  
22 their job was to market Paxil?

23 **A. Yes.**

24 Q. Okay. Now, there is a yellow  
25 sticky as part of that document. Do you

<p style="text-align: right;">Page 86</p> <p>1 see that?</p> <p>2 <b>A. Yes, I do.</b></p> <p>3 Q. And do you see that first slide</p> <p>4 on the top?</p> <p>5 <b>A. Yes.</b></p> <p>6 Q. Can you read that into the</p> <p>7 record, please?</p> <p>8 <b>A. "Regional Targeting School</b></p> <p>9 <b>Programs. Educate school RNs, child</b></p> <p>10 <b>psychologists, state/local health</b></p> <p>11 <b>officials, and teachers on social anxiety</b></p> <p>12 <b>disorder."</b></p> <p>13 Q. Okay. And was it your</p> <p>14 understanding that this meeting was to</p> <p>15 promote Paxil -- or figure out ways to</p> <p>16 promote Paxil for the use of social</p> <p>17 anxiety disorder?</p> <p>18</p> <p>19 MR. DAVIS: Object to the form of</p> <p>20 the question.</p> <p>21 THE WITNESS: Again, this meeting</p> <p>22 I do remember going to it. I don't</p> <p>23 remember the details of the meeting, but</p> <p>24 I recall that this was more of a broad</p> <p>25 educational effort on the disorder.</p>	<p style="text-align: right;">Page 88</p> <p>1 Q. Okay. And the different ways in</p> <p>2 which Paxil can be utilized throughout</p> <p>3 society; right?</p> <p>4</p> <p>5 MR. DAVIS: Object to the form.</p> <p>6 THE WITNESS: It's a pretty broad</p> <p>7 question.</p> <p>8</p> <p>9 (BY MR. MURGATROYD):</p> <p>10 Q. Okay. The purpose of the meeting</p> <p>11 was to figure out how to promote the drug</p> <p>12 Paxil.</p> <p>13</p> <p>14 MR. DAVIS: Object to the form of</p> <p>15 the question. It's been asked and</p> <p>16 answered.</p> <p>17 THE WITNESS: I can tell you what</p> <p>18 I read here. I don't remember many of</p> <p>19 the specifics of this all day meeting.</p> <p>20</p> <p>21 (BY MR. MURGATROYD):</p> <p>22 Q. Okay. Did the meetings have to</p> <p>23 do with the promotion the Paxil?</p> <p>24 <b>A. In part, yes.</b></p> <p>25 Q. Okay. Great. Was one of the</p>
<p style="text-align: right;">Page 87</p> <p>1</p> <p>2 (BY MR. MURGATROYD):</p> <p>3 Q. Okay. So that physicians would</p> <p>4 know to treat it with Paxil; correct?</p> <p>5</p> <p>6 MR. DAVIS: Object to the form.</p> <p>7 THE WITNESS: I can't answer for</p> <p>8 the objectives of the marketing team.</p> <p>9 This was probably the closest we ever got</p> <p>10 to the inner workings of what their</p> <p>11 objectives or their sales strategy or</p> <p>12 whatever was.</p> <p>13</p> <p>14 (BY MR. MURGATROYD):</p> <p>15 Q. Okay. But again this had to do</p> <p>16 with the marketing of the drug Paxil?</p> <p>17</p> <p>18 MR. DAVIS: Object to the form.</p> <p>19 THE WITNESS: The meeting was</p> <p>20 called by the promotional team, yes.</p> <p>21</p> <p>22 (BY MR. MURGATROYD):</p> <p>23 Q. Okay. And it's actually has to</p> <p>24 do specifically with the drug Paxil?</p> <p>25 <b>A. Yes.</b></p>	<p style="text-align: right;">Page 89</p> <p>1 audiences or one of the segments of</p> <p>2 society that was suggested be educated</p> <p>3 with regard to the condition SAD or</p> <p>4 Social Anxiety Disorder?</p> <p>5 <b>A. Yes.</b></p> <p>6 Q. And would what you described</p> <p>7 include school nurses?</p> <p>8 <b>A. When I look at this slide, it</b></p> <p>9 <b>would appear so. Do I have recollection</b></p> <p>10 <b>of that? No. I just don't remember that</b></p> <p>11 <b>meeting very well.</b></p> <p>12 Q. But that is what the slide says;</p> <p>13 correct?</p> <p>14 <b>A. That is what this slide says.</b></p> <p>15 Q. And it also includes child</p> <p>16 psychiatrists?</p> <p>17 <b>A. Child psychologists.</b></p> <p>18</p> <p>19 MR. MURGATROYD: Okay. Can I see</p> <p>20 that document for a second.</p> <p>21 THE WITNESS: Sure. Okay. Why</p> <p>22 don't I give this document back to you.</p> <p>23</p> <p>24 (BY MR. MURGATROYD):</p> <p>25 Q. If you would turn to that tab</p>

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1 section again. And beginning -- that  
2 first slide that you just read into the  
3 record discusses targeting; right?

4 **A. That is the title. Regional  
5 Targeting is the title of the slide.**

6 Q. Okay. And what specifically is  
7 being discussed as being targeted there?

8 MR. DAVIS: Object to the form.

9 THE WITNESS: The subtitle of the  
10 slide is School Programs.

11 (BY MR. MURGATROYD):

12 Q. And how many slides subsequent to  
13 that talk about targeting school  
14 programs?

15 **A. Eight.**

16 Q. Okay. Were you ever involved in  
17 any such targeting activities with regard  
18 to school programs?

19 **A. No.**

20 Q. Okay. Was STI to your knowledge  
21 involved in targeting school programs for  
22 Paxil?

23 **A. Well I was an employee of STI.**

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1 **So anything I did was as an employee of  
2 STI, and I don't remember anything that  
3 STI did.**

4 Q. With regard to targeting  
5 schools?

6 **A. I don't recall so, no.**

7 Q. How about with regard to  
8 targeting physicians who treat  
9 children?

10 **A. Can you define "targeting"? I  
11 don't know exactly what you mean by  
12 targeting.**

13 Q. Just how it's used in that  
14 document.

15 **A. Regional Targeting. We had no  
16 involvement with schools at all.**

17 Q. Okay. Were you aware that Torre  
18 Lazur was involved with targeting  
19 schools?

20 MR. DAVIS: Object to the form.  
21 No foundation to the question.

22 THE WITNESS: This was the first  
23 time I had ever been at this level of  
24 discussion. So I don't know who was  
25

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1 involved with what. I don't remember if  
2 this was something that had happened  
3 already or if they planned this to  
4 happen. So I don't know who did what  
5 where in this regard.

6 (BY MR. MURGATROYD):

7 Q. Okay. Do you know why you were  
8 asked to attend that session?

9 **A. Because we were involved in a lot  
10 of their large CME programs, and helped  
11 with publications.**

12 MR. MURGATROYD: Okay. Now going  
13 back to -- can I see Exhibit two, please.  
14 Thank you. Let me go back to Exhibit two  
15 for a second.

16 (BY MR. MURGATROYD):

17 Q. And Exhibit two had to do with  
18 the Advisory Board meeting that you  
19 helped set up for GSK. Do you recall  
20 that?

21 **A. Yes.**

22 Q. Okay. And that was done through  
23

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1 the marketing department of GSK with  
2 Bonnie Rossello?

3 **A. Yes.**

4 Q. Okay. If you would, can you  
5 identify for the record what the document  
6 that I have folded out in Exhibit two.  
7 What that is?

8 **A. It is an invitation for a  
9 scientist to attend that Advisory Board  
10 meeting.**

11 Q. Was that prepared by you?

12 **A. Yes.**

13 Q. And does that appear to be  
14 authentic?

15 **A. Yes.**

16 Q. Okay. Thank you. Can you read  
17 the third paragraph into the record,  
18 please?

19 **A. "The objectives of this Advisory  
20 Board meeting are to review the Paxil  
21 clinical research program and seek Board  
22 member -- "**

23 MR. MURGATROYD: Wait a minute.  
24 You can't read too fast. The Court  
25

1 Reporter can't get it down. Why don't we  
2 start from the beginning slowly.

3 THE WITNESS: "The objectives of  
4 this Advisory Board meeting are to review  
5 the Paxil clinical research program, and  
6 seek input about the direction of future  
7 clinical studies and promotional efforts  
8 and means of making inroads into the  
9 primary care setting. An agenda and  
10 brief position papers on selected topics  
11 will be forwarded to all attendees for  
12 review before the meeting."

13  
14 (BY MR. MURGATROYD):

15 Q. Okay. And again that is  
16 something you wrote; correct?

17 A. Yes.

18 Q. Okay. Did that have to be  
19 approved by GSK prior to you sending that  
20 out?

21  
22 MR. DAVIS: Object to the form.

23 THE WITNESS: I don't think so.  
24 I don't recall.  
25

1 A. The promotional efforts or the  
2 clinical studies?

3 Q. Promotional efforts?

4 A. I guess, yes.

5 Q. Okay. With regard to how many  
6 Advisory Board meetings did you help set  
7 up for GSK with regard to Paxil. Do you  
8 recall?

9 A. I don't remember.

10 Q. Was it more than five?

11 A. Maybe not. It could have been  
12 around -- not a lot.

13 Q. Okay. Do you recall where the  
14 locations were?

15 A. I remember the Florida meeting.  
16 It was a huge group of people. Other  
17 than that, I don't remember.

18 Q. Okay. And were each of those  
19 meetings designed to determine how to  
20 make inroads into different areas of  
21 physicians to promote Paxil?

22 A. No.

23 Q. This one was though; correct?

24 A. In part.  
25

1 (BY MR. MURGATROYD):

2 Q. Okay. It talks about promotional  
3 efforts; correct? As part of the  
4 meeting?

5  
6 MR. DAVIS: Object to the form.  
7

8 (BY MR. MURGATROYD):

9 Q. Does it use the word promotional  
10 efforts?

11 A. Yes, it does.

12 Q. And what does it say  
13 specifically?

14 A. You want me to read it again?

15 Q. Just the promotional efforts  
16 part. Just so I have it clear.

17 A. I will read that line.

18 Q. Okay.

19 A. "Clinical studies and promotional  
20 efforts and means of making inroads."

21 Q. Inroads to where?

22 A. "Primary care setting."

23 Q. And did that have to do with  
24 getting Paxil used by primary care  
25 physicians?

1 MR. MURGATROYD: Okay. Now, let  
2 me show you the next Exhibit. The next  
3 Exhibit order is five. Todd, do you want  
4 to see this?

5  
6 (Plaintiff's Exhibit 5, marked)  
7

8 MR. DAVIS: Please. GSK  
9 designates this document subject to the  
10 protective order, and discussions related  
11 thereto.

12  
13 (BY MR. MURGATROYD):

14 Q. Have you had a chance to review  
15 that document?

16 A. Yes.

17 Q. Can you identify it for the  
18 record, please?

19 A. This is a proposal for a project  
20 from STI to GlaxoSmithKline.

21 Q. And was that prepared by you?

22 A. I don't believe so, no.

23 Q. Does that document appear to be  
24 authentic?

25 A. Yes, it does.

1 Q. And does it say proposal --  
2 you're submitting the proposal; right?

3 **A. Myself and the President of the**  
4 **company.**

5 Q. Was this prepared in the ordinary  
6 course of STI's business, to your  
7 knowledge?

8 **A. Yes.**

9 Q. Okay. Now, what is this a  
10 proposal for?

11 **A. It's a proposal for the**  
12 **publication of this Study 329.**

13 Q. Okay. I see it's addressed to  
14 Ivan Gergel?

15 **A. Yes.**

16 Q. G-E-R-G-E-L. He's an MD;  
17 correct?

18 **A. Yes.**

19 Q. Did you know Dr. Gergel?

20 **A. I had been introduced to him,**  
21 **yes.**

22 Q. Okay. And do you know what his  
23 position was at GSK?

24 **A. He may -- at GSK? At the time he**  
25 **was in the Medical Department he may have**

1 **been head of the Medical Department, or**  
2 **whatever that title is. Or close to the**  
3 **head of the department.**

4 Q. Okay. And does -- this is a  
5 proposal for a contract; right?

6 **A. Yes.**

7 Q. Okay. And it had to do with the  
8 drafting manuscript regarding the results  
9 of Study 329?

10 **A. Yes.**

11 Q. Was this entered into with GSK?

12 **A. Yes.**

13 Q. Does this contract lay out the  
14 duties and responsibilities of STI and  
15 yourself included?

16 **A. Yes.**

17 Q. Okay. And what specifically were  
18 they?

19 **A. In other words, you want me to --**  
20 **what is it you're asking me?**

21 Q. What was your understanding that  
22 you were supposed to do under this  
23 contract? What were your  
24 responsibilities?

25 **A. My responsibilities were to come**

1 **up with a first draft of a manuscript**  
2 **suitable for publication in a peer review**  
3 **journal based on the clinical study**  
4 **report from Study 329.**

5 Q. Okay. And did you do that?

6 **A. Yes, I did.**

7 Q. Okay. Now, according to page  
8 five, third paragraph it says, "STI will  
9 develop up to six drafts. Draft I is the  
10 initial draft that will be reviewed by  
11 the sponsor." Did I read that  
12 correctly?

13 **A. Yes, you did.**

14 Q. And by "sponsor" there that means  
15 "GSK"?

16 **A. Yes.**

17 Q. Okay. Then it says, "Comments on  
18 draft I will be incorporated into draft  
19 II. Which will be sent to the primary  
20 author and the sponsor for comments." Is  
21 that correct?

22 **A. Yes.**

23 Q. Okay. Is this the procedure that  
24 you followed with regard to the draft for  
25 Study 329?

1 **A. I don't recall exactly, because**  
2 **this is very standard language for**  
3 **something like this. It is very likely.**  
4 **I don't remember if draft I only went to**  
5 **GSK. It may have also gone to Dr.**  
6 **Keller.**

7 Q. Okay. And it's your  
8 understanding that Dr. Martin Keller was  
9 to be the primary author?

10 **A. Yes.**

11 Q. Okay. Now, do you recall when  
12 you first started working on the first  
13 draft of the manuscript for Study 329?

14 **A. Based on the date of this**  
15 **proposal, it was probably late spring of**  
16 **1998.**

17 Q. Okay. And the date of this  
18 proposal is April 3, 1998; correct?

19 **A. Yes.**

20 Q. Okay. And just so the record is  
21 clear, are you guessing on that date or  
22 are you actually just refreshing your  
23 recollection?

24 **A. On the April 3rd Date? It says**  
25 **it right here.**

1 Q. No. On when you first began  
2 drafting the first draft?

3 **A. I do not know the exact date I**  
4 **started drafting this paper.**

5 Q. Okay. When you were at STI, did  
6 you keep time records on how you spent  
7 your time?

8 **A. Yes.**

9 Q. Okay. And were the time records  
10 that STI -- well I guess I don't know if  
11 you know who has it or may have it.  
12 Exist that would say when the first date  
13 was you started to work on the first  
14 draft of the manuscript for Study 329?

15 **A. We kept time sheets based on work**  
16 **on any given project. So the answer to**  
17 **that would be "yes". There probably was**  
18 **a time sheet biweekly.**

19 Q. Okay. To your knowledge, did STI  
20 maintain those records?

21 **A. I do not know.**

22 Q. Okay. Now, I don't think I ever  
23 got the address of STI. Is it still  
24 located where it was when you worked for  
25 it?

1 **A. I haven't been there in four**  
2 **years.**

3 Q. Okay. What was the last address  
4 you knew for it?

5 **A. Springfield, New Jersey. Morris**  
6 **Avenue. I don't remember the exact the**  
7 **street address on Morris Avenue.**

8 Q. Okay. And it's your  
9 understanding that the company is still  
10 in existence?

11 **A. Yes. The company is still in**  
12 **existence.**

13 Q. Okay. Is it still being operated  
14 by John -- I can't pronounce his last  
15 name.

16 **A. It's been operated by John**  
17 **Romankowitz.**

18 Q. Okay. That's  
19 R-O-M-A-N-K-I-E-W-I-C-Z?

20 **A. Actually, can I clarify that?**

21 Q. Yes.

22 **A. When I left STI, it was being**  
23 **operated by John Romankiewicz. I don't**  
24 **know if it still is.**

25 Q. Okay. That's fine. But again

1 it's your understanding there would be --  
2 if they still exist, a time record of  
3 when you first performed any activities  
4 with regard to the first drafted  
5 manuscript of Study 329?

6 **A. Yes.**

7 Q. Okay. Now, have you reviewed the  
8 first manuscript recently? The first  
9 draft of the manuscript?

10 **A. I reviewed the document.**

11 Q. That I sent you?

12 **A. Yes. And was the first draft in**  
13 **there?**

14 Q. I don't believe so.

15 **A. Then I have not.**

16  
17 MR. MURGATROYD: Actually, I just  
18 found the first draft very recently.  
19 Let's see. Let's go off the record for a  
20 second. I need to make sure I have a  
21 copy. Let's take a five-minute break.  
22 This will be like a morning break.

23 VIDEOGRAPHER: The time is 11:49.  
24 We are off the record.  
25

1 (Off the record)

2  
3 (Back on the record)

4  
5 VIDEOGRAPHER: Stand by. Okay.  
6 We are back on the record. The time is  
7 11 minutes after 12:00.

8 MR. MURGATROYD: Okay.

9  
10 (Plaintiff's Exhibit 6, marked)

11  
12 (BY MR. MURGATROYD):

13 Q. While we were off the record, did  
14 you have a chance to look at what we have  
15 marked as Exhibit 6?

16 **A. Yes.**

17 Q. Can you identify it for the  
18 record, please?

19 **A. Well this is the first draft of**  
20 **this document, preceded by a cover**  
21 **letter from myself to Jim McCafferty.**

22 Q. Okay. Let's take the cover  
23 letter first. Does that appear to be  
24 authentic?

25 **A. Yes.**

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<p>1 Q. It was prepared by you in the 2 ordinary course of your business at 3 STI? 4 <b>A. Yes.</b> 5 Q. And attached to this cover letter 6 is the first draft of the manuscript for 7 Study 329; is that correct? 8 <b>A. Yes.</b> 9 Q. And does that appear to be 10 authentic? 11 <b>A. Yes.</b> 12 Q. Okay. Was that prepared by you 13 in the ordinary course of your business 14 at STI? 15 <b>A. Yes.</b> 16 Q. Okay. Now for the record, what 17 is the date of the cover letter? 18 <b>A. December 18, 1998.</b> 19 Q. Okay. And that's also reflected 20 on the first page of the draft where it 21 says draft Roman numeral I. Do you see 22 the date below that? 23 <b>A. Yes.</b> 24 Q. That is the same date? 25 <b>A. Yes.</b></p>	<p>1 two? 2 3 MR. DAVIS: Object to the form. 4 THE WITNESS: A clinical study 5 report that STI would normally receive 6 would probably be about 200 pages in 7 length. 8 9 (BY MR. MURGATROYD): 10 Q. Okay. Would that be considered a 11 synopsis of the report? Or would that be 12 considered a part of the report? Or do 13 you know? 14 <b>A. I believe it's considered a</b> 15 <b>synopsis of the report, rather than each</b> 16 <b>individual patient's data.</b> 17 18 MR. MURGATROYD: Okay. Well, let 19 me show you what I will mark as the next 20 Exhibit. Which I will mark as Exhibit 7. 21 Which is entitled Final Clinical Report. 22 And this portion of it is 129 pages. 23 24 (Plaintiff's Exhibit 7, marked) 25</p>
<p>Page 107</p> <p>1 Q. Do you know why it took you until 2 December 18, 1998 to prepare the first 3 draft of this Study 329? 4 <b>A. No.</b> 5 Q. Okay. Where did the data come 6 from that ended up in this first draft? 7 <b>A. A clinical study report was</b> 8 <b>provided to me.</b> 9 Q. Okay. Who was that provided 10 by? 11 <b>A. I don't remember the person who</b> 12 <b>sent it to me.</b> 13 Q. Okay. But it came from GSK? 14 <b>A. Yes.</b> 15 Q. Did you receive the entire 16 clinical study report, over 1400 pages? 17 <b>A. Probably not. I don't think so,</b> 18 <b>no. Wait.</b> 19 Q. Go ahead. 20 <b>A. It's my understanding that that</b> 21 <b>would not be called the clinical study</b> 22 <b>report. The whole big thing. Rather a</b> 23 <b>distillation of that. Which is typically</b> 24 <b>about this pig.</b> 25 Q. Okay. Indicating like an inch or</p>	<p>Page 109</p> <p>1 MR. DAVIS: Just for the record, 2 this document is available on GSK's 3 website. The only thing that is 4 confidential is the identity of the 5 authors. So that is what we would 6 designate as per the protective order. 7 MR. MURGATROYD: Just the first 8 page? 9 MR. DAVIS: The first page, and 10 there may be some person's name 11 identified on the second page. The 12 person who signs the report. 13 MR. MURGATROYD: Okay. So the 14 first two pages. You agree that all the 15 rest of the report is not confidential? 16 MR. DAVIS: I believe that if 17 this is the copy that is on GSK's 18 website, and this includes the 120 pages 19 that you identified, that that is 20 correct. I just haven't had the chance 21 to compare the two up. 22 MR. MURGATROYD: Okay. And why 23 do you contend the authors names are 24 confidential? Into 25 MR. DAVIS: Privacy and</p>

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<p>1 confidentiality with respect to their 2 privacy. We haven't had a problem with 3 this in the past. 4 MR. MURGATROYD: No, I am sure we 5 will though. But I am just making sure I 6 get the lay of the land. 7 8 (BY MR. MURGATROYD): 9 Q. The document that I have marked 10 as Exhibit seven is the final clinical 11 report for Study 329; is that correct? 12 A. Yes. 13 Q. Okay. Is this a document that 14 you were referring to that you got the 15 data from? 16 A. <b>I don't recall what specific 17 document I did receive. Whether it was 18 this was one. I mean yes, this would be 19 what I would have gotten. I don't recall 20 getting it.</b> 21 Q. You don't recall ever receiving 22 it, but you know you got it; right? 23 A. <b>Yes, I got it. Yes. I don't 24 recall receiving it.</b> 25 Q. Okay. This provided you with</p>	<p>1 A. <b>Yes.</b> 2 Q. And you see that it has a section 3 for primary efficacy parameters. Do you 4 see that? 5 A. <b>Yes.</b> 6 Q. And then another section for 7 secondary efficacy parameters. You see 8 that? 9 A. <b>Yes.</b> 10 Q. And it's referring to pages 41 11 through 44? 12 A. <b>Yes.</b> 13 Q. Okay. Now if you turn to those 14 pages, please. To page actually 43. At 15 the bottom it says primary efficacy 16 parameters. Do you see that? 17 A. <b>Yes.</b> 18 Q. And how many are listed? 19 A. <b>Two.</b> 20 Q. Okay. And then below that there 21 is the section on secondary efficacy 22 parameters. Do you see that? 23 A. <b>Yes.</b> 24 Q. How many are listed there? 25 A. <b>Five.</b></p>
<p>Page 111</p> <p>1 information that you then utilized to 2 prepare the first draft of the manuscript 3 for Study 329? 4 A. <b>Yes.</b> 5 Q. Okay. Was it your responsibility 6 alone to create the first draft of Study 7 329 or did you get help from some of your 8 colleagues? 9 A. <b>I believe I created it on my 10 own.</b> 11 Q. Okay. Did Martin Keller tell you 12 what to put in the first draft? 13 A. <b>I don't recall. I don't think I 14 had any conversation with him until we 15 were -- you know afterwards.</b> 16 Q. Okay. After you prepared the 17 first manuscript? 18 A. <b>To the best of my recollection, 19 yes.</b> 20 Q. Okay. Now, if you look at the 21 document that is entitled "The Final 22 Clinical Report". You will see on the 23 third page of the Table of Contents, it 24 talks about efficacy parameters under 25 section 3.9. Do you see that?</p>	<p>Page 113</p> <p>1 Q. Okay. Now turning to your first 2 draft. And so the record is clear, on 3 the second page of the first draft it 4 says manuscript prepared by, and it has 5 your name; correct? 6 A. <b>Yes.</b> 7 Q. Okay. And it says this was 8 prepared by James P. McCafferty; 9 correct? 10 A. <b>Yes.</b> 11 Q. Okay. Is it Dr. McCafferty or 12 Mr. McCafferty? Do you know? 13 A. <b>I believe he has a Masters 14 degree. That's my recollection.</b> 15 Q. Okay. Was Mr. McCafferty your 16 contact person at GSK with regard to 17 drafting this manuscript? 18 A. <b>Yes.</b> 19 Q. Okay. So the information 20 contained on this page is accurate and 21 correct? 22 A. <b>To the best of my recollection.</b> 23 Q. Okay. Now going to the abstract 24 portion which is on the third page. It 25 says "Main Outcome Measures." Do you see</p>

<p style="text-align: right;">Page 114</p> <p>1 that?</p> <p>2 <b>A. Yes.</b></p> <p>3 Q. Okay. And how many are listed</p> <p>4 there?</p> <p>5 <b>A. Eight.</b></p> <p>6 Q. Okay. And are the eight</p> <p>7 separated by primary and secondary</p> <p>8 efficacy measures?</p> <p>9 <b>A. No.</b></p> <p>10 Q. Okay. Why not?</p> <p>11 <b>A. I don't know. I don't</b></p> <p>12 <b>remember.</b></p> <p>13 Q. Okay. Do you know whose idea it</p> <p>14 was to create eight outcome measures?</p> <p>15</p> <p>16 MR. DAVIS: Object to the form of</p> <p>17 the question.</p> <p>18 THE WITNESS: No.</p> <p>19 MR. MURGATROYD: Okay.</p> <p>20 THE WITNESS: Actually, can you</p> <p>21 clarify that, please.</p> <p>22</p> <p>23 (BY MR. MURGATROYD):</p> <p>24 Q. In here you list eight main</p> <p>25 outcome measures; correct?</p>	<p style="text-align: right;">Page 116</p> <p>1 efficacy Parameters. It doesn't say</p> <p>2 variables. So you want to ask her based</p> <p>3 upon the accurate representation of what</p> <p>4 it says.</p> <p>5 MR. MURGATROYD: That is a good</p> <p>6 point.</p> <p>7</p> <p>8 (BY MR. MURGATROYD):</p> <p>9 Q. Is there a difference between an</p> <p>10 outcome measure and a variable?</p> <p>11 <b>A. I don't know.</b></p> <p>12 Q. Okay. Do you know what an</p> <p>13 outcome measure is?</p> <p>14 <b>A. Yes, I do.</b></p> <p>15 Q. What is an outcome measure?</p> <p>16 <b>A. My understanding is that an</b></p> <p>17 <b>outcome measure is some objective</b></p> <p>18 <b>measurement by which you assess whether</b></p> <p>19 <b>or not the drug did what it was supposed</b></p> <p>20 <b>to do.</b></p> <p>21 Q. Okay. And is that any different</p> <p>22 from an efficacy variable?</p> <p>23 <b>A. No. I think these can be</b></p> <p>24 <b>interchanged.</b></p> <p>25 Q. Okay. Thank you. So in the</p>
<p style="text-align: right;">Page 115</p> <p>1 <b>A. Yes.</b></p> <p>2 Q. And you can't tell from reading</p> <p>3 these whether any or all of them are</p> <p>4 primary or secondary; correct?</p> <p>5 <b>A. Correct.</b></p> <p>6 Q. Okay. My question was do you</p> <p>7 know whose idea it was to not distinguish</p> <p>8 between primary and secondary efficacy</p> <p>9 measures?</p> <p>10</p> <p>11 MR. DAVIS: Object to the form.</p> <p>12 THE WITNESS: This was a first</p> <p>13 draft. So this came straight from me.</p> <p>14 This was I guess my interpretation. I'm</p> <p>15 remembering this may have been my</p> <p>16 interpretation of the data.</p> <p>17</p> <p>18 (BY MR. MURGATROYD):</p> <p>19 Q. Okay. Yet the study report</p> <p>20 clearly defines the primary efficacy</p> <p>21 variables and the secondary efficacy</p> <p>22 variables --</p> <p>23</p> <p>24 MR. MARGOLIS: Well let's</p> <p>25 clarify. The report says primary</p>	<p style="text-align: right;">Page 117</p> <p>1 draft you would agree that there is no --</p> <p>2 a reader could not distinguish which are</p> <p>3 the primary and which are the secondary</p> <p>4 outcome measures or efficacy variables;</p> <p>5 correct?</p> <p>6</p> <p>7 MR. DAVIS: Object to the form.</p> <p>8 MR. MURGATROYD: Correct?</p> <p>9 THE WITNESS: A reader cannot?</p> <p>10</p> <p>11 (BY MR. MURGATROYD):</p> <p>12 Q. Yes, could not. From reading</p> <p>13 this portion of the main outcome measures</p> <p>14 portion of the abstract. A reader could</p> <p>15 not determine which is the primary and</p> <p>16 which is the secondary?</p> <p>17 <b>A. A sophisticated reader would</b></p> <p>18 <b>probably infer that the first one -- you</b></p> <p>19 <b>know that it goes in decreasing order of</b></p> <p>20 <b>importance. But it's not spelled out in</b></p> <p>21 <b>this abstract.</b></p> <p>22 Q. Okay. Well let's take a look at</p> <p>23 the first one. "Percentage remission at</p> <p>24 endpoint. HAM-D score less than 8 at end</p> <p>25 point". Do you see that?</p>

Page 118	Page 120
<p>1       <b>A. Yes.</b>  2       Q. Is that a primary outcome measure  3 according to the report?  4       <b>A. No. Not as specified in this</b>  5 <b>report.</b>  6  7       MR. MURGATROYD: Okay. Let me  8 show you what I am going to mark as  9 Exhibit eight. Which is the Statistical  10 Report section of the final report.  11  12       (Plaintiff's Exhibit 8, marked)  13  14       MR. MURGATROYD: The page I'm  15 going to ask you questions about, at the  16 top it says 001459.  17       THE WITNESS: Yes.  18  19       (BY MR. MURGATROYD):  20       Q. Do you see that page?  21       <b>A. Yes, I do.</b>  22       Q. Okay. For the record, the  23 document which I marked is entitled,  24 "Statistical Report". Do you see table  25 two in front of you?</p>	<p>1       Can you tell me how many of those you can  2 find in this listing in table two?  3       <b>A. Two specifically listed here.</b>  4 <b>But I do not know what SPP or AFC or SIP</b>  5 <b>refer to.</b>  6       Q. Okay. So AFC is the Autonomous  7 Functioning Checklist. That's AFC;  8 right?  9       <b>A. I don't know. I never heard of</b>  10 <b>that term.</b>  11       Q. Well it's in with your paper?  12       <b>A. It's in this paper?</b>  13       Q. It's in your draft.  14       <b>A. This?</b>  15       Q. Yes, it's under outcome measures.  16       <b>A. Okay. I'm working off of</b>  17 <b>memory.</b>  18       Q. I understand. I'm just trying to  19 help you. So do you know what AFC means  20 now?  21       <b>A. Yes, I do.</b>  22       Q. Okay. And do you understand that  23 SIP is Sickness Impact Profile?  24       <b>A. Well the abstract says Sickness</b>  25 <b>Impact Scale.</b></p>
Page 119	Page 121
<p>1       <b>A. On page 1459?</b>  2       Q. Yes?  3       <b>A. Yes.</b>  4       Q. And it lists efficacy parameters;  5 right?  6       <b>A. Yes.</b>  7       Q. And how many are in that list?  8       <b>A. Twenty-two.</b>  9       Q. Okay. Does your draft I of Study  10 329 discuss 22 efficacy parameters that  11 were analyzed by GSK?  12  13       MR. DAVIS: Object to the form.  14       THE WITNESS: Does it discuss  15 that?  16  17       (BY MR. MURGATROYD):  18       Q. That there were 22 efficacy  19 parameters that were analyzed?  20       <b>A. No.</b>  21       Q. Okay. Well let's compare the  22 main outcome measures that you list in  23 your first draft of the manuscript, to  24 the 22 efficacy parameters that are  25 listed on the Exhibit in front of you.</p>	<p>1       Q. Okay. Is that your understanding  2 that is what SIP is?  3       <b>A. I don't recall.</b>  4       Q. When it has SPP. Do you see that  5 on table two?  6       <b>A. Yes.</b>  7       Q. Okay. And that would be Self  8 Perception Profile?  9       <b>A. Self Perception Profile is in the</b>  10 <b>abstract of the manuscript.</b>  11       Q. And that would be SPP; right?  12 That's the initials?  13       <b>A. I would assume so.</b>  14       Q. Okay. Would you assume also SIP  15 refers to the Sickness Impact Scale?  16       <b>A. That would be my assumption.</b>  17       Q. Okay. And I think you stated  18 that of the eight that are listed, does  19 that mean outcome measures? Only two  20 were in this listing?  21       <b>A. Yes.</b>  22       Q. And which two are those?  23       <b>A. Depressed mood of the HAM-D. And</b>  24 <b>the depressed item of K-SADS-L.</b>  25       Q. Where do see the depressed item</p>

1 for K-SADS in table two?  
 2 **A. That is the second. That's**  
 3 **listed as the second.**  
 4 Q. And is that an item or is that  
 5 the whole scale listed there?  
 6 **A. I don't know.**  
 7 Q. Okay. HAM-D total is included in  
 8 your first manuscript; right? Your first  
 9 draft?  
 10 **A. Yes.**  
 11 Q. Where did you get the other ones  
 12 that aren't listed in table two?  
 13 **A. I do not remember. It's possible**  
 14 **that they were not included in this type**  
 15 **of efficacy -- statistical analysis.**  
 16 **Which could be why they weren't in this**  
 17 **table.**  
 18 Q. Okay.  
 19 **A. Whether they are categoric or**  
 20 **continuous. So that is one possibility,**  
 21 **but I do not remember.**  
 22 Q. Okay. So according to table two  
 23 there is 22 efficacy parameters, and then  
 24 you have several more that are listed in  
 25 your paper. Different ones; correct?

1  
 2 MR. DAVIS: Object to the form.  
 3 THE WITNESS: Yes.  
 4  
 5 (BY MR. MURGATROYD):  
 6 Q. Okay. And do you know what the  
 7 term "statistical significance" means?  
 8 **A. Yes.**  
 9 Q. What does that mean?  
 10 **A. I am not a biostatistician.**  
 11 Q. Okay. What does it mean to you  
 12 as a lay person?  
 13 **A. It's my understanding that based**  
 14 **on predetermined levels of -- statistical**  
 15 **significance of the tests designed to**  
 16 **show that results did not happen by**  
 17 **chance.**  
 18 **A. Okay.**  
 19 Q. And there is a point that is used  
 20 to determine statistical significance of  
 21 .05; is that correct?  
 22 **A. It's not standard, but that is**  
 23 **often used.**  
 24 Q. Okay. And using that standard  
 25 .05 --

1 **A. It's not a standard to my**  
 2 **knowledge, but I'm not a biostatistician.**  
 3 Q. Okay. Well using that point --  
 4 using .05 --  
 5  
 6 MR. MARGOLIS: Just to clarify,  
 7 you're going to hypothetically say that  
 8 we should use .05 for this question?  
 9 MR. MURGATROYD: Yes.  
 10  
 11 (BY MR. MURGATROYD):  
 12 Q. We understand that is called a P  
 13 value; correct?  
 14 **A. Yes.**  
 15 Q. Okay. And that is a P value used  
 16 by the FDA to determine whether or not a  
 17 drug passes our standards. Is that your  
 18 understanding?  
 19 **A. I'm not an expert on this.**  
 20 Q. I understand, but is that your  
 21 understanding?  
 22  
 23 MR. DAVIS: Object to the form.  
 24 Calls for speculation.  
 25 THE WITNESS: I honestly don't

1 know the specific requirements of the  
 2 FDA.  
 3 MR. MURGATROYD: Okay. Well,  
 4 let's go back to -- let me ask you a  
 5 simple question.  
 6  
 7 (BY MR. MURGATROYD):  
 8 Q. Of the two primary efficacy  
 9 variables that are listed on page 44 of  
 10 the final study report?  
 11 **A. Yes.**  
 12 Q. Did either of those to your  
 13 knowledge reach statistical significance  
 14 in favor of Paxil?  
 15 **A. I would have to refer back to the**  
 16 **document. I don't recall all the details**  
 17 **of it. I recall very few details of this**  
 18 **study. So I would have to look back to**  
 19 **the document.**  
 20 Q. Okay. Which document would you  
 21 like to look back into?  
 22 **A. I will look into this.**  
 23 Q. Okay. Fine.  
 24  
 25 MR. MARGOLIS: Just so the record

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<p>1 is clear, you're looking at Exhibit --  2 what is that Exhibit?  3 THE WITNESS: Six.  4 MR. MURGATROYD: The first draft.  5 MR. MARGOLIS: And that is the  6 first draft of the report?  7 MR. MURGATROYD: That is correct.  8 It's the first draft.  9 THE WITNESS: And what were you  10 asking me?  11  12 (BY MR. MURGATROYD):  13 Q. Whether or not either of the  14 primary efficacy valuables reached  15 statistical significance in favor of  16 Paxil using the P value of .05?  17 <b>A. According to this, the remission  18 of 8 weeks.</b>  19 Q. Is remission of 8 weeks a primary  20 efficacy variable according to the final  21 clinical report?  22 <b>A. It's not stated there.</b>  23 Q. Okay. So according to the final  24 clinical report, there are two primary  25 efficacy variables; correct?</p>	<p>1 the final study report?  2 <b>A. I'm sorry. What?</b>  3 Q. The second primary efficacy  4 variable?  5 <b>A. Percent responders.</b>  6 Q. Okay. And according to your  7 first manuscript, did that primary  8 efficacy variable reach statistical  9 significance in favor of Paxil?  10 <b>A. No.</b>  11 Q. Okay. And that's the second  12 variable listed in your table three;  13 correct?  14 <b>A. Yes.</b>  15 Q. Okay. Now the title of your  16 table three. Can you read that into the  17 record, please?  18 <b>A. "Summary of primary efficacy  19 variables in adolescents with major  20 depression who were treated with  21 paroxetine, imipramine, or placebo."</b>  22 Q. Okay. Do you know why you said  23 there were eight primary efficacy  24 variables when the study report said  25 there was only two?</p>
<p>Page 127</p> <p>1 <b>A. Yes.</b>  2 Q. What are they?  3 <b>A. Change from baseline, and the  4 total score on the HAM-D from beginning  5 of treatment to end of the 8 week acute  6 phase.</b>  7 Q. Okay. Now did that efficacy  8 variable reach statistical significance  9 in favor of Paxil according to your first  10 draft?  11 <b>A. Change data. It doesn't look  12 like -- there is a difference between  13 reporting a change in something or the  14 actual score that was achieved. And it  15 looks like the first draft report is the  16 actual score.</b>  17 Q. Okay. And that's the last item  18 on table three?  19 <b>A. Yes.</b>  20 Q. Okay. And did it reach  21 statistical significance in favor of  22 Paxil?  23 <b>A. No.</b>  24 Q. Okay. What is the secondary  25 primary efficacy variable according to</p>	<p>Page 129</p> <p>1 <b>A. I do not know why.</b>  2 Q. Okay. According to on table  3 four, the next page of your first draft.  4 You have a listing of secondary  5 variables; correct?  6 <b>A. Yes.</b>  7 Q. Okay. And how many do you list  8 there?  9 <b>A. Three.</b>  10 Q. Okay. And did any of those reach  11 statistical significance in favor of  12 Paxil?  13 <b>A. No.</b>  14 Q. Okay. Now let's go to page 44 of  15 the final report. You see it lists the  16 secondary efficacy parameters, which you  17 talked about a minute ago; correct?  18 <b>A. Yes.</b>  19 Q. The first one says depression  20 subscale of school of K-SADS-L;  21 correct?  22 <b>A. Yes.</b>  23 Q. Is that listed as a secondary  24 variable on table four of your first  25 manuscript?</p>

Page 130	Page 132
<p>1       <b>A. No.</b>  2       Q. Is that listed as a primary  3 efficacy variable in table three of your  4 manuscript?  5       <b>A. Yes.</b>  6       Q. The entire subscale? It's the  7 sixth item down; is that correct?  8       <b>A. The nine item depression</b>  9 <b>subscore?</b>  10       Q. Yes?  11       <b>A. What was your question?</b>  12       Q. Is that referring to the  13 depression subscale of K-SADS-L?  14       <b>A. I don't remember.</b>  15       Q. Did it reach statistical  16 significance in favor of Paxil?  17       <b>A. No.</b>  18       Q. Okay. Let's go to the next  19 secondary efficacy parameter according to  20 the final study report. The CGI  21 Improvement Score. Do you see that?  22       <b>A. Yes.</b>  23       Q. Okay. And is that listed as a  24 secondary variable in your first  25 manuscript?</p>	<p>1               THE WITNESS: Again, I am not an  2 expert on this.  3               MR. MURGATROYD: Right. I  4 understand. Let's go down to seven.  5  6               (BY MR. MURGATROYD):  7               Q. What is seven? I'm sorry. The  8 seventh item of your table three.  9               <b>A. Mean CGI Score.</b>  10              Q. Okay. Is that referring to the  11 secondary efficacy parameter listed on  12 page 44, the CGI improvement score?  13              <b>A. I'm not sure, because there are</b>  14 <b>different vagaries of the CGI score. So</b>  15 <b>I can't answer with certainty.</b>  16              Q. Okay. Was it the one -- the  17 seventh item here, mean CGI score in your  18 table three in the first manuscript of  19 the Study 329 reach statistical  20 significance in favor of Paxil?  21              <b>A. No.</b>  22              Q. Okay. Now what is the next  23 secondary efficacy parameter listed in  24 the final Study report on page 44?  25              <b>A. Autonomic Function Checklist.</b></p>
Page 131	Page 133
<p>1       <b>A. What part of the manuscript are</b>  2 <b>you referring to?</b>  3       Q. Table four?  4       <b>A. Okay. No.</b>  5       Q. Okay. Is it listed as a primary  6 efficacy variable?  7       <b>A. Yes.</b>  8       Q. Okay. And which one is it in the  9 listing on table three?  10       <b>A. Five. Number five.</b>  11       Q. Okay. This says -- pointing to  12 the final clinical report, CGI  13 Improvement Score. Five is just one item  14 from that score; correct?  15  16       MR. MARGOLIS: What table are you  17 on?  18       THE WITNESS: Table three?  19       MR. MURGATROYD: Yes, table  20 three.  21       THE WITNESS: Do we define -- I  22 believe that that is construed as an  23 improvement score.  24       MR. MURGATROYD: Well let's go  25 all the way down to seven.</p>	<p>1       Q. Okay. Now you do have that  2 listed as a secondary efficacy variable  3 in table four of your manuscript;  4 correct?  5       <b>A. Yes.</b>  6       Q. Did that reach statistical  7 significant in favor of Paxil?  8       <b>A. No.</b>  9       Q. What is the next secondary  10 efficacy parameter on page 44?  11       <b>A. Self Perception Profile.</b>  12       Q. Okay. And that is listed in  13 table four as a secondary efficacy  14 variable in your manuscript; correct?  15       <b>A. Yes.</b>  16       Q. Did that reach statistical  17 significance in favor of Paxil?  18       <b>A. No.</b>  19       Q. Okay. What is the last secondary  20 efficacy variable or parameter that is  21 listed on page 44 of the final study  22 report?  23       <b>A. Sickness Impact Scale.</b>  24       Q. Okay. And is that contained in  25 table 4 as a secondary efficacy variable</p>

<p style="text-align: right;">Page 134</p> <p>1 in your manuscript?</p> <p>2 <b>A. Yes.</b></p> <p>3 Q. And did that reach statistical</p> <p>4 significance in favor of Paxil?</p> <p>5 <b>A. No.</b></p> <p>6 Q. Okay. So would you agree that</p> <p>7 the two primary efficacy variables stated</p> <p>8 in the final report did not reach</p> <p>9 statistical significance in favor of</p> <p>10 Paxil?</p> <p>11 <b>A. Table three?</b></p> <p>12 Q. I'm sorry. No, I'm looking at</p> <p>13 the two primary efficacy variables as</p> <p>14 defined by the final clinical report on</p> <p>15 page 43. Okay?</p> <p>16 <b>A. Yes.</b></p> <p>17 Q. Do you agree that neither of</p> <p>18 those reached statistical significance in</p> <p>19 favor of Paxil?</p> <p>20 <b>A. I see response, which is the</b></p> <p>21 <b>second. But it did not produce P value</b></p> <p>22 <b>less than .05.</b></p> <p>23 Q. Okay. And then you have the</p> <p>24 total HAM-D score, which is number eight;</p> <p>25 correct?</p>	<p style="text-align: right;">Page 136</p> <p>1 Q. Do you believe that it might be</p> <p>2 the heading that you have called HAM-D</p> <p>3 total score?</p> <p>4 <b>A. I do not know.</b></p> <p>5 Q. Okay. Now, according to the</p> <p>6 final report. The primary and efficacy</p> <p>7 variables listed in the final report that</p> <p>8 we just went through. Would you agree</p> <p>9 that Paxil failed to achieve statistical</p> <p>10 significance with regard to any of those</p> <p>11 variables?</p> <p>12</p> <p>13 MR. DAVIS: Object to the form.</p> <p>14 Can I have that question read back.</p> <p>15 MR. MURGATROYD: I will ask the</p> <p>16 question again.</p> <p>17</p> <p>18 (BY MR. MURGATROYD):</p> <p>19 Q. Would you agree if Paxil failed</p> <p>20 to achieve statistical significance with</p> <p>21 regard to any of the primary efficacy</p> <p>22 parameters or secondary efficacy</p> <p>23 parameters set forth in the final study</p> <p>24 report that we just went over?</p> <p>25</p>
<p style="text-align: right;">Page 135</p> <p>1 <b>A. Yes.</b></p> <p>2 Q. In your table three?</p> <p>3 <b>A. Yes.</b></p> <p>4 Q. Did that reach statistical</p> <p>5 significance in favor of Paxil?</p> <p>6 <b>A. No. Just from reading this right</b></p> <p>7 <b>now right here today, that the total</b></p> <p>8 <b>HAM-D score is the same as a change in</b></p> <p>9 <b>baseline. Those are two different</b></p> <p>10 <b>things.</b></p> <p>11 Q. Okay. Well do you reference the</p> <p>12 change from baseline in the total score</p> <p>13 of the HAM-D from beginning of treatment</p> <p>14 to the end of the eighth week acute phase</p> <p>15 in table three of your first</p> <p>16 manuscript?</p> <p>17 <b>A. The change? No.</b></p> <p>18 Q. So that primary efficacy variable</p> <p>19 is not even included in table three?</p> <p>20</p> <p>21 MR. DAVIS: Object to the form.</p> <p>22 THE WITNESS: As worded here,</p> <p>23 it's not no.</p> <p>24</p> <p>25 (BY MR. MURGATROYD):</p>	<p style="text-align: right;">Page 137</p> <p>1 MR. DAVIS: Object to the form.</p> <p>2 Mischaracterizes the document.</p> <p>3 THE WITNESS: Well there are</p> <p>4 values here on table three that do</p> <p>5 achieve statistical significance.</p> <p>6</p> <p>7 (BY MR. MURGATROYD):</p> <p>8 Q. I understand. But where are</p> <p>9 those in the final study?</p> <p>10 <b>A. I don't know.</b></p> <p>11 Q. Do you see them in the final</p> <p>12 study report?</p> <p>13 <b>A. I do not see them on this page.</b></p> <p>14 <b>These three pages, no.</b></p> <p>15 Q. Were you ever told by GSK that of</p> <p>16 the 25 efficacy parameters that were</p> <p>17 analyzed by GSK with regard to 329, only</p> <p>18 four reached statistical significance?</p> <p>19</p> <p>20 MR. DAVIS: Object to the form.</p> <p>21 THE WITNESS: I don't remember.</p> <p>22</p> <p>23 (BY MR. MURGATROYD):</p> <p>24 Q. Okay. As a medical writer and</p> <p>25 your understanding of pharmacology, would</p>

<p style="text-align: right;">Page 138</p> <p>1 you think a study in which only four of 2 the efficacy parameters that were 3 analyzed reached statistical significance 4 would show that the drug is an effective 5 drug? 6 7 MR. DAVIS: Object to the form of 8 the question. There is no foundation. 9 Outside the witness expertise. 10 THE WITNESS: No. I would not 11 agree. If I heard your question 12 correctly. Could you repeat it. 13 MR. MURGATROYD: Well let me ask 14 you this. 15 16 (BY MR. MURGATROYD): 17 Q. Do you think that in a study in 18 which four of the 25 efficacy parameters 19 achieve statistical significance, would 20 show that the drug was effective? 21 <b>A. I'm not a trialist. I don't</b> 22 <b>design clinical studies. I'm not a</b> 23 <b>biostatistician. That is not my</b> 24 <b>expertise at all. I can't answer that</b> 25 <b>question.</b></p>	<p style="text-align: right;">Page 140</p> <p>1 (BY MR. MURGATROYD): 2 Q. Okay. So it specifically states 3 paroxetine is an effective treatment of 4 depression in the adolescent patient; 5 correct? 6 <b>A. Yes.</b> 7 Q. Okay. And when you wrote those 8 words, were you aware that Paxil failed 9 to achieve statistical significance in 10 any but four of the 25 efficacy 11 parameters that were analyzed by GSK? 12 13 MR. DAVIS: Object to the form. 14 Also misconstrues the date. 15 THE WITNESS: I don't remember 16 you know what I was aware of. This does 17 not look outside the realm of what is 18 standard. I reported the data accurately 19 as far as I can tell in this result 20 section that listed the items that were 21 statistically significant. 22 23 (BY MR. MURGATROYD): 24 Q. Where are all the other items? 25 <b>A. I don't know. You know one of</b></p>
<p style="text-align: right;">Page 139</p> <p>1 Q. Okay. Do you think that would be 2 important for you to know that when you 3 use the words in your first manuscript in 4 the results. In your conclusion of the 5 abstract that says paroxetine is a safe 6 and effective treatment of depression in 7 the adolescent patient. 8 9 MR. DAVIS: Object to the form of 10 the question. 11 THE WITNESS: I didn't follow 12 from the first to the second part of what 13 your question was. 14 MR. MURGATROYD: That's fine. 15 Your conclusion states -- actually can 16 you read your conclusion from the 17 abstract of the first draft into the 18 record, please. 19 THE WITNESS: Yes. "Paroxetine 20 is a safe and effective treatment of 21 depression in the adolescent patient. 22 Further studies are warranted to 23 determine the optimal dose and duration 24 of therapy". 25</p>	<p style="text-align: right;">Page 141</p> <p>1 <b>the purposes is to take a document this</b> 2 <b>big and condense it into something this</b> 3 <b>big. And often not everything is put in</b> 4 <b>in my broader experience.</b> 5 Q. Well the final clinical study 6 report clearly identifies two primary 7 efficacy variables; right? 8 <b>A. Yes.</b> 9 Q. Yet your table three lists 10 eight? 11 <b>A. Yes.</b> 12 Q. How did that happen? 13 <b>A. I don't know.</b> 14 Q. The primary study report lists 15 five secondary efficacy variables. Your 16 table four entitled Secondary Efficacy 17 Variables lists three. 18 <b>A. Yes.</b> 19 Q. How did that happen? 20 <b>A. Again, I do not remember those</b> 21 <b>specifics.</b> 22 Q. With regard to what you call 23 primary efficacy variables in table 24 three, how many of those achieve 25 statistical significance in favor of</p>

<p style="text-align: right;">Page 142</p> <p>1 Paxil?</p> <p>2 <b>A. Four.</b></p> <p>3 Q. Okay. And which four?</p> <p>4 <b>A. Remission, HAM-D depressed mood</b></p> <p>5 <b>item, K-SADS depressed mood item, and CGI</b></p> <p>6 <b>score of one or two.</b></p> <p>7 Q. Okay. Now turning to page 44 of</p> <p>8 the final clinical report. How many of</p> <p>9 those are mentioned as secondary efficacy</p> <p>10 parameters in your final study report?</p> <p>11 <b>A. Three are mentioned as secondary</b></p> <p>12 <b>efficacy variables in table four.</b></p> <p>13 Q. Okay. And which three?</p> <p>14 <b>A. The autonomous functioning</b></p> <p>15 <b>checklist --</b></p> <p>16 Q. No, I'm sorry. Of the four that</p> <p>17 reach statistical significance that you</p> <p>18 just read into the record.</p> <p>19 <b>A. Yes.</b></p> <p>20 Q. In your table three.</p> <p>21 <b>A. Yes.</b></p> <p>22 Q. How many of those are mentioned</p> <p>23 under the heading secondary efficacy</p> <p>24 parameters in the final?</p> <p>25 <b>A. None.</b></p>	<p style="text-align: right;">Page 144</p> <p>1 <b>depressed items is the same as the</b></p> <p>2 <b>subscale of the K-SADS-L.</b></p> <p>3 Q. I think if you read the paragraph</p> <p>4 below the bolded items, it may sort that</p> <p>5 out for you?</p> <p>6 <b>A. Okay.</b></p> <p>7 Q. Does that help clarify additional</p> <p>8 efficacy variables that were added?</p> <p>9</p> <p>10 MR. DAVIS: Object to form of</p> <p>11 question.</p> <p>12 THE WITNESS: I see what it says.</p> <p>13 I understand what this says. I do not</p> <p>14 remember this happening. I just don't</p> <p>15 remember this element of this very long</p> <p>16 and very complicated project.</p> <p>17</p> <p>18 (BY MR. MURGATROYD):</p> <p>19 Q. Okay. Well, do you see that it</p> <p>20 says that prior to opening the blind, the</p> <p>21 sponsor and investigators developed a</p> <p>22 plan to analyze the efficacy data. That</p> <p>23 is what it says; right?</p> <p>24 <b>A. Yes.</b></p> <p>25 Q. And it talks about -- in the</p>
<p style="text-align: right;">Page 143</p> <p>1</p> <p>2 MR. DAVIS: And just for the</p> <p>3 record, I object to the form of the</p> <p>4 question because you're misinterpreting</p> <p>5 the document.</p> <p>6 But if you want to go down that</p> <p>7 road, that's all right because I will fix</p> <p>8 it.</p> <p>9 MR. MURGATROYD: You can do what</p> <p>10 you want, Todd.</p> <p>11</p> <p>12 (BY MR. MURGATROYD):</p> <p>13 Q. Now none of the ones that have</p> <p>14 bullet points; right?</p> <p>15 <b>A. Sorry?</b></p> <p>16 Q. None of the ones that have bullet</p> <p>17 points in front of them? None of the</p> <p>18 secondary variables that have bullet</p> <p>19 points in front of them; correct?</p> <p>20 <b>A. None of them what?</b></p> <p>21 Q. Were among the four that achieved</p> <p>22 statistical significance according to</p> <p>23 your table three?</p> <p>24 <b>A. I don't know about the CGI. And</b></p> <p>25 <b>I don't know specifically if the K-SADS</b></p>	<p style="text-align: right;">Page 145</p> <p>1 third sentence it says these included the</p> <p>2 depression items from the HAM-D; right?</p> <p>3 <b>A. Yes.</b></p> <p>4 Q. And that is one of the efficacy</p> <p>5 parameters that you listed in your table</p> <p>6 three; correct?</p> <p>7 <b>A. Yes.</b></p> <p>8 Q. And the K-SADS-L instrument</p> <p>9 depression item from the K-SADS-L</p> <p>10 instrument?</p> <p>11 <b>A. Yes.</b></p> <p>12 Q. That's also listed in your table</p> <p>13 three; correct?</p> <p>14 <b>A. Yes.</b></p> <p>15 Q. And plan provided status of</p> <p>16 remission. That's also included in table</p> <p>17 three of your first manuscript; right?</p> <p>18 <b>A. Yes.</b></p> <p>19 Q. Is there any reference anywhere</p> <p>20 in section 3.9.2, secondary efficacy</p> <p>21 parameters, of the final study report</p> <p>22 that talks specifically about CGI score</p> <p>23 of one or two?</p> <p>24</p> <p>25 MR. DAVIS: Object to the form.</p>

<p style="text-align: right;">Page 146</p> <p>1 THE WITNESS: Again, I cannot say 2 with certainty that that is just a 3 different way of saying the CGI 4 improvement score. 5 6 (BY MR. MURGATROYD): 7 Q. Well you already have the CGI 8 improvement score as number seven in your 9 table; correct? 10 <b>A. It does not say CGI improvement</b> 11 <b>score.</b> 12 Q. What does it say? 13 <b>A. It says means CGI score.</b> 14 Q. Okay. Well my question was 15 anywhere in this section does it 16 specifically talk about a CGI score of 17 one or two? 18 <b>A. And again I will say that I do</b> 19 <b>not know if these are being used</b> 20 <b>interchangeably.</b> 21 Q. Okay. Do you see the words one 22 or two in there? 23 <b>A. Yes, I do.</b> 24 Q. CGI one or two? 25 <b>A. Yes, I do.</b></p>	<p style="text-align: right;">Page 148</p> <p>1 <b>A. Yes.</b> 2 Q. That did not reach statistical 3 significance in favor of Paxil; 4 correct? 5 <b>A. Yes.</b> 6 Q. Okay. 7 <b>A. That's what the table shows.</b> 8 Q. Okay. Now do you even know what 9 CGI score of one or two is? Is that a 10 subset of that, do you know? 11 <b>A. Again, I am not an expert in</b> 12 <b>psychiatric clinical trials or design of</b> 13 <b>these.</b> 14 Q. Well let me ask you this. Do you 15 know what a primary efficacy variable 16 is? 17 <b>A. Yes.</b> 18 Q. What is it? 19 <b>A. It's something that is determined</b> 20 <b>in the design of the study.</b> 21 Q. Okay. Is it that which is being 22 tested? 23 <b>A. Yes.</b> 24 Q. Okay. And what is the difference 25 between a primary efficacy variable and a</p>
<p style="text-align: right;">Page 147</p> <p>1 Q. Where is that -- in the final 2 clinical report? 3 <b>A. No.</b> 4 Q. It's not in there, is it? 5 <b>A. No.</b> 6 7 MR. DAVIS: Object to the form. 8 Ms. Laden, can you tell us which page 9 you're looking at, please. 10 THE WITNESS: I'm looking at page 11 of the study report, 44. 12 13 (BY MR. MURGATROYD): 14 Q. Okay. And you agree that CGI one 15 or two, there is no reference to it 16 whatsoever on that page? 17 <b>A. Again this could be something</b> 18 <b>that's used interchangeably.</b> 19 Q. Okay. I'm asking the words one 20 or two? 21 <b>A. The words one or two are not on</b> 22 <b>page 44 of this document.</b> 23 Q. Okay. But what is the difference 24 -- in your table three you have a means 25 CGI score; correct?</p>	<p style="text-align: right;">Page 149</p> <p>1 secondary efficacy variable? 2 <b>A. Honestly I can't tell you a good</b> 3 <b>definition. I don't know.</b> 4 Q. Okay. But you understand what 5 the importance of a primary efficacy 6 variable is? 7 <b>A. Yes.</b> 8 Q. Okay. And do you think a study 9 that fails to reach statistical 10 significance on any of the primary 11 efficacy variables predefined, which 12 showed that the drug is an effective 13 drug? 14 15 MR. DAVIS: Object to the form. 16 No foundation. 17 THE WITNESS: I can't answer 18 that. It's not my area of expertise. 19 There are a lot of vagaries and clinical 20 trial design that I'm just not an expert 21 in. 22 23 (BY MR. MURGATROYD): 24 Q. Okay. Well when you wrote your 25 manuscript, were you aware that both of</p>

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Page 151	Page 153

1 the primary efficacy variables failed to  
2 achieve statistical significance in favor  
3 of Paxil?

4 **A. I don't know.**

5 Q. Okay.

6  
7 MR. DAVIS: Skip, how much longer  
8 do you got before a lunch break?

9 MR. MURGATROYD: What time is it?

10 MR. DAVIS: It's 1:00.

11 MR. MURGATROYD: It's 1:00  
12 o'clock? Gee, time flies when you're  
13 having fun.

14 MR. DAVIS: It will fly a little  
15 bit faster a little bit later today. I  
16 promise you.

17 MR. MURGATROYD: Well let's take  
18 45 minutes for lunch. Is that okay?

19 MR. DAVIS: Sure.

20 MR. MURGATROYD: And we will meet  
21 back here at 1:45.

22 VIDEOGRAPHER: Okay. The time is  
23 one minute after 1:00. We are off the  
24 record.

1 Q. Okay. Would the fact that the  
2 final clinical report is dated November  
3 24, 1998 help explain that?

4 **A. First I have no recollection that  
5 this is the exact document that I used to  
6 prepare this.**

7  
8 MR. MARGOLIS: So the record is  
9 clear, she is pointing to Exhibit 7.

10 THE WITNESS: Exhibit 7 which is  
11 the final clinical report. It is a final  
12 clinical report. I don't know if this  
13 was the document I used.

14  
15 (BY MR. MURGATROYD):

16 Q. And that's the type of document  
17 that you used in preparing first  
18 manuscripts -- first drafts?

19 **A. Yes.**

20 Q. Okay. Now -- and what is the  
21 date of it?

22 **A. November 24, 1998.**

23 Q. All right. Would that help  
24 explain why your first draft wasn't until  
25 December 18th?

1 (Off the record)

2  
3 (Back on the record)

4  
5 VIDEOGRAPHER: We are back on the  
6 record. This is tape number three. The  
7 time is 1:54.

8  
9 (BY MR. MURGATROYD):

10 Q. Now I think we established prior  
11 to taking a break that your draft is  
12 dated in December; is that correct?

13 **A. Yes.**

14 Q. Okay. And what is the exact  
15 date?

16 **A. December 18, 1998.**

17 Q. Okay. And again, you don't  
18 recall why it took from April until  
19 December for you to prepare the first  
20 draft?

21  
22 MR. DAVIS: Objection.

23 THE WITNESS: No.

24  
25 (BY MR. MURGATROYD):

1 **A. I don't remember why my first  
2 draft was not until December 18th.**

3 Q. Okay. Have you ever prepared a  
4 first draft of an article to be published  
5 in a medical journal from documents other  
6 than a clinical study report for GSK?

7  
8 MR. DAVIS: Object to the form.

9 THE WITNESS: I cannot  
10 remember.

11  
12 (BY MR. MURGATROYD):

13 Q. Okay. Is that your normal  
14 practice? Your ordinary practice to use  
15 a final study report as the basis for  
16 your first draft?

17 **A. That is standard practice.**

18 Q. Okay.

19 **A. That's ideal.**

20 Q. Okay. That has been your  
21 standard practice as a medical writer?

22 **A. I have had examples where -- this  
23 says final clinical report. Where  
24 perhaps I may have started with a  
25 preliminary version that is not final.**

1 **But in this case, I just do not**  
2 **remember.**

3 Q. Okay. That is fine. Now prior  
4 to you preparing the first draft of the  
5 manuscript for Study 329, were you made  
6 aware of a position piece that GSK had  
7 internally developed that discussed the  
8 results of Study 329?

9 **A. I don't remember.**

10  
11 MR. MURGATROYD: Okay. Let me  
12 show it to you.

13  
14 (Plaintiff's Exhibit 9, marked)

15  
16 MR. DAVIS: I will object to the  
17 use of that document. This witness --  
18 there wouldn't be any foundation that can  
19 possibly be laid that the witness is  
20 familiar with it or had any involvement  
21 with it.

22 And if you grant me a standing  
23 objection, that will prevent me from  
24 having to object every time. Any problem  
25 with that?

1 MR. MURGATROYD: I think we have  
2 already agreed Todd that all you have to  
3 object to is the form of the question.  
4 All other objections are reserved for the  
5 Court's ruling.

6 MR. DAVIS: So will you grant me  
7 that objection, both of you?

8 MR. MURGATROYD: I'm not going to  
9 grant you any objection. We already  
10 agreed that all objections are reserved  
11 until time of trial, with the exception  
12 to the form of the question.

13 I mean I know you like to say  
14 things on the record to --

15 MR. DAVIS: Let's just move this  
16 along. We don't need the commentary.  
17 Let's just progress it along.

18 MR. MURGATROYD: Then why don't  
19 we just agree on the objections are to  
20 the form, and no others?

21 MR. DAVIS: Let's move it along.

22 MR. MURGATROYD: I know this  
23 document is very upsetting to you and  
24 GSK, but that's tough.

25 MR. DAVIS: It's not upsetting.

1 It's just the fact that we are here  
2 talking about a document with a witness  
3 that doesn't know anything about it.  
4 It's not a very effective use of  
5 everyone's time. But again, it's your  
6 nickle.

7 MR. MURGATROYD: Well, have you  
8 talked to Mrs. Laden to determine that?

9 MR. DAVIS: I have not had any  
10 discussions with Mrs. Laden prior to the  
11 deposition.

12 MR. MURGATROYD: Then how do you  
13 know that she is not familiar with the  
14 content of that document?

15 MR. DAVIS: She's not on the  
16 distribution list. It's pretty clear.

17 MR. MURGATROYD: Well isn't that  
18 a matter of public record --

19 MR. DAVIS: Let's not argue.  
20 Let's just ask Ms. Laden questions. We  
21 are wasting time.

22 MR. MURGATROYD: Okay. Isn't  
23 that document part of medical journal  
24 records accusing GSK of fraud?

25 MR. DAVIS: Let's go. You're

1 wasting everybody's time. Let's go.

2 MR. MURGATROYD: Well Todd I  
3 disagree. The witness hasn't had a  
4 chance to see the document.

5  
6 (BY MR. MURGATROYD):

7 Q. Have you had a chance to take a  
8 look at that document?

9  
10 **A. I did not read every word, but**  
11 **yes I looked through the pages.**

12 Q. And it's marked as Exhibit?

13 **A. Nine.**

14 Q. Nine? Okay. Have you ever seen  
15 either the cover page or the position  
16 piece that is attached to it before?

17 **A. I don't believe so.**

18 Q. Have you ever read about those in  
19 various medical journals?

20 **A. Read about what?**

21 Q. The position piece that is  
22 discussed there?

23 **A. I don't think so, no.**

24 Q. Okay. Can you tell me what the  
25 date is of the E-mail that -- or the  
E-mail that precedes the position

<p style="text-align: right;">Page 158</p> <p>1 piece?</p> <p>2 <b>A. October 14, 1998.</b></p> <p>3 Q. Okay. That is two months -- a</p> <p>4 little over two months prior to your</p> <p>5 first draft being submitted to GSK;</p> <p>6 correct?</p> <p>7 <b>A. Yes.</b></p> <p>8 Q. Okay. Were you made aware that</p> <p>9 GSK was disappointed about the results of</p> <p>10 Study 329?</p> <p>11 <b>A. No.</b></p> <p>12 Q. Okay. Do you see the second</p> <p>13 paragraph of the E-mail that is attached</p> <p>14 to this Exhibit?</p> <p>15 <b>A. Yes.</b></p> <p>16 Q. Okay. And can you read that</p> <p>17 first sentence in the second paragraph</p> <p>18 into the record, please?</p> <p>19 <b>A. "As you well know, the results of</b></p> <p>20 <b>the studies were disappointing in that we</b></p> <p>21 <b>did not reach statistical significance on</b></p> <p>22 <b>the primary end points. And thus the</b></p> <p>23 <b>data do not support a label claim for the</b></p> <p>24 <b>treatment of adolescent depression."</b></p> <p>25 Q. Okay.</p>	<p style="text-align: right;">Page 160</p> <p>1 Q. That's what it says in this</p> <p>2 E-mail; right?</p> <p>3 <b>A. Which I have never seen before.</b></p> <p>4 Q. I understand that. That's what</p> <p>5 it says in the E-mail?</p> <p>6 <b>A. That's what it says in the</b></p> <p>7 <b>E-mail.</b></p> <p>8 Q. Okay. Let's take a look at the</p> <p>9 position piece that is attached to this</p> <p>10 E-mail. Do you see that?</p> <p>11 <b>A. Yes.</b></p> <p>12 Q. And at the top it says</p> <p>13 confidential for internal use only, and</p> <p>14 it has a date; correct?</p> <p>15 <b>A. Yes.</b></p> <p>16 Q. And what is that date?</p> <p>17 <b>A. October, 1998.</b></p> <p>18 Q. And again, that's two months</p> <p>19 prior to you submitting your first draft</p> <p>20 of the manuscript for Study 329?</p> <p>21 <b>A. Yes.</b></p> <p>22 Q. And this first page talks about</p> <p>23 study 329 in the second paragraph;</p> <p>24 correct?</p> <p>25 <b>A. In part, yes.</b></p>
<p style="text-align: right;">Page 159</p> <p>1</p> <p>2 MR. DAVIS: Excuse me. And of</p> <p>3 course there has been no foundation laid</p> <p>4 by the questioning that this witness can</p> <p>5 answer any questions about this document.</p> <p>6 But if you want to spend your nickle, go</p> <p>7 right ahead.</p> <p>8 MR. MURGATROYD: Todd, we agreed</p> <p>9 that the objections are restricted to</p> <p>10 form.</p> <p>11 MR. DAVIS: Please proceed.</p> <p>12</p> <p>13 (BY MR. MURGATROYD):</p> <p>14 Q. Now were you told by anyone at</p> <p>15 GSK prior to you creating your first</p> <p>16 manuscript, your first draft of the</p> <p>17 manuscript for Study 329, that -- well</p> <p>18 first of all, that the -- 329 did not --</p> <p>19 Paxil did not reach statistical</p> <p>20 significance with regard to either of the</p> <p>21 efficacy variables with regard to 329?</p> <p>22 <b>A. I don't recall that.</b></p> <p>23 Q. Okay. Yet that's what it says in</p> <p>24 this E-mail; right?</p> <p>25 <b>A. On the what?</b></p>	<p style="text-align: right;">Page 161</p> <p>1 Q. Okay. Can you read the second</p> <p>2 sentence into the record, please?</p> <p>3 <b>A. "However the study failed to</b></p> <p>4 <b>demonstrate a statistically significant</b></p> <p>5 <b>difference from placebo on the primary</b></p> <p>6 <b>efficacy measures."</b></p> <p>7 Q. Okay. And we discussed that a</p> <p>8 second ago. That is something that you</p> <p>9 were not told by GSK prior to you</p> <p>10 performing the first draft of the</p> <p>11 manuscript?</p> <p>12</p> <p>13 MR. DAVIS: Object to the form.</p> <p>14 THE WITNESS: No. That was not</p> <p>15 discussed to the best of my</p> <p>16 recollection.</p> <p>17</p> <p>18 (BY MR. MURGATROYD):</p> <p>19 Q. Okay. Now, if you would can you</p> <p>20 go to the second to last page -- I'm</p> <p>21 sorry. The third to the last page of the</p> <p>22 position piece. And it has in the middle</p> <p>23 of the page in large bold type</p> <p>24 "Target"?</p> <p>25 <b>A. Yes.</b></p>

1 Q. Do you see that?

2 A. Yes.

3 Q. Okay. Can you read that sentence  
4 into the record, please?

5 A. **"To effectively manage the  
6 dissemination of this data in order to  
7 minimize any potential negative  
8 commercial impact."**

9 Q. Okay. Do you -- are you familiar  
10 with the term potential negative  
11 commercial impact?

12  
13 MR. DAVIS: Object to the form.  
14 This witness cannot speak to that  
15 document and what it means. And you have  
16 already deposed somebody. We are wasting  
17 our time.

18 MR. MURGATROYD: I'm sorry. you  
19 can object to the form.

20 MR. DAVIS: I object to the form.  
21 I also object that this is just a  
22 complete waste of time to ask this  
23 witness questions about a document she  
24 knows nothing about.

25 MR. MURGATROYD: Todd, just

1 object to the form and let's move on.

2 That's the rules.

3 MR. DAVIS: When did you say  
4 you're going to be done, because I'm  
5 going to hold you -- this is silly. It's  
6 silly.

7 MR. MURGATROYD: Todd, I'm sorry  
8 this is upsetting to you.

9 MR. DAVIS: It's not upsetting.  
10 It's a waste of time.

11 MR. MURGATROYD: I'm sorry. We  
12 are going to move to strike all these  
13 comments which are improper, and let's go  
14 on.

15  
16 (BY MR. MURGATROYD):

17 Q. Potential negative commercial  
18 impact. Are you familiar with that  
19 term?

20  
21 MR. DAVIS: Object to the form.

22 THE WITNESS: I know what each of  
23 the words means. I don't think I have  
24 ever -- you know it's not a phrase I use  
25 in my professional life.

1

2 (BY MR. MURGATROYD):

3 Q. Okay. What does it mean to you  
4 though?

5

6 MR. DAVIS: Object to the form.  
7 Excuse me. This witness cannot speak to  
8 what that means in that document. I  
9 object to the form.

10 MR. MURGATROYD: Todd, object to  
11 the form is fine. Go ahead.

12

13 (BY MR. MURGATROYD):

14 Q. What does that mean to you in  
15 ordinary language?

16 A. **"Potential" means possible.  
17 "Negative" means the opposite of  
18 positive. Something bad. "Commercial"  
19 means something is for sale. And  
20 "impact" means the effect of something on  
21 something else.**

22 Q. Okay. Now do you see that there  
23 are proposals for that target below that  
24 are listed in bullet points. Do you see  
25 there are three bullet points? One going

1 on to the next page?

2 A. **I see three bullet points and  
3 nothing going on to the next page.**

4 Q. Okay. The third bullet point is  
5 on the next page; right?

6 A. **No, it is not. Not on this.**

7 Q. Okay. I have a different copy on  
8 my computer. Okay. The three bullet  
9 points. Can you read the second bullet  
10 point into the record, please?

11 A. **"Positive data from Study 329  
12 will be published in abstract form at the  
13 ECMP Paris November, 1998. And a full  
14 manuscript of the 329 data will be  
15 progressed."**

16 Q. Okay. Now prior to you drafting  
17 the -- preparing the first draft of the  
18 manuscript 329, were you told that your  
19 article was a part of a proposal -- I'm  
20 sorry. Part of a target to effectively  
21 manage the dissemination of the data of  
22 these negative studies?

23

24 MR. DAVIS: Object to the form of  
25 the question.

1 THE WITNESS: No.

2 (BY MR. MURGATROYD):

3 Q. Okay. Were you ever told by GSK  
4 that your writing that paper was part of  
5 a program to make sure that the Paxil  
6 sales for adults were not effected by the  
7 disappointing results of Study 329 and  
8 377?  
9

10 MR. DAVIS: Excuse me. Object to  
11 the form of the question.

12 THE WITNESS: No.

13 (BY MR. MURGATROYD):

14 Q. Okay. Were you aware that  
15 simultaneous to 329, there was another  
16 pediatric study being taken place in  
17 Europe?  
18

19 **A. I believe I was aware that there  
20 were other studies. I don't know when I  
21 knew that. Where they were taking place.**

22 Q. Okay. Were you aware  
23 specifically of the study which is known  
24 as 377?  
25

1 **A. No.**

2 Q. Were you ever told prior to you  
3 drafting your -- preparing your first  
4 draft of the manuscript for 329 that 377  
5 trial had concluded. And that Paxil  
6 failed to reach statistical significance  
7 on any single efficacy variable that was  
8 being tested in that study?  
9

10 **A. I don't recall being told about  
11 any -- the details of any other  
12 studies.**

13 Q. Okay. Were -- would you have  
14 liked to have known that Europe working  
15 with GSK, and in preparing the manuscript  
16 for Study 329 was part of a target to  
17 effectively manage the dissemination of  
18 the negative pediatric study data?  
19

20 MR. DAVIS: Object to the form of  
21 the question.

22 THE WITNESS: I'm not sure how to  
23 answer that.

24 (BY MR. MURGATROYD):

25 Q. Is that something that you would

1 want to know when you were preparing that  
2 manuscript? That you were part of a  
3 target to minimize the commercial impact  
4 of Paxil because of the disappointing  
5 results of Studies 329 and 377?  
6

7 MR. DAVIS: Object to the form.

8 THE WITNESS: My job was to work  
9 with this data, and that is what I  
10 focused on. The data that was given to  
11 me.  
12

13 (BY MR. MURGATROYD):

14 Q. I understand. But did you want  
15 to know that you were part of this  
16 target?  
17

18 MR. MARGOLIS: I'm going to  
19 object to that. This is way beyond  
20 anything that she has any knowledge of.

21 MR. MURGATROYD: Well, my  
22 question is would she want to have  
23 knowledge of that in order to  
24 participate?  
25

MR. MARGOLIS: But she already

1 testified that she was working for STI.  
2 That she was to help prepare a paper  
3 relating to Study 329, and that was her  
4 limited role.

5 MR. MURGATROYD: Okay.

6 MR. MARGOLIS: That was her  
7 limited role.

8 MR. MURGATROYD: Okay. My  
9 question is --

10 MR. MARGOLIS: She is not saying  
11 that she was --  
12

13 (BY MR. MURGATROYD):

14 Q. In doing your duties, do you  
15 think now --  
16

17 MR. MARGOLIS: Her duties were  
18 defined as preparing an article that  
19 related to the 329 Study. Not to  
20 generally take any position regarding  
21 Paxil or GSK or anything else.

22 MR. MURGATROYD: Well let me ask  
23 you this.  
24

25 (BY MR. MURGATROYD):

1 Q. Were you aware that GSK -- and  
2 again so the record is clear. Who are  
3 the people that the E-mail is addressed  
4 to that is attached to this position  
5 piece?

6 **A. Well I know some of the people.  
7 Most I do not.**

8 Q. Okay. Well let's fake the  
9 first -- well let's take Barry Brand?

10 **A. Yes.**

11 Q. Did you work with Barry Brand?

12 **A. Yes.**

13 Q. Okay. And he was in marketing at  
14 GSK; correct?

15 **A. Yes.**

16 Q. The second one is Bonnie  
17 Rossello. I think we have already come  
18 across her name; right? Did you work  
19 with Bonnie Rossello?

20 **A. Yes.**

21 Q. Was she in the marketing  
22 department at GSK?

23 **A. Yes.**

24 Q. Are these people that you relied  
25 upon to give you accurate information

1 regarding the work that you were to do on  
2 Study 329?

3 **A. No.**

4 Q. Okay. Who did you rely upon for  
5 accurate information regarding 329?

6 **A. Jim McCafferty.**

7 Q. Okay. Now, did Jim McCafferty  
8 ever tell you that GSK had found that the  
9 results of 329 to be quote,  
10 "disappointing"?

11 **A. I do not remember.**

12 Q. Okay. Do you think that is  
13 something you would remember?

14 **A. I just said I don't remember.**

15 Q. Okay. Is that something that you  
16 think you would remember if somebody told  
17 you the results were disappointing?

18  
19 MR. MARGOLIS: I'm going to  
20 object to that question because it's  
21 completely asking her to speculate, when  
22 she already said she doesn't remember.

23  
24 (BY MR. MURGATROYD):

25 Q. Okay. I'm asking her is that

1 something you think you would remember?

2 **A. I don't know.**

3 Q. Well when you drafted up the  
4 first -- when you prepared the first  
5 draft of the manuscript of 329, was it in  
6 your head that the results of 329 were  
7 disappointing?

8 **A. No. I don't remember. I had it  
9 in front of me, and that's what I worked  
10 with.**

11 Q. Okay. Well do you think the  
12 conclusion that you prepared in the first  
13 draft stating that Paxil is an effective  
14 treatment of depression in the adolescent  
15 patient is consistent with GSK's  
16 statement that the results of Study 329  
17 are disappointing?

18  
19 MR. DAVIS: Object to the form.  
20 Asked and answered.

21 THE WITNESS: Can you repeat the  
22 question, please.

23  
24 (BY MR. MURGATROYD):

25 Q. Do you think the conclusion that

1 you wrote for the first draft of Study  
2 329 that states Paxil is effective  
3 treatment of depression in the adolescent  
4 patient, is consistent with GSK's  
5 statement that the results of Study 329  
6 were disappointing?

7  
8 MR. DAVIS: Object to the form of  
9 the question. It's also improper  
10 foundation, and mischaracterizes the  
11 data.

12 THE WITNESS: I wrote the  
13 manuscript on a document similar -- a  
14 compilation of the data from this study.  
15 And based on that -- that is what I wrote  
16 the document from.

17  
18 (BY MR. MURGATROYD):

19 Q. Okay. My question was whether or  
20 not that your statement -- do you agree  
21 now as you're sitting here that a  
22 statement that Paxil is effective for the  
23 treatment of adolescent depression, is  
24 consistent with a finding by GSK that the  
25 results of Study 329 were disappointing?

1  
2 MR. MARGOLIS: Same objection.  
3 THE WITNESS: I'm not an expert  
4 in clinical trial design or  
5 interpretation. And clinical data can be  
6 interpreted many different ways. That is  
7 not my expertise, which I think I would  
8 need to answer the question.  
9

10 (BY MR. MURGATROYD):

11 Q. Well did you have the expertise  
12 to come to the conclusion that Paxil is  
13 an effective treatment for adolescent  
14 depression? Did you have the expertise  
15 to do that?

16 **A. No. But if that was what the  
17 clinical study report said, that is  
18 what -- I mean I wrote it from the  
19 clinical study report.**

20 Q. So you basically relied upon  
21 GSK's statements in preparing your  
22 report; correct?

23 **A. In a clinical study report that  
24 was provided to me, yes.**

25 Q. By GSK?

1 MR. MURGATROYD: You can do what  
2 you want. Thank you. Go ahead.

3 THE WITNESS: I'm sorry. Ask me  
4 the question again.  
5

6 (BY MR. MURGATROYD):

7 Q. Yes. Were you aware that every  
8 single regulatory body in the world --  
9 well first of all let me ask you this.  
10 Were you aware that Study 329 was the  
11 study that caused world wide regulatory  
12 bodies to look at the fact that Paxil was  
13 associated with the events of  
14 suicidality in adolescents taking the  
15 drug? Were you aware of that?  
16

17 MR. DAVIS: Object to the form of  
18 the question. In addition to many  
19 problems with that, including --

20 MR. MURGATROYD: Just say "form"  
21 and let's get on with it. That's your  
22 objection. That's all you get. If you  
23 want to get the Court on the line, we  
24 will do it. You get to say objection to  
25 the form. No more speeches, Todd.

1 **A. By GSK.**

2 Q. Okay. Now, maybe I am just a  
3 little confused. Prior to writing this  
4 first draft, didn't GSK come to you and  
5 say listen we had a problem with 329 and  
6 we had disappointing results. But we  
7 want you to you know put lipstick on that  
8 pig?  
9

10 **A. No.**

11 MR. DAVIS: Object to the form.  
12 It's argumentative.  
13

14 (BY MR. MURGATROYD):

15 Q. Were you aware that every single  
16 regulatory body who looked at Study 329,  
17 came back with the result that it was a  
18 failed study that failed to show efficacy  
19 of Paxil?  
20

21 MR. DAVIS: Object to the form of  
22 question. There is no foundation laid  
23 that the witness can speak to regulatory  
24 issues, and she has already said that she  
25 can't.

1 MR. DAVIS: Skip, don't yell at  
2 me.  
3

4 MR. MURGATROYD: Good. Then just  
5 follow the rules.

6 MR. DAVIS: No. I'm not going to  
7 follow your instructions, because we are  
8 sitting here wasting time with this  
9 witness who doesn't know anything about  
10 regulatory issues, because that is not  
11 her area. She helped with this  
12 manuscript --

13 MR. MURGATROYD: Todd, I don't  
14 want a lecture. You can object to the  
15 form and let's move on.

16 MR. DAVIS: If you want to cut me  
17 off, that's fine. I will just keep  
18 going. And I'm not going to allow you to  
19 use this as some kind of forum where we  
20 are all wasting our time on issues  
21 that -- and documents that the witness is  
22 not familiar with. And there is no  
23 reason to go into those areas.

24 But if you want to use your  
25 nickle that's fine. And I'm going to  
make my objections as I see fit. I'm not

1 going to be yelled at about that. So go  
2 ahead and ask your next question.

3 MS. LEVINE: I'm just going to  
4 object without a time frame. I think  
5 that question is too broad to answer as  
6 framed.

7 MR. MURGATROYD: That's fine.

8  
9 (BY MR. MURGATROYD):

10 Q. Are you aware that every single  
11 regulatory body in the world that looked  
12 at this study -- let me strike that.

13 Were you aware that study 329 was  
14 the instigating study for Paxil being  
15 contraindicated in the UK for the  
16 treatment of depression in kids?

17  
18 MR. DAVIS: Object to the form.  
19 It also mischaracterizes the history.

20 THE WITNESS: I'm aware of the  
21 controversy.

22  
23 (BY MR. MURGATROYD):

24 Q. Okay. Were you aware that 329  
25 was the focus or the beginning point of

1

2 (BY MR. MURGATROYD):

3 Q. Well you wrote the conclusion;  
4 right? Didn't we already establish  
5 that?

6 **A. I'm a medical writer, not a  
7 clinical trialist or a psychiatrist. I  
8 prepare the document based on data that  
9 is given to me. And in this data are  
10 conclusions.**

11 Q. Well are you stating there are  
12 conclusions in the final study report  
13 that Paxil is safe and effective for the  
14 treatment of adolescent depression?

15 **A. I would have to look at it again.  
16 I don't recall. That is standard  
17 practice, though. That's how I  
18 practice.**

19 Q. Were you aware that there is --  
20 well I take it you are aware of -- well,  
21 strike that. Let me just back up.

22 Were you aware that 329 because  
23 of the number of suicide events that  
24 occurred in that single trial. That that  
25 was the instigating document that was

1 why Paxil was contraindicated in the UK  
2 for the treatment of depression in kids?

3  
4 MR. DAVIS: Same objections.

5 THE WITNESS: No, I'm not aware  
6 of that.

7  
8 (BY MR. MURGATROYD):

9 Q. Okay. Were you aware that the  
10 FDA analyzed 329 and came back with the  
11 conclusion that it was a negative or  
12 failed study?

13 **A. I am not familiar with the FDA's  
14 decision on this.**

15 Q. Okay. Would you agree that an  
16 FDA decision that 329 was a failed or  
17 negative study is inconsistent with your  
18 conclusion that Paxil is an effective  
19 treatment for depression in adolescents?

20  
21 MR. DAVIS: Object to the form of  
22 the question. No foundation as well.

23 MS. LEVINE: And I'm going to  
24 object to the form to using her  
25 conclusion.

1 used by regulatory bodies around the  
2 world to issue warnings about Paxil  
3 causing suicidality in kids?

4 **A. No.**

5  
6 MR. DAVIS: Object to the form.

7  
8 (BY MR. MURGATROYD):

9 Q. Have you ever seen any of the  
10 analyses that have been done by any of  
11 the regulatory bodies regarding Study  
12 329?

13 **A. No.**

14 Q. Have you -- let me ask you this.  
15 As a medical writer, aren't you entitled  
16 to have information such as GSK's finding  
17 that the results were disappointing in  
18 329 prior to you preparing the  
19 manuscript?

20  
21 MR. DAVIS: Object to the form.

22  
23 (BY MR. MURGATROYD):

24 Q. Isn't that part of your rights as  
25 a medical writer?

1 **A. No. I don't know what my rights**  
 2 **as a medical writer are. My job is to**  
 3 **take the data, and to the best of my**  
 4 **ability to put it -- condense it into a**  
 5 **manuscript, and work with the authors to**  
 6 **make sure they are happy with the data as**  
 7 **presented.**

8 Q. Well is it part of your job to  
 9 make sure that you accurately portray the  
 10 effectiveness of a drug that you are  
 11 writing about?

12 **A. Yes.**

13 Q. Are you aware as you sit here  
 14 today that a statement that Paxil is  
 15 effective in the treatment of adolescent  
 16 depression has been repudiated by not  
 17 only every regulatory body in the world,  
 18 but also by GSK?

19  
 20 MR. DAVIS: Object to the form.  
 21 Mischaracterizes.

22 THE WITNESS: I cannot speak to  
 23 every regulatory body in the world. Am I  
 24 familiar with the controversy? Yes I  
 25 followed it somewhat, but I had moved on.

1 I wasn't -- you know, when this happened  
 2 that happened well after this was done.

3  
 4 (BY MR. MURGATROYD):

5 Q. Well as a medical writer isn't it  
 6 important to you to know what has  
 7 happened with a project that you were  
 8 integral in?

9  
 10 MR. DAVIS: Object to the form.

11 THE WITNESS: Am I curious?  
 12 Yes.

13  
 14 (BY MR. MURGATROYD):

15 Q. Okay. Have you gone back and --  
 16 have you read the Lanser article that  
 17 says is GSK guilty of fraud that  
 18 specifically referenced the position  
 19 piece you just read?

20  
 21 MR. DAVIS: Object to the form.

22 THE WITNESS: I have not read  
 23 that article.

24  
 25 (BY MR. MURGATROYD):

1 Q. Okay. Have you seen the various  
 2 medical -- letters to the editor of the  
 3 medical journal articles that talk about  
 4 fraud being perpetrated by GSK with  
 5 regard to Study 329 results?

6  
 7 MR. DAVIS: Object to the form.  
 8 It also misconstrues the literature and  
 9 the data discussing 329.

10  
 11 (BY MR. MURGATROYD):

12 Q. Have you read that?

13 **A. I don't recall reading that.**

14 Q. Okay. Do you recall reading  
 15 Attorney General Spitzer's statements  
 16 regarding the fraud that he alleged GSK  
 17 committed regarding Paxil's effectiveness  
 18 for the treatment of depression in kids?

19  
 20 MR. DAVIS: Object to the form.

21 THE WITNESS: No.

22 MR. MURGATROYD: Okay. Now,  
 23 let's look at your first draft. I just  
 24 want to make sure I have something  
 25 straight.

1  
 2 (BY MR. MURGATROYD):

3 Q. When you go to table three, you  
 4 list eight primary efficacy variables;  
 5 correct? We have established that?

6 **A. Yes.**

7 Q. And out of those, how many  
 8 achieve statistical significance for  
 9 Paxil?

10  
 11 MR. DAVIS: Just so the record is  
 12 clear, we are talking about a draft  
 13 manuscript that was never published. But  
 14 if you want to spend your nickle, have at  
 15 it.

16 THE WITNESS: Four.

17  
 18 (BY MR. MURGATROYD):

19 Q. Four of the eight?

20 **A. Yes.**

21 Q. Turning to table four. How many  
 22 of those efficacy variables reached  
 23 statistical significance in favor of  
 24 Paxil?

25 **A. None.**

1 Q. So total we have eight and three,  
2 which would be eleven; correct? Total  
3 efficacy variables?

4 A. Yes.

5 Q. Okay. So seven out of the eleven  
6 failed to reach statistical significance  
7 for Paxil; correct?

8 A. **According to these two tables;  
9 that is correct.**

10 Q. And there is no difference  
11 between your results in these tables than  
12 those that are published in the final  
13 article, are there?

14 A. **I would have to compare them side  
15 by side.**

16  
17 MR. MURGATROYD: Well, let's do  
18 that. Let the record reflect that I'm  
19 marking Exhibit 10. Which is the  
20 published journal article entitled  
21 "Efficacy of Paroxetine in the Treatment  
22 of Adolescent Major Depression: A  
23 Randomized, Controlled Trial." And if  
24 you would please take a look at that.  
25

1 that we just discussed?

2 A. **I have not checked every data  
3 point, but it looks very similar.**

4 Q. Okay. And table two is what we  
5 were referring to in the article; right?  
6 The published article?

7 A. Yes.

8 Q. And how many of the efficacy  
9 variables reached statistical  
10 significance in favor of Paxil in that  
11 table two.

12 A. **Four.**

13 Q. Okay. The same four that are in  
14 your draft; correct? The first draft of  
15 the manuscript?

16 A. Yes.

17 Q. Okay. Now, with regard to table  
18 four that's in your first manuscript.  
19 That is nowhere to be found in the  
20 published article; correct? The table?

21 A. **I'm looking. No.**

22 Q. Okay. Now, in reading your  
23 article, can -- do you tell the reader  
24 that both of the primary efficacy  
25 variables failed to reach statistical

1 (Plaintiff's Exhibit 10, marked)

2 (BY MR. MURGATROYD):

3 Q. Did you get a chance to look at  
4 it?

5 A. Yes.

6 Q. Okay. Great. Can you identify  
7 for the record what that is? Let me  
8 start that again so the record is clear.  
9 You have had a chance to look at the  
10 document; correct?

11 A. Yes.

12 Q. And can you identify it for the  
13 record, please?

14 A. **This is the Keller et al article  
15 that was published in the Journal of  
16 American Academy Child Adolescent  
17 Psychiatry in 2001.**

18 Q. Okay. And that is the end result  
19 of your manuscript that you drafted the  
20 first draft of?

21 A. Yes.

22 Q. Okay. And turning to that  
23 article. Are the results any different  
24 with regard to the efficacy variables  
25

1 significance in favor of Paxil?

2 A. **First, it's not my paper, and I'm  
3 not telling here. The list of people  
4 here, it's their paper. They are the  
5 ones -- this is from the authors. The  
6 investigators of the study.**

7 Q. Well, is there any difference  
8 between your first manuscript -- well let  
9 me ask you this. Let's look at the  
10 conclusion of the abstract. Can you read  
11 it into the record, please.

12 A. **"Paroxetine is generally well  
13 tolerated and effective for major  
14 depression in adolescents."**

15 Q. Okay. Now with regards to the  
16 effectiveness of Paxil. Is there any  
17 difference in the conclusion of this  
18 abstract, and the conclusion that you  
19 wrote in the first draft of the  
20 manuscript?  
21

22 MR. DAVIS: Object to the form.  
23 Misconstrues both documents.

24 THE WITNESS: Yes. It's not the  
25 same language.

<p style="text-align: right;">Page 190</p> <p>1</p> <p>2 (BY MR. MURGATROYD):</p> <p>3 Q. Okay. The conclusion in the</p> <p>4 abstract of the published article says</p> <p>5 with regard to efficacy, Paxil is</p> <p>6 effective for major depression in</p> <p>7 adolescents; right?</p> <p>8 <b>A. The conclusion of the abstract in</b></p> <p>9 <b>this paper? No. That's not what it</b></p> <p>10 <b>says.</b></p> <p>11 Q. With regard to just the efficacy,</p> <p>12 what does it say?</p> <p>13 <b>A. It says Paxil is generally well</b></p> <p>14 <b>tolerated and effective for major</b></p> <p>15 <b>depression in adolescents.</b></p> <p>16 Q. That's right. It says that it's</p> <p>17 effective; right?</p> <p>18 <b>A. Yes. I thought you were reading</b></p> <p>19 <b>something that was supposed to be</b></p> <p>20 <b>verbatim here. That's fine.</b></p> <p>21 Q. What did you conclude in your</p> <p>22 first draft?</p> <p>23</p> <p>24 MR. DAVIS: Object to the form of</p> <p>25 the question.</p>	<p style="text-align: right;">Page 192</p> <p>1 you wrote --</p> <p>2 MR. MARGOLIS: Without</p> <p>3 characterizing whether or not -- you</p> <p>4 know, she indicated that she hasn't</p> <p>5 reviewed this entire study in a long</p> <p>6 time. And the same conclusion may be</p> <p>7 written in here. So she may have just</p> <p>8 written something that was repetitious.</p> <p>9 MR. MURGATROYD: Well maybe we</p> <p>10 need to get that sorted out. Why don't</p> <p>11 we take a little bit of time and have you</p> <p>12 look at the final study report, and see</p> <p>13 if there is anywhere in there that it</p> <p>14 says Paxil is effective for the treatment</p> <p>15 of adolescent depression. Okay. Let's</p> <p>16 go off the record.</p> <p>17 VIDEOGRAPHER: The time is 2:33.</p> <p>18 We are off the record.</p> <p>19</p> <p>20 (Off the record)</p> <p>21</p> <p>22 (Back on the record)</p> <p>23</p> <p>24 VIDEOGRAPHER: We are back on the</p> <p>25 record. The time is 2:36.</p>
<p style="text-align: right;">Page 191</p> <p>1 THE WITNESS: This first draft</p> <p>2 says, "Paroxetine is a safe and effective</p> <p>3 treatment of depression in the adolescent</p> <p>4 patient. Further studies are warranted</p> <p>5 to determine the optimal dose and</p> <p>6 duration of therapy."</p> <p>7</p> <p>8 (BY MR. MURGATROYD):</p> <p>9 Q. Okay. Now with regard to whether</p> <p>10 or not Paxil is effective for the</p> <p>11 treatment of adolescent depression.</p> <p>12 Would you agree that your conclusion in</p> <p>13 the first draft is similar to the</p> <p>14 conclusion in the published article?</p> <p>15</p> <p>16 MR. MARGOLIS: I object to the</p> <p>17 form. When you say "her conclusion", I</p> <p>18 think what you're saying is, is what was</p> <p>19 written here --</p> <p>20 MR. MURGATROYD: By her?</p> <p>21 MR. MARGOLIS: The same?</p> <p>22 MR. MURGATROYD: Right. That's</p> <p>23 correct.</p> <p>24 MR. MARGOLIS: By her you know --</p> <p>25 MR. MURGATROYD: Right. Was what</p>	<p style="text-align: right;">Page 193</p> <p>1</p> <p>2 (BY MR. MURGATROYD):</p> <p>3 Q. Okay. You had a chance to look</p> <p>4 through that?</p> <p>5 <b>A. Yes.</b></p> <p>6 Q. Okay. And did you find the</p> <p>7 language you were looking for?</p> <p>8 <b>A. Tell me the language I'm looking</b></p> <p>9 <b>for again, please.</b></p> <p>10 Q. A statement that Paxil is</p> <p>11 effective for the treatment of adolescent</p> <p>12 depression?</p> <p>13 <b>A. Yes. In this document?</b></p> <p>14 Q. Yes?</p> <p>15 <b>A. That I'm looking at?</b></p> <p>16 Q. Yes?</p> <p>17 <b>A. Again I cannot attest that this</b></p> <p>18 <b>was the one I used, that form. But the</b></p> <p>19 <b>one that is in front of me, it looks like</b></p> <p>20 <b>if you go to page 121.</b></p> <p>21 Q. I'm sorry, 121?</p> <p>22 <b>A. Yes, 121.</b></p> <p>23 Q. Okay.</p> <p>24 <b>A. The first sentence in the first</b></p> <p>25 <b>paragraph. The results of this double</b></p>

1 **blind placebo controlled trial supports**  
2 **that Paroxetine is beneficial in treating**  
3 **adolescents with major depression.**

4 Q. Okay. So that's where you think  
5 you got that?

6 **A. And I see another part in this**  
7 **document on page 124. That it is the**  
8 **conclusion -- I'm on paragraph -- the**  
9 **conclusion that begins by saying "This**  
10 **study supports that Paroxetine is**  
11 **beneficial in treating adolescents with**  
12 **major depression. Although the support**  
13 **is derived mainly from secondary**  
14 **measures."**

15 Q. Okay. And in your first draft of  
16 the manuscript, do you point out that the  
17 support for efficacy of Paxil in the  
18 treatment of adolescent depression comes  
19 from secondary measures?

20 **A. I have to look.**

21 Q. Okay.

22 **A. The abstract specifically sites**  
23 **the four items -- the four outcome**  
24 **measures in which there was a statistical**  
25 **difference between Paroxetine and**

1 **placebo.**

2 Q. But you list those as primary  
3 efficacy variables, don't you? didn't  
4 you in the first draft?

5 **A. In table three. In the first**  
6 **draft.**

7 Q. Yes. They were listed as primary  
8 efficacy variables?

9 **A. Yes.**

10 Q. But they weren't, were they?

11 **A. Not according to this document**  
12 **that is in front of me.**

13  
14 MR. MURGATROYD: Okay. Now, let  
15 me show you -- so the record is clear.  
16 What was written by the FDA when they  
17 looked at Study 329.

18  
19 (BY MR. MURGATROYD):

20 Q. Do you know who Andrew Mosholder  
21 is?

22 **A. No.**

23 Q. Okay. You were aware though that  
24 the FDA did investigate Paxil's use in  
25 kids; right?

1 **A. At what time point?**

2 Q. At any time point? You're aware  
3 that that investigation has taken place?

4 **A. Yes. I am aware of that now.**

5 Q. Okay. And you're aware that as a  
6 result of that investigation, there is a  
7 black box warning for Paxil for the  
8 treatment of adolescent depression?

9 **A. I am aware that there is a black**  
10 **box warning on the labeling. I can't say**  
11 **that I know the chain of events that led**  
12 **to that decision.**

13 Q. Okay. That's fine.

14  
15 MR. DAVIS: Objection.

16  
17 (BY MR. MURGATROYD):

18 Q. And do you know what a black box  
19 warning mean to you? You have a pharmacy  
20 degree; right?

21 **A. Yes.**

22 Q. What does a black box warning  
23 mean to you?

24 **A. It's my understanding that a**  
25 **black box warning is mandated by the FDA**

1 **to highlight information that they feel**  
2 **is particularly important.**

3 Q. And do you know what is  
4 highlighted -- what is in the black box  
5 for the warning for kids with regard to  
6 Paxil?

7 **A. I haven't looked at a Paxil**  
8 **product label for many years. I know**  
9 **there is a black box warning. But have I**  
10 **read one in the last five years? No.**

11 Q. Okay. But are you aware that it  
12 has to do with the issue of  
13 suicidality?

14 **A. I am aware that that's the case**  
15 **for all anti-depressants now.**

16 Q. Okay. Including Paxil?

17 **A. Yes. And having said that, I**  
18 **have not read an anti-depressant label**  
19 **for a long, long time.**

20  
21 MR. MURGATROYD: Okay. We will  
22 get to that later today. Let me show you  
23 what I am going to mark as Exhibit 11.  
24 It's a clinical review done by Andrew  
25 Mosholder of the FDA.

1 And the portion I'm going to ask  
2 you about has to do with Study 329.  
3 Okay? So you're obviously free to read  
4 the rest of it. But what we are going to  
5 be discussing is 329. Okay?

6  
7 (Plaintiff's Exhibit 11, marked)

8  
9 (BY MR. MURGATROYD):

10 Q. Did you get a chance to read what  
11 Dr. Mosholder had to say about Study  
12 329?

13 **A. Yes.**

14 Q. Did he conclude that 329 was  
15 considered what is called a failed study?

16  
17 MR. DAVIS: Object to the form.

18 THE WITNESS: This document  
19 concludes that -- wait a minute.

20  
21 (BY MR. MURGATROYD):

22 Q. What specifically does it  
23 state?

24 **A. Well the conclusion is -- there  
25 are several sentences in his conclusion.**

1 Q. Okay. Does it talk about a  
2 failed study?

3 **A. The last sentence says, "On  
4 balance, this trial should be considered  
5 as a failed trial, in that neither active  
6 treatment group showed superiority over  
7 placebo by a statistically significant  
8 margin."**

9 Q. Okay. Would you agree that that  
10 finding is inconsistent with GSK's  
11 statement that Paxil is effective for the  
12 treatment of adolescent depression?

13  
14 MR. DAVIS: Object to the form.

15 THE WITNESS: I don't have the  
16 expertise to agree with that.

17  
18 (BY MR. MURGATROYD):

19 Q. What expertise do you think you  
20 need to have?

21 **A. I think this is a very narrow  
22 interpretation of that data. And you  
23 know I think it could be argued that  
24 perhaps -- I am not an expert on this.  
25 I'm very uncomfortable giving my opinion**

1 **not being an expert.**

2 Q. Okay. Well, let me ask you this.  
3 Have you had any contact with GSK since  
4 the allegations of fraud surrounding 329  
5 have started?

6 **A. I don't recall so, no.**

7 Q. Okay. Have you had any contact  
8 with GSK's lawyers?

9 **A. Yes.**

10 Q. Which ones?

11 **A. Todd contacted me, and a group of  
12 other people for a conference call in  
13 December of 2005.**

14 Q. Okay. And were you here in  
15 Connecticut when that call took place?

16 **A. Yes.**

17 Q. And who was on that conference  
18 call?

19 **A. Specifically I don't -- I know  
20 Todd was.**

21 Q. Okay. Who else?

22 **A. I don't recall their names.**

23 Q. Were they other lawyers?

24 **A. I believe they were.**

25 Q. Okay. And was Tamar Halpern one

1 of the --

2 **A. I don't remember.**

3 Q. Was there a woman involved in the  
4 call?

5 **A. There was a woman on the call.**

6 Q. How long did this call take  
7 place?

8 **A. How long was the call?**

9 Q. Yes, how long?

10 **A. It may have been an hour, 45  
11 minutes.**

12 Q. Okay. And did you take any notes  
13 as a result of that call?

14 **A. I took some notes, yes.**

15 Q. And do you still have those  
16 notes?

17 **A. Yes, I do.**

18 Q. Okay. And do you mind providing  
19 those to me?

20  
21 MR. MURGATROYD: Todd, didn't you  
22 say on the record awhile ago you never  
23 talked to her?

24 MR. DAVIS: No. I said I never  
25 talked to her prior to the deposition.

1 THE WITNESS: Here is December  
2 22nd.

3  
4 (BY MR. MURGATROYD):

5 Q. Okay. Are there other notes that  
6 you have taken from other  
7 conversations?

8 **A. Notes setting up the conference  
9 call.**

10 Q. Yes. What are the other notes  
11 that are in front of you?

12 **A. This is a note that says I may  
13 get a subpoena.**

14 Q. Okay. And who is that from?

15 **A. That is from Todd Davis from King  
16 & Spalding.**

17 Q. He called you and told you  
18 that?

19 **A. Yes.**

20 Q. Okay. So what are the other  
21 notes that you have in your hand?

22 **A. This is a note from -- I think  
23 this was a note setting up -- saying can  
24 we set up a conference call from Erin  
25 Fisher from the Dechert firm.**

1 Q. Okay. Is there anything else --  
2 do you have a problem with me making  
3 copies of all of these notes that you  
4 brought with you today?

5 **A. No.**

6  
7 MR. MURGATROYD: Okay. Why don't  
8 we go off the record for a minute. Let  
9 me run down stairs and get these copied.  
10 Then we will come back.

11 VIDEOGRAPHER: The time is 2:50.  
12 We are off the record.

13  
14 (Off the record)

15  
16 (Back on the record)

17  
18 VIDEOGRAPHER: Back on the  
19 record. The time is 2:58.

20 MR. MURGATROYD: Okay.

21  
22 (BY MR. MURGATROYD):

23 Q. Okay. Now it's my understanding  
24 that there are actually four different  
25 documents here; is that correct.

1 One two-page document dated  
2 12-22-05, handwritten. One handwritten  
3 document dated April 5, 2006. One  
4 handwritten document that has Dechert  
5 Firm at the top. Then there is an E-mail  
6 to you from Marion Philips; correct.

7 **A. Yes.**

8  
9 MR. MURGATROYD: I'm going to  
10 mark these each as separate documents.

11  
12 (BY MR. MURGATROYD):

13 Q. And which is the earliest  
14 document in time? Is that the April 5,  
15 2006 -- I'm sorry. They -- why don't you  
16 tell me. I don't want to put words in  
17 your mouth. Which is the first document?

18 **A. The handwritten page that begins  
19 Dechert firm.**

20  
21 MR. MURGATROYD: Let's take that.  
22 I'm going to mark that as Exhibit 12.

23  
24 (Plaintiff's Exhibit 12, marked)  
25

1 MR. MURGATROYD: And if you  
2 would, can you just decipher your  
3 handwriting for me.

4 MR. MARGOLIS: Read the document.

5 THE WITNESS: Read the document?  
6

7 (BY MR. MURGATROYD):

8 Q. Yes. Does this document refresh  
9 your recollection of these telephone  
10 calls?

11 **A. Somewhat.**

12 Q. Okay. Just tell me from this  
13 first document. What does it refresh  
14 your recollection about? What happened  
15 here?

16 **A. Someone from the Dechert firm by  
17 the name of Andrea Perry who is  
18 representing GSK called.**

19 Q. Do you know that she is in fact  
20 in-house counsel for GSK?

21 **A. No.**

22 Q. She didn't tell you that?

23 **A. I don't know. I don't  
24 remember.**

25 Q. Do you think she was from the

1 Dechert firm?

2 **A. Yes -- No. I don't know what I**  
3 **remember. It's based on these notes. I**  
4 **guess I'm interpreting that arrow to say**  
5 **she is representing GSK, but I don't know**  
6 **for certain.**

7 Q. Okay. That is fine.

8 **A. And then Erin Fisher from Dechert**  
9 **representing GSK and a phone number. And**  
10 **a list of topics to discuss.**

11 Q. Was this the pre-phone call to  
12 set up the conference call?

13 **A. Yes. I think so.**

14 Q. Okay. What were the list of  
15 topics you were going to discuss?

16 **A. The list of STI's Paxil program.**  
17 **What did STI do. Who did we work for.**  
18 **And then it says CME and forums. And**  
19 **those are two different types of**  
20 **projects.**

21 Q. That STI did for --

22 **A. That STI did.**

23 Q. For GSK?

24 **A. Yes.**

25 Q. Was that regarding Paxil?

1 **piece of paper that I continued on where**  
2 **I called this woman back.**

3 Q. Okay. And so does Marion Philips  
4 work with STI?

5 **A. Yes.**

6 Q. Is that a woman or a man?

7 **A. Man. It's a woman.**

8 Q. Okay. Is she a lawyer? She just  
9 works for STI?

10 **A. Yes. She works for STI.**

11 Q. Okay. And so I'm going to mark  
12 that as Exhibit 13.

13  
14 (Plaintiff's Exhibit 13, marked)

15  
16 (BY MR. MURGATROYD):

17 Q. And that just says that you were  
18 allowed to talk to GSK concerning  
19 projects that STI had with GSK that you  
20 participated in?

21 **A. Yes.**

22 Q. Okay. And then the next document  
23 in order. Would that be the two-page  
24 12-22-05 notes?

25 **A. Yes.**

1 **A. Yes.**

2 Q. Okay. And then below that?

3 **A. That looks like I would make that**  
4 **note that I called Erin Fisher. Agreed**  
5 **to speak with her. Gave my availability**  
6 **through January 6th. And she will check**  
7 **those dates and confirm by E-mail and**  
8 **call me.**

9 Q. Okay. Now, is the next document  
10 of order the E-mail you received from  
11 Marion Philips?

12 **A. I'm guessing that -- go back to**  
13 **the first document that starts with**  
14 **Dechert Firm. I didn't put a date on**  
15 **that. But my recollection would be that**  
16 **somebody called me saying can you talk**  
17 **about this.**

18 **And then I on Tuesday, November**  
19 **22nd -- or at some point I would have**  
20 **contacted my former employer saying I**  
21 **want to let you know what is going on.**  
22 **May I speak on behalf of the company as a**  
23 **former employee.**

24 Q. Right.

25 **A. And then probably I had this**

1

2 MR. MURGATROYD: Okay. I'm going  
3 to mark that as Exhibit 14.

4  
5 (Plaintiff's Exhibit 14, marked)

6  
7 (BY MR. MURGATROYD):

8 Q. I take it the copy I have is an  
9 authentic copy of the original you gave  
10 me; correct?

11 **A. I didn't make the copies.**

12 Q. Okay. Does it appear to be  
13 authentic? Either I am going to have to  
14 put your original in the record or am I  
15 going to use this copy?

16 **A. This appears to be the**  
17 **original.**

18 Q. Okay. So this copy is  
19 authentic?

20 **A. It looks authentic, yes.**

21 Q. Okay. And this is your  
22 handwriting; correct?

23 **A. Yes.**

24 Q. And that is the same for all of  
25 the documents that we are discussing here

1 that have your handwriting. They are all  
2 authentic, and you created them; correct?

3  
4 MR. DAVIS: Object to the form.  
5 THE WITNESS: Yes.

6  
7 (BY MR. MURGATROYD):

8 Q. Okay. Now -- so this is dated at  
9 the top 2-22-05?

10 A. 12-22.

11 Q. I'm sorry. 12-22-05. A couple  
12 of days before Christmas?

13 A. Yes.

14 Q. Okay. Was this the conference  
15 call?

16 A. Yes.

17 Q. Okay. Now, is this a list of the  
18 people who were present at that  
19 conference call?

20 A. **As fast as I could take the  
21 notes, I believe it is.**

22 Q. Okay. And so it appears that  
23 there is a person named Tom Lee?

24 A. Yes.

25 Q. And you have brackets by him

1 marketing activities". Do you see  
2 that?

3 A. Yes.

4 Q. What does that refer to?

5 A. **I'm not sure. I'm not sure if  
6 that was the purpose -- if I wrote. I  
7 don't know why I wrote that down**

8 Q. Okay. Did somebody tell you that  
9 the FDA was looking into to GSK?

10 A. **Somebody must have, yes.**

11 Q. Okay. So basically if there is a  
12 note there, this is what somebody is  
13 saying and you're writing it down?

14 A. Yes.

15  
16 MR. MURGATROYD: Okay. Why don't  
17 you just take me through the document,  
18 and explain to me what your handwriting  
19 says. And what it meant to you when you  
20 wrote it.

21 THE WITNESS: Yes. This is -- my  
22 note taking fizzles out at the end. It  
23 happens with me. I didn't necessarily  
24 write -- they went through some of my  
25 major projects, and we talked about the

1 indicating that he may work at Dechert?

2 A. Yes.

3 Q. Okay. And also Sarah  
4 Westbrook?

5 A. Yes.

6 Q. Works at Dechert?

7 A. **According to the notes.**

8 Q. Okay. And then Todd Davis, and  
9 it says Atlanta law firm; correct?

10 A. Yes.

11 Q. It says product liability?

12 A. Yes.

13 Q. Okay. And it has Tammy Halpern.  
14 Buffalo law firm, products liability?

15 A. Yes.

16  
17 MR. MURGATROYD: Let me finish  
18 asking my question.

19 THE WITNESS: Sorry.

20 MR. MURGATROYD: Okay. Thank  
21 you.

22 (BY MR. MURGATROYD):

23 Q. Now in the right-hand side it  
24 says "FDA looking into sales and  
25

1 process. And who I worked with or  
2 whatever was involved. And so we started  
3 with the hidden diagnosis.

4  
5 (BY MR. MURGATROYD):

6 Q. Okay. What does that say above  
7 that? Something background?

8 A. **S.L. Those are my initials.**

9 Q. Oh, okay. Okay.

10 A. **The purpose of the call to my  
11 understanding was for me to describe my  
12 work with Paxil.**

13 Q. Okay. That was based upon the  
14 background information that the FDA was  
15 investigating GSK into the marketing  
16 practices?

17 MR. DAVIS: Object to the form.

18 THE WITNESS: I don't know. I  
19 don't know that.

20 (BY MR. MURGATROYD):

21 Q. Were you aware at this point that  
22 the Attorney General of the United States  
23 was performing a criminal investigation  
24  
25

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<p>1 of GSK?</p> <p>2</p> <p>3 MR. DAVIS: Object to the form.</p> <p>4 THE WITNESS: No.</p> <p>5 MR. MURGATROYD: Okay. Let's go</p> <p>6 through your notes.</p> <p>7 THE WITNESS: The first project</p> <p>8 we discussed was called the Hidden</p> <p>9 Diagnosis. And I believe -- I think I</p> <p>10 wrote down here more of what the</p> <p>11 questions were or the general topic of</p> <p>12 discussion. So the question was, was</p> <p>13 this a CME program. And my recollection</p> <p>14 was that it was yes.</p> <p>15 MR. MURGATROYD: Okay.</p> <p>16 THE WITNESS: Through the</p> <p>17 Annenberg Center.</p> <p>18</p> <p>19 (BY MR. MURGATROYD):</p> <p>20 Q. What is the Annenberg Center?</p> <p>21 <b>A. What is the Annenberg Center.</b></p> <p>22 <b>It's a big -- it's a health center</b></p> <p>23 <b>located in Palm Springs. And they have a</b></p> <p>24 <b>big education department that does --</b></p> <p>25 <b>that is certified.</b></p>	<p>1 <b>talk about Paxil.</b></p> <p>2 Q. Okay. Some of them did?</p> <p>3 <b>A. Some of them may have. I think</b></p> <p>4 <b>probably yes some of them did.</b></p> <p>5 Q. Was this a conference that was --</p> <p>6 this was a CME?</p> <p>7 <b>A. In was a -- this was a CD.</b></p> <p>8 Q. A CD?</p> <p>9 <b>A. Yes.</b></p> <p>10 Q. Like something that you can put</p> <p>11 in a VCR and watch on TV?</p> <p>12 <b>A. In a computer.</b></p> <p>13 Q. In a computer?</p> <p>14 <b>A. A CD.</b></p> <p>15 Q. Do you have that CD still?</p> <p>16 <b>A. Yes. I think I do.</b></p> <p>17</p> <p>18 MR. MURGATROYD: Okay. Wow, I</p> <p>19 asked for this kind of stuff. You never</p> <p>20 gave it to me.</p> <p>21 MR. DAVIS: Skip, I don't know</p> <p>22 what you asked for. You will have to</p> <p>23 write me and ask again.</p> <p>24 MR. MURGATROYD: Okay.</p> <p>25</p>
<p>Page 215</p> <p>1 Q. A forum for having meetings?</p> <p>2 <b>A. In part, yes.</b></p> <p>3 Q. Okay. What is the other part?</p> <p>4 <b>A. I don't know.</b></p> <p>5 Q. Okay. Fine.</p> <p>6 <b>A. I think they do training there.</b></p> <p>7</p> <p>8 MR. MURGATROYD: Okay. That is</p> <p>9 fine. Can you keep reading, please.</p> <p>10 THE WITNESS: We discussed one of</p> <p>11 the patient's interviewed on the Hidden</p> <p>12 Diagnosis was an adolescent patient that</p> <p>13 for the purpose of this we gave her a</p> <p>14 fake name, Maria.</p> <p>15 MR. MURGATROYD: Okay.</p> <p>16</p> <p>17 (BY MR. MURGATROYD):</p> <p>18 Q. And what did she discuss?</p> <p>19 <b>A. She was an actual patient, and</b></p> <p>20 <b>she talked about her experience with</b></p> <p>21 <b>major depression.</b></p> <p>22 Q. Okay. And did she discuss Paxil</p> <p>23 in any regard?</p> <p>24 <b>A. I don't know. Not all the</b></p> <p>25 <b>patients in this -- in fact many did not</b></p>	<p>Page 217</p> <p>1 (BY MR. MURGATROYD):</p> <p>2 Q. All right. Well, okay. So this</p> <p>3 is a CD, and it had an adolescent patient</p> <p>4 as part of the program?</p> <p>5 <b>A. Yes.</b></p> <p>6 Q. And talking about their</p> <p>7 depression?</p> <p>8 <b>A. Talking about her experience with</b></p> <p>9 <b>depression.</b></p> <p>10 Q. And what was the purpose of this</p> <p>11 CD?</p> <p>12 <b>A. The purpose was to use it as</b></p> <p>13 <b>training material for physicians to give</b></p> <p>14 <b>presentations on all sorts of different</b></p> <p>15 <b>mood and anxiety disorders.</b></p> <p>16 Q. Okay. Including adolescent</p> <p>17 depression?</p> <p>18 <b>A. Yes.</b></p> <p>19</p> <p>20 MR. MURGATROYD: Okay. Can you</p> <p>21 keep going down there for me.</p> <p>22 THE WITNESS: All right. And</p> <p>23 then the discussion was about papers.</p> <p>24</p> <p>25 (BY MR. MURGATROYD):</p>

1 Q. Okay. Well what does it say any  
2 discussion with GSK about this being off  
3 label. Do you see that?

4 **A. I believe the question was, was  
5 there any discussion with GSK about this  
6 being off label. And we knew it was off  
7 label. It wasn't indicated, but this was  
8 a CME project, and it was valid to  
9 discuss data out there. A lot of data  
10 was discussed for other drugs too that  
11 were off label.**

12 Q. In this CD?

13 **A. Yes.**

14 Q. This CD talked about drugs other  
15 than Paxil?

16 **A. Oh, yes.**

17 Q. Okay. And who created this CD?

18 **A. STI.**

19 Q. Okay. On behalf of who?

20 **A. GSK.**

21 Q. Okay.

22 **A. And so GSK knew that the  
23 discussion was going to involve off label  
24 uses of Paxil?**

1 MR. DAVIS: Object to the form.

2 THE WITNESS: It was a CME  
3 program in which off label use is  
4 appropriate.

5 MR. MURGATROYD: Okay. I have  
6 never heard of that before. Okay.

7 (BY MR. MURGATROYD):

8 Q. Where did you get that idea?

9 MR. DAVIS: Object to the form.

10 THE WITNESS: That is my  
11 understanding at the time.

12 (BY MR. MURGATROYD):

13 Q. Did somebody at GSK tell you  
14 that?

15 MR. DAVIS: Object to the form.

16 THE WITNESS: No. This was --  
17 this was approved by the Annenberg  
18 Center. Who was a CME provider.

19 (BY MR. MURGATROYD):

20 Q. Okay. Do you know what year this

1 was?

2 **A. No, not precisely. Mid '90's  
3 maybe. I don't know.**

4 Q. Okay. Prior to you preparing the  
5 first draft?

6 **A. I don't know.**

7 MR. MURGATROYD: Okay. Let's  
8 move down to the next part.

9 THE WITNESS: That's when we  
10 discussed papers, and I described the  
11 process of how we went about drafting a  
12 manuscript. And I don't know what the  
13 second thing means.

14 (BY MR. MURGATROYD):

15 Q. "STI paid GSK"?

16 **A. Yes. I think I must have made a  
17 mistake there.**

18 Q. Had that reversed?

19 **A. Possibly. We were hired by GSK  
20 is what I believe I meant to write.**

21 Q. Okay. And then the next part,  
22 please?

23 **A. Talked about the paper in**

1 **question.**

2 Q. Meaning that says, "Keller child  
3 adolescent paper. Study 329"?

4 **A. Yes. That is what it says.**

5 Q. Okay. And go ahead. What does  
6 it say next?

7 **A. It says "GSK driven with Jim."  
8 Meaning Jim McCafferty was my -- provided  
9 the data to me, and he was my contact.**

10 Q. Okay.

11 **A. And we talked about Dr. Keller's  
12 role.**

13 Q. Do you recall what you said  
14 there?

15 **A. That he was the main author, and  
16 he was very involved in the manuscript.  
17 Throughout -- from the draft one. Right  
18 to the very last minute.**

19 Q. Okay. Who else?

20 **A. Who else was involved? There  
21 were other authors. That's who else was  
22 involved. All of the other ones or some  
23 of the others.**

24 **A. Some had more. They were all  
25 involved. Some had much more input than**

1 others.

2 Q. Okay.

3 A. And then we discussed the time  
4 line. And again at this point -- well I  
5 was not working for STL. So I must have  
6 been working off of memory.

7 That the first thing that  
8 happened, it was submitted to the journal  
9 of the American Medical Association. It  
10 was rejected. I don't know what that  
11 means. Maybe -- perhaps that means it  
12 was rejected late.

13 It look a long time -- I don't  
14 know what that means, to be honest with  
15 you. That first line.

16 Q. Okay.

17 A. Then it says if I can interpret  
18 my writing, it says submitted the paper  
19 on June 20th to the Journal American  
20 Academy. And it was accepted December  
21 20th.

22 Q. Okay.

23 A. And it was published in July of  
24 2001.

25 Q. Okay.

1 A. Then we discussed when I got  
2 involved. And I couldn't remember the  
3 dates when we were asked to do this  
4 project.

5 Q. Okay.

6 A. But the first draft was early in  
7 1999.

8 Q. You were close. It's actually  
9 late 1998.

10 A. And I was working from memory  
11 here.

12 Q. Yes. That is good.

13 A. There were letters to the editor,  
14 and did I get involved.

15 Q. And did you?

16 A. I was aware that there were  
17 letters to the editor. If I was involved  
18 in those, it was in a very peripheral  
19 kind of way. I don't have a lot of  
20 recollection of that process

21 Q. Okay. The second page?

22 A. And then we discussed what was  
23 called the forum project.

24 Q. And what were those?

25 A. Those were meetings for

1 physicians to come in here. Speakers on  
2 a lot of different topics.

3 Q. Okay. And were you involved in  
4 those?

5 A. It was a big team effort. My job  
6 was to help the speakers. Whoever the  
7 speakers were, prepare their slides.

8 Q. No kidding? Was one of those  
9 people Dr. Karen Wagner?

10 A. I believe she was involved in  
11 that. In the forum project.

12 Q. Okay. And did you help prepare  
13 any of her slides?

14 A. What happened was they would send  
15 slides to us and the speaker. And a lot  
16 of times they were a mess, and we would  
17 clean them up and reference them, and  
18 make them legible. That kind of thing.

19 Q. And these were the forum projects  
20 --

21  
22 MR. MURGATROYD: Why don't we  
23 mark as Exhibit 15 a document entitled,  
24 "Forum 2001 Update". And I will just  
25 show that to you quickly.

1 MR. DAVIS: This is Exhibit 16?

2 MR. MURGATROYD: 15. Yes, 14 is  
3 the notes.

4 MR. DAVIS: GSK designates  
5 Exhibit, which is the Forum 2001 Update  
6 document, as confidential subject to  
7 protective order. As well as all  
8 discussions related thereto.

9  
10 (Plaintiff's Exhibit 15, marked)

11  
12 (BY MR. MURGATROYD):

13 Q. Okay. Is that -- the document I  
14 showed you, Exhibit 15. That references  
15 a forum project involving Paxil;  
16 correct?

17 A. Yes.

18 Q. Is that the kind of forum project  
19 that you were referring to in your notes  
20 here?

21 A. Yes.

22 Q. Okay. And that is where speakers  
23 come and give talks about Paxil?

24 A. They give talks on a wide variety  
25 of different topics.

1 Q. Okay. And I think I asked you  
2 about Karen Wagner, Dr. Karen Wagner. Do  
3 remember who she is?

4 **A. Yes.**

5 Q. Have you worked with her?

6 **A. She was a speaker at a forum  
7 meeting.**

8 Q. Was she speaking about adolescent  
9 depression?

10 **A. Yes.**

11 Q. Okay. And do you recall her  
12 being present -- not that forum, but a  
13 different forum where she stated that  
14 Paxil was an effective treatment for  
15 depression in adolescents?

16 **A. I don't recall the details of her  
17 presentation.**

18 Q. Okay. Do you recall she is an  
19 adolescent psychiatrist; right?

20 **A. Yes.**

21 Q. Okay. And did you help set up  
22 these forums? Is that what you all  
23 do?

24 **A. It was a big group effort. Our  
25 job was to help speakers with slides, and**

1 **you know kind of babysit the speakers to  
2 make sure they got where they had to be  
3 once they got there.**

4 Q. Did STI pay those speakers or  
5 were they paid by GSK?

6 **A. I don't remember. I don't  
7 remember. I don't remember.**

8 Q. Okay. Now who were the  
9 audiences?

10 **A. Physicians.**

11 Q. Okay. And is this -- according  
12 to your notes, is this an area that GSK  
13 was worried about as being off label  
14 promotion for Paxil?

15  
16 MR. DAVIS: Object to the form of  
17 the question.

18 THE WITNESS: I don't know what  
19 they were worried about.

20  
21 (BY MR. MURGATROYD):

22 Q. Well did they tell you -- well it  
23 says at the top, the first page. It  
24 says, "FDA looking into sales and  
25 marketing activities." Did you

1 understand that they were being  
2 investigated; GSK?

3 **A. Yes.**

4 Q. Okay. And was it your  
5 understanding when you were talking about  
6 topics in which the investigation may  
7 look at?

8 **A. My understanding was to describe  
9 what we did at STI for Paxil.**

10 Q. Okay. It's your understanding is  
11 that because this could relate to what  
12 the FDA was investigating with regard to  
13 the marketing practices of GSK with  
14 regard to Paxil?

15  
16 MR. DAVIS: Object to the form.

17 MS. LEVINE: Object to the  
18 form.

19 THE WITNESS: Can you repeat it,  
20 please.

21  
22 (BY MR. MURGATROYD):

23 Q. Yes. Is it you're understanding  
24 that these topics were chosen because the  
25 FDA was looking into the marketing

1 practices of GSK with regard to Paxil?

2 **A. I don't know why these topics  
3 were chosen.**

4 Q. Okay. But at the same time  
5 somebody did inform you that the FDA was  
6 looking into GSK's marketing practices --

7  
8 MR. MARGOLIS: At what time? The  
9 time frame?

10 MR. MURGATROYD: The conference.

11 MR. MARGOLIS: The time of the  
12 conference or the time of the conference  
13 call?

14 MR. MURGATROYD: Conference call.

15 MR. MARGOLIS: So in 2005?

16 MR. MURGATROYD: Correct.

17 MR. MARGOLIS: Okay.

18 THE WITNESS: They wanted to hear  
19 what my role was, and what the process  
20 was with our different projects.

21  
22 (BY MR. MURGATROYD):

23 Q. Okay. Did they tell you that the  
24 FDA may be contacting you?

25 **A. No.**

1 Q. Okay. Now, did they tell you  
2 that Plaintiff's lawyers may be  
3 contacting you?

4 **A. No.**

5 Q. Now, were you aware of the  
6 various lawsuits that were around the  
7 country regarding Paxil's use by children  
8 and adolescents?  
9

10 MR. DAVIS: Object to the form.

11 MR. MARGOLIS: At what time? The  
12 time of this?

13 MR. MURGATROYD: Yes. The time  
14 of this call.

15 THE WITNESS: Well, this was  
16 after -- I probably was, based on the  
17 date on the top of the notes.

18 MR. MURGATROYD: Okay. All  
19 right. Let's keep going.

20 THE WITNESS: Okay.

21 (BY MR. MURGATROYD):

22 Q. I think we stopped at letters to  
23 the editor. Did you get involved?  
24

25 **A. That's to the best of my**

1 **can change things at the last minute.**

2 **So we would sit with the speaker.**

3 **And if they didn't like the way something**  
4 **looked, we would you know make it**  
5 **prettier or whatever we would do.**

6 Q. Okay. That's fine. So let's  
7 pick up from there then.

8 **A. The next point says did GSK have**  
9 **involvement in the agenda, and yes.**

10 Q. Okay. And that would be the  
11 agenda of who spoke and what they spoke  
12 about?

13 **A. Yes.**

14 Q. Okay. And I don't want to repeat  
15 myself, but you were aware that Karen  
16 Wagner was talking about pediatric  
17 issues; correct?

18 MR. DAVIS: Object to the form.  
19 Asked and answered. She didn't know.

20 THE WITNESS: Say the question  
21 again.  
22

23 (BY MR. MURGATROYD):

24 Q. Karen Wagner was there to speak  
25

1 **recollection.**

2 Q. Oh, I'm sorry. The forum  
3 projects?

4 **A. Right.**

5 Q. And it says what was STI's role?  
6 slides and speakers. You described what  
7 your role was?

8 **A. Yes.**

9 Q. So you helped with the slides,  
10 and you helped to make sure the  
11 speakers -- did you provide them  
12 transportation and make sure --

13 **A. No. We did not provide**  
14 **transportation. Another cog in the wheel**  
15 **did that. Our job was slides and**  
16 **speakers.**

17 Q. Okay. And by speaker, would you  
18 meet with somebody like Karen Wagner and  
19 make sure that she was prepared?

20 **A. When a speaker came on site for**  
21 **the actual meeting, we would sit down and**  
22 **go through their slides. And these were**  
23 **at this point all on power point. The**  
24 **good thing is you can change things at**  
25 **the last minute, and the bad thing is you**

1 about pediatric issues?

2 **A. She is a child psychiatrist. So**  
3 **she spoke about adolescents mood and**  
4 **anxiety disorders.**

5 Q. Okay. And I may have asked you  
6 this question. Do you recall her  
7 speaking about Paxil for the treatment of  
8 those issues?

9 **A. She spoke about all drugs, all**  
10 **antidepressants. All antidepressants**  
11 **being studied for the treatment of**  
12 **depression.**

13 Q. Including Paxil?

14 **A. Including Paxil.**  
15

16 MR. MURGATROYD: Okay. I am  
17 going to find the slide at the next break  
18 where she talks about Paxil being  
19 effective for the treatment of depression  
20 for adolescents.  
21

22 (BY MR. MURGATROYD):

23 Q. Do you recall helping her prepare  
24 that slide?  
25

**A. I helped them with all of their**

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<p>1 <b>slides. So by default I must have.</b></p> <p>2 Q. Okay. Now, let's go to the next</p> <p>3 point. Your next bullet point?</p> <p>4 <b>A. Who invited the audience? And I</b></p> <p>5 <b>don't know. It was not STI. That was</b></p> <p>6 <b>not our role.</b></p> <p>7 Q. Okay. And were you aware that in</p> <p>8 some of the forums it was not just</p> <p>9 doctors, but also GSK neuroscience sales</p> <p>10 force people were there?</p> <p>11 <b>A. There were people from marketing</b></p> <p>12 <b>and medical that I knew that were</b></p> <p>13 <b>there.</b></p> <p>14 Q. Okay. How about actual sales</p> <p>15 people?</p> <p>16 <b>A. I don't know. I didn't know any</b></p> <p>17 <b>of the sales people, so.</b></p> <p>18 Q. Okay. And let's go to the next</p> <p>19 point.</p> <p>20 <b>A. Did workbooks go through copy</b></p> <p>21 <b>approval? And I don't recall whether</b></p> <p>22 <b>they did or not.</b></p> <p>23 Q. Okay. And what was a workbook?</p> <p>24 <b>A. A workbook would be an abstract</b></p> <p>25 <b>summary of the presentation. The</b></p>	<p>1 Q. Okay. R-i-n-g?</p> <p>2 <b>A. Yes.</b></p> <p>3 Q. Okay. Is it like a bound book?</p> <p>4 What did it look like? Is it like a</p> <p>5 bound --</p> <p>6 <b>A. It's anything from a bunch of</b></p> <p>7 <b>papers stapled together nicely, to a</b></p> <p>8 <b>bound book.</b></p> <p>9 Q. Okay. And would any of those</p> <p>10 contain like CDs, as well as power point</p> <p>11 slides?</p> <p>12 <b>A. My recollection is that it was</b></p> <p>13 <b>all paper.</b></p> <p>14 Q. Including the slides that was</p> <p>15 being shown at the conference?</p> <p>16 <b>A. Right.</b></p> <p>17 Q. Okay.</p> <p>18 <b>A. All though the slides -- the</b></p> <p>19 <b>presentations were in flux. And often a</b></p> <p>20 <b>presenter did not want to show his or her</b></p> <p>21 <b>data that per se had not been published</b></p> <p>22 <b>yet. In fear of jeopardizing</b></p> <p>23 <b>publication. That was up to the speaker</b></p> <p>24 <b>as to what went in.</b></p> <p>25 Q. Okay.</p>
<p>Page 235</p> <p>1 <b>speaker's bio. Sometimes there may be</b></p> <p>2 <b>copies of slides. May or may not be.</b></p> <p>3 <b>There could be a reference list. It is</b></p> <p>4 <b>different for each kind of thing.</b></p> <p>5 Q. Okay. Is that something that is</p> <p>6 handed out to the participants?</p> <p>7 <b>A. Yes.</b></p> <p>8 Q. Or the audience members?</p> <p>9 <b>A. Yes.</b></p> <p>10 Q. Okay. And they get to take them</p> <p>11 home with them?</p> <p>12 <b>A. I guess, yes.</b></p> <p>13 Q. Okay. And was that part of STI's</p> <p>14 activities to put those workbooks</p> <p>15 together?</p> <p>16 <b>A. Yes.</b></p> <p>17 Q. Okay. And did you personally</p> <p>18 participate in those activities?</p> <p>19 <b>A. At this point there was a</b></p> <p>20 <b>co-worker helping me, but yes we were</b></p> <p>21 <b>involved in it.</b></p> <p>22 Q. Who was the co-worker?</p> <p>23 <b>A. Her name was Deirdra Ring.</b></p> <p>24 Q. I'm sorry Ring?</p> <p>25 <b>A. Ring. As in wedding ring.</b></p>	<p>Page 237</p> <p>1</p> <p>2 VIDEOGRAPHER: The time is 3:28.</p> <p>3 This is the end of tape number three. We</p> <p>4 are off the record.</p> <p>5</p> <p>6 (Off the record)</p> <p>7</p> <p>8 (Back on the record)</p> <p>9</p> <p>10 VIDEOGRAPHER: Okay. We are back</p> <p>11 on the record. This is tape number four.</p> <p>12 The time is 3:30.</p> <p>13</p> <p>14 (BY MR. MURGATROYD):</p> <p>15 Q. Okay. So we talked about the</p> <p>16 workbooks. And now I think we are down</p> <p>17 to the next topic.</p> <p>18 <b>A. Which is an APA symposia.</b></p> <p>19 Q. Okay. Did STI help -- well you</p> <p>20 tell me. What -- go ahead. Keep taking</p> <p>21 me through this.</p> <p>22 <b>A. We worked on a number of APA --</b></p> <p>23 <b>the American Psychiatric Association has</b></p> <p>24 <b>an annual meeting some time in the spring</b></p> <p>25 <b>every year. And for many years we helped</b></p>

1 **them with programs, symposia at the**  
 2 **APA.**  
 3 Q. Okay. And so what is the next  
 4 topic here?  
 5 **A. It says who chose topics and**  
 6 **speakers.**  
 7 Q. Okay. And what was the answer to  
 8 that?  
 9 **A. The general topics say depression**  
 10 **in the elderly would be chosen by GSK.**  
 11 **Saying can you help us with the symposium**  
 12 **on that. And we have already spoken to a**  
 13 **Chairperson. Now will you work with the**  
 14 **Chairperson to come up with the agenda**  
 15 **and the speakers for this program.**  
 16 Q. Okay. Do you recall setting up  
 17 speakers to talk on the topic of  
 18 adolescent depression?  
 19 **A. Sometimes we did. I don't**  
 20 **remember if we did one at APA or not.**  
 21 Q. I'm sorry?  
 22 **A. I don't remember if there was an**  
 23 **APA symposia on adolescent depression.**  
 24 Q. Okay. Do you know Neil Ryan, Dr.  
 25 Neil Ryan?

1 **A. Yes.**  
 2 Q. Did you ever work with him?  
 3 **A. Yes.**  
 4 Q. He's a child psychiatrist;  
 5 right?  
 6 **A. Yes.**  
 7 Q. Did he speak on behalf of GSK in  
 8 any symposium?  
 9  
 10 MR. DAVIS: Object to the form.  
 11 THE WITNESS: Yes.  
 12  
 13 (BY MR. MURGATROYD):  
 14 Q. Okay. And do you recall him  
 15 presenting power point slides that said  
 16 that Paxil was safe and effective for the  
 17 treatment of adolescent depression?  
 18  
 19 MR. DAVIS: Object to the form.  
 20 THE WITNESS: I don't recall the  
 21 specifics of his slides.  
 22  
 23 (BY MR. MURGATROYD):  
 24 Q. Okay. But you recall that he did  
 25 speak on behalf of GSK at different

1 symposiums?

2  
 3 MR. DAVIS: Object to the form.  
 4 THE WITNESS: I don't remember  
 5 which -- I don't want to say to forum,  
 6 because I don't remember which venue.  
 7 MR. MURGATROYD: Right.  
 8 THE WITNESS: It was, where he  
 9 spoke. But yes, he did speak.

10  
 11 (BY MR. MURGATROYD):  
 12 Q. Okay. Was it on more than one  
 13 venue, to your knowledge?  
 14 **A. I don't remember.**  
 15 Q. Okay. Would these be contained  
 16 in STI's records?  
 17 **A. Yes.**  
 18 Q. Okay. And so GSK chose the  
 19 topics of the speakers. And your job was  
 20 to follow-up and make sure that they were  
 21 on board?  
 22 **A. No. GSK chose a general topic,**  
 23 **and suggested a Chairperson.**  
 24 Q. Okay.  
 25 **A. And then generally we worked --**

1 **STI would work with that Chairperson**  
 2 **saying you want to do it? Okay. You**  
 3 **know, what do you recommend be included**  
 4 **in the symposium. And who would you**  
 5 **recommend as speakers.**  
 6 Q. Okay. And would you prepare any  
 7 written materials or slides for that  
 8 speaker?  
 9 **A. The process was a planning**  
 10 **session. And several months -- as early**  
 11 **as possible, but sometimes it was just**  
 12 **several months before the program where**  
 13 **all the speakers would meet someplace in**  
 14 **a room like this and brainstorm about**  
 15 **what they are going to talk about.**  
 16 **Or bring the slides that they had**  
 17 **prepared. And then they would pick apart**  
 18 **each other's slides. And we would go**  
 19 **home and try to address all those**  
 20 **concerns from the other speakers. And**  
 21 **that was -- that is how we developed the**  
 22 **slides.**  
 23 Q. Okay. And how many times do you  
 24 recall helping with different venues on  
 25 the issue of adolescent issues? Either

<p style="text-align: right;">Page 242</p> <p>1 depression or anxiety or any others?  2 <b>A. How many times? I don't remember</b>  3 <b>how many times.</b>  4 Q. Okay. Do you have a ball park  5 idea?  6  7 MR. DAVIS: Object to the form.  8 THE WITNESS: Honestly I don't.  9 We did a lot of different programs, and I  10 don't remember.  11  12 (BY MR. MURGATROYD):  13 Q. Okay. You recall that there were  14 some that involved adolescent issues?  15  16 MR. DAVIS: Object to form. It's  17 vague and ambiguous as to what specific  18 meeting or topic or discussions are being  19 referenced.  20 THE WITNESS: There were a number  21 of different types of programs that we  22 did. At this stage this far away, I  23 can't put a given program with a given  24 set of speakers or whatever.  25</p>	<p style="text-align: right;">Page 244</p> <p>1 (BY MR. MURGATROYD):  2 Q. Okay. Which provider did you all  3 work with?  4 <b>A. Honestly I don't remember the</b>  5 <b>names.</b>  6 Q. It was different ones?  7 <b>A. Sometimes, yes. There were</b>  8 <b>different groups, and I don't recall the</b>  9 <b>names.</b>  10 Q. Okay. And then it talks about  11 planning sessions. We discussed that?  12 <b>A. Yes.</b>  13 Q. Okay. And then the next one,  14 reprints?  15 <b>A. We talked about whether or not I</b>  16 <b>got involved in reprints. And generally</b>  17 <b>I did not. However, if someone -- if one</b>  18 <b>of the authors of a paper wanted</b>  19 <b>reprints, sometimes they would call me</b>  20 <b>and say can we have reprints? And I</b>  21 <b>would say I don't know. I have to check.</b>  22 <b>And that is how it would work.</b>  23 Q. Okay. Do you recall ordering  24 reprints for Dr. Keller for 329?  25 <b>A. I believe we did.</b></p>
<p style="text-align: right;">Page 243</p> <p>1 (BY MR. MURGATROYD):  2 Q. Okay. But you were aware that  3 issues involving adolescent depression  4 were discussed?  5  6 MR. DAVIS: Object to the form.  7 THE WITNESS: Yes.  8 MR. MURGATROYD: Let's go to the  9 next part of this.  10 THE WITNESS: The next section it  11 says "reprints".  12 MR. MURGATROYD: Oh, no I'm  13 sorry. It says who paid STI.  14 THE WITNESS: Oh. So how was STI  15 paid was the question.  16 MR. MURGATROYD: Okay.  17 THE WITNESS: And I think in the  18 early early days it may have been GSK  19 directly. But in the later days, because  20 STI was not an accredited CME provider.  21 We worked with an accredited CME provider  22 who oversaw the whole process, and was  23 pretty much an intermediary. And we were  24 paid by the CME provider.  25</p>	<p style="text-align: right;">Page 245</p> <p>1  2 MR. MURGATROYD: Okay. We will  3 get into that a little bit later today.  4 Okay. Let's go to the next one.  5 THE WITNESS: The next section is  6 posters and abstracts.  7 MR. MURGATROYD: Okay.  8 THE WITNESS: And the name Neil  9 Pitts. Who worked in medical, and is a  10 colleague of Jim McCafferty. And I did a  11 poster on late life depression and  12 Paxil.  13  14 (BY MR. MURGATROYD):  15 Q. Okay. And you do you recall any  16 other parts of that conference call,  17 other than the notes you have?  18 <b>A. No. I don't recall.</b>  19 Q. Okay. You don't recall anything  20 else that was said?  21 <b>A. I stopped taking notes, and I do</b>  22 <b>not remember if that was it or if we</b>  23 <b>spoke about other things.</b>  24 Q. Okay. And did any of the lawyers  25 that you talked to express any opinions</p>

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<p>1 to you on the phone?</p> <p>2</p> <p>3 MR. DAVIS: Object to the form.</p> <p>4 THE WITNESS: Opinions about</p> <p>5 what?</p> <p>6 MR. MURGATROYD: Anything.</p> <p>7 THE WITNESS: They said it looked</p> <p>8 like a lot of work. That was an</p> <p>9 opinion.</p> <p>10</p> <p>11 (BY MR. MURGATROYD):</p> <p>12 Q. Okay. That you had done a lot of</p> <p>13 work?</p> <p>14 A. Yes.</p> <p>15 Q. Okay. Did they express any</p> <p>16 opinion on whether or not they considered</p> <p>17 it as an off label promotion?</p> <p>18</p> <p>19 MR. DAVIS: Object to the form.</p> <p>20 THE WITNESS: No.</p> <p>21</p> <p>22 (BY MR. MURGATROYD):</p> <p>23 Q. Okay. When you hung up from this</p> <p>24 conference call, was it your</p> <p>25 understanding that that was going to be</p>	<p>1 MR. MURGATROYD: Okay.</p> <p>2 THE WITNESS: And that is when he</p> <p>3 said just a heads up that you may be</p> <p>4 getting a subpoena to be a third party</p> <p>5 fact witness.</p> <p>6 MR. MURGATROYD: Okay.</p> <p>7 THE WITNESS: And they may ask me</p> <p>8 to produce documents in my possession.</p> <p>9</p> <p>10 (BY MR. MURGATROYD):</p> <p>11 Q. Okay. And have you produced</p> <p>12 documents in your possession?</p> <p>13 A. <b>We are looking at them right</b></p> <p>14 <b>now.</b></p> <p>15 Q. Okay. Are there any others?</p> <p>16 A. <b>No.</b></p> <p>17 Q. These are the only documents that</p> <p>18 you have?</p> <p>19 A. <b>Yes.</b></p> <p>20 Q. Okay. And next?</p> <p>21 A. <b>May want to get drafts.</b></p> <p>22 Q. Okay.</p> <p>23 A. <b>I don't know what that means.</b></p> <p>24 Q. Okay. Drafts of the</p> <p>25 manuscript?</p>
<p>Page 247</p> <p>1 it with regards to communications with</p> <p>2 these lawyers?</p> <p>3 A. <b>I don't recall if that was just</b></p> <p>4 <b>thank you and goodbye. Or if we -- I</b></p> <p>5 <b>don't think there was anything else as</b></p> <p>6 <b>the next step plan.</b></p> <p>7 Q. Okay. Did you ever talk to any</p> <p>8 of those lawyers again?</p> <p>9 A. <b>Todd Davis called me on April 5,</b></p> <p>10 <b>2006 to say that I may be getting a</b></p> <p>11 <b>subpoena to be a fact witness.</b></p> <p>12</p> <p>13 MR. MURGATROYD: Okay. I'm going</p> <p>14 to mark that as Exhibit 16.</p> <p>15</p> <p>16 (Plaintiff's Exhibit 16, marked)</p> <p>17</p> <p>18 MR. MURGATROYD: Can we start at</p> <p>19 the top and work your way down.</p> <p>20 THE WITNESS: I noted the date</p> <p>21 and the time. I noted Todd's name.</p> <p>22 Tried to catch what firm he was with and</p> <p>23 a phone number. And if I'm interpreting</p> <p>24 this right that he is national counsel to</p> <p>25 GSK or the firm.</p>	<p>Page 249</p> <p>1 A. <b>It's drafts. I don't know who</b></p> <p>2 <b>may want to get drafts. I don't remember</b></p> <p>3 <b>what that meant.</b></p> <p>4 Q. Okay.</p> <p>5 A. <b>And then this is where I learned</b></p> <p>6 <b>that there was a law firm in Los Angeles</b></p> <p>7 <b>about GSK committing fraud. And then</b></p> <p>8 <b>that's where I learned about the Elliot</b></p> <p>9 <b>Spitzer case.</b></p> <p>10 Q. Todd told you about it?</p> <p>11 A. <b>Yes.</b></p> <p>12 Q. Did you ever receive any</p> <p>13 documents from any of the lawyers?</p> <p>14 A. <b>No.</b></p> <p>15 Q. Did you go on the Internet and</p> <p>16 look up the Elliot Spitzer?</p> <p>17 A. <b>No, not at this time. No.</b></p> <p>18 Q. Have you ever?</p> <p>19 A. <b>No.</b></p> <p>20 Q. So the only thing you know about</p> <p>21 Elliot Spitzer is what Todd told you?</p> <p>22 A. <b>I know about Elliot Spitzer from</b></p> <p>23 <b>reading the papers. He was an aggressive</b></p> <p>24 <b>Attorney General, and won a lot of cases</b></p> <p>25 <b>in New York.</b></p>

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<p>1 Q. I'm talking about specifically 2 with regards to pediatric Paxil? 3 <b>A. No.</b> 4 Q. So the only thing you know about 5 Elliot Spitzer is what Todd told you? 6 <b>A. That Elliot Spitzer prosecuted a 7 similar -- or was in charge of a similar 8 case in June of 2005, and that's it.</b> 9 Q. In which fraud was alleged with 10 regard to pediatric Paxil? 11 <b>A. And that it was a similar case.</b> 12 Q. Okay. Now, did -- I know I asked 13 you if the Justice Department has 14 contacted you, and you said no; correct? 15 Regarding criminal prosecution of GSK? 16 17 MR. DAVIS: Object to the form. 18 THE WITNESS: No. They have not 19 contacted me. 20 21 (BY MR. MURGATROYD): 22 Q. Has anybody from the FDA to your 23 knowledge contacted you or your lawyer? 24 <b>A. No.</b> 25 Q. Okay. Is GSK paying for your</p>	<p>1 2 MR. DAVIS: Object to the form. 3 THE WITNESS: She called me, 4 yes. 5 6 (BY MR. MURGATROYD): 7 Q. Okay. Let me make sure I have 8 that straight. Well, let me ask you 9 this. In the conference call that we 10 just discussed on 12-22-05? 11 <b>A. Yes.</b> 12 Q. Who did most of the talking among 13 the lawyers on the phone; if you 14 recall? 15 <b>A. They all spoke.</b> 16 Q. Okay. And with regard to the 17 Exhibit that has Dechert firm Andrea 18 Perry? 19 <b>A. Yes.</b> 20 Q. That was just -- again that was 21 just a set up to a subsequent call? 22 <b>A. Yes.</b> 23 Q. She called and said can you speak 24 to us? 25 <b>A. Can you speak to us, and I said I</b></p>
<p>1 lawyer today? 2 <b>A. No.</b> 3 Q. Okay. 4 5 MR. MARGOLIS: Let me just 6 clarify the record. I got a phone call 7 from somebody at the Justice Department 8 last week just asking about -- you know, 9 the fact that this deposition was coming 10 up. And they were calling me obviously 11 because I represent Sally. 12 MR. MURGATROYD: All right. 13 MR. MARGOLIS: So she hasn't got 14 a call, but I got a call on her behalf. 15 MR. MURGATROYD: But she hasn't 16 been interviewed by the Justice 17 Department, to your knowledge? 18 MR. MARGOLIS: No. 19 20 (BY MR. MURGATROYD): 21 Q. Okay. Now other than these 22 contacts with GSK's lawyers, I think you 23 said you have not had contact with GSK 24 employees; right? Oh, except for Andrea 25 Perry?</p>	<p>1 <b>don't know. I have to find out. Okay.</b> 2 <b>Can you call my associate Aaron Fisher,</b> 3 <b>is my recollection of what happened.</b> 4 Q. Okay. Thanks. Now, after the 5 first draft of the -- you completed the 6 first draft of the manuscript. What 7 process did you go through in terms of 8 getting comments from authors and 9 progressing with that manuscript. Can 10 you take me through that process, 11 please? 12 <b>A. I don't recall the specifics, but</b> 13 <b>I can tell you in general. At the</b> 14 <b>beginning my recollection is that it went</b> 15 <b>to Jim McCafferty and Dr. Keller.</b> 16 Q. Okay. The first draft? 17 <b>A. Yes. I think the first draft.</b> 18 <b>And the process is if it's horrible then</b> 19 <b>you keep going until it's a quality</b> 20 <b>piece. And until Dr. Keller says okay</b> 21 <b>now I'm ready to let other people see it.</b> 22 <b>And when Dr. Keller says it's</b> 23 <b>okay to let other people see it, then it</b> 24 <b>goes to the other authors.</b> 25 Q. Okay. And was it part of your</p>

1 job to get a manuscript that Dr. Keller  
2 approved out to the other authors?

3 **A. I don't remember if STI sent them**  
4 **out. We probably did.**

5 Q. Okay. Now, you did review the  
6 documents that I sent you? I think we  
7 sent you documents?

8 **A. Yes.**

9 Q. Do you recall seeing comments  
10 from Dr. Keller saying you did a superb  
11 job?

12 MR. DAVIS: Object to the form.

13 THE WITNESS: I recall seeing  
14 those comments.

15 (BY MR. MURGATROYD):

16 Q. And if you were to look at the  
17 manuscript as a finished product, as the  
18 published manuscript. How much of that  
19 work do you believe was your's as opposed  
20 to anybody else's?

21 MR. DAVIS: Object to the form.

22 MR. MARGOLIS: You're asking

1 first draft.

2 MR. MARGOLIS: From?

3 MR. MURGATROYD: From the  
4 clinical study report. Right. I think  
5 we have established that.

6 THE WITNESS: Right.

7 MR. MURGATROYD: Okay. And then  
8 at that point after the first draft.

9 Then you started getting input from  
10 primarily -- well actually I think there  
11 is -- we got a lot of exhibits floating  
12 around. But let's go to your first

13 draft, because I actually have some  
14 points highlighted there that I wanted to  
15 ask you about. Let's go off the record.

16 VIDEOGRAPHER: The time is 3:46.  
17 We are off the record.

18 (Off the record)

19 (Back on the record)

20 VIDEOGRAPHER: Back on the  
21 record. The time is two minutes after  
22 4:00.

1 based upon first of all the final  
2 clinical study that she got? And then I  
3 mean how does she attribute?

4 MR. MURGATROYD: Right. How much  
5 of that final published article does she  
6 contribute to her own work effort.

7 THE WITNESS: Well this was all  
8 based on two sources of information.  
9 Whatever the clinical study report was  
10 that I had, and extensive input from the  
11 authors.

12 MR. MURGATROYD: Okay. All  
13 right.

14 THE WITNESS: I acted at their  
15 direction.

16 (BY MR. MURGATROYD):

17 Q. Okay. But not initially. You  
18 took the task on, and then you asked for  
19 their input; correct?

20 MR. DAVIS: Object to the form.

21 MR. MARGOLIS: When you say the  
22 "task", what task did she take on?

23 MR. MURGATROYD: Preparing the

1 MR. MURGATROYD: Okay. I think  
2 we are going back to your first draft;  
3 correct? And you will notice that on  
4 some of the pages footnotes are  
5 highlighted. Can you turn to those,  
6 please.

7 (BY MR. MURGATROYD):

8 Q. And I think there are two  
9 different types that I saw in the  
10 manuscript. One says reviewers, and one  
11 says SP reviewers; right? Do you see  
12 that?

13 **A. Yes.**

14 Q. And was that you needing  
15 information from -- it's your  
16 understanding that the SP reviewers were  
17 obviously going to be Jim McCafferty and  
18 the GSK people; correct?

19 **A. Yes.**

20 Q. And the other reviewers would be  
21 the physicians?

22 **A. The authors.**

23 Q. The authors. Okay. And were you  
24 looking for -- well if you look on page  
25

1 14. Can you turn to page 14. Do you see  
2 that where it says reviewers P values are  
3 available?

4 **A. Yes.**

5 Q. So does that indicate that you  
6 were asking -- that went to all reviewers  
7 or would that just be SmithKline Beecham?

8  
9 MR. DAVIS: Object to the form.

10 THE WITNESS: Well at this stage  
11 the reviewers were Jim McCafferty and Dr.  
12 Keller.

13  
14 (BY MR. MURGATROYD):

15 Q. Okay. And who were you expecting  
16 to get P values from?

17 **A. That would be from whatever data  
18 I was provided by GSK.**

19 Q. Okay. And I take it that you  
20 relied totally on what GSK provided you  
21 as opposed to you doing your own research  
22 into the accuracy of the data?

23  
24 MR. DAVIS: Object to the form of  
25 the question.

1 THE WITNESS: This is -- how  
2 could I do that?

3  
4 (BY MR. MURGATROYD):

5 Q. Well, you could look at the raw  
6 material.

7 **A. That is just not done. I mean  
8 that's just not in my experience.**

9 Q. I understand. I'm saying you  
10 relied on GSK for them being accurate;  
11 correct?

12  
13 MR. DAVIS: Object to the form.

14 THE WITNESS: I relied on  
15 whatever documents I was given.

16  
17 (BY MR. MURGATROYD):

18 Q. And you were given documents by  
19 GSK?

20 **A. Yes.**

21 Q. Okay. So you relied upon GSK in  
22 providing you with accurate information;  
23 correct?

24 **A. Yes.**

25 Q. And to the degree that that

1 information is inaccurate, that's not  
2 your fault; right?

3  
4 MR. DAVIS: Object to form.

5 THE WITNESS: It's not my fault?

6  
7 (BY MR. MURGATROYD):

8 Q. Yes. If you wrote something in  
9 the manuscript that's inaccurate. That  
10 was based upon information that was  
11 provided to you by GSK. It would not be  
12 your fault if you wrote something  
13 inaccurate; correct?

14  
15 MR. DAVIS: Object to form.

16 THE WITNESS: I guess correct.

17  
18 (BY MR. MURGATROYD):

19 Q. Okay. Now -- I mean do medical  
20 writers have the responsibility to go  
21 back and look at the raw data to see if  
22 the interpretation of that data is  
23 correct?

24 **A. I don't believe so.**

25 Q. Okay. Is that something you have

1 ever done in your career?

2 **A. No.**

3 Q. Okay. Is that something you even  
4 have the expertise to do?

5 **A. No.**

6 Q. Okay. You know GSK coded the  
7 suicide events in Study 329 as Emotional  
8 Liability. Are you aware of that?

9 **A. Yes.**

10 Q. Were you aware of that fact at  
11 the time you prepared the first draft of  
12 the manuscript?

13 **A. I don't know.**

14 Q. How did you become aware that  
15 that term was being used to cover suicide  
16 attempts?

17 **A. It must have been in a document.  
18 In whatever document I was given.**

19 Q. Okay. So when you prepared the  
20 first draft, you knew that Emotional  
21 Liability was included?

22 **A. Again, I don't know if I had this  
23 at the time of the first draft. I don't  
24 know. I cannot say that I had this  
25 document that is sitting in front of me**

1 **at the time I wrote the first draft. And**  
2 **I would have to look and see what is in**  
3 **here.**

4 Q. Okay. Well, let me maybe back up  
5 for a second. When you prepared the  
6 first draft of the manuscript. Were you  
7 aware of the number of adolescents who  
8 experienced events involving  
9 suicidality? Just suicidality events,  
10 suicide events?

11 **A. Completed suicide?**

12 Q. No, no, no. Just events  
13 involving suicidality?

14 **A. I don't recall.**

15 Q. Can you look at your draft?

16 **A. I can look at the draft.**

17 Q. Okay.

18 **A. Okay.**

19 Q. Okay. Is there any -- did you  
20 find something in the first draft that  
21 talks about suicidality?

22 **A. There is the Emotional Lability.**

23 Q. Okay. How about suicidality?

24 **A. No.**

25 Q. Okay. To answer my question. Is

1  
2 (BY MR. MURGATROYD):

3 Q. There is no reference there that  
4 would indicate that; right?

5 **A. No.**

6 Q. Okay. Is there any reference --  
7 let's go to your final published paper.  
8 Is there any -- can you look through that  
9 paper and tell me how many children or  
10 adolescents -- I'm sorry. Adolescents  
11 experienced an event of suicidality from  
12 reading that paper?

13  
14 MR. DAVIS: Object to the form.

15 THE WITNESS: On page 769 in the  
16 first column, half way through the first  
17 full paragraph. The text outlines the  
18 general categories of adverse events.  
19 One being Emotional Lability. For  
20 example, suicidal ideation gestures, five  
21 patients.

22 Q. Okay. And I'm sorry. What page  
23 is that again?

24 **A. 769.**

25 Q. Okay. Is that on the left-hand

1 there any reference in the manuscript to  
2 suicidality?

3 **A. Not in this draft.**

4 Q. Okay. And when you wrote that  
5 draft, were you aware that GSK was coding  
6 suicide events as Emotional Lability?

7 **A. I don't know. It is very typical**  
8 **to under say chest pain -- under the**  
9 **cardiovascular system to group a bunch of**  
10 **different things. So I don't know what I**  
11 **saw when.**

12 Q. Okay. My question is, do you  
13 know what the term Emotional Lability  
14 means?

15 **A. "Emotional" means you have**  
16 **emotions. "Lability" means you're waxing**  
17 **and waning.**

18 Q. Okay. And when you wrote the  
19 manuscript, did you know that that was  
20 the topic that GSK stuck the suicide  
21 events under?

22  
23 MR. DAVIS: Object to the form.

24 THE WITNESS: I don't know. I  
25 don't remember.

1 side at the top?

2 **A. Yes.**

3 Q. And can you read -- it says  
4 "Emotional Lability i.e. suicidal  
5 ideation gestures five". Right?

6 **A. Yes.**

7 Q. Does it say how many kids tried  
8 to kill themselves?

9  
10 MR. DAVIS: Object to the form.

11 MR. MURGATROYD: You can answer  
12 that.

13  
14 (BY MR. MURGATROYD):

15 Q. Did it say how many adolescents  
16 tried to kill themselves?

17 **A. It says five patients had these**  
18 **symptomS.**

19 Q. I'm asking about suicide  
20 attempts?

21 **A. It doesn't specify suicide**  
22 **attempts**

23 Q. Okay. Were you aware that if you  
24 look at the -- let me just back up for a  
25 second. If you look at table three, it

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<p>1 talks about adverse events. Do you see 2 that? 3 <b>A. Yes.</b> 4 Q. Okay. And you see Emotional 5 Lability; right? 6 <b>A. Yes.</b> 7 Q. And how many does it say? 8 <b>A. It says six.</b> 9 Q. Okay. How many for Placebo? 10 <b>A. One.</b> 11 Q. Okay. 12 <b>A. Yes.</b> 13 Q. Okay. Let me show you. I think 14 we talked about you are aware that the 15 FDA did analyze Study 329; correct? With 16 regard to the adverse events? 17 18 MR. DAVIS: Object to the form. 19 MR. MURGATROYD: Were you aware 20 of that? 21 THE WITNESS: I'm aware of 22 that. 23 MR. MURGATROYD: Okay. Let me 24 show you their results. 25</p>	<p>1 <b>A. Yes.</b> 2 Q. Okay. And it says drug, meaning 3 Paxil, 6.5 percent. Placebo, 1.1 4 percent. Risk ratio equals 5.9. Do you 5 see that? 6 <b>A. I see that.</b> 7 Q. Do you know what a risk ratio 8 is? 9 <b>A. In general terms.</b> 10 Q. Okay. What is your understanding 11 of that? 12 <b>A. My understanding is that it's</b> 13 <b>statistical language comparing one thing</b> 14 <b>with another, of the probability of an</b> 15 <b>event happening.</b> 16 Q. Okay. In this instance an 17 adolescent taking Paxil, is almost six 18 times at the risk of experiencing 19 possible suicide related event. Compared 20 to an adolescent taking placebo; correct? 21 22 MR. DAVIS: Object to the form. 23 It mischaracterizes that data. 24 MR. MURGATROYD: Correct? 25 MR. MARGOLIS: That is one</p>
<p>Page 267</p> <p>1 (Plaintiff's Exhibit 17, marked) 2 3 MR. DAVIS: Object to the use of 4 this document with this witness, because 5 there is no foundation for it. 6 MR. MURGATROYD: Do you see there 7 is a section that says "Paroxetine/329"? 8 THE WITNESS: What page? 9 MR. MURGATROYD: The second 10 page -- or right at the bottom of the 11 first page. It says, "Paroxetine/329". 12 MR. MARGOLIS: There is no claim 13 that she has ever seen this before. Or 14 that it's anything that relates to 15 anything that she did with the Paxil 16 project? 17 MR. MURGATROYD: Correct. 18 MR. MARGOLIS: Okay. Go ahead. 19 20 (BY MR. MURGATROYD): 21 Q. Do you see the section that says 22 "Paroxetine/329"? 23 <b>A. Yes.</b> 24 Q. It says possibly suicide 25 related?</p>	<p>Page 269</p> <p>1 question. The other question is whether 2 or not you can tell if that is a 3 depressed adolescent or not. 4 MR. MURGATROYD: It's Study 329. 5 MR. DAVIS: Well, there is no 6 foundation that the witness can answer 7 that question. 8 MR. MURGATROYD: It says 9 Paroxetine Study 329. That was depressed 10 adolescents; right? 11 THE WITNESS: Yes. 12 13 (BY MR. MURGATROYD): 14 Q. Okay. That has a risk ratio of 15 5.9 for possibly suicide related events; 16 correct? 17 18 MR. DAVIS: Object to the form. 19 THE WITNESS: That is what this 20 document says. 21 22 (BY MR. MURGATROYD): 23 Q. And my question is, were you 24 aware when you prepared the manuscript 25 for Study 329 that there was a risk ratio</p>

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<p>1 showing that an adolescent on Paxil, was 2 nearly six times at risk of experiencing 3 a possible suicide related event. 4 Compared to an adolescent on Placebo? 5 6 MR. DAVIS: Object to the form. 7 8 (BY MR. MURGATROYD): 9 Q. Did you know that? 10 A. No. 11 Q. Okay. Let's go down to suicide 12 attempts. Do you see that? 13 A. Yes. 14 Q. And what percentage of Paxil 15 patients tried to kill themselves in 16 Study 329, according to this document? 17 18 MR. DAVIS: Object to the form. 19 THE WITNESS: This document says 20 drug equals 5.4 percent. Placebo equals 21 0 percent. Risks ration -- I think 22 that's ratio equals, and then there is 23 not a number. 24 25 (BY MR. MURGATROYD):</p>	<p>1 MR. MURGATROYD: Todd, that's 2 your opinion. 3 4 (BY MR. MURGATROYD): 5 Q. My question is when you wrote 6 your manuscript, were you aware that over 7 5 percent of the kids taking Paxil tried 8 to kill themselves? 9 10 MR. DAVIS: Object to form. That 11 mischaracterizes that data. 12 THE WITNESS: It was not my 13 manuscript, and no I have never seen this 14 before. Ever. 15 16 (BY MR. MURGATROYD): 17 Q. Okay. I don't care whether you 18 seen that before. I just want to know 19 whether or not you were aware at the time 20 you wrote the manuscript that over 5 21 percent of the kids taking Paxil 22 attempted suicide? 23 24 MR. DAVIS: Objection. Same 25 objections.</p>
<p>Page 271</p> <p>1 Q. Right. You can't have a risk 2 ratio when there is a zero. You know 3 that; right? 4 5 MR. DAVIS: Object to the form. 6 No foundation. 7 THE WITNESS: I don't know 8 that. 9 10 (BY MR. MURGATROYD): 11 Q. Okay. Well, let me ask you this. 12 In a study in which over 5 percent of the 13 adolescents who participate in the study 14 try to kill themselves on Paxil -- 15 16 MR. MARGOLIS: I'm going to 17 object on the the basis I thought we were 18 talking about suicidal ideations. 19 MR. MURGATROYD: This is 20 attempts. This says specifically 21 "attempts". This is attempts. 22 MR. DAVIS: There is no 23 foundation laid that this witness can 24 answer that question. I mean, we are 25 here wasting time.</p>	<p>Page 273</p> <p>1 THE WITNESS: No. 2 3 (BY MR. MURGATROYD): 4 Q. Okay. Would you as a lay person 5 consider a drug to be safe for children 6 and adolescents, where over 5 percent of 7 them who were on Paxil in this case tried 8 to kill themselves? 9 10 MR. DAVIS: Excuse me, Ms. Laden. 11 That question is not appropriate for a 12 witness where there is no establishment 13 that the witness has the qualifications 14 and the expertise. And it doesn't matter 15 what a lay person would think in order 16 for it to be admissible. It has to be 17 something more in order to be admissible. 18 MR. MURGATROYD: Save your 19 objection until time of trial. 20 MR. DAVIS: I'm putting an 21 objection on the record. 22 MR. MURGATROYD: You got it. 23 MR. DAVIS: That it is an 24 inappropriate question. The witness 25 cannot answer that question. She has</p>

1 testified she doesn't have the expertise.

2 MR. MURGATROYD: Well I knew you  
3 were very upset when Dr. Ryan said that  
4 he didn't think it was safe when you have  
5 these kind of figures, but with --

6 MR. DAVIS: Come on. Move ahead.  
7 Move ahead. Move ahead.

8 MR. MARGOLIS: This is not only  
9 not relevant, but this couldn't lead to  
10 relevant testimony because she is not an  
11 expert. And now you're asking her a  
12 general question for lay people. It has  
13 nothing to do with anything that she did  
14 with regard to the Paxil project.

15 MR. MURGATROYD: Okay. I will  
16 strike the question based on Stuart's  
17 objection.

18 (BY MR. MURGATROYD):

19 Q. Now, do you think it's proper to  
20 promote Paxil as safe when over 5 percent  
21 of the adolescents taking Paxil attempted  
22 suicide during Study 329?

23 MR. MARGOLIS: I object to that  
24  
25

1 also, because you're talking about  
2 promoting. And again, A she is not an  
3 expert. And B, she is not involved in  
4 the Paxil promotion. She is involved  
5 with the article.

6 MR. MURGATROYD: Okay. Well,  
7 it's the Plaintiff's contention that this  
8 article is a means of promotion, and that  
9 would be for a Jury to sort out.

10 MR. DAVIS: I join in that  
11 objection.

12 MR. MURGATROYD: That's fine.  
13 Can you answer that question, please.

14 THE WITNESS: Can you repeat the  
15 question, please.

16 (BY MR. MURGATROYD):

17 Q. Do you think it's appropriate to  
18 promote Paxil as safe when over 5 percent  
19 of the adolescents taking Paxil during  
20 clinical trials of 329 attempted suicide?

21 MR. DAVIS: Same objections.

22 THE WITNESS: I can't answer that  
23 question. I am not an expert to know  
24  
25

1 whether 5 percent is a dangerous risk  
2 risk in a dangerous disease or 50 percent  
3 is a dangerous risk in a dangerous  
4 disease. An expert would know that. I'm  
5 not an expert.

6 (BY MR. MURGATROYD):

7 Q. Well has GSK shared any of the  
8 information that it has received from  
9 it's experts on that very issue with you?

10 MR. DAVIS: Object to the form.

11 THE WITNESS: No.

12 (BY MR. MURGATROYD):

13 Q. Okay. Were you aware that  
14 another study -- let me show you. How  
15 many adolescent studies were you aware of  
16 did GSK perform with regard to  
17 adolescents?

18 **A. I knew there was a clinical trial  
19 program. I don't know if I ever knew how  
20 many other studies there were. And I  
21 don't know -- I don't -- did not know the  
22 details of this. Still don't.**  
23  
24  
25

1 MR. DAVIS: For the record, that  
2 was a question that was answered and  
3 asked three hours ago. The witness gave  
4 the exact same answer about that same  
5 time.

6 MR. MURGATROYD: I am not worried  
7 about that, Todd. Thank you very much.  
8 Let me show you what I will mark as the  
9 next Exhibit. Okay.

10 (Plaintiff's Exhibit 18, marked)

11 (BY MR. MURGATROYD):

12 Q. Okay. Let me ask you this. If  
13 you had been aware that over 5 percent of  
14 the adolescents taking Paxil in Study 329  
15 attempted suicide. Would you have put  
16 that in your draft?

17 MR. DAVIS: Object to the form.  
18 Again, it's the same question asked a  
19 different way in terms of asking this  
20 witness to offer an opinion about things  
21 that she says she is not qualified to  
22  
23  
24  
25

1 answer.

2 MR. MURGATROYD: Todd the  
3 objection is "form". That is it.

4 MR. DAVIS: You can say whatever  
5 you want, but this is a colossal waste of  
6 time. It's in appropriate. You're  
7 taking advantage of the situation.

8  
9 (BY MR. MURGATROYD)

10 Q. If you had been made aware of the  
11 fact --

12  
13 MR. MARGOLIS: How about if we  
14 just ask whether or not the final study  
15 report indicated the fact that over 5  
16 percent.

17 MR. MURGATROYD: Yes. Okay.  
18 That's a good question. Let me ask you  
19 this a little bit different.

20  
21 (BY MR. MURGATROYD):

22 Q. Does the final published article  
23 indicate anywhere in there that 5.4  
24 percent of the Paxil patients attempted  
25 suicide?

1 patients -- or the children, adolescents  
2 who were on both Paxil and Clomipramine;  
3 right?

4 A. Yes.

5 Q. And more adolescents had a  
6 suicidal act. More adolescents taking  
7 Paxil had a suicide act as opposed to  
8 adolescents taking Clomipramine; correct?

9  
10 MR. DAVIS: Object to the form.  
11 It's also outside the witness's  
12 expertise.

13 THE WITNESS: This paper cites 8  
14 out of 63 Paroxetine treated patients.  
15 Versus 7 out of 58 Clomipramine treated  
16 patients.

17  
18 (BY MR. MURGATROYD):

19 Q. Okay. Now that specifically says  
20 suicidal act; correct?

21 A. Yes.

22 Q. Okay. Do you know why your paper  
23 said Emotional Liability as opposed to  
24 suicidal act?

25 A. No.

1 A. The published paper does not  
2 specify the number or percent of patients  
3 who attempted suicide.

4  
5 MR. MURGATROYD: Okay. Now let  
6 me show you what I have marked as Exhibit  
7 18. Which is the published result of  
8 Study 511. Which compared Paxil and  
9 Clomipramine; C-L-O-M-I-P-R-A-M-I-N-E,  
10 and Paroxetine. Now I am going to show  
11 you the adverse events table, which is  
12 table four.

13  
14 (BY MR. MURGATROYD):

15 Q. Did you get a chance to look at  
16 table four of that paper?

17 A. Yes.

18 Q. And that discusses the adverse  
19 events that occurred during that study;  
20 correct?

21 A. Yes.

22 Q. Okay. Do you see a section there  
23 for -- it's entitled "Suicidal Act"?

24 A. Yes.

25 Q. And it gives a percentage for the

1 Q. Did you ever discuss with Jim  
2 McCafferty or anybody at GSK about using  
3 the term suicide or suicidal act as  
4 opposed to the term Emotional Liability?

5  
6 MR. DAVIS: Object to the form.  
7 mischaracterizes the article.

8 THE WITNESS: I don't recall.

9  
10 (BY MR. MURGATROYD):

11 Q. Do you understand that Emotional  
12 Liability to a doctor can also mean  
13 crying, mood swings?

14  
15 MR. DAVIS: Object to the form.  
16 Calls for speculation as well.

17 THE WITNESS: Well that would be  
18 my understanding of the phrase.

19  
20 (BY MR. MURGATROYD):

21 Q. Okay. Do you think that the  
22 phrase "Suicidal Act" is a more  
23 definitive term if you're trying to  
24 determine how many acts of suicide there  
25 were during a clinical trial, as opposed

1 to "Emotional Liability"?

2

3 MR. DAVIS: Object to the form.

4 No foundation that this witness can

5 answer questions, which she said she is

6 incapable of in terms of answering

7 questions about clinical trial design.

8 MR. MURGATROYD: That was a

9 nonsensical objection. I move to strike

10 it.

11 MR. DAVIS: Come on. Let's get

12 to what is important.

13 MR. MURGATROYD: This is

14 important, Todd. Kids were killing

15 themselves in this study, and --

16 MR. DAVIS: No one killed

17 themselves, Skip.

18 MR. MURGATROYD: They were

19 reporting it as "Emotional Liability". I

20 want to know why they didn't use the term

21 "Suicidal Act". That's all. That's the

22 question.

23

24 (BY MR. MURGATROYD):

25 Q. Why wasn't the term "Suicidal

1 Act" used?

2 **A. I cannot answer that question. I**

3 **did not set up the study. I did set up**

4 **the parameters by which the data were**

5 **reported in the clinical study report and**

6 **aggregated. So I just cannot answer that**

7 **for you.**

8 Q. Okay. That is fine. Now, you

9 were the moving force in getting the

10 manuscript ultimately published; correct?

11 That was your job?

12

13 MR. DAVIS: Object to the form.

14 Mischaracterizes the process.

15 THE WITNESS: Dr. Keller was the

16 moving force as the lead author.

17

18 (BY MR. MURGATROYD):

19 Q. But you were the moving force in

20 actually arranging for it to get

21 published; correct?

22

23 MR. DAVIS: Same objections.

24 THE WITNESS: I guess I'm

25 confused by the term "moving force".

1

2 (BY MR. MURGATROYD):

3 Q. Who was moving the project

4 forward? Getting the manuscripts to the

5 potential publications? Whose job was

6 that?

7 **A. Dr. Keller submitted the**

8 **manuscript directly to the journal**

9 **himself.**

10 Q. At your direction?

11

12 MR. DAVIS: Object to the form.

13 THE WITNESS: When all the

14 authors signed off on whatever version it

15 was, then Dr. Keller said okay. And I

16 sent it to him and he sent it to the

17 journal.

18

19 (BY MR. MURGATROYD):

20 Q. You actually prepared the cover

21 letter, and gave him all the copies he

22 needed. And all he did was just forward

23 it to the journal; correct?

24

25 MR. DAVIS: Object to the form.

1 THE WITNESS: After discussion

2 with him about what he wanted to say.

3 MR. MURGATROYD: Okay. Well,

4 let's go through a series of documents.

5 Okay. We have ten to go through.

6

7 (Plaintiff's Exhibit 19, marked)

8

9 MR. MURGATROYD: Let me show you

10 what I have marked as Exhibit 19. We can

11 go off the record. I'm just going to

12 show you a sequence of documents, and we

13 can just go them in chronological

14 sequence. Okay?

15 VIDEOGRAPHER: The time is the

16 4:33. We are off the record.

17

18 (Off the record)

19

20 (Back on the record)

21

22 VIDEOGRAPHER: We are back on the

23 record. The time is ten minutes to

24 5:00.

25

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<p>1 (Plaintiff's Exhibit 20, marked)</p> <p>2</p> <p>3 (Plaintiff's Exhibit 21, marked)</p> <p>4</p> <p>5 (Plaintiff's Exhibit 22, marked)</p> <p>6</p> <p>7 (Plaintiff's Exhibit 23, marked)</p> <p>8</p> <p>9 (Plaintiff's Exhibit 24, marked)</p> <p>10</p> <p>11 (Plaintiff's Exhibit 25, marked)</p> <p>12</p> <p>13 (Plaintiff's Exhibit 26, marked)</p> <p>14</p> <p>15 (Plaintiff's Exhibit 27, marked)</p> <p>16</p> <p>17 (Plaintiff's Exhibit 28, marked)</p> <p>18</p> <p>19 (Plaintiff's Exhibit 29, marked)</p> <p>20</p> <p>21 (Plaintiff's Exhibit 30, marked)</p> <p>22</p> <p>23 (BY MR. MURGATROYD):</p> <p>24 Q. Now, before you is a series of</p> <p>25 documents; correct?</p>	<p>1 physician or I think it's PHD at UCLA?</p> <p>2 <b>A. I don't know where he is.</b></p> <p>3</p> <p>4 MR. MURGATROYD: Okay. That's</p> <p>5 fine. Actually, we will be talking to</p> <p>6 him very shortly. He just got</p> <p>7 subpoenaed.</p> <p>8</p> <p>9 (BY MR. MURGATROYD):</p> <p>10 Q. Does that document appear to be</p> <p>11 authentic?</p> <p>12 <b>A. Yes.</b></p> <p>13 Q. Do you recall receiving that</p> <p>14 document?</p> <p>15 <b>A. I don't recall receiving many of</b></p> <p>16 <b>these documents, but it looks</b></p> <p>17 <b>authentic.</b></p> <p>18 Q. But that is the type of document</p> <p>19 you did receive from Dr. Keller?</p> <p>20 <b>A. Yes.</b></p> <p>21 Q. And is he complimenting you in</p> <p>22 that letter?</p> <p>23 <b>A. Yes.</b></p> <p>24 Q. What does he say?</p> <p>25 <b>A. He says "Dear Sally, you did a</b></p>
<p>Page 287</p> <p>1 <b>A. Yes.</b></p> <p>2 Q. And they all relate to the</p> <p>3 publication of the manuscript of Study</p> <p>4 329?</p> <p>5 <b>A. Yes.</b></p> <p>6 Q. Okay. And I had provided these</p> <p>7 to you prior to your deposition so you</p> <p>8 could review them; correct?</p> <p>9 <b>A. These were all in that folder?</b></p> <p>10 Q. Yes.</p> <p>11 <b>A. I reviewed what was in the</b></p> <p>12 <b>folder.</b></p> <p>13 Q. Okay. Let's take the first</p> <p>14 document in front of you. What is the</p> <p>15 lowest numbered Exhibit?</p> <p>16 <b>A. 19.</b></p> <p>17 Q. Okay. Can you identify for the</p> <p>18 record please what that Exhibit is?</p> <p>19 <b>A. It's a letter from Dr. Keller to</b></p> <p>20 <b>myself. That must have accompanied a</b></p> <p>21 <b>draft of the manuscript, asking me to</b></p> <p>22 <b>look at the changes that Dr. Keller made.</b></p> <p>23 <b>And Dr. Ryan and it must have been Mike</b></p> <p>24 <b>Strober.</b></p> <p>25 Q. Okay. Mike Strober is the</p>	<p>Page 289</p> <p>1 <b>superb job with this."</b></p> <p>2 Q. Which draft is he referring to in</p> <p>3 that letter?</p> <p>4 <b>A. It doesn't say.</b></p> <p>5 Q. Okay. Now, does it say the</p> <p>6 extent of the changes that he had made to</p> <p>7 the manuscript at that point?</p> <p>8 <b>A. He describes the changes from</b></p> <p>9 <b>himself and the other two authors as</b></p> <p>10 <b>rather minor changes.</b></p> <p>11 Q. Okay. Now, let's go to the next</p> <p>12 document.</p> <p>13 <b>A. Yes.</b></p> <p>14 Q. Can you identify for the record</p> <p>15 what that document is?</p> <p>16 <b>A. That is a letter from myself to</b></p> <p>17 <b>Jim McCafferty. It's kind of a status</b></p> <p>18 <b>report. After Dr. Keller sent the paper</b></p> <p>19 <b>to JAMA; J-A-M-A.</b></p> <p>20 Q. And what is the date of that</p> <p>21 document?</p> <p>22 <b>A. December 9th -- I'm sorry.</b></p> <p>23 <b>December 7, 1999.</b></p> <p>24 Q. Okay. And was that a document</p> <p>25 prepared by you?</p>

1 **A. Yes.**  
 2 Q. Does it appear to be authentic?  
 3 **A. Yes.**  
 4 Q. Did you write that during the  
 5 ordinary course of your business at  
 6 STI?  
 7 **A. Yes.**  
 8 Q. Okay. What information were you  
 9 transmitting in that document?  
 10 **A. I am letting Jim McCafferty know**  
 11 **that the Paper was rejected by JAMA. And**  
 12 **I am -- I guess I'm summarizing the**  
 13 **action plan based on a conference call**  
 14 **with myself and three authors and Jim**  
 15 **McCafferty.**  
 16 Q. Okay. What is the action plan to  
 17 do?  
 18 **A. That I would work with Jim**  
 19 **McCafferty to summarize the reviewer's**  
 20 **comments and outline them.**  
 21 Q. Okay.  
 22 **A. And that outline would be sent to**  
 23 **all the authors for their review and**  
 24 **approval.**  
 25 Q. Okay.

1 **means they have experts that review a**  
 2 **paper, and determine in their opinion if**  
 3 **it's suitable for publication in that**  
 4 **journal. And they generally -- the**  
 5 **reviewers -- there could be anywhere from**  
 6 **three to five or one to five; whatever.**  
 7 **Provide reasons why they think it should**  
 8 **or should not be accepted or should or**  
 9 **should not be revised.**  
 10 Q. Okay. And in this case with  
 11 regard to JAMA's rejection of the  
 12 transcript or the manuscript, did you get  
 13 the reviewer's comments?  
 14 **A. Yes.**  
 15 Q. Okay. And are they -- did you --  
 16 was part of your -- were you tasked to  
 17 summarize their or say what their reviews  
 18 were? And then how to correct any  
 19 deficiencies in the manuscript to address  
 20 those reviews?  
 21 **A. Dr. Keller sent these to me,**  
 22 **and --**  
 23 Q. Dr. Keller sent what to you?  
 24 **A. The reviewer's comments.**  
 25 Q. Okay.

1 **A. And the current draft will be**  
 2 **revised and circulated to all the authors**  
 3 **for review and approval.**  
 4 Q. Okay. And you and Jim McCafferty  
 5 were to do that?  
 6 **A. I believe we also worked with**  
 7 **these authors, if not more.**  
 8 Q. Okay. Let's -- so the record is  
 9 clear, the manuscript for 329 was  
 10 originally submitted to a publication  
 11 called JAMA?  
 12 **A. The journal, yes.**  
 13 Q. And what does that stand for?  
 14 **A. That's the Journal of the**  
 15 **American Medical Association.**  
 16 Q. And that association, that  
 17 journal rejected the manuscript;  
 18 correct?  
 19 **A. Yes. It sent it out to review,**  
 20 **and decided not to publish it.**  
 21 Q. Okay. And when you say it got  
 22 sent out to review, what does that mean  
 23 to a juror or a lay person? What is the  
 24 process?  
 25 **A. It's a peer review journal. That**

1 **A. Because they were returned to**  
 2 **him.**  
 3 Q. Okay.  
 4 **A. He looked them over, and again I**  
 5 **don't recall the specific events. But**  
 6 **I'm looking at this, and it looks like we**  
 7 **had a conference call to discuss what the**  
 8 **reviewers said.**  
 9 Q. Okay. And were you tasked to  
 10 provide a response to those comments?  
 11 **A. I was tasked to take a stab at --**  
 12 **you know to do what I could with what**  
 13 **information I had. Many times in the**  
 14 **reviewer comment, the reviewer asks for**  
 15 **you know levels of expert clinical**  
 16 **opinions that I just don't have.**  
 17 Q. Okay. Let's turn to -- with  
 18 regard to this specific paper, did you  
 19 address the reviewer's comments?  
 20 **A. To the best of my ability -- I**  
 21 **did to the best of my ability make a**  
 22 **draft of a response to the reviewer's**  
 23 **comments. In conjunction and under the**  
 24 **direction of these people.**  
 25 Q. Okay. Now, attached to that

1 document is the reviewer's comments; is  
2 that correct? Or is that another  
3 document?

4 **A. No. This is just a one-page**  
5 **document.**

6  
7 MR. MURGATROYD: Okay. That's  
8 fine. I think we will get to it in a  
9 minute. Okay. Let's go to the next --  
10 what number Exhibit was that again?

11 MR. MARGOLIS: 20.

12 MR. MURGATROYD: Okay. Let's go  
13 to 21.

14  
15 (BY MR. MURGATROYD):

16 Q. Can you identify for the record  
17 what that document is?

18 **A. This is a letter from myself to**  
19 **Jim McCafferty, in which I'm enclosing a**  
20 **draft of the response to the JAMA**  
21 **reviewers.**

22 Q. Okay. That you prepared?

23 **A. Yes.**

24 Q. Okay. Now, is that letter  
25 authentic?

1 Q. Okay. And it was addressed to  
2 just those two individuals?

3 **A. It was addressed to Jim**  
4 **McCafferty.**

5 Q. With a cc to Barry Brand?

6 **A. Yes.**

7 Q. Okay. And in the attached  
8 document did you address the JAMA  
9 reviewer's comments?

10 **A. Yes.**

11 Q. Okay. Now, with regard to  
12 reviewer number one. Do you see the  
13 comments of reviewer number one?

14 **A. Yes.**

15 Q. And does reviewer number one say  
16 that the article was potentially  
17 dangerous?

18  
19 MR. DAVIS: Object to the form.

20 THE WITNESS: I don't see where  
21 this reviewer says it's dangerous.

22 MR. MURGATROYD: Okay. Can I  
23 see -- let me see if I have a copy first.  
24 Wait a minute.  
25

1 **A. Yes.**

2 Q. Okay. And is the response  
3 attached thereto also authentic?

4 **A. It appears to be.**

5 Q. Okay. And were the documents  
6 prepared by you during the ordinary  
7 course of your business with STI?

8 **A. Yes.**

9 Q. Okay. So what is the date of  
10 that letter, please?

11 **A. December 10, 1999.**

12 Q. Okay. And is it to just Jim  
13 McCafferty?

14 **A. It is copied to Barry Brand.**

15 Q. Okay. Barry Brand is another  
16 marketing person at GSK?

17  
18 MR. DAVIS: Object to the form.

19 THE WITNESS: Jim McCafferty is  
20 not a marketing person.

21  
22 (BY MR. MURGATROYD):

23 Q. No, I'm sorry. Barry Brand is a  
24 marketing person?

25 **A. Yes.**

1 (BY MR. MURGATROYD):

2 Q. Well, actually before I do that.

3 In terms of the cover letter that was  
4 written by you, it states in the second  
5 paragraph: "We handle the JAMA reviewer  
6 comments by retyping them in a new  
7 document. And then in italicizing text,  
8 listing suggested revisions". Is that  
9 correct?

10 **A. That's what it says.**

11 Q. When you have the "we". Does  
12 that mean you and somebody helped you?  
13 Or is that just "we" meaning STI?

14 **A. That is "we" as the corporate**  
15 **"we".**

16 Q. Okay. But you were the actual  
17 person who did the work?

18 **A. To the best of my recollection.**

19 Q. Okay.

20 **A. You know, it's possible that**  
21 **someone -- I had some member of the**  
22 **clerical staff type it, as a time saving.**  
23 **But I don't recall.**

24 Q. Okay. But you were the one who  
25 put the suggested revisions together for

1 the reviewers?

2 **A. Yes.**

3 Q. Okay. Now, going to reviewer  
4 number one. Can you read the last  
5 sentence of reviewer number one's  
6 comments under section one beginning with  
7 the word, "Thus".

8 **A. "Thus this study could do more  
9 harm than good, unless the authors devote  
10 much more attention in their discussions  
11 to the fact that the bulk of the  
12 effectiveness study was a result of good  
13 clinical management and not the  
14 medication."**

15 Q. Okay. And did you agree with  
16 that statement?

17 **A. I was not in a position then, and  
18 not now in a position to be able to agree  
19 with that.**

20 Q. Okay. But you provided a  
21 suggested response to that?

22 **A. Yes.**

23 Q. Okay.

24 **A. After discussion.**

25 Q. You mean this was prepared after

1 discussion? Or did you prepare this, and  
2 then submit it for discussion?

3 **A. I don't recall specifically. It  
4 appears that there was a conference call  
5 prior to this, and I took direction from  
6 the office.**

7 Q. In responding to these comments  
8 you did?

9 **A. I believe that is my  
10 recollection.**

11 Q. Okay. When you were drafting the  
12 paper, do you remember the various  
13 comments by reviewers -- and actually I  
14 think letters to the editor that  
15 commented on the fact that adolescents  
16 were allowed in this study who had a  
17 HAM-D score of greater than or equal to  
18 12?

19 MR. DAVIS: Object to the form.

20 (BY MR. MURGATROYD):

21 Q. Do recall that topic?

22 **A. Are you asking me if this  
23 reviewer's -- I'm sorry. Can you repeat  
24 reviewer's -- I'm sorry. Can you repeat  
25 reviewer's -- I'm sorry. Can you repeat**

1 **the question.**

2 Q. Yes. Do you remember fielding or  
3 responding to comments of reviewers of  
4 the fact that this study included  
5 adolescents whose HAM-D score at baseline  
6 was 12 or greater?

7 **A. I would have to read this.**

8 THE WITNESS: Can I do that?

9 MR. MURGATROYD: That is fine.  
10 Sure.

11 (Pause in proceeding)

12 (BY MR. MURGATROYD):

13 Q. Okay. What does the reviewer say  
14 about the fact that adolescents in this  
15 study had a HAM-D score of 12?

16 **A. This reviewer says, "Many  
17 patients with a value of 12 on this scale  
18 would be considered responders in most  
19 clinical trials of antidepressants."**

20 Q. Okay. And was that criticism --  
21 do you recall that criticism being  
22 restricted to this reviewer? Or is that  
23 restricted to this reviewer? Or is that  
24 restricted to this reviewer? Or is that  
25 restricted to this reviewer?

1 the criticism that you recall hearing  
2 from others?

3 **A. I don't recall whether it was  
4 just this reviewer or whether there were  
5 others.**

6 Q. And do you understand this  
7 criticism? What it means? Do you  
8 understand the significance of it?

9 **A. I am not sure what you are  
10 asking.**

11 Q. Well, do you understand why there  
12 is a criticism of including adolescents  
13 whose HAM-D scores were 12 at that  
14 clinical trial?

15 MR. DAVIS: Object to the form.

16 THE WITNESS: I am not sure I can  
17 answer that.

18 (BY MR. MURGATROYD):

19 Q. Okay. Well did you try to answer  
20 it in the suggested revisions?

21 MR. DAVIS: Object to the form.

22 THE WITNESS: Let's see what I  
23  
24  
25

1 said. At the direction of the authors  
2 I'm sure this is what I wrote after going  
3 back to the clinical study report.

4  
5 (BY MR. MURGATROYD):

6 Q. Well do you know why -- it says  
7 right here, "Many patients with the value  
8 of 12 on this scale would be considered  
9 responders in most clinical trials of  
10 antidepressants." Did I read that  
11 correctly?

12 A. Yes.

13 Q. Okay. So in this Study 329,  
14 adolescents were let in who had an HAM-D  
15 of 12; correct?

16  
17 MR. DAVIS: Object to the form.

18 THE WITNESS: I would have to go  
19 back to the clinical study report and  
20 look.

21  
22 (BY MR. MURGATROYD):

23 Q. Okay. Well assume for the  
24 purpose of this question that adolescents  
25 with HAM-D scores of 12 were allowed in

1 the 329. Do you understand this  
2 reviewer's criticism that that adolescent  
3 would be already considered a responder  
4 before they ever took the drug?

5  
6 MR. DAVIS: Object to the form of  
7 the question. It's also argumentative.

8 THE WITNESS: I understand what  
9 this reviewer is trying to say.

10  
11 (BY MR. MURGATROYD):

12 Q. Okay. Why don't you tell me what  
13 he is trying to say.

14 A. He's trying to say that a patient  
15 with a value of 12 would be already be  
16 considered a responder.

17 Q. Right. And did you ever find out  
18 why somebody who would already be  
19 consider a responder would be included in  
20 a trial?

21  
22 MR. DAVIS: Object to the form.

23 THE WITNESS: That was really up  
24 to the authors. Not all reviewers --  
25 people don't always agree with reviewers.

1 I mean, reviewers are not always the real  
2 experts that they tend to be. So this  
3 was a judgment call from the authors and  
4 investigators of this study.

5  
6 (BY MR. MURGATROYD):

7 Q. Well did the authors and the  
8 investigators of the study ever tell you  
9 that the reason that adolescents with a  
10 HAM-D score of 12 were included, because  
11 they couldn't get anymore kids for the  
12 Study?

13  
14 MR. DAVIS: Object to the form.  
15 Argumentative.

16 THE WITNESS: No.

17  
18 (BY MR. MURGATROYD):

19 Q. They never told you that?

20  
21 MR. DAVIS: Object to the form.

22 THE WITNESS: I don't recall  
23 that.

24  
25 (BY MR. MURGATROYD):

1 Q. Do you think it's proper to  
2 include in a study a person who would  
3 already be considered a responder to that  
4 study? Do you think that's proper?

5  
6 MR. DAVIS: Object to the form.

7 THE WITNESS: I'm not an expert,  
8 and I can't answer that question.

9  
10 (BY MR. MURGATROYD):

11 Q. Well as an intelligent person  
12 what do you think?

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

16  
17 (BY MR. MURGATROYD):

18 Q. Doesn't that seem to be setting  
19 up the trial where you can't lose if you  
20 put somebody in that already qualifies as  
21 a responder?

22  
23 MR. MARGOLIS: Objection. She's  
24 just a fact witness.

25 THE WITNESS: I can't answer that

1 question.

2 MR. MURGATROYD: Okay.

3  
4 (BY MR. MURGATROYD):

5 Q. Well, when you were drafting up  
6 this manuscript for Study 329, did it  
7 ever occur to you that you were being  
8 asked to put a positive spin on a  
9 negative study?

10  
11 MR. DAVIS: Object to the form.

12 THE WITNESS: No.

13  
14 (BY MR. MURGATROYD):

15 Q. Okay. So let's go to the next  
16 Exhibit in front of you. Why don't you  
17 identify that for the record, please?

18 **A. That is a letter from myself to  
19 Jim McCafferty.**

20 Q. Okay. What is the date of that  
21 letter?

22 **A. April 26, 2000.**

23 Q. Okay. Now is this letter  
24 authentic?

25 **A. To the best of my knowledge.**

1 Q. Okay. Now does this appear to be  
2 authentic?

3 **A. Yes.**

4 Q. Are you familiar with this woman  
5 -- it's a woman; right? Erika?

6 **A. Yes.**

7 Q. E-R-I-K-A?

8 **A. Yes.**

9 Q. Did she work with you?

10 **A. She worked for STI.**

11 Q. Okay. What does this letter  
12 purport to tell Dr. Keller or provide Dr.  
13 Keller?

14 **A. This is providing Dr. Keller with  
15 the materials required by the journal  
16 when submitting a paper for  
17 publication.**

18 Q. Okay. So you were -- STI was  
19 making it easier for Dr. Keller to get  
20 this paper off to the journal; is that  
21 correct?

22 **A. STI made copies as required by  
23 the journal. Apparently the journal  
24 required an electronic copy on a  
25 diskette, and that is what was contained**

1 Q. Okay. It was prepared by you?

2 **A. Yes.**

3 Q. During the ordinary course of  
4 your business at STI?

5 **A. Yes.**

6 Q. What are you communicating to Mr.  
7 McCafferty in this letter?

8 **A. I am sending him the revised  
9 manuscript based on the JAMA reviewer  
10 comments that -- in other words, I did  
11 what I could to address the comments.  
12 And I was turning it back to Jim and the  
13 authors to help.**

14 Q. Okay. So you took the lead. You  
15 corrected the manuscript, and then you  
16 submitted it to Jim and the lead authors  
17 to take it from there?

18 **A. For their approval, yes.**

19 Q. Okay. Let's go to the next  
20 document. Can you identify for the  
21 record what that is?

22 **A. That is a letter from an STI copy  
23 editor to Dr. Keller.**

24 Q. Okay. And the date of this?

25 **A. June 12, 2000.**

1 **here.**

2 Q. Okay. And also a letter that Dr.  
3 Keller was instructed to retype on his  
4 own letterhead for the submission;  
5 right?

6 **A. It's a draft cover letter that he  
7 could do with what he wanted.**

8 Q. Okay. But it says please retype  
9 on your letterhead and revise as you  
10 like; right?

11 **A. Yes.**

12 Q. Okay. So was this the  
13 original -- JAMA was the original  
14 targeted journal for this manuscript;  
15 correct?

16 **A. The first journal that it was  
17 submitted to was JAMA.**

18 Q. Okay. And after it was rejected  
19 there, what journal did you try next?

20  
21 MR. DAVIS: Object to the form.  
22 THE WITNESS: I don't recall  
23 specifically, but I believe we submitted  
24 it to -- Dr. Keller submitted it to  
25 another journal before this final

<p style="text-align: right;">Page 310</p> <p>1 journal.</p> <p>2</p> <p>3 (BY MR. MURGATROYD):</p> <p>4 Q. Okay. And do you recall the name</p> <p>5 of that one?</p> <p>6 <b>A. It could have been Archives of</b></p> <p>7 <b>General Psychiatry. I don't recall.</b></p> <p>8 Q. And was it rejected by that</p> <p>9 journal?</p> <p>10 <b>A. My recollection is yes.</b></p> <p>11 Q. Okay. So not it's being</p> <p>12 submitted to the journal of the</p> <p>13 American -- the manuscript of Study 329</p> <p>14 is being submitted to the Journal of the</p> <p>15 American Academy of Child &amp; Adolescent</p> <p>16 Psychiatry; correct?</p> <p>17 <b>A. Yes.</b></p> <p>18 Q. Okay. Let's go to the next</p> <p>19 document please. Can you identify for</p> <p>20 the record -- what number Exhibit are we</p> <p>21 up to?</p> <p>22 <b>A. 24.</b></p> <p>23 Q. Okay. Can you identify for the</p> <p>24 record what that document is, please?</p> <p>25 <b>A. This is an E-mail from myself to</b></p>	<p style="text-align: right;">Page 312</p> <p>1 Q. Okay. Addressing the reviewer's</p> <p>2 comments?</p> <p>3 <b>A. Yes.</b></p> <p>4 Q. Okay. Did you participate in</p> <p>5 that activity?</p> <p>6 <b>A. Yes.</b></p> <p>7 Q. Okay. And did you then revise</p> <p>8 the manuscript accordingly?</p> <p>9 <b>A. I must have.</b></p> <p>10</p> <p>11 MR. MURGATROYD: Okay. And --</p> <p>12 well can I take a look at that Exhibit</p> <p>13 just for a second, please. Thank you.</p> <p>14</p> <p>15 (BY MR. MURGATROYD):</p> <p>16 Q. Okay. Do you see the highlighted</p> <p>17 portions of that document?</p> <p>18 <b>A. Yes.</b></p> <p>19 Q. Can you read the first one into</p> <p>20 the record, please?</p> <p>21 <b>A. "With the assistance of Jim</b></p> <p>22 <b>McCafferty, STI has been able to make</b></p> <p>23 <b>most of the revisions."</b></p> <p>24 Q. Okay. So that's you and Jim;</p> <p>25 right?</p>
<p style="text-align: right;">Page 311</p> <p>1 <b>two of the authors, and copying Dr.</b></p> <p>2 <b>Keller and Jim McCafferty at the request</b></p> <p>3 <b>of Dr. Keller.</b></p> <p>4 Q. Okay. And what is the date of</p> <p>5 the document?</p> <p>6 <b>A. August 24, 2000.</b></p> <p>7 Q. Okay. And is that document</p> <p>8 authentic?</p> <p>9 <b>A. To the best of my knowledge.</b></p> <p>10 Q. Okay. And did you prepare it?</p> <p>11 <b>A. To the best of my knowledge.</b></p> <p>12 Q. Okay. And you did that as the</p> <p>13 ordinary course of your business at STI;</p> <p>14 right?</p> <p>15 <b>A. Yes.</b></p> <p>16 Q. What communication again are you</p> <p>17 providing there?</p> <p>18 <b>A. This is -- the paper was</b></p> <p>19 <b>submitted to the Journal of the American</b></p> <p>20 <b>Academy. And as is expected, they will</b></p> <p>21 <b>have some questions. So it comes back to</b></p> <p>22 <b>Dr. Keller with the questions. And the</b></p> <p>23 <b>process was that I would work with Jim</b></p> <p>24 <b>McCafferty and the authors in addressing</b></p> <p>25 <b>those questions.</b></p>	<p style="text-align: right;">Page 313</p> <p>1 <b>A. Yes.</b></p> <p>2 Q. Okay. And what does the next</p> <p>3 highlighted portion say?</p> <p>4 <b>A. The next highlighted sentence is,</b></p> <p>5 <b>"Therefore we are not going to be sending</b></p> <p>6 <b>the revisions to the entire list of 22</b></p> <p>7 <b>authors beforehand. A courtesy copy will</b></p> <p>8 <b>go to each other at the same time the</b></p> <p>9 <b>revised manuscript is resubmitted to the</b></p> <p>10 <b>journal."</b></p> <p>11 Q. Okay. So some of the authors got</p> <p>12 the revised manuscript, some of them</p> <p>13 didn't; right?</p> <p>14 <b>A. They all got the revised</b></p> <p>15 <b>manuscript.</b></p> <p>16 Q. Okay. But some of them didn't</p> <p>17 get the comments?</p> <p>18</p> <p>19 MR. DAVIS: Object to the form.</p> <p>20 THE WITNESS: They always had</p> <p>21 time to comment.</p> <p>22</p> <p>23 (BY MR. MURGATROYD):</p> <p>24 Q. Before submission?</p> <p>25 <b>A. This is re-submission.</b></p>

1 Q. Right.  
 2 **A. Some of the authors did not.**  
 3 Q. Okay. Let's go to the next  
 4 document, please. Can you identify for  
 5 the record what that document is?  
 6 **A. This is -- it looks like an**  
 7 **E-mail from Jim McCafferty to myself.**  
 8 Q. What is the date of that?  
 9 **A. September 29, 2000.**  
 10 Q. Okay. And it's also an E-mail  
 11 from you to Jim McCafferty; right?  
 12 **A. Yes.**  
 13 Q. It's two E-mails. It's your  
 14 E-mail and his response; correct?  
 15 **A. Yes.**  
 16 Q. Okay. Does this document appear  
 17 to be authentic?  
 18 **A. Somebody could have retyped**  
 19 **this.**  
 20 Q. Does it appear to be authentic?  
 21 **A. It appears to be authentic.**  
 22 Q. And this again was -- the bottom  
 23 part you prepared; right?  
 24 **A. Yes.**  
 25 Q. Okay. And can you read the first

1 Dr. -- I'm sorry. From Kelly Griffin to  
 2 you?  
 3 **A. Yes.**  
 4 Q. Okay. Whose Kelly Griffin?  
 5 **A. I have to assume that she was one**  
 6 **of the Doctor's many, many assistants.**  
 7 Q. Dr. Keller's?  
 8 **A. Yes.**  
 9 Q. Okay. And he had many, many  
 10 assistants?  
 11 **A. It's a very busy department, I**  
 12 **guess. I don't know.**  
 13 Q. Okay. What is Sally -- I'm  
 14 sorry. What is Kelly addressing to you?  
 15 What is she asking?  
 16 **A. She is asking about the status.**  
 17 Q. Okay. And did you then pass that  
 18 request along to Jim McCafferty?  
 19 **A. Yes, I did.**  
 20 Q. Okay. And does this document  
 21 appear to be authentic?  
 22 **A. Appears to be.**  
 23 Q. And prepared by you? The  
 24 portions in here that are prepared by  
 25 you?

1 sentence into the record, please?  
 2 **A. "Thank you for helping me finish**  
 3 **this paper."**  
 4 Q. Okay. And at this point  
 5 September 29th of 2000, did you consider  
 6 the paper to be finished?  
 7 **A. I am not sure where we stand on**  
 8 **the whole process at that date.**  
 9 Q. Okay. What does the sentence  
 10 say?  
 11 **A. "Thank you for helping me finish**  
 12 **this paper."**  
 13 Q. So do you assume that the paper  
 14 is finished at that point?  
 15 **A. That is what the sentence says.**  
 16 Q. Okay. Let's go to the next  
 17 Exhibit. Can you identify for the record  
 18 what that is?  
 19 **A. That is a memo from Jim**  
 20 **McCafferty to myself, dated November 1,**  
 21 **2000.**  
 22 Q. Okay. And this is a series of  
 23 E-mails; correct? Three E-mails?  
 24 **A. Yes.**  
 25 Q. Okay. And the first one is from

1 **A. Yes.**  
 2 Q. Okay. What was Mr. McCafferty's  
 3 response?  
 4 **A. He said that he had**  
 5 **recommendations from the MDs. I am not**  
 6 **sure what that is. And legal regarding**  
 7 **the paper, and he will call me the next**  
 8 **day with any suggested revisions.**  
 9 Q. Okay. And were you aware that  
 10 the legal department at GSK had to  
 11 approve the manuscript before it could be  
 12 submitted to a publication?  
 13 **A. At this point I was.**  
 14 Q. Okay. I think if you go to the  
 15 next document. Can you identify the next  
 16 document for the record, please?  
 17 **A. This is a memo from me to Jim**  
 18 **McCafferty.**  
 19  
 20 MR. MURGATROYD: Okay. Actually,  
 21 I might have them slightly out of order.  
 22 Can I see the remaining few. Thanks.  
 23 Yes actually, they are a little bit out  
 24 of time order. Let me rearrange these.  
 25 They are a little out of order, just

1 slightly. We are going to go to Exhibit  
2 26. Actually, yes that is Exhibit 26.

3  
4 (BY MR. MURGATROYD):

5 Q. Can you identify for the record  
6 what Exhibit 26 is, please?

7 **A. It's a series of E-mails.**

8 Q. Okay. And who are they  
9 between?

10 **A. Myself to Jim McCafferty. And**  
11 **myself and Dr. Keller's office back to**  
12 **me. And myself to Dr. Keller's office.**

13 Q. Okay. And is this also  
14 discussing legal -- GSK's legal  
15 involvement in the publication of the  
16 manuscript?

17 **A. Yes.**

18 Q. Okay. Did you ever receive any  
19 revisions from the legal department at  
20 GSK regarding the revisions directly?

21 **A. I don't recall that I did, no.**

22 Q. Okay. Do you recall what any of  
23 their revisions were?

24 **A. I do not recall what they were.**

25 Q. Okay. Let's go to this order.

1 Can you please identify for the record  
2 what the next Exhibit is, please?

3 **A. This is Exhibit 28. It's a memo**  
4 **from myself to Jim McCafferty responding**  
5 **to the journal's request for changes to**  
6 **the manuscript. January 5, 2001.**

7 Q. So that journal would be the  
8 Journal of the American Academy of Child  
9 Adolescent & Psychiatry?

10 **A. Yes.**

11 Q. Okay. Is that document  
12 authentic?

13 **A. It appears to be.**

14 Q. Okay. It was prepared by you?

15 **A. It's got my name on it, yes.**

16 Q. Do you think you prepared it?

17 **A. I must have, yes.**

18 Q. Okay. Great. And what exactly  
19 are you saying there in the highlighted  
20 portion?

21 **A. "I have addressed all of the**  
22 **journal's requests. And the revised**  
23 **manuscript and response to Dr. Dulcan are**  
24 **attached."**

25 Q. Okay. Do you recall doing

1 that?

2 **A. Do I recall specifically doing**  
3 **that? I don't recall specifically doing**  
4 **that.**

5 Q. Okay. But in your letter you  
6 said you did?

7 **A. That's right.**

8 Q. Okay. Let's go to the next  
9 Exhibit. Was that part of your original  
10 contract with STI? Between STI and GSK?  
11 That not only would you help in the  
12 preparation of the initial draft and  
13 editing the subsequent draft, but also  
14 address reviewer's comments?

15 **A. I believe so.**

16 Q. Okay. That's fine. And is that  
17 typically a medical writer's job?

18 **A. I don't know what a typical**  
19 **medical writer's job is. So I can't**  
20 **answer that.**

21 Q. Is it something that you have  
22 typically done in your career?

23 **A. Yes, I have done it in the**  
24 **past.**

25 Q. And in this instance you did

1 it?

2 **A. Yes.**

3 Q. Okay. And let's go to the next  
4 Exhibit. Can you identify for the record  
5 what that is?

6 **A. Exhibit 29. It's an E-mail from**  
7 **myself to Barry Brand and some of his**  
8 **co-workers. I guess it's an update.**  
9 **Status update on the status of the**  
10 **paper.**

11 Q. Okay. Is that prepared by you?

12 **A. Yes, it is.**

13 Q. And is it authentic?

14 **A. It appears to be.**

15 Q. And what is the number of that  
16 Exhibit?

17 **A. 29.**

18 Q. Okay. And the date?

19 **A. November -- I'm sorry. January**  
20 **11, 2001.**

21 Q. And what does the highlighted  
22 portion state?

23 **A. It says, "At long last the**  
24 **Journal of the American Academy of Child**  
25 **and Adolescent Psychiatry has accepted**

Page 322	Page 324
<p>1 <b>the manuscript entitled "Efficacy of</b>  2 <b>Paroxetine in the Treatment of Adolescent</b>  3 <b>Major Depression: A Randomized,</b>  4 <b>Controlled Trial."</b>  5 Q. Okay. And so your manuscript  6 that you helped work on was ultimately  7 accepted by the journal; correct?  8 <b>A. Yes.</b>  9 Q. And it was in fact published.  10 Which is an Exhibit we talked about  11 earlier; correct?  12 <b>A. Yes.</b>  13 Q. Now after -- I think there is one  14 more Exhibit which was out of order.  15 Let's just cover it so everything is  16 line. The Exhibit prior to that was  17 actually out of order. But that is a  18 letter -- was that written by you? The  19 next number is 30?  20 <b>A. Yes.</b>  21 Q. Is that a letter written by  22 you?  23 <b>A. It's a letter written by STI copy</b>  24 <b>editor.</b>  25 Q. Okay. And that was to Dr.</p>	<p>1 Psychiatry?  2 <b>A. No, I don't recall.</b>  3  4 MR. MURGATROYD: Okay. Let me  5 show you a document.  6 VIDEOGRAPHER: This is the end of  7 tape number four. The time is 5:26. We  8 where off the record.  9  10 (Off the record)  11  12 (Back on the record)  13  14 VIDEOGRAPHER: Okay. We are back  15 on the record. This is tape number five.  16 The time is 5: MR. DAVIS:  17  18 (Plaintiff's Exhibit 31, marked)  19  20 (BY MR. MURGATROYD):  21 Q. Okay. What I have put before you  22 is Exhibit 31. Do you see that?  23 <b>A. Yes.</b>  24 Q. Have you had a chance to look at  25 that?</p>
<p>Page 323</p> <p>1 Keller?  2 <b>A. Yes.</b>  3 Q. And that was to help him submit  4 the manuscript to JAMA?  5 <b>A. Yes.</b>  6 Q. Okay. And what date was that?  7 <b>A. July 26, 1999.</b>  8 Q. Okay. Is that document  9 authentic?  10 <b>A. It appears to be.</b>  11 Q. Okay. It was produced during the  12 ordinary course of STI's business?  13 <b>A. Yes.</b>  14 Q. Okay. You can put that one away.  15 Now, the people at -- I think we were  16 talking about Cohn &amp; Wolfe earlier;  17 correct?  18 <b>A. Yes.</b>  19 Q. Are they in advertising or a nPR  20 outfit or both?  21 <b>A. I don't remember.</b>  22 Q. Okay. Do you recall how they  23 received the news about the manuscript of  24 329 being published in the American  25 Journal of child and Adolescent</p>	<p>Page 325</p> <p>1 <b>A. Yes.</b>  2 Q. I can't remember if you're CCd or  3 directly E-mailed in that?  4 <b>A. It's the top of the E-mail. It's</b>  5 <b>an E-mail from Sheila Hood to myself.</b>  6 Q. Do you recall who Sheila Hood is  7 or was?  8 <b>A. She works for GSK.</b>  9 Q. What is the date of that  10 E-mail?  11 <b>A. March 5, 2001.</b>  12 Q. Okay. Does that appear to be  13 authentic?  14 <b>A. It appears to be, yes.</b>  15 Q. You received that during the  16 ordinary course of your business?  17 <b>A. I must have, yes.</b>  18 Q. Okay. And do you see their  19 statement about the publication --  20 actually, whose statement is it in the  21 major paragraph towards the bottom of  22 that E-mail?  23 <b>A. This one?</b>  24 Q. Yes?  25 <b>A. It looks like it would be Holly</b></p>

Page 326	Page 328
<p>1 <b>White.</b>  2 Q. Okay. Do you know who Holly  3 White is or was?  4 <b>A. Well based on her E-mail address,</b>  5 <b>Cohn &amp; Wolfe.</b>  6 Q. Okay. Which is either the PR or  7 Ad company for GSK; right?  8 <b>A. Yes.</b>  9 Q. And can you read into the record  10 what she has to say?  11 <b>A. "Yes, please. Originally we had</b>  12 <b>planned to do extensive media relations</b>  13 <b>surrounding this study until we actually</b>  14 <b>viewed the results. Essentially the</b>  15 <b>study did not really show Paxil was</b>  16 <b>effective in treating adolescent</b>  17 <b>depression, which is not something we</b>  18 <b>want to publicize. However, we should</b>  19 <b>prepare a Q &amp; A and key messages in case</b>  20 <b>reporters do cover this study. The</b>  21 <b>proofs would definitely come in handy."</b>  22 Q. Okay. Now, after the manuscript  23 that you helped prepare for Study 329 was  24 published, did you participate in any  25 public relations program to get that</p>	<p>1 say about the efficacy of the study?  2  3 MR. DAVIS: Object to the form.  4 THE WITNESS: This memo says,  5 "Essentially the study did not really  6 show Paxil was effective in treating  7 adolescent depression. Which is not  8 something we want to publicize."  9  10 (BY MR. MURGATROYD):  11 Q. Okay. And do you recall  12 receiving that E-mail?  13 <b>A. I don't recall.</b>  14  15 MR. MURGATROYD: Okay. Can I see  16 it for a second.  17 THE WITNESS: Sure.  18 MR. MURGATROYD: It says,  19 "Essentially the study did not really  20 show Paxil was effective in treating  21 adolescent depression. Which is not  22 something we want to publicize."  23  24 (BY MR. MURGATROYD):  25 Q. Is that the first time that you</p>
<p>1 manuscript promoted?  2 <b>A. Well according to this E-mail, I</b>  3 <b>was asked to send a copy of the</b>  4 <b>manuscript to Sheila Hood and Holly</b>  5 <b>White.</b>  6 Q. Okay. Did you participate in any  7 promotional activities regarding the  8 publication of the article?  9  10 MR. DAVIS: Object to the form of  11 the question.  12 THE WITNESS: Through Cohn &amp;  13 White, no.  14  15 (BY MR. MURGATROYD):  16 Q. Through any source?  17 <b>A. I didn't see our role as</b>  18 <b>promotional. So I would have to say</b>  19 <b>no.</b>  20 Q. Okay. And Cohn &amp; White has  21 stated they are not going to do  22 promotion; right?  23 <b>A. Well I'm not sure how to</b>  24 <b>interpret that.</b>  25 Q. Okay. Is there -- what did they</p>	<p>1 had heard somebody say that Study 329  2 didn't really show Paxil was effective in  3 treating adolescent depression?  4 <b>A. I don't remember.</b>  5 Q. Okay. This would seem to be a  6 pretty important E-mail. Do you recall  7 receiving this E-mail?  8  9 MR. DAVIS: Objection.  10 THE WITNESS: I don't recall  11 receiving it.  12 MR. DAVIS: And I move to strike  13 Counsel's colloquy about the importance  14 of the E-mail.  15  16 (BY MR. MURGATROYD):  17 Q. Well, I think we have just  18 established that you have spent quite a  19 bit of time and effort in getting the  20 manuscript of 329 published; right?  21 <b>A. Yes.</b>  22 Q. Okay. And here comes a person  23 from GSK's either ad or PR company that  24 says the results really didn't show Paxil  25 was effective. But yet your article --</p>

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<p>1 the article you helped get published says 2 that it was effective. Didn't you find 3 that disconcerting? 4 5 MR. MARGOLIS: Object to the 6 form. 7 MR. DAVIS: Object to the form. 8 THE WITNESS: No. 9 10 (BY MR. MURGATROYD): 11 Q. Okay. Did you realize when you 12 were preparing your article that Paxil 13 really didn't show that it was effective 14 in treating adolescent depression? 15 A. <b>The manuscript was prepared at 16 the direction of the authors, based on 17 the data that I was provided.</b> 18 Q. Okay. But you had an 19 instrumental part in making sure it got 20 published; right? 21 22 MR. DAVIS: Object to the form. 23 THE WITNESS: As an employee of 24 of STL. 25</p>	<p>1 2 (BY MR. MURGATROYD): 3 Q. Okay. You have two documents in 4 front of you; correct? 5 A. <b>Yes.</b> 6 Q. Okay. And what are the Exhibit 7 numbers? 8 A. <b>32 and 33.</b> 9 Q. Okay. Let's take 32 First. Have 10 you ever seen that document before? 11 A. <b>I don't recall.</b> 12 13 MR. MURGATROYD: Okay. What that 14 document is is an abstract of Study 329 15 submitted by Martin Keller to the APA 16 that met on June 2, 1998 in Toronto, 17 Canada. 18 It was produced by GSK to the 19 United States Congress. When there was a 20 congressional investigation into the 21 activity of GSK. 22 MR. DAVIS: I move to strike the 23 colloquy. 24 MR. MURGATROYD: That's what the 25 document is. She asked what it was. I</p>
<p>Page 331</p> <p>1 (BY MR. MURGATROYD): 2 Q. Okay. Were you aware that Dr. 3 Keller had given a presentation at the 4 APA regarding results of 329, prior to 5 your first draft of the manuscript for 6 Study 329? 7 A. <b>I don't recall.</b> 8 9 MR. MURGATROYD: Okay. I'm going 10 to show you two documents in conjunction 11 with each other. 12 13 (Plaintiff's Exhibit 32, marked) 14 15 (Plaintiff's Exhibit 33, marked) 16 17 VIDEOGRAPHER: The time is 5:46. 18 We are off the record. 19 20 (Off the record) 21 22 (Back on the record) 23 24 VIDEOGRAPHER: Okay. We are back 25 on the record. The time is 5:48.</p>	<p>Page 333</p> <p>1 told her what it is. 2 MR. DAVIS: I'm just moving to 3 strike it. 4 5 (BY MR. MURGATROYD): 6 Q. Okay. Were you aware that -- and 7 the next document. Can you identify for 8 the record -- we will talk about these 9 both together, 33. Do you see what that 10 is? 11 A. <b>This is a letter from Jim 12 McCafferty to Sharyn Arnold.</b> 13 Q. It's actually an E-mail; right? 14 A. <b>I guess, yes.</b> 15 Q. Okay. What is the date of it? 16 A. <b>May 20, 1998.</b> 17 Q. Okay. And it talks about a press 18 release; correct? 19 A. <b>Yes.</b> 20 Q. Okay. And what does the press 21 release talk about? 22 A. <b>It talks about Study 329.</b> 23 Q. What does it say about Study 24 329? 25 A. <b>"The antidepressant Paroxetine</b></p>

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<p>1 <b>(Paxil, SmithKline Beecham) is effective</b>  2 <b>in treating major depression in</b>  3 <b>adolescents, according to a study</b>  4 <b>presented today at the 1998 annual</b>  5 <b>meeting of the American Psychiatric</b>  6 <b>Association."</b>  7 Q. Okay. So that is referring to  8 Dr. Keller's presentation on June 2nd?  9 <b>A. I guess.</b>  10 Q. Okay.  11 <b>A. The dates aren't the same, and I</b>  12 <b>don't know.</b>  13  14 MR. MARGOLIS: Yes. And I want a  15 clarification. This E-mail is dated May  16 20th.  17 MR. MURGATROYD: Right.  18 MR. MARGOLIS: And the  19 presentation is supposed to be June 2nd?  20 MR. MURGATROYD: Correct. What  21 does it say under the press release?  22 What is the date of the press release?  23 MR. DAVIS: It's a draft.  24 MR. MARGOLIS: Oh, okay.  25 MR. MURGATROYD: What is the</p>	<p>1 presentation. What is the date of  2 that?  3 <b>A. June 2nd.</b>  4 Q. Okay. And is Dr. Keller talking  5 about Study 329, and the effectiveness of  6 Paxil treating adolescents with  7 depression in Exhibit 32?  8 <b>A. Yes.</b>  9 Q. Okay. Do you see how the two  10 documents correlate?  11 <b>A. Yes, I do.</b>  12 Q. Okay. And my question is did you  13 help participate in either the press  14 release or the abstract for that  15 presentation?  16 <b>A. I don't recall so.</b>  17  18 (Plaintiff's Exhibit 34, marked)  19  20 MR. MURGATROYD: Okay. Now let  21 me show you what I have marked as Exhibit  22 34.  23 THE WITNESS: Okay.  24 MR. MURGATROYD: And while you're  25 looking at it, may I see Exhibit 33.</p>
<p>Page 335</p> <p>1 date?  2 MR. MARGOLIS: It says Toronto,  3 June 2, 1998.  4 MR. MURGATROYD: Correct.  5 MR. MARGOLIS: It's an E-mail, I  6 guess.  7 MR. MURGATROYD: Correct.  8 MR. MARGOLIS: Okay. I was  9 trying to figure out what it is.  10 MR. MURGATROYD: It's a draft  11 press release; right? Do you understand  12 that that is what it is?  13 MR. MARGOLIS: Well she has  14 testified that she hasn't seen that  15 document before.  16  17 (BY MR. MURGATROYD):  18 Q. But it says it right there on the  19 document that it's a draft press release,  20 doesn't it?  21 <b>A. It says press release.</b>  22 Q. Okay. And it's for June 2, 1998;  23 correct?  24 <b>A. Yes.</b>  25 Q. And Exhibit 32, Dr. Keller's</p>	<p>Page 337</p> <p>1 Thank you.  2 MR. DAVIS: Just for the record,  3 there is no foundation for that document  4 with this witness. And it also speaks to  5 issues that are outside the US regulatory  6 requirements and labeling requirements.  7 MR. MURGATROYD: As if that has  8 to do with anything.  9 MR. DAVIS: It has a lot to do  10 with it.  11 THE WITNESS: Okay.  12  13 (BY MR. MURGATROYD):  14 Q. Before I ask about that. Exhibit  15 33 has a sentence. Second from the end.  16 It says "This study". Can you see that?  17 Can you read that into the record,  18 please. Starting with "This study"?  19 <b>A. "This study marks an important</b>  20 <b>step in identifying Paroxetine as an</b>  21 <b>effective treatment of depression in this</b>  22 <b>age group."</b>  23 Q. Okay. Now let's go to Exhibit  24 34. Exhibit 34 is a document that is on  25 GSK letterhead; correct?</p>

1 **A. Yes.**

2  
3 MR. MURGATROYD: Okay. And let  
4 me show one part. Can you read -- I will  
5 put a check by the two paragraphs that I  
6 would like you to read into the record,  
7 and I will ask you a question. Can you  
8 read those two sentences into the record,  
9 please. Those two paragraphs.

10 THE WITNESS: "In pediatric  
11 patients with major depressive disorder,  
12 (MDD), Paxil is contraindicated due to  
13 additional evidence of lack of efficacy."

14 MR. MURGATROYD: Okay. And the  
15 next paragraph, please.

16 THE WITNESS: "There is new  
17 evidence from three pediatric placebo  
18 controlled trials in MDD of an increased  
19 risk of suicidal thinking, suicide  
20 attempts or self-harm."

21 MR. MURGATROYD: Okay. Keep  
22 going.

23 THE WITNESS: "The incidence of  
24 these events in the Paxil group as  
25 compared to the placebo group was 5.3%

1 (20/378) versus 2.8% (8/285),  
2 respectively."

3 MR. MURGATROYD: Okay. And the  
4 next sentence.

5 THE WITNESS: "Some of these  
6 events occurred during the tapering off  
7 period of the studies."

8 MR. MURGATROYD: Okay. I think  
9 there's one more sentence; correct?

10 THE WITNESS: "The three trials  
11 also demonstrated that Paxil failed to  
12 show greater efficacy than placebo in  
13 MDD."

14  
15 (BY MR. MURGATROYD):

16 Q. Okay. Now let's take that last  
17 sentence. Do you believe that that  
18 sentence is consistent with the statement  
19 by Mr. McCafferty in the press release  
20 that's marked as Exhibit 33?

21  
22 MR. DAVIS: Object to the form.  
23 No foundation for the witness to answer  
24 that question.

25 MR. MURGATROYD: Take the

1 sentence, this study, and compare it to  
2 that last sentence that you just read.

3 MR. MARGOLIS: I think that is  
4 calling for an expert opinion.

5 MR. MURGATROYD: No. It's just a  
6 common ordinary person's opinion.

7 MR. MARGOLIS: Why are you asking  
8 her who works for STI, as opposed to a  
9 person on the street?

10 MR. MURGATROYD: I just want her  
11 opinion.

12 MR. MARGOLIS: But these are two  
13 documents that are five years apart;  
14 correct?

15 MR. MURGATROYD: That is  
16 correct.

17 THE WITNESS: So -- I'm sorry.  
18 Ask the question again, please.

19  
20 (BY MR. MURGATROYD):

21 Q. Do you believe that Mr.  
22 McCafferty's draft press release where it  
23 says that Paxil as an effective treatment  
24 for adolescent depression, is consistent  
25 with that last sentence of that GSK

1 letter that you just read?

2  
3 MR. DAVIS: Object to the form.  
4 Mischaracterizes the document. No  
5 foundation for this witness to answer the  
6 question.

7 THE WITNESS: By reading these  
8 for the first time here, this language is  
9 different.

10  
11 (BY MR. MURGATROYD):

12 Q. Okay. Have you now been made  
13 aware of the fact that GSK acknowledges  
14 that Paxil is not effective for the  
15 treatment of adolescent depression?

16  
17 MR. DAVIS: Object to the form.

18 MR. MARGOLIS: Made aware by who?

19 MR. MURGATROYD: I'm sorry?

20 MR. MARGOLIS: Made aware by who?

21 MR. MURGATROYD: GSK.

22 MR. MARGOLIS: I don't  
23 understand. How did she become aware?

24 MR. MURGATROYD: I just want to  
25 know if she is aware.

<p style="text-align: right;">Page 342</p> <p>1</p> <p>2 (BY MR. MURGATROYD):</p> <p>3 Q. Are you aware that GSK has now</p> <p>4 stated publicly that Paxil is not</p> <p>5 effective for the treatment of adolescent</p> <p>6 depression?</p> <p>7</p> <p>8 MR. DAVIS: Object to the form of</p> <p>9 the question.</p> <p>10 THE WITNESS: No, I'm not aware</p> <p>11 that there was a public statement.</p> <p>12</p> <p>13 (BY MR. MURGATROYD):</p> <p>14 Q. Okay. Is there a public</p> <p>15 statement in that last sentence that you</p> <p>16 just read in that letter?</p> <p>17 <b>A. I'm sorry. This is a Glaxo</b></p> <p>18 <b>document?</b></p> <p>19 Q. Yes?</p> <p>20 <b>A. Then this is a Glaxo document,</b></p> <p>21 <b>and it does state that.</b></p> <p>22 Q. Okay. Did GSK give you the</p> <p>23 courtesy of calling you and telling you</p> <p>24 that they were going to publicly state</p> <p>25 something that was inconsistent with the</p>	<p style="text-align: right;">Page 344</p> <p>1 THE WITNESS: To my recollection</p> <p>2 I don't -- I do not recall hearing a</p> <p>3 public statement from GSK.</p> <p>4</p> <p>5 (BY MR. MURGATROYD):</p> <p>6 Q. Okay. That Paxil was not an</p> <p>7 effective treatment for adolescent</p> <p>8 depression?</p> <p>9 <b>A. I do not recall hearing that.</b></p> <p>10 Q. Okay. But you would agree that</p> <p>11 such a statement is consistent with the</p> <p>12 conclusion in the abstract of the journal</p> <p>13 article that was ultimately published</p> <p>14 regarding Study 329?</p> <p>15</p> <p>16 MR. DAVIS: Object to the form.</p> <p>17 THE WITNESS: There is a</p> <p>18 difference, yes.</p> <p>19</p> <p>20 (BY MR. MURGATROYD):</p> <p>21 Q. They are inconsistent; correct?</p> <p>22</p> <p>23 MR. DAVIS: Object to form.</p> <p>24 THE WITNESS: There is a</p> <p>25 difference.</p>
<p style="text-align: right;">Page 343</p> <p>1 manuscript that you helped prepare and</p> <p>2 get published?</p> <p>3</p> <p>4 MR. DAVIS: Object to the form.</p> <p>5 THE WITNESS: No.</p> <p>6</p> <p>7 (BY MR. MURGATROYD):</p> <p>8 Q. Okay. At what time, if at any</p> <p>9 time other than today, were you aware</p> <p>10 that GlaxoSmithKline agreed and</p> <p>11 acknowledged that Paxil is not an</p> <p>12 effective treatment for adolescent</p> <p>13 depression?</p> <p>14</p> <p>15 MR. DAVIS: Object to the form.</p> <p>16 THE WITNESS: I don't recall any</p> <p>17 public statements by GlaxoSmithKline to</p> <p>18 that effect. Other than reading this</p> <p>19 here.</p> <p>20</p> <p>21 (BY MR. MURGATROYD):</p> <p>22 Q. So today is the first time you</p> <p>23 have ever heard that?</p> <p>24</p> <p>25 MR. DAVIS: Object to the form.</p>	<p style="text-align: right;">Page 345</p> <p>1</p> <p>2 (BY MR. MURGATROYD):</p> <p>3 Q. Okay. One says "effective", and</p> <p>4 one says "ineffective"?</p> <p>5 <b>A. The paper said that that data</b></p> <p>6 <b>from that study showed -- demonstrated</b></p> <p>7 <b>efficacy. This talks about additional</b></p> <p>8 <b>evidence and pre-trials, of which I know</b></p> <p>9 <b>nothing of the other two.</b></p> <p>10 Q. Well you know something about</p> <p>11 377. You said you did.?</p> <p>12 <b>A. I'm sorry?</b></p> <p>13</p> <p>14 MR. DAVIS: Object to the form.</p> <p>15</p> <p>16 (BY MR. MURGATROYD):</p> <p>17 Q. You said -- we discussed 377.</p> <p>18 <b>A. Earlier today we did.</b></p> <p>19 Q. Yes. Well you know about two of</p> <p>20 them?</p> <p>21</p> <p>22 MR. DAVIS: Excuse me. The</p> <p>23 witness has answered that question</p> <p>24 before, and she said she was aware of the</p> <p>25 program.</p>

1 MR. MURGATROYD: Okay. All  
2 right. My question is really simple.

3  
4 (BY MR. MURGATROYD):

5 Q. You know that GSK was going to  
6 take the position that Paxil is not  
7 effective for the treatment of adolescent  
8 depression. Would you have stated or  
9 allowed your name to be associated with a  
10 manuscript that said just the opposite?

11  
12 MR. MARGOLIS: I object to that.  
13 That's complete speculation. You're  
14 talking about asking her about something  
15 five years hence.

16 MR. MURGATROYD: Okay. She can  
17 answer.

18 THE WITNESS: I have no idea what  
19 I would have done.

20 MR. MURGATROYD: Okay. That's  
21 fine. I have no further questions.

22 MR. DAVIS: Mr. Braslow, do you  
23 have questions on behalf of the clients  
24 you represent?

25 MR. BRASLOW: Yes. I don't think

1 it will be too long. My name is Derek  
2 Braslow. I represent other Plaintiffs  
3 involved in the Paxil litigation. Good  
4 evening. Just a follow-up on the last  
5 answer that you gave.

6  
7 CROSS EXAMINATION

8  
9 BY MR. BRASLOW:

10 Q. I think I would like to talk to  
11 you just real briefly -- and you have  
12 gone over this many times, about your job  
13 responsibilities as the focus and  
14 primarily as the medical writer.

15 It's not part of your job  
16 responsibility as a medical writer -- or  
17 it wasn't to question the protocol of any  
18 particular study; right?

19 **A. What do you mean by "protocol"?**

20 Q. Like the protocol of the clinical  
21 trial. The parameters of the clinical  
22 trial?

23 **A. No.**

24 Q. Okay. And it's not your job to  
25 question the data that comes to you?

1 Whether or not it's accurate or not. You  
2 take the data as it is, and you put  
3 together a report based on it?

4 **A. My job is to make sure that my  
5 work is accurate based on what I was  
6 doing.**

7 Q. Based upon what you were given.  
8 And the conclusions from a particular  
9 study that are given to you. It's not  
10 your job to question whether or not those  
11 conclusions are accurate or not; right?  
12 Or is it?

13 **A. I guess I would assume then that  
14 I would be an expert if I am questioning  
15 that, and I don't consider myself an  
16 expert.**

17 Q. Okay. And because you don't  
18 consider yourself an expert, you don't  
19 question the results -- the conclusions  
20 of any particular studies that are given  
21 to you?

22 **A. Do I question the results?**

23 Q. Is that part of your job? Or was  
24 it part of your job?

25 **A. My job was to accurately portray,**

1 **condense, distill, whatever you want to  
2 say the data that I was given.**

3 Q. Well, you were also given  
4 conclusions?

5 **A. Yes.**

6 Q. Let's talk about the Study 329  
7 that was talked about. You were given  
8 conclusions with respect to the data you  
9 were given; right?

10 **A. Yes.**

11 Q. Okay. And part of your job  
12 responsibility was not to question those  
13 conclusions, was it?

14 **A. No.**

15 Q. And you didn't?

16  
17 MR. MARGOLIS: Object to the  
18 form.

19 THE WITNESS: I don't recall, no.  
20 I don't recall if I did or not.

21  
22 (BY MR. BRASLOW):

23 Q. Would that have been -- I guess  
24 my question is was that part of your job  
25 responsibility, to question the

1 conclusions that are given to you from  
2 any particular study? And particularly  
3 Study 329?

4 **A. My job was to get something done**  
5 **on paper, based on the data that I was**  
6 **given. And work with the experts, the**  
7 **authors who were study investigators who**  
8 **knew the data. Knew the field. Knew the**  
9 **implications, et cetera, et cetera of all**  
10 **of this. To work with them in making**  
11 **sure that their views on this were**  
12 **accurately represented.**

13 Q. The doctors were the experts, not  
14 you?

15 **A. I am not an expert.**

16 Q. Well if you believed or if you  
17 had come to the opinion that Study 329  
18 showed that Paxil was ineffective for the  
19 treatment of depression in adolescents.  
20 That is not something that you would  
21 relay to the doctors who were the  
22 experts?

24 MR. DAVIS: Object to the form.

25 THE WITNESS: I don't know. Say

1 **the information that I was given, and to**  
2 **work with the authors to make sure that**  
3 **happened. That their views were**  
4 **represented in this also.**

5 Q. And it wasn't your job to  
6 question those views?

7 **A. I'm not an expert. So how can I**  
8 **question the views of an expert?**

9 Q. And you didn't question their  
10 views?

11 **A. I don't know what I did or did**  
12 **not do. I don't remember.**

13 Q. Okay. Well that is what I want  
14 to know. You don't remember questioning  
15 their views at any time?

16 **A. I don't remember, no.**

17 Q. Were you -- you were paid a  
18 salary when you worked with STI?

19 **A. Yes.**

20 Q. Do you remember how much you were  
21 paid?

22 **A. At that time, no.**

23 Q. Well at any time?

24 **A. I think yes, I do remember at any**  
25 **time.**

1 it again, please. I am not sure I  
2 understood.

4 (BY MR. MURGATROYD):

5 Q. Okay. I guess my question is did  
6 you come to an opinion with respect to  
7 study -- I know the opinion that you  
8 wrote in the article stated that it was  
9 effective. Paxil was effective for the  
10 treatment of adolescent depression?

11 **A. Yes.**

12 Q. But did you believe at the time  
13 that you wrote it that that was  
14 accurate?

15 **A. I wish I could tell you I**  
16 **remember what I believed at the time. I**  
17 **don't remember what I believed at the**  
18 **time.**

19 Q. Well I guess what I'm asking you  
20 is, did that matter what you believed?

21 **A. No. It didn't matter what I**  
22 **believed.**

23 Q. Your job was to write the  
24 conclusion?

25 **A. My job was to accurately portray**

1 Q. How much were you paid?

2 **A. I believe when I left -- I know**  
3 **it sounds silly not to remember. When I**  
4 **left in 2003, I think I was making**  
5 **\$100,000, \$110,000.**

6 Q. And currently? Do you currently  
7 do any work for GlaxoSmithKline?

8 **A. No.**

9 Q. And let me just wrap-up by asking  
10 you a little bit about when you provided  
11 the original draft to Dr. Keller. He had  
12 never seen anything before that with  
13 respect to the journal article that you  
14 had written? In other words, the only  
15 thing that you had provided him was the  
16 article that you had drafted?

18 MR DAVIS: Object to the form.

19 THE WITNESS: Well it was the  
20 first time anyone saw it.

22 (BY MR. BRASLOW):

23 Q. That's right. That was the first  
24 time anyone had saw it. But I guess I'm  
25 asking you, did you give him any other

1 materials when you provided him with that  
2 draft?

3 **A. I don't remember.**

4 Q. And finally -- and I think this  
5 may have been asked earlier. At anytime  
6 did you write a negative article  
7 throughout your time at STI with respect  
8 to a particular drug?

9 **A. Can you tell me what in your view  
10 a "negative article" is?**

11 Q. An article which said that the  
12 drug was ineffective for whatever  
13 indication or they were studying?

14 **A. I don't believe -- I don't recall  
15 writing something saying a drug was  
16 ineffective. It's really hard for me to  
17 answer that question, because there were  
18 a lot of different projects. Not always  
19 dealing with efficacy.**

20 **We staked our reputation on  
21 trying to be as fair balanced as  
22 possible. So it's very hard for me to  
23 say whether that happened or not.**

24 MR. BRASLOW: Thank you.  
25

1 MR. DAVIS: Ms. Laden, before I  
2 start my questioning, do you need a break  
3 of any kind?

4 THE WITNESS: Maybe just a  
5 five-minute walk around.

6 MR. DAVIS: That's okay. Let's  
7 do that.

8 VIDEOGRAPHER: The time is ten  
9 minutes after 6:00. We are off the  
10 record.

11 (Off the record)

12 (Back on the record)

13 VIDEOGRAPHER: We are back on the  
14 record. The time is 6:23.

15 MR. DAVIS: Ms Laden, my name is  
16 Todd Davis. I represent GlaxoSmithKline  
17 in the lawsuit that have been filed by  
18 the Plaintiff's lawyers.

19 I'm here to ask you some  
20 questions about your involvement with the  
21 Keller article. And also some questions  
22 to follow-up on some of the issues that  
23  
24  
25

1 were raised by the Plaintiff's lawyers.  
2 If you don't understand one of my  
3 questions, will you please let me know?

4 THE WITNESS: Yes.

5 MR. DAVIS: Thank you.  
6

7 CROSS EXAMINATION

8  
9 BY MR. DAVIS:

10 Q. Have you and I talked at all  
11 about the substance of your deposition  
12 testimony?

13 **A. No.**

14 Q. Have you talked with any other  
15 GlaxoSmithKline lawyer or in-house GSK  
16 employee about the substance of your  
17 testimony before today?

18 **A. No.**

19 Q. All right. I want to ask you  
20 some questions about the authors of the  
21 Keller article. Who were some of the  
22 authors -- well let me back up.

23 What was the reputation of the  
24 authors on the Keller article?  
25

1 MR. BRASLOW: Object to the form.

2 THE WITNESS: What kind of  
3 reputation?

4 MR. DAVIS: Fair enough.  
5

6 (BY MR. DAVIS):

7 Q. What was the reputation of the  
8 authors of the Keller article in the  
9 field of psychiatry?  
10

11 MR. BRASLOW: Objection.

12 THE WITNESS: Not being a  
13 psychiatrist, because they were very well  
14 known. I don't know what other  
15 psychiatrists felt or feel about these  
16 people. They were published, widely  
17 published. Several I think were chairs  
18 of their department. At least Dr. Keller  
19 was.

20 Q. Did a number of them work at  
21 recognized clinical institutions or  
22 educational institutions where the focus  
23 was psychiatry?  
24

25 **A. Where the focus of that  
institution was just psychiatry?**

1 Q. Let me ask you in a different  
2 way. Did a number of the authors of the  
3 Keller article work in psychiatric  
4 departments of well known medical  
5 institutions?

6 **A. I believe so, yes.**

7 Q. All right. Now, have you met any  
8 of the scientists or psychiatrists who  
9 were co-authors of the Keller article  
10 before you worked on drafting the Keller  
11 article?

12 **A. I have met some of these people.  
13 I don't recall the time period. Whether  
14 it was before or after.**

15 Q. Now, were the authors of the  
16 Keller article -- were they. I'm sorry.  
17 Go ahead. Do you want to say  
18 something?

19 **A. I just want to clarify that I was  
20 involved in some projects where I met --  
21 I believe I met some of these people  
22 after I left STI. So I cannot tell you  
23 when I met these people.**

24 Q. Now were the scientists and  
25 psychiatrists who were the authors of the

1 Keller article. Were they also involved  
2 as the clinical investigators for the  
3 study that is known as 329; which is the  
4 subject of the Keller article?

5 **A. I believe so, yes.**

6 Q. When you worked on the Keller  
7 article, and worked with the co-authors.  
8 What was the level of their involvement  
9 with the article?

10 **A. It varied.**

11 Q. Okay. Can you explain that,  
12 please?

13 **A. Some were extremely involved, and  
14 others were much less involved by their  
15 own choice.**

16 Q. Who was extremely involved?

17 **A. Keller, Ryan, Strober, Klein,  
18 Kutcher. I think Dr. Birmaher, if I  
19 recall were very very involved.**

20 Q. And -- go ahead.

21 **A. Again it's hard to say. I think  
22 the people that were really really  
23 involved are near the top of the  
24 authorship. But it appears that the rest  
25 are in alphabetical order.**

1 Q. Now by meaning that they were  
2 very very involved. What kind of  
3 interactions did you have with Dr.  
4 Keller, Dr. Ryan, Dr. Strober, Dr. Klein,  
5 Dr. Kutcher, and Dr. Birmaher?

6 **A. Well through the process of this  
7 there were several long conference calls,  
8 and a lot of back and forth with the  
9 manuscripts. A lot of back and forth.**

10 Q. And by back and forth, what do  
11 you mean by that?

12 **A. It means draft "X" went out to  
13 the authors. Who commented on it either  
14 by writing a note on a kitchen napkin or  
15 commenting in the actual manuscript and  
16 then they sent it back. And then it was  
17 my job to decipher what they were saying,  
18 and address it in the next version.**

19 Q. Okay. And did that process  
20 continue what these authors who were  
21 mainly -- very very involved with the  
22 publication of the Keller article from  
23 the beginning of the first draft, until  
24 the end process when it was actually  
25 published?

1 **A. Well my recollection is that Dr.  
2 Keller was the only person on this, other  
3 than Jim McCafferty who saw the first  
4 draft.**

5 Q. Okay.

6 **A. After that I don't remember at  
7 which point it went to the whole  
8 authorship, but very soon.**

9 Q. All right. Now, when you worked  
10 on the Keller article about Study 329,  
11 did you defer to the author's  
12 interpretation of the efficacy data?

13 **A. Yes.**

14 Q. And did you also defer to the  
15 author's revisions and comments about how  
16 to present the efficacy data?

17 **A. Yes.**

18 Q. When you worked on the Keller  
19 article about Study 329, did you defer to  
20 the author's interpretation of the safety  
21 data?

22 **A. Yes.**

23 Q. Did you also defer to the  
24 author's revisions and comments about how  
25 to present the safety data?

1 **A. Yes. They directed it.**

2 Q. Did STI or you ever get to  
3 override or veto what the outside authors  
4 wanted to say about the safety and  
5 efficacy results?

6 **A. I don't recall. And that does  
7 happen. And then we would always go back  
8 and say what did you really mean by that  
9 kind of thing to get clarification.**

10 Q. Okay. But my question is a  
11 little bit different. I'm not asking for  
12 clarification, but whether or not you or  
13 STI ever said you're wrong about that  
14 interpretation. We are not going to put  
15 that in there. We are going to put it  
16 this way, because this is the way we  
17 think it ought to read?

18 **A. Not to my recollection.**

19 Q. Now is it fair to say that it was  
20 the outside -- correct that. Was it fair  
21 to say that the researchers and  
22 scientists who were the authors of the  
23 Keller article, and had the expertise in  
24 psychiatry, drove and controlled the  
25 content of the Keller article?

1

2 (BY MR. DAVIS):

3 Q. Okay. Is this the proposal that  
4 STI made to GSK about the editorial  
5 assistance for the Keller article?

6 **A. Yes.**

7 Q. And is it dated April 3, 1998?

8 **A. Yes.**

9 Q. Can you turn to page four, please  
10 Ma'am. Do you see on page four where it  
11 says that Dr. Keller will be the primary  
12 author of this paper?

13 **A. Yes.**

14 Q. And was Dr. Keller in fact the  
15 primary author of the paper?

16 **A. Yes.**

17 Q. Who decided that Dr. Keller was  
18 the primary author?

19 **A. I don't know.**

20 Q. Did STI or you have any  
21 involvement in selecting Dr. Keller as  
22 the primary author of the paper?

23 **A. No.**

24 Q. And does it say also on page four  
25 that "STI will work with Jim McCafferty

1 MR. BRASLOW: Objection.

2 THE WITNESS: Can you repeat,  
3 please.

4 MR. DAVIS: Sure.

5 (BY MR. DAVIS):

6 Q. Did the outside authors -- strike  
7 that. Did the psychiatrists and  
8 scientists who were authors of the Keller  
9 article, drive the contents of what was  
10 presented about the safety and efficacy  
11 results?  
12

13 MR. BRASLOW: Objection.

14 THE WITNESS: My recollection is  
15 that my job was to take the data provided  
16 in the clinical study report, and do the  
17 best I could of putting it in into the  
18 document. And then their interpretation  
19 of "yes" or "no" or expand or not expand.  
20 They were the boss.

21 MR. DAVIS: Okay. Let's see if  
22 you can turn to Plaintiff's Exhibit 5, if  
23 you will.  
24  
25

1 of SmithKline Beecham as our primary  
2 contact for acquisition of data and  
3 coordination of reviews by SmithKline  
4 Beecham"?

5 **A. Yes, it says that.**

6 Q. And did you receive data from Jim  
7 McCafferty?

8 **A. Yes, I did.**

9 Q. And did you work with Jim  
10 McCafferty to coordinate reviews by  
11 GlaxoSmithKline?

12 **A. Yes.**  
13

14 MR. DAVIS: All right. Now on  
15 page five. If you turn to page five.  
16 Look at the second paragraph there. Can  
17 you read that, please.

18 THE WITNESS: "We will need to  
19 discuss journal submission, coordination  
20 of the review process, and number of  
21 draft(s) with the authors at the start of  
22 the review process to minimize untimely  
23 delays in the review and commentary  
24 process."  
25

1 (BY MR. DAVIS):  
2 Q. Do you believe that that  
3 occurred?

4 **A. I don't remember discussing**  
5 **number of draft(s), but otherwise yes.**  
6 **That is my recollection.**

7 Q. What do you recall before the  
8 start of the review process about  
9 discussions with the authors about  
10 journal submission and coordination of  
11 the review process?

12 **A. I don't recall discussing that**  
13 **with the authors.**

14 Q. Do you typically have that  
15 conversation with authors?

16 **A. If they ask. Sometimes it**  
17 **happens. Sometimes it doesn't happen.**

18 Q. And I know it's been almost ten  
19 years since this proposal was submitted.  
20 But can you recall one way or the other  
21 whether or not you those discussions with  
22 the authors of the Keller article?

23 **A. I don't recall.**

24 Q. Would it have been your standard  
25 practice to have such discussions?

1 (BY MR. DAVIS):  
2 Q. Okay. I'm going to hand you what  
3 has been marked as Defendant's Exhibit  
4 one, and ask if you can identify this  
5 document for the record, please.

7 MR. MARGOLIS: Why is this  
8 different than the one that we already  
9 have marked?

10 MR. DAVIS: If I've got another  
11 one marked, I'm happy to use that one  
12 instead. I just didn't recall one being  
13 marked. Well, let's just kind of speed  
14 up the process. I don't want to go and  
15 look for it.

16 MR. MURGATROYD: You're going to  
17 use the same Exhibit twice?

19 (BY MR. DAVIS):

20 Q. Ms. Laden, is this a letter dated  
21 December 18, 1998 from you to Mr. Jim  
22 McCafferty at GSA?

23 **A. Yes.**

24 Q. Does it enclose a copy of the  
25 draft of the manuscript of the Keller

1 **A. Probably not. Could I clarify**  
2 **that?**

3 Q. Yes?

4 **A. When you say "discussions", what**  
5 **do you mean? Face-to-face?**

6 Q. Either communication by way of  
7 E-mail, or letters, or telephone  
8 conversations, or face-to-face  
9 meetings?

10 **A. It would have been standard to**  
11 **outline the process.**

12 Q. Okay.

13 **A. In a letter.**

14 Q. Okay. And do you have any reason  
15 to believe that that procedure wasn't  
16 followed with respect to the Keller  
17 article, and the authors of the Keller  
18 article?

19 **A. In terms of?**

20 Q. Outlining the process of how it  
21 would work?

22 **A. No, I don't.**

24 (Defendant's Exhibit 1, marked)

1 article?

2 **A. Yes.**

4 MR. DAVIS: All right. Now, can  
5 you read for the Jury's benefit please,  
6 what the first two paragraphs say.

7 THE WITNESS: You want me to read  
8 the first two paragraphs?

9 MR. DAVIS: Yes.

10 THE WITNESS: "I am pleased to  
11 enclose Draft 1 of the manuscript  
12 entitled "Paroxetine and Imipramine  
13 Treatment of Adolescent Depression: A  
14 Randomized Controlled Trial." A copy is  
15 being sent to Marty Keller also. Note  
16 that the body of the manuscript is  
17 triple-spaced per the request of Dr.  
18 Keller.

20 (BY MR. DAVIS):

21 Q. Let me stop you there for a  
22 second. Do you recall why Dr. Keller had  
23 requested that the manuscript be  
24 triple-spaced?

25 **A. Yes, I do recall.**

1 Q. Why is that?

2 **A. He couldn't read it. His**  
3 **eyesight.**

4  
5 MR. DAVIS: Okay. And would you  
6 read the second paragraph, please.

7 THE WITNESS: "As you read the  
8 manuscript, please keep the following  
9 points in mind: The discussion section  
10 (Comment section) is not complete.

11 Rather it is presented in Draft 1 as a  
12 partially completed outline. I am  
13 looking for direction from you and Dr.  
14 Keller before completing the discussion,  
15 which will be completed for Draft II.

16  
17 (BY MR. DAVIS):

18 Q. Okay. Did you in fact have  
19 communications either by way of E-mail or  
20 telephone or letter with Dr. Keller and  
21 Mr. McCafferty about getting direction  
22 from them about completion of the  
23 discussion or comment section?

24 **A. Well that is what this letter**  
25 **says.**

1 Q. Okay. So did you in fact receive  
2 feedback from both Dr. Keller and Mr.  
3 McCafferty about getting their comments  
4 on the discussion or comment section?

5 **A. I don't specifically remember.**  
6 **That was a long time ago. But I must**  
7 **have, because that was eventually filled**  
8 **in.**

9  
10 MR. DAVIS: Okay. Let's see.  
11 Let's turn if you will to the comment  
12 section. I think it's page 19.

13  
14 (BY MR. DAVIS):

15 Q. And were you looking -- by  
16 preparation of this draft manuscript,  
17 were you wanting to get input from Mr.  
18 McCafferty and Dr. Keller about what to  
19 put in the comment or discussion  
20 section?

21 **A. Yes.**

22  
23 MR. DAVIS: All right. Now, let  
24 me hand you what I prepared as a graphic  
25 to your deposition. And I'm going to ask

1 you if you can -- I'm going to mark this  
2 as Exhibit two.

3  
4 (Defendant's Exhibit 2, marked)

5  
6 (BY MR. DAVIS):

7 Q. If you can compare this graphic  
8 Ms. Laden, to your cover letter. And  
9 tell me whether it's a true and accurate  
10 description of the comments that are  
11 reflected in your cover letter?

12 **A. The called out box repeats**  
13 **verbatim what is in this letter.**

14 Q. And does Exhibit 2 accurately and  
15 fairly portray what has been marked as  
16 Exhibit one in terms of -- strike that.

17 Does Exhibit 2 accurately and  
18 fairly described the information that is  
19 in Exhibit one of your cover letter.

20 **A. The language in the called out**  
21 **box is the same as in this letter.**

22 Q. The answer is "yes"?

23 **A. Is that accurately --**

24 Q. Yes. Does it accurately and  
25 fairly portray what is in your cover

1 letter?

2 **A. Yes.**

3  
4 MR. BRASLOW: Objection. I'm  
5 going to just object in that this  
6 document marked as Exhibit 2, there is  
7 emphasis that is underlined that is not  
8 underlined in the original letter. That  
9 is it. That's my objection.

10 MR. DAVIS: Okay. Let me hand  
11 you what is going to be marked as exhibit  
12 three to your deposition. Defendant's  
13 Exhibit three.

14  
15 (Defendant's Exhibit 3, marked)

16  
17 (BY MR. DAVIS):

18 Q. Ms. Laden, can you identify what  
19 that document is, please?

20 **A. This is a copy of the same**  
21 **letter, December 18, 1998. I'm sorry.**  
22 **This is a letter dated December 18, 1998**  
23 **from myself to Dr. Keller.**

24 Q. And does this contain handwritten  
25 notes by Dr. Keller?

1 **A. Yes.**

2 Q. Okay. And does it also reflect  
3 that it appears that Dr. Keller faxed  
4 this information to STI, the company that  
5 you worked for at the time?

6 **A. Well, there is a word up here  
7 that may be faxed. Other than that --  
8 oh, wait. Yes. Oh, yes there is a fax  
9 machine tag.**

10 Q. Okay. Now, do you see Dr.  
11 Keller's handwritten note down at the  
12 bottom of that page?

13 **A. Yes.**

14  
15 MR. DAVIS: Okay. Can you read  
16 what it says, please.

17 THE WITNESS: Dear Jim and Sally,  
18 dated December 25, 1998. It's hard to  
19 read his handwriting. Fantastic job on  
20 the first draft. I am much appreciative.  
21 I hope you -- something about having a  
22 healthy and happy holiday season. I hope  
23 you are both enjoying -- I guess. A  
24 healthy and happy holiday season. I am  
25 extremely -- something -- by this

1 manuscript. And I am -- something,  
2 something repeatedly -- oh, no. It's  
3 very hard to read his handwriting.

4 MR. DAVIS: Let me see if I can  
5 help out. Does it say that I am  
6 extremely excited by this manuscript, and  
7 I am turning around rapidly so as to keep  
8 it moving. Words to that effect?

9 THE WITNESS: So we may keep it  
10 moving. I guess.

11 MR. DAVIS: Is that --

12 THE WITNESS: That is what it  
13 could be.

14  
15 (BY MR. DAVIS):

16 Q. Okay. And does it say in the  
17 next line that he received input from  
18 Neil Ryan and Mike Strober?

19 **A. Something received input  
20 something from Neil Ryan and Mike  
21 Strober, the two something members of  
22 the --**

23 Q. Group?

24 **A. Group.**

25 Q. The group. Does it say two

1 senior members of the group?

2 **A. It could. Yes, I suppose that  
3 would be.**

4 Q. And is this Dr. Keller sending  
5 back comments to you on Draft I of the  
6 draft manuscript of the Keller article?

7 **A. Yes.**

8 Q. Now, does this also include on  
9 page three of what is faxed. Does it  
10 also include a typed out version of  
11 information to be included in the  
12 manuscript?

13 **A. Yes.**

14 Q. Okay. And then does it also  
15 attach a paper that Dr. Ryan authored?

16 **A. Yes.**

17 Q. And is that additional  
18 information that Dr. Keller or Dr. Ryan  
19 or Dr. Strober were providing for  
20 purposes of the draft manuscript?

21 **A. Yes.**

22 Q. Okay. And if you continue on  
23 throughout the fax. If you look at pages  
24 9 through 27. Does that include  
25 additional revisions and edits by either

1 Dr. Ryan, Dr. Keller, or Dr. Strober?

2  
3 THE WITNESS: Can you identify  
4 page 9?

5 MR. DAVIS: Yes. There is a  
6 circle with a "9" at the top. Actually,  
7 it just says "9" at the top.

8 THE WITNESS: Where it says  
9 abstract 404?

10 MR. DAVIS: Yes.

11 THE WITNESS: Okay.

12  
13 (BY MR. DAVIS):

14 Q. And my question is on pages 9  
15 through 27 of the fax, are there  
16 additional revisions and edits by either  
17 Dr. Keller, Dr. Ryan or Dr. Strober on  
18 Draft I?

19  
20 MR. BRASLOW: Objection. I just  
21 wanted to know are you referring to one  
22 author or three authors?

23  
24 (BY MR. DAVIS):

25 Q. I think the question was do you

1 see that pages 9 through 27 of the fax  
2 contain additional edits and revisions by  
3 either Dr. Keller, Dr. Ryan or Dr.  
4 Strober to draft one of the  
5 manuscripts?

6 **A. There are lots of revisions**  
7 **here.**

8  
9 MR. DAVIS: Okay. I want you to  
10 hold up those up. I want you to hold up  
11 pages 9, and I want the camera to zoom in  
12 on what those edits are.

13 I want the Jury to be able to see  
14 the edits that the authors made to this  
15 draft that you circulated.

16 MR. MURGATROYD: Start on page 9;  
17 correct?

18 MR. DAVIS: That's right.

19 MR. MURGATROYD: Do you have  
20 pages one through eight?

21 MR. DAVIS: You ready? Okay --

22 THE WITNESS: Yes.

23 MR. DAVIS: Are you zoomed in  
24 yet? Okay. If you can go to the next  
25 page. Okay. Can you go to the next

1 page. To the next page slowly. The next  
2 page, please. Next page, please. Next  
3 page. Next page. Go to the next page.  
4 Next page. Next page, please.

5 Okay. And then one more. Okay.  
6 Next page. Can we get the next page.  
7 Next one. Next one. All right. One  
8 more or two more. Okay. And then one  
9 more. Okay. Thank you.

10  
11 (BY MR. DAVIS):

12 Q. All right. Now after you  
13 received these edits from Dr. Ryan, Dr.  
14 Keller and Dr. Strober, did you  
15 incorporate them in the next version?

16 **A. Yes.**

17 Q. Okay. Now, do you -- in the  
18 stack of documents that have been marked  
19 as Plaintiff's Exhibits. Do you see Dr.  
20 Keller, Dr. Ryan and Dr. Strober's  
21 revisions to the Draft 1 anywhere in that  
22 set of materials that the Plaintiff's  
23 lawyers showed you?

24 **A. No.**

25 Q. Okay. Is that any part of the

1 material that he sent you to look at  
2 before the deposition?

3 **A. I'm not sure.**

4 Q. Okay. Is it fair to say that  
5 today he didn't share that version of the  
6 draft manuscript showing Dr. Ryan, Dr.  
7 Keller, and Dr. Strober's edits with you  
8 when he was questioning you?

9 **A. Yes.**

10  
11 (Defendant's Exhibit 4, marked)

12  
13 MR. DAVIS: Okay. Let's go to --  
14 I'm going to hand you what has been  
15 marked as Exhibit four. Okay. If you  
16 can please let me have that back. I  
17 mis-marked it. Sorry.

18  
19 (BY MR. DAVIS):

20 Q. I'm going to hand you what has  
21 been marked as Exhibit four. Defendant's  
22 Exhibit four, and ask if you can identify  
23 that document for us, please.

24 **A. This is a letter from Dr. Keller**  
25 **to myself. Dated February 11, 1999.**

1  
2 MR. DAVIS: Okay. Can you pull  
3 out Exhibit 19 from the list of Exhibits;  
4 Plaintiff's Exhibits.

5  
6 (BY MR. DAVIS):

7 Q. Is this the same cover letter  
8 that is marked as Plaintiff's Exhibit 19.

9 **A. Yes.**

10 Q. Okay. Now, on the document that  
11 the Plaintiff's lawyer showed you. Did  
12 he include the attachments and enclosures  
13 to the February 11, 1999 letter that has  
14 now been marked as Defendant's Exhibit  
15 four?

16 **A. No.**

17 Q. Okay. And any time during his  
18 questioning of you, did he share that  
19 information with you?

20 **A. What information?**

21 Q. The information that now has been  
22 marked as attached to Defendant's Exhibit  
23 four. Which is the enclosures which were  
24 included within the February 11, 1999  
25 letter?

1 **A. No.**

2 Q. Okay. Now let's take a look at  
3 that. This is just for the Jury's  
4 benefit. This is the cover letter where  
5 Dr. Keller says that enclosed are rather  
6 minor changes from me, Neil and Mike; is  
7 that right?

8 **A. Yes.**

9 Q. Okay. Let's look at those  
10 changes for a second. Let's look at that  
11 enclosure. Part of that package that Dr.  
12 Keller sent you. Did it include a  
13 memorandum from him dated February 12,  
14 1999 to his co-authors on the Keller  
15 article?

16 **A. Yes.**

17 Q. Okay. And does that memorandum  
18 say that -- does he reference that  
19 memorandum in the cover letter where he  
20 says, "I would ask you to take my cover  
21 memo and send the revisions which  
22 incorporates the comments I am sending  
23 you directly to all co-authors?"

24 **A. Yes.**

25 Q. Okay. And is the memorandum that

1 is dated February 22, 1999 the memorandum  
2 which he references?

3 **A. I believe so.**

4 Q. Okay. And then he says -- in the  
5 cover memo to his co-authors, does he say  
6 "Enclosed is draft number three of acute  
7 phase efficacy manuscript. Neil, Mike  
8 and Jim have edited the first two drafts  
9 with me."

10 **A. Yes. That is what it says.**

11 Q. And is he referring to Neil  
12 Ryan -- Dr. Neil Ryan, Dr. Michael  
13 Strober, and Jim McCafferty at GSK?

14 **A. Yes.**

15 Q. Okay. And then does -- in the  
16 next paragraph does Dr. Keller say,  
17 "Please send your suggestions  
18 simultaneous to me, Neil and Mike within  
19 two weeks so we may move this along  
20 rapidly"?

21 **A. Yes, it does.**

22 Q. Okay. And attached to the  
23 memorandum which he enclosed to you. Are  
24 there further edits and revisions to the  
25 draft manuscript?

1 **A. Yes.**

2 Q. Okay. And are these revisions  
3 dated February 13, 1999 per the  
4 handwritten note by Dr. Keller?

5 **A. It says, 2-13-99 revision  
6 something from Keller and Strober.**

7 Q. Okay. And again does this  
8 provide further revisions to Dr. Keller  
9 and his co-authors. Provide additional  
10 provisions to the draft manuscript?

11 **A. Yes.**

12  
13 MR. DAVIS: Okay. I don't want  
14 to -- I want to have the Jury to have the  
15 benefit to see their changes. Can you  
16 hold up those comments again, please.

17 MR. MURGATROYD: You mean the  
18 minor changes.

19 MR. DAVIS: The changes that are  
20 listed. Okay. Can we see the next one.  
21 Can we see the next one. Okay. Can we  
22 see the next one. Okay. Let's see the  
23 next one.

24 THE WITNESS: Keep going?

25 MR. DAVIS: Yes, please. I will

1 tell you to slow down or not. Okay.  
2 Let's go slowly through it. Are the rest  
3 references?

4 THE WITNESS: There are the  
5 tables and a figure at the back.

6 MR. DAVIS: Okay. Great. All  
7 right. Are there any changes in those?

8 MR. BRASLOW: There is an edit on  
9 the third to last page if you want to get  
10 it?

11 MR. DAVIS: No. That is okay. I  
12 am just trying to move this along.

13  
14 (Defendant's Exhibit 5, marked)

15  
16 (BY MR. DAVIS):

17 Q. Ms. Laden, I'm going to hand you  
18 what has been marked as Defendant's  
19 Exhibit five, and ask if you can look at  
20 Defendant's Exhibit five and compare it  
21 to Dr. Keller's February 22, 1999 memo.  
22 And ask if that accurately portrays what  
23 Dr. Keller put in his cover memo to his  
24 co-authors.

1 MR. BRASLOW: Objection.

2 THE WITNESS: The language is the  
3 same. There is the addition in Exhibit  
4 number five of the underscoring.

5 MR. DAVIS: Okay. Thank you.

6  
7 (Defendant's Exhibit 6, marked)

8  
9 (BY MR. DAVIS):

10 Q. I'm going to hand you what has  
11 been marked as Defendant's Exhibit 6, and  
12 ask you if you can identify that document  
13 for the record, please?

14 **A. This is a memo on Brown**  
15 **University letterhead, dated April 16,**  
16 **1999. From Marty Keller to Dr. Ryan,**  
17 **Strober and McCafferty. CC'd to me.**

18 Q. And does it reference the draft  
19 manuscript for Study 329? Which  
20 ultimately became the Keller article?

21 **A. Yes.**

22  
23 MR. DAVIS: Okay. And can you  
24 read for the benefit of the jury what the  
25 memo that Dr. Keller sent to Dr. Ryan,

1 about the contents of the article?

2 **A. Yes.**

3 Q. Was Dr. Keller the author on the  
4 Keller article who for practical purposes  
5 took the lead in trying to generate input  
6 and comments, and collecting input and  
7 comments from his co-author?

8 **A. Yes.**

9  
10 (Defendant's Exhibit 7, marked)

11  
12 (BY MR. DAVIS):

13 Q. Okay. All right. I'm going to  
14 hand you what has been marked as  
15 Defendant's Exhibit 7, and ask you if  
16 this graphic that I prepared accurately  
17 and fairly reflects what the April 16,  
18 1999 memo from Dr. Keller to Dr. Ryan,  
19 Strober and McCafferty that we just went  
20 over?

21 **A. Yes. The same language is in**  
22 **both.**

23  
24 (Defendant's Exhibit 8, marked)

1 Dr. Strober and Mr. McCafferty and copied  
2 you on.

3 THE WITNESS: "Enclosed are the  
4 comments I received from Drs. Carlson,  
5 Klein, Kutcher, Wagner and Geller, and my  
6 response to these comments."

7 MR. DAVIS: Okay.

8 THE WITNESS: "Would you please  
9 review these materials, answer any  
10 queries, and send me your additional  
11 edits and/or approval for submission.

12 I will then collate or set up a  
13 call if there is any controversy. If all  
14 is routine, I will forward to Sally Laden  
15 and ask her to put in final form for  
16 submission to JAMA. Thank you so much.  
17 As always, all my best."

18  
19 (BY MR. DAVIS):

20 Q. And in terms of the memos that we  
21 have been looking at from Dr. Keller to  
22 his co-authors. Does that refresh your  
23 recollection that in fact Dr. Keller had  
24 communications with his co-authors in  
25 which he solicited their input and advice

1 (BY MR. DAVIS):

2 Q. I'm going to hand you what has  
3 been marked as Defendant's Exhibit 8, and  
4 ask you if you can identify this document  
5 for the record, please?

6 **A. This is a fax cover sheet to me**  
7 **from Dr. Stan Kutcher dated -- I don't**  
8 **see a date.**

9 Q. Is this fax concerning the draft  
10 of the Keller article?

11 **A. Yes.**

12 Q. Okay. And does this fax -- does  
13 Dr. Kutcher also send this fax to Dr.  
14 Keller, Dr. Ryan, and Dr. Strober?

15 **A. They are copied on this fax.**

16 Q. And does it appear that Dr.  
17 Keller's handwritten notes are on this  
18 fax as well?

19 **A. Yes.**

20 Q. Okay. And Dr. Kutcher was  
21 co-author of the article?

22 **A. Yes, he was.**

23  
24 (Defendant's Exhibit 9, marked)

1 MR. DAVIS: You can put that one  
2 aside.

3  
4 (BY MR. DAVIS):

5 Q. I'm going to hand you what has  
6 been marked as Defendant's Exhibit 9.  
7 And I ask if you can identify that  
8 document for the record, please?

9 **A. This is a letter from the STI  
10 copy editor to Dr. Keller.**

11 Q. Okay. Now, look down at the  
12 fourth bullet. Can you tell the Jury  
13 what that fourth bullet says?

14 **A. It says, "A draft of a cover  
15 letter to Dr. Richard Glass, the editor  
16 of JAMA (Please retype on your letterhead  
17 and revise as you like)."**

18 Q. Now, was there any effort by STI  
19 or you while you were working on the  
20 drafts of the Keller article, or trying  
21 to submit it to various journals for  
22 publication. Was there any effort by you  
23 or STI to try to dictate or control what  
24 the author said about the safety or  
25 efficacy results when they were

1 submitting them to the journal?  
2

3 MR. BRASLOW: Objection.  
4 THE WITNESS: No.

5  
6 (BY MR. DAVIS):

7 Q. Now, is this package which  
8 encloses the various materials such as  
9 copies of the manuscript, four sets of  
10 laser copy illustrations, and diskettes  
11 containing illustrations. Are those the  
12 kind of standard material that journals  
13 require when they are considering a  
14 manuscript for publication?  
15

16 MR. BRASLOW: Objection.

17 THE WITNESS: Each journal has  
18 it's own -- it's called different things.  
19 It's generally called instructions for  
20 authors that list these things exactly  
21 like this. How many copies they need.  
22 Whether they will accept electronic  
23 files, et cetera.  
24

25 (BY MR. DAVIS):

1 Q. And as part of the effort that  
2 you provided to -- you and STI provided  
3 to the authors of the Keller article.  
4 Did you assemble that information for  
5 them so that they would not have to do  
6 that?

7 **A. Yes.**  
8

9 VIDEOGRAPHER: This is the end of  
10 tape number five. The time is 7:13.

11 (Off the record)  
12

13 (Back on the record)  
14

15 VIDEOGRAPHER: We are back on the  
16 record. This is tape number six. The  
17 time is 7:15.  
18

19 (Defendant's Exhibit 10, marked)  
20

21 MR. DAVIS: Ms. Laden, I have  
22 shown you what has been marked as -- I  
23 put in front of you what has been marked  
24 as Defendant's Exhibit 10.  
25

1 (BY MR. DAVIS):  
2

3 Q. Is that a letter from you to Mr.  
4 McCafferty at GSK that's dated April 26,  
5 2000?  
6

7 **A. Yes.**

8 Q. And is this letter discussing the  
9 reviewer comments that had been received  
10 in from the Journal of the American  
11 Medical Association after the draft  
12 manuscript had been submitted to it?  
13

14 **A. Yes.**

15 MR. DAVIS: All right. And then  
16 down at the bottom of that letter, can  
17 you read for the Jury's benefit what it  
18 says beginning with "After hearing".

19 THE WITNESS: "After hearing back  
20 from yourself and the three lead authors,  
21 I will address your comments, circulate  
22 the revised draft to all authors for  
23 their approval, and signed release forms  
24 for American Journal of Psychiatry."  
25

(BY MR. DAVIS):

1 Q. Okay. Now, by sending this out  
2 to Mr. McCafferty, were you telling him  
3 that you were seeking his input and  
4 comment about the drafts of the response  
5 to the reviewer comments received from  
6 the Journal of American Medical  
7 Association?

8  
9 MR. BRASLOW: Objection.

10 THE WITNESS: Was I what? I'm  
11 sorry. Can you repeat that.

12  
13 (BY MR. DAVIS):

14 Q. Yes. Were you telling -- were  
15 you soliciting -- by writing that in this  
16 letter, what were you informing Mr.  
17 McCafferty about?

18  
19 MR. BRASLOW: Objection.

20 THE WITNESS: That there was a  
21 delay and --

22 MR. DAVIS: No, I'm sorry. The  
23 paragraph I had you read where it says  
24 after hearing back.  
25

1 been marked as Defendant's Exhibit 11,  
2 and ask you by comparing that graphic  
3 that I put together, and comparing it  
4 against the last paragraph that we read  
5 into the record. Is that a true and  
6 accurate depiction of what is contained  
7 in that paragraph?

8 A. Yes.

9 Q. Okay. Thanks. You can put that  
10 aside. After looking at these various  
11 drafts and these communications that you  
12 have with the authors of the Keller  
13 article. How would you describe the  
14 amount of time and resources that the  
15 authors of the Keller article devoted to  
16 getting it published?  
17

18 MR. BRASLOW: Objection.

19 THE WITNESS: I can't answer. I  
20 don't know how long it would take them to  
21 read the article or to mark up the  
22 comments. I don't know.  
23

24 (BY MR. DAVIS):

25 Q. Okay. Do you believe that they

1 (BY MR. DAVIS):

2 Q. What information were you trying  
3 to communicate to Mr. McCafferty?  
4

5 MR. BRASLOW: Objection.

6 THE WITNESS: That it was going  
7 out to himself, Mr. McCafferty, and the  
8 three lead authors. And I was asking for  
9 comments from all four of them.  
10

11 (BY MR. DAVIS):

12 Q. And do you believe in fact that  
13 you sent this draft out to the three  
14 other lead authors referenced in the  
15 letter to in fact solicit comments back  
16 from them?

17 A. Again, I don't recall the actual  
18 act of doing that. But I would have to  
19 say based on this letter that I did  
20 that.  
21

22 (Defendant's Exhibit 11, marked)  
23

24 (BY MR. DAVIS):

25 Q. I'm going to show you what has

1 had substantial input into the contents  
2 of the article?  
3

4 MR. BRASLOW: Objection.

5 THE WITNESS: Yes, I do.  
6

7 (BY MR. DAVIS):

8 Q. How would you describe the level  
9 of their involvement with respect to the  
10 contents of the article?  
11

12 MR. BRASLOW: Objection.

13 THE WITNESS: How would I  
14 describe the?  
15

16 (BY MR. DAVIS):

17 Q. The level of involvement that the  
18 authors had with respect to the contents  
19 of the Keller article?  
20

21 MR. BRASLOW: Objection.

22 THE WITNESS: I recall a great  
23 deal of involvement.  
24

25 (Defendant's Exhibit 12, marked)

1  
2 (BY MR. DAVIS):  
3 Q. I'm going to hand you what is  
4 marked as Defendant's Exhibit 12, and ask  
5 you if you can identify that document for  
6 the record, please.

7 **A. This is a letter from the editor  
8 of the Journal of the American Medical  
9 Association to Dr. Keller.**

10 Q. So this is a letter from JAMA or  
11 the Journal of the American Medical  
12 Association?

13 **A. Yes.**

14 Q. And it's dated October 22,  
15 1999?

16 **A. It's very fuzzy. It's hard to  
17 tell. I can see October 22nd. I can't  
18 say with certainty what the year was.**

19 Q. All right. And is your name  
20 written at the top in someone's  
21 handwriting?

22 **A. Yes.**

23 Q. Okay. And do you recall  
24 receiving a copy of this?

25 **A. Do I recall receiving a copy of**

1 group."

2 MR. DAVIS: Can you read --

3  
4 (BY MR. DAVIS):

5 Q. Well, do you recall discussions  
6 with the authors about resubmitting the  
7 Keller article to another scientific  
8 journal?

9 **A. I don't recall specific  
10 conversations.**

11 Q. Okay. Do you know whether or not  
12 in fact the Keller article was submitted  
13 to the American Journal of Psychiatry?

14 **A. Yes.**

15 Q. You believe it was?

16 **A. Based on these documents, I think  
17 it was submitted.**

18 Q. Okay.

19 **A. I am a little fuzzy on that at  
20 this moment.**

21 Q. Okay. Has it been some time  
22 since you were involved in the process of  
23 whether or not it was submitted?

24 **A. It's been a long time.**  
25

1 **this? I don't recall.**

2 Q. Do you have any reason to doubt  
3 that you received a copy of it?

4 **A. No.**  
5

6 MR. DAVIS: All right. Now,  
7 there was a discussion earlier in the day  
8 about the fact the Journal of the  
9 American Medical Association did not  
10 accept for publication the Keller  
11 article. Can you look at the first  
12 paragraph of the letter, and read that  
13 for the Jury's benefit.

14 THE WITNESS: I will attempt to  
15 do that. It's very fuzzy. "We have  
16 completed our review of your manuscript.  
17 And report that we are unable to accept  
18 it for publication in JAMA. This --  
19 something -- is no reflection on the  
20 scientific quality of your manuscript,  
21 but the publication priorities of the  
22 journal are such that we -- something,  
23 something -- be extremely selective.  
24 However, we believe that your paper maybe  
25 well suited for another journal in our

1 (Defendant's Exhibit 13, marked)  
2

3 (BY MR. DAVIS):

4 Q. Okay. I'm going to hand you  
5 what has been marked as Defendant's  
6 Exhibit 13, and ask if you can identify  
7 that document for the record, please?

8 **A. This is a letter from myself to  
9 Jim McCafferty.**

10 Q. Okay. Is it a true and accurate  
11 copy of the letter?

12 **A. I don't recall.**

13 Q. Does it look like it's a true and  
14 correct copy of the letter?

15 **A. It looks to be an authentic.**

16 Q. Is that your signature at the  
17 bottom?

18 **A. Yes, it is.**

19 Q. Was this document prepared during  
20 the ordinary course of business of STI?

21 **A. Yes, it was.**  
22

23 MR. DAVIS: Can you read for the  
24 Jury's benefit what the first paragraph  
25 says.

<p style="text-align: right;">Page 402</p> <p>1 THE WITNESS: "Enclosed is the 2 draft rebuttal to the JAMA reviewer 3 comments for PAR 329." 4 5 (BY MR. DAVIS): 6 Q. Is that Study 329? 7 A. Yes. 8 9 MR. DAVIS: Okay. 10 THE WITNESS: "As was agreed in 11 the conference call with Drs. Keller, 12 Ryan and Strober on November 15th we will 13 1) Seek approval from the authors on the 14 planned revisions to be made. 2) Will 15 make the revisions. And 3) Will submit 16 the manuscript to the American Journal of 17 Psychiatry." 18 19 (BY MR. DAVIS): 20 Q. Okay. Now, with respect to the 21 first two items. Seeking approval from 22 the authors on the planned -- let me 23 backup for a second. 24 Does this refresh your 25 recollection that there was a conference</p>	<p style="text-align: right;">Page 404</p> <p>1 Keller article? 2 3 MR. BRASLOW: Objection. 4 THE WITNESS: To the extent that 5 I took the clinical study report, 6 whatever document they gave me, and 7 transferred that into a manuscript. That 8 is how I controlled the contents. 9 10 (BY MR. DAVIS): 11 Q. But let me ask it a different 12 way. In terms of controlling the 13 contents of the article -- let me back 14 up. 15 In terms of controlling the 16 contents of the article, over what the 17 authors of the article wanted. Did you 18 or STI do that? 19 20 MR. BRASLOW: Objection. 21 THE WITNESS: No. 22 MR. DAVIS: Okay. 23 THE WITNESS: Not to my 24 recollection, no. 25</p>
<p style="text-align: right;">Page 403</p> <p>1 call with you, Dr. Keller, Dr. Ryan, and 2 Dr. Strober some time on November 15, 3 1999? 4 A. I do recall conference calls, and 5 this does help me remember one of them. 6 Q. Okay. And as part of that 7 conference call, was there discussion 8 about seeking approval for the authors of 9 planned revisions to be made to the 10 manuscript? 11 A. I don't recall what we talked 12 about in the conference call. I can only 13 tell you what is in this letter. 14 Q. All right. Do you have any 15 reason to doubt that you did not seek 16 approval from the authors on the planned 17 revisions to be made to the manuscript? 18 A. No. 19 Q. Do you have any reason to doubt 20 that the revisions that were discussed 21 with the authors were not made to the 22 manuscript? 23 A. No. 24 Q. Okay. Now did either STI or you 25 control the contents of what was in the</p>	<p style="text-align: right;">Page 405</p> <p>1 (BY MR. DAVIS): 2 Q. During the entire time that the 3 Keller article was being prepared for 4 publication, did you ever get the sense 5 that any GSK employee was attempting to 6 assert improper influence over the 7 contents of the article? 8 A. My only contact with regard to 9 content was with Jim McCafferty, and I 10 never felt that way. 11 Q. Did Mr. McCafferty ever say to 12 you we have to present the data in this 13 way and not in this way. Otherwise it 14 will hurt Paxil's sales or harm the 15 profile of the product? 16 A. I don't recall any conversation 17 like that. 18 Q. Is that a conversation that you 19 think would stand out in your mind? 20 21 MR. BRASLOW: Objection. 22 THE WITNESS: It's hard to say. 23 I don't recall him saying that. 24 25 (BY MR. DAVIS):</p>

1 Q. And did you ever get the  
2 impression that Mr. McCafferty was trying  
3 to spin the results of Study 329, to make  
4 the data on the adolescent depression  
5 study look better than what the actual  
6 results showed?

7 **A. My recollection was that Jim  
8 McCafferty bent over backwards making  
9 sure that everything was accurate and  
10 above board.**

11 Q. Did you ever get the impression  
12 that any of the authors of the Keller  
13 article such as Dr. Ryan, Dr. Strober,  
14 Dr. Kutcher, Dr. Wagner were trying to  
15 spin the results of Study 329 in such a  
16 way to make Paxil look better in treating  
17 adolescent depression than what the  
18 actual results showed?

19 **A. Not to my recollection.**

20 Q. And did you ever try to present  
21 data on Study 329 in such a way to make  
22 it look better than what the actual data  
23 showed?

24 **A. No.**  
25

1 (Defendant's Exhibit 14, marked)  
2

3 (BY MR. DAVIS):

4 Q. Okay. I'm going to hand you what  
5 has been marked as Exhibit 14, and ask if  
6 you can identify that document for the  
7 record.

8 **A. This is a fax to Jim McCafferty  
9 from myself. Dated August 16, 2000.**

10 Q. And does it attach comments from  
11 the Journal of the American Academy of  
12 Child and Adolescent Psychiatry on the  
13 manuscript that was presented to them?

14 **A. Yes.**

15 Q. Okay. And let's turn a little  
16 bit. You sent these on to Jim  
17 McCafferty; is that right?

18 **A. Yes.**

19 Q. Okay. And you did that in a fax  
20 that is dated August 16, 2000?

21 **A. Yes.**

22 Q. And does the cover letter that  
23 was received in from the Journal of  
24 American Academy of Child and Adolescent  
25 Psychiatry, which was sent to Dr. Keller,

1 say that that journal will further  
2 consider the manuscript if certain  
3 changes were made?

4 **A. Yes.**  
5

6 MR. DAVIS: Okay. I want to turn  
7 your attention to a couple of the  
8 comments. If you could find the reviewer  
9 comments for reviewer number 216.  
10 Towards the back. I think it's page  
11 eight of the fax.

12 THE WITNESS: Okay.  
13

14 (BY MR. DAVIS):

15 Q. Down at the bottom of the page --  
16 well let me back up. These are reviewer  
17 comments that were received in from the  
18 reviewers at the Journal of the American  
19 Academy of Child and Adolescent  
20 Psychiatry; right?

21 **A. Yes.**  
22

23 MR. DAVIS: Okay. And can you  
24 make out what it says down in the bottom  
25 of that for results.

1 THE WITNESS: This is especially  
2 blurry.

3 MR. DAVIS: Okay.

4 THE WITNESS: It says, Results  
5 based on the description, I maybe more --  
6 it maybe more appropriate to --  
7 something -- in the adverse effects  
8 section that prevention.  
9

10 MR. BRASLOW: Objection. How can  
11 she read it?

12 MR. DAVIS: Let me see if I can  
13 help you, Ms. Laden. Let me hand you a  
14 cleaner copy to allow you to read it.  
15

16 (BY MR. DAVIS):

17 Q. Do you see that what I have  
18 presented to you is a cleaner copy of the  
19 exact same reviewer comments by reviewer  
20 number 216?

21 **A. Yes.**  
22

23 MR. DAVIS: Okay. If you can  
24 look down at that cleaner copy of the  
25 results section. I've got some

Page 410	Page 412
<p>1 highlighting on there. Could you please 2 read in what the reviewer says. 3 THE WITNESS: "Based on the 4 descriptions, it may be more appropriate 5 to note in the adverse effects subsection 6 that Paroxetine was generally or usually 7 well tolerated" 8 MR. DAVIS: Now I want you to 9 take the Plaintiff's Exhibit 10. Which 10 is a copy of the published Keller 11 article, and turn to the adverse events 12 section, please. I believe it's on page 13 768. 14 THE WITNESS: Yes. 15 MR. DAVIS: Okay. And underneath 16 where it says adverse events -- adverse 17 effects. Can you read for the Jury's 18 benefit what the final published article 19 said? In the first sentence. 20 THE WITNESS: "Paroxetine was 21 generally well tolerated in this 22 adolescent population, and most adverse 23 effects were not serious." 24 25 (BY MR. DAVIS):</p>	<p>1 Q. Yes. Is that Defendant's Exhibit 2 14? 3 A. Yes. 4 5 MR. DAVIS: Okay. Turn to the 6 second reviewer's comments. 7 THE WITNESS: That would be fax 8 page what? 9 MR. DAVIS: Page 10. 10 THE WITNESS: Okay. 11 MR. DAVIS: Can you read that 12 comment in from the reviewer at the 13 journal. The second paragraph of that, 14 please. 15 THE WITNESS: "This study has 16 multiple strengths. Including large 17 sample size, randomized controlled 18 design, and the use of standardized 19 measures addressing multiple domains. 20 Moreover the study addresses an important 21 area of clinical child psychiatry, the 22 efficacy of antidepressant therapy in 23 depressed youth. The results are clearly 24 presented. Denoting? There is a word I 25 cant --</p>
<p>Page 411</p> <p>1 Q. Now, is that statement that 2 appeared in the final published article, 3 consistent with the reviewers comment 4 from the Journal of American Academy of 5 Child and Adolescent Psychiatry which you 6 read into the record? 7 A. There is the same language. 8 Q. Do you believe -- well strike 9 that. 10 11 VIDEOGRAPHER: The time is 7:37. 12 We are off the record. 13 14 (Off the record) 15 16 (Back on the record) 17 18 VIDEOGRAPHER: We are back on the 19 record. The time is 7:39. 20 21 (BY MR. DAVIS): 22 Q. Okay. Turning back to the fax; 23 August 15, 2000 fax. I think it's 24 Defendant's Exhibit 14. Am I correct? 25 A. That is an August 16, 2000 fax?</p>	<p>Page 413</p> <p>1 2 MR. DAVIS: Demonstrating? Is 3 that Demonstrating? 4 MR. MARGOLIS: Documenting. 5 MR. DAVIS: Documenting. Thank 6 you. 7 THE WITNESS: Documenting looks 8 closer. "Documenting that Paroxetine has 9 efficacy in adolescent depression is an 10 important finding." 11 12 (BY MR. DAVIS): 13 Q. Okay. With respect to the 14 comment by this reviewer, that the 15 results are clearly presented. Do you 16 believe that the results are clearly 17 presented in the final published article? 18 19 MR. BRASLOW: Objection. 20 21 (BY MR. DAVIS): 22 Q. Based upon your review of the 23 clinical trial report that you received 24 from GSK, and the input that you received 25 from the outside authors about the</p>

<p style="text-align: right;">Page 414</p> <p>1 contents of the article? 2 3 MR. BRASLOW: Objection. 4 THE WITNESS: I again feel I 5 might need to be an expert to say whether 6 they were clearly presented. 7 8 (BY MR. DAVIS): 9 Q. Okay. Ms. Laden, how many -- 10 rough estimate. How many hours do you 11 think you spent incorporating the authors 12 comments and revisions to the Keller 13 article? 14 <b>A. Many. I can't give you an</b> 15 <b>estimate.</b> 16 Q. When you were receiving in 17 comments from them throughout the process 18 of preparing the draft manuscript. When 19 you got comments in from them, would it 20 take up the majority of your time? 21 22 MR. BRASLOW: Objection. 23 THE WITNESS: I was also doing a 24 lot of other projects. No, I don't 25 recall exactly. This was a time</p>	<p style="text-align: right;">Page 416</p> <p>1 <b>the question, please.</b> 2 Q. Sure. Is this E-mail from Mr. 3 McCafferty, which you're copied on. 4 Which was sent to several of the 5 co-authors of the Keller article, discuss 6 that the Journal of the American Academy 7 of Child and Adolescent Psychiatry has 8 received in two letters commenting on the 9 findings of the Keller article? 10 <b>A. Yes.</b> 11 Q. And does it say at the bottom 12 that -- does Mr. McCafferty ask at the 13 bottom that if these outside scientists 14 could provide thoughts on the response 15 that Sally Laden and he could summarize 16 the comments? 17 <b>A. Yes.</b> 18 Q. Okay. And was this another 19 example of the psychiatrists and 20 scientists who were co-authors of the 21 Keller article, having input and 22 involvement in responding to letters that 23 were received in from the Journal about 24 the publication? 25</p>
<p style="text-align: right;">Page 415</p> <p>1 consuming project. I can't quantitate 2 it. 3 4 (Defendant's Exhibit 15, marked) 5 6 (BY MR. DAVIS): 7 Q. I'm going to hand you what has 8 been marked as Defendant's Exhibit 15, 9 and ask if you can identify that document 10 for the record, please? 11 <b>A. This is an E-mail from Jim</b> 12 <b>McCafferty to Drs. Wagner, Strober, and</b> 13 <b>Ryan. And CC'd Barbara Ryan at Brown and</b> 14 <b>myself.</b> 15 Q. Okay. And is it dated September 16 14, 2001? 17 <b>A. Yes.</b> 18 Q. And does it describe that the 19 Journal of the American Academy -- excuse 20 me. The Journal of the American Academy 21 of Child and Adolescent Psychiatry has 22 received in some letters concerning the 23 reported results for Study 329 that was 24 published in the Keller article? 25 <b>A. Can I read it? Can you repeat</b></p>	<p style="text-align: right;">Page 417</p> <p>1 MR. BRASLOW: Objection. 2 THE WITNESS: This is an 3 example. 4 5 (Defendant's Exhibit 16, marked) 6 7 (BY MR. DAVIS): 8 Q. Okay. I'm going to hand you what 9 has been marked as Defendant's Exhibit 10 16, and ask if you can identify this 11 document for the record? 12 <b>A. This is an E-mail from myself to</b> 13 <b>Barbara Ryan at Brown. Dated October 2,</b> 14 <b>2001.</b> 15 Q. Why are you sending this E-mail 16 to Dr. Barbara Ryan at Brown? 17 <b>A. It's my recollection that she was</b> 18 <b>an assistant to Dr. Keller.</b> 19 Q. I'm sorry. So she's not a 20 physician? 21 <b>A. Not to my knowledge.</b> 22 Q. Okay. So she's Dr. Keller's 23 assistant? 24 <b>A. My recollection is yes.</b> 25 Q. Okay. In this E-mail you inform</p>

<p style="text-align: right;">Page 418</p> <p>1 Dr. Keller that there is a response -- a 2 draft response letter to the Journal of 3 American Academy of Child and Adolescent 4 Psychiatry in which Jim McCafferty, Dr. 5 Karen Wagner, and Dr. Neil Ryan have all 6 seen and approved? 7 <b>A. Yes.</b> 8 9 (Defendant's Exhibit 17, marked) 10 11 (BY MR. DAVIS): 12 Q. Okay. I'm going to hand you what 13 has been marked as Defendant's Exhibit 14 17, and ask if you can identify that 15 document for the record? 16 <b>A. This is a cover memo on Brown 17 University letter head to Jim McCafferty 18 and myself from Dr. Keller.</b> 19 Q. What is the reason for Dr. Keller 20 sending the fax? 21 22 MR. BRASLOW: Objection. 23 THE WITNESS: It looks that Dr. 24 Keller is okaying the response to the 25 letter to the editors. Letters to the</p>	<p style="text-align: right;">Page 420</p> <p>1 Marty." 2 3 (Defendant's Exhibit 18, marked) 4 5 (BY MR. DAVIS): 6 Q. Let me hand you what has been 7 marked as Defendant's Exhibit 18, and ask 8 you if you can identify that, please? 9 <b>A. This looks like an E-mail from 10 Dr. Ryan to Dr. Keller, myself, Dr. 11 Strober, Jim McCafferty, Dr. Keller -- 12 and Dr. Keller.</b> 13 Q. Okay. And is this concerning 14 another letter that has been received in 15 from the Journal of the American Academy 16 of Child and Adolescent Psychiatry? 17 <b>A. This is concerning a letter to 18 the journal. I don't know if it's the 19 same as in the previous.</b> 20 Q. Who prepared the initial draft of 21 the response according to that E-mail? 22 <b>A. It is signed -- well the names of 23 Dr. Keller and Dr. Ryan appear at the 24 end.</b> 25 Q. Okay. Does the E-mail -- the</p>
<p style="text-align: right;">Page 419</p> <p>1 editor. 2 3 (BY MR. DAVIS): 4 Q. Okay. And does the attachment to 5 the fax show that Jim McCafferty was 6 involved in preparing the response? 7 <b>A. Yes.</b> 8 Q. Okay. And Mr. McCafferty is one 9 of the co-authors of the Keller 10 article? 11 <b>A. Yes.</b> 12 13 MR. DAVIS: And what does the fax 14 from Dr. Keller say about the draft 15 response. 16 THE WITNESS: This cover? 17 MR. DAVIS: Yes. 18 THE WITNESS: "To Jim McCafferty 19 and Sally Laden. This looks great to me. 20 If Sally could prepare a brief cover 21 letter, I could send this to the Journal 22 along with a statement that we would like 23 to respond to the two letters separately, 24 and will send another letter in a few 25 weeks if that is okay. Many thanks.</p>	<p style="text-align: right;">Page 421</p> <p>1 original E-mail. Did that come from Dr. 2 Ryan where it says Draft 1? 3 <b>A. Yes.</b> 4 Q. Okay. Does that refresh your 5 recollection that Dr. Ryan prepared the 6 initial draft of the response? 7 <b>A. Honestly, I can't remember.</b> 8 Q. Did you have any involvement in 9 preparing that draft responsible? 10 <b>A. I don't remember.</b> 11 Q. Okay. Did you receive a copy of 12 the E-mail that Dr. Ryan sent out? 13 <b>A. This E-mail?</b> 14 Q. Yes? 15 <b>A. I have to assume so, because I am 16 copied on it.</b> 17 18 MR. DAVIS: Okay. Can you pull 19 Plaintiff's Exhibit 10 again. Which is 20 the draft of the Keller article. 21 22 (BY MR. DAVIS): 23 Q. Excuse me. That is the published 24 copy of the Keller article; is that 25 right?</p>

<p style="text-align: right;">Page 422</p> <p>1       <b>A. Yes.</b>  2       Q. On the very first page of that  3 article, if you can look down into the  4 italicized part at the bottom of the  5 right. Do you see that you're identified  6 as someone who provided editorial  7 assistance?  8       <b>A. Yes.</b>  9       Q. And that was your role with  10 respect to the preparation of the Keller  11 manuscript?  12       <b>A. Yes.</b>  13       Q. And in the abstract section of  14 the published article, does that identify  15 the two primary outcome measures?  16       <b>A. Yes.</b>  17       Q. Okay. And are those the same  18 primary outcome measures that are  19 identified in the clinical report that  20 Plaintiff's counsel showed you earlier?  21       <b>A. Yes.</b>  22       Q. Okay. And with respect to the  23 depression, does the abstract also  24 describe that other depression related  25 variables were assessed?</p>	<p style="text-align: right;">Page 424</p> <p>1 related variables that were identified in  2 the abstract?  3       <b>A. Yes.</b>  4       Q. Okay.  5       <b>A. Oh, wait. The two primary</b>  6 <b>variables are there. Yes.</b>  7  8           (Defendant's Exhibit 19, marked)  9  10          (Defendant's Exhibit 20, marked)  11  12          (BY MR. DAVIS):  13        Q. I'm going to hand you what has  14 been marked as Exhibits 19 and 20. Which  15 are graphics that I prepared.  16        And ask you if they accurately  17 and fairly depict what is in number on --  18 let me start again.  19        With respect to Exhibit 19, does  20 that fairly and accurately depict the  21 primary outcome measures that are  22 identified in the abstract of the  23 published Keller article that you read  24 earlier?  25       <b>A. Yes.</b></p>
<p style="text-align: right;">Page 423</p> <p>1       <b>A. Yes.</b>  2       Q. Okay. Now, do those other  3 variables include the HAM-D depressed  4 mood item?  5       <b>A. Yes.</b>  6       Q. The depression item of the  7 K-SADS-L?  8       <b>A. Yes.</b>  9       Q. Rating scale?  10       <b>A. Yes.</b>  11       Q. And then the clinical global  12 impression score of one or two?  13       <b>A. Yes.</b>  14       Q. And the nine item depression  15 sub-scale of K-SADS-L?  16       <b>A. Yes.</b>  17       Q. And the means CGI improvement  18 score?  19       <b>A. Yes.</b>  20       Q. And if you turn to the efficacy  21 and safety evaluation section. Does this  22 section which is describing the method by  23 which the study was conducted. Does that  24 also describe the two primary outcome  25 measures, as well as the other depression</p>	<p style="text-align: right;">Page 425</p> <p>1       Q. Okay. With respect to Exhibit  2 20, does it fairly and accurately depict  3 the primary and secondary depression  4 related variables that are identified in  5 the safety and -- excuse me. The  6 efficacy and safety evaluation section  7 that is on page 764 of the Keller  8 article?  9       <b>A. Yes.</b>  10  11       MR. DAVIS: Okay. And if you  12 turn to table 2 that is in the article  13 itself. Does that article identify the  14 depression related variables that are  15 discussed in the abstract and also the --  16 let me strike that.  17       You got questions asked earlier  18 about the adverse events that were  19 described in the Keller article. I want  20 you to turn to page 769 if you could of  21 the article. Where it discusses the  22 adverse events.  23  24       (BY MR. DAVIS):  25       Q. Do you see in the left-hand</p>

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1 column that the article describes that  
 2 Emotional Lability -- the term Emotional  
 3 Lability includes both suicidal ideation  
 4 and gestures?  
 5 **A. Yes.**  
 6 Q. Okay. And is the term Emotional  
 7 Lability -- I mean in terms of what falls  
 8 underneath that category. Is that  
 9 identified for the readers?  
 10 **A. The paper says Emotional**  
 11 **Lability. And in parenthesis it says**  
 12 **(eg: suicidal ideations/gestures).**  
 13 Q. Did the scientists and physicians  
 14 who were the authors of the Keller  
 15 article, have substantial input into the  
 16 Keller article?  
 17  
 18 MR. BRASLOW: Objection.  
 19 THE WITNESS: Can you repeat  
 20 that.  
 21 MR. DAVIS: Sure.  
 22  
 23 (BY MR. DAVIS):  
 24 Q. Did the scientists and physicians  
 25 who were the authors of the Keller

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1 article, have substantial input into the  
 2 Keller article?  
 3  
 4 MR. BRASLOW: Objection.  
 5 THE WITNESS: Yes.  
 6  
 7 (BY MR. DAVIS):  
 8 Q. Did the scientists and physicians  
 9 who were the authors of the Keller  
 10 article substantially revise, draft,  
 11 prepare by STI or you?  
 12  
 13 MR. BRASLOW: Objection.  
 14 THE WITNESS: Yes.  
 15  
 16 (BY MR. DAVIS):  
 17 Q. Did the scientists and physicians  
 18 who were the authors of the Keller  
 19 article tell you and others at STI how  
 20 they wanted to describe the efficacy  
 21 results in the article?  
 22 **A. I don't recall.**  
 23 Q. Did the scientists and physicians  
 24 who were the authors of the article tell  
 25 you or others at STI how they wanted to

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1 describe the safety results of the  
 2 article?  
 3 **A. I don't recall that, no.**  
 4 Q. Were you -- again, were you  
 5 looking to the outside authors to inform  
 6 you of how the safety and efficacy  
 7 results would be described in the  
 8 article?  
 9  
 10 MR. BRASLOW: Objection.  
 11 THE WITNESS: I prepared the  
 12 drafts of this paper based on the  
 13 documents provided to me, and revised  
 14 based on the comments from the authors.  
 15  
 16 (BY MR. DAVIS):  
 17 Q. Did those comments include both  
 18 the comments both on the safety and  
 19 efficacy results of the study?  
 20 **A. I believe so yes.**  
 21 Q. Did the scientists and physicians  
 22 who were the authors of the Keller  
 23 article just rubber stamp any draft of  
 24 the article that you or STI prepared?  
 25

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1 MR. BRASLOW: Objection.  
 2 THE WITNESS: Not every author  
 3 looked at every draft. But the primary  
 4 authors were very heavily involved with  
 5 revising the manuscript.  
 6  
 7 (BY MR. DAVIS):  
 8 Q. Okay. But by rubber stamp, what  
 9 I'm talking about is that the authors  
 10 don't spend any time looking or analyzing  
 11 the draft. They just say it's got my  
 12 name on it. It looks good to me.  
 13  
 14 MR. BRASLOW: Objection.  
 15 THE WITNESS: I can't say what  
 16 they did or did not do.  
 17  
 18 (BY MR. DAVIS):  
 19 Q. But did you ever prepare the  
 20 draft with the idea in mind that all they  
 21 would do was just basically not look at  
 22 it, not critique it, and not analyze it  
 23 to give you their best input about how  
 24 the results should be described?  
 25

1 MR. BRASLOW: Objection.

2 THE WITNESS: I can't answer -- I  
3 can't comment on what their input best or  
4 otherwise was. But it was our job to  
5 obtain comments from the authors, and  
6 make sure that their comments and wishes  
7 were reflected in the subsequent  
8 drafts.

9  
10 (Defendant's Exhibit 21 not marked)

11 (Defendant's Exhibit 22, marked)

12 MR. DAVIS: Okay. Let me hand  
13 you what has been marked as Defendant's  
14 Exhibit 22.

15 (BY MR. DAVIS):

16 Q. Can you identify that document  
17 for the record, please?

18 **A. This looks like an E-mail from  
19 Sheila Hood to Sherri Jaffe and Holly  
20 White.**

21 Q. Okay. And below that is there an  
22 E-mail string between you and Matt Battin  
23

1 at GlaxoSmithKline?

2 **A. Yes.**

3 Q. Okay. Can you read what -- and  
4 what is the date of this E-mail?

5 **A. The date from Sheila Hood is  
6 April 27, 2001.**

7 Q. What is the date of the E-mail  
8 between you and Matt Battin?

9 **A. Matt Battin's E-mail is dated  
10 April 25, 2001.**

11 Q. So does this E-mail exchange  
12 occur before the publication of the  
13 Keller article?

14 **A. Yes.**

15 MR. DAVIS: And can you read into  
16 the record what Mr. Battin says.

17 THE WITNESS: "Sally because Dr.  
18 Keller is a member of our advisory board,  
19 and an influential KOL, we will support  
20 his request to purchase 500 reprints."  
21

22 (BY MR. DAVIS):

23 Q. Now, if you look at the article  
24 that's identified -- that has been marked  
25

1 as Exhibit 10. Which is the published  
2 article authored by Dr. Keller and  
3 others. Does it say that requests for  
4 reprints are to come to Dr. Keller?

5 **A. Yes.**

6 Q. Okay. And so is that unusual and  
7 out of the ordinary that the person who  
8 is receiving requests for reprints would  
9 ask that those reprints be sent to him,  
10 and that that be funded so that he could  
11 have a collection of reprints?

12 **A. Dr. Keller is the corresponding  
13 author. Which means he is the one people  
14 contact for reprints. It works all sorts  
15 of different ways. Often reprints, a  
16 small supply are provided free to the  
17 corresponding author.**

18 MR. DAVIS: Okay. Can you read  
19 the next sentence in Mr. Battin's E-mail  
20 dated April 25, 2001.

21 THE WITNESS: It says, "Terri,  
22 since this info is off label, we won't be  
23 able to use in promotion. However, we  
24 might be able to work with Traci Lee to  
25

1 have reprints sent out as part of our med  
2 query on the use of Paxil in children."

3 (BY MR. DAVIS):

4 Q. Okay. And in this E-mail is  
5 Mr. Battin saying to those people on this  
6 E-mail, including yourself, that the  
7 information in the Keller article  
8 concerns an off label use. And it won't  
9 be able to be used in promotion?

10 **A. The memo says, "Since this info  
11 is off label, we won't be able to use in  
12 promotion."**

13 Q. Okay. And when you were putting  
14 together -- working at the direction of  
15 the authors of the Keller article, did  
16 you ever -- were you ever doing it for  
17 purposes of promoting Paxil for use in  
18 pediatric patients?  
19

20 MR. BRASLOW: Objection.

21 THE WITNESS: The purpose of STI  
22 being hired for this project was to work  
23 with the authors, and take data provided  
24 by GSK. Condense it into a manuscript.  
25

1 Work with the authors in making  
2 revisions. And work with them through  
3 the process.

4  
5 (BY MR. DAVIS):

6 Q. I know. But in terms of what STI  
7 or you were doing. Was it ever for the  
8 purposes of promoting Paxil in the  
9 pediatric population?

10  
11 MR. BRASLOW: Objection.

12 THE WITNESS: No.

13  
14 (BY MR. DAVIS):

15 Q. And at any time did Mr.  
16 McCafferty or anyone at GlaxoSmithKline  
17 say to you, that the reason we want to  
18 have the Keller article published is to  
19 promote either directly or indirectly  
20 Paxil for use in the pediatric  
21 population?

22 **A. I don't recall that  
23 conversation.**

24 Q. During the time that you provided  
25 editorial assistance on the Keller

1 (BY MR. DAVIS):

2 Q. Okay. And during the time that  
3 you were providing editorial assistance  
4 on the Keller article, did you send out  
5 multiple drafts to the co-authors for  
6 their comments and analysis?

7 **A. There were multiple drafts  
8 involved in this project.**

9 Q. And were those sent out to the  
10 co-authors for their comment and  
11 analysis?

12 **A. Yes.**

13 Q. Okay. Now, during the time that  
14 you provided editorial assistance on the  
15 Keller article, did you receive multiple  
16 revisions, changes and edits from the  
17 co-authors on the drafts you circulated  
18 their comments?

19  
20 MR. BRASLOW: Objection.

21 THE WITNESS: Yes.

22  
23 (BY MR. DAVIS):

24 Q. And during the time you provided  
25 editorial assistance on the Keller

1 article, did you have multiple telephone  
2 calls and E-mail exchanges with the named  
3 authors about the contents of the  
4 article?

5  
6 MR. BRASLOW: Objection. Asked  
7 and answered.

8 THE WITNESS: Yes.

9  
10 (BY MR. DAVIS):

11 Q. Okay. During the time that you  
12 provided editorial assistance of the  
13 Keller article, did you receive  
14 instructions and advice from the named  
15 authors about how to describe the results  
16 of Study 329 which are reflected in the  
17 Keller article?

18  
19 MR. BRASLOW: Objection.

20 THE WITNESS: They commented on a  
21 draft. And it was my job to address  
22 those comments, and turn around a  
23 subsequent draft reflecting their  
24 comments.

1 article, did you work a host of hours on  
2 revising the drafts of the article to  
3 incorporate the authors comments,  
4 analysis, and changes?

5  
6 MR. MARGOLIS: Objection.

7 THE WITNESS: I can't tell you  
8 how many hours. I can't even begin to  
9 guess how many hours in terms of  
10 estimating.

11 MR. DAVIS: And I'm not trying to  
12 tell you -- ask you to tell me it was ten  
13 hours or five.

14  
15 (BY MR. DAVIS):

16 Q. But do you consider that the work  
17 that you did in terms of revising the  
18 draft of the article to incorporate the  
19 authors comments, their analysis, and  
20 their changes. Is that a host of hours  
21 in your mind?

22  
23 MR. MARGOLIS: Objection.

24 THE WITNESS: It was a lot of  
25 time.

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<p>1 2 (BY MR. DAVIS): 3 Q. If STI or you had ghost written 4 the Keller article, would you have 5 then -- would there have been any need to 6 do any of this work that we have been 7 discussing? 8 9 MR. MARGOLIS: Objection. 10 THE WITNESS: Can you tell me 11 what you mean by "ghost written". 12 MR. DAVIS: Ghost written where 13 the authors of the article have no input 14 at all into the contents of the article. 15 16 MR. BRASLOW: Objection. 17 THE WITNESS: And then can you 18 repeat the question, please. 19 MR. DAVIS: Sure. 20 21 (BY MR. DAVIS): 22 Q. With that identification of ghost 23 writing in mind. If STI or you had ghost 24 written the Keller article, would there 25 have been any need to do any of the items</p>	<p>1 doing all of this coordination with the 2 authors if you were a ghost writer for 3 the Keller article? 4 5 MR. MARGOLIS: Objection. 6 THE WITNESS: I can't answer that 7 question. 8 9 (BY MR. DAVIS): 10 Q. Why can't you answer that? 11 <b>A. Because I don't believe I was a 12 ghost writer.</b> 13 Q. Were you ever instructed by 14 anyone at GSK to publish the results of 15 Study 329 in the Keller article for the 16 purposes of promoting or marketing Paxil 17 in pediatric patients? 18 19 MR. BRASLOW: Objection. 20 THE WITNESS: I don't recall 21 that. 22 23 (BY MR. DAVIS): 24 Q. Okay. Did you ever get the 25 impression from anyone in all the time</p>
Page 439	Page 441
<p>1 that we discussed in terms of your 2 editorial assistance? 3 4 MR. BRASLOW: Objection. 5 THE WITNESS: That's a hard 6 question to answer, because that didn't 7 happen. 8 9 (BY MR. DAVIS): 10 Q. Is it your testimony that you did 11 not ghost Study 329 -- well, excuse me. 12 Is it your testimony that you did not 13 ghost write the Keller article, which was 14 published in the journal of the American 15 Academy of Child and Adolescent 16 Psychiatry? 17 18 MR. MARGOLIS: Objection. 19 THE WITNESS: Based on your 20 definition of ghost writing, 21 absolutely. 22 23 (BY MR. DAVIS): 24 Q. Would you have bothered to waste 25 your time, your effort, and your energy</p>	<p>1 that you were dealing with individuals at 2 GlaxoSmithKline on a variety of projects, 3 that they were trying to get the results 4 of 329 published in the Keller article 5 for the purposes of direct or indirect 6 promotion of Paxil in the pediatric 7 population? 8 9 MR. MARGOLIS: Objection. 10 THE WITNESS: All I know is what 11 we were hired to do. But I mean, that 12 was the flow of information. 13 14 (BY MR. DAVIS): 15 Q. And was that STI ever hired for 16 the purpose of promoting Paxil, either 17 directly or indirectly, in the pediatric 18 population by way of getting the Keller 19 article published? 20 21 MR. BRASLOW: Objection. 22 THE WITNESS: That was not our 23 job. 24 25 (BY MR. DAVIS):</p>

1 Q. At any time that you were working  
2 on providing editorial assistance to the  
3 Keller article, did you ever -- did  
4 anyone ever instruct you to spin only  
5 positive data, and downplay or hide  
6 negative data?

7 **A. Not to my recollection.**

8 Q. Do you believe that you tried  
9 your best to present the data from Study  
10 329 in a fair and balanced manner?

11 MR. BRASLOW: Objection.

12 THE WITNESS: That is how I try  
13 to do my work. So I would have to say  
14 "yes".

15 (BY MR. DAVIS):

16 Q. Okay. And if anyone ever  
17 instructed you to present only positive  
18 data, and downplay or hide negative data  
19 would you have done it?

20 MR. BRASLOW: Objection.

21 THE WITNESS: That didn't happen  
22 to my recollection. So I don't know what

1 I would have done. I certainly hope I  
2 would have said "no".

3 MR. DAVIS: Can you turn to  
4 Plaintiff's Exhibit 2. Okay.

5 (BY MR. DAVIS):

6 Q. Does this document say -- there  
7 is some questions there about what was  
8 discussed at this particular advisory  
9 board meeting that you prepared this  
10 draft agenda for. Do you remember those  
11 discussions?

12 **A. You mean discussions today?**

13 Q. Yes, this morning?

14 **A. Yes, I do.**

15 Q. Okay. Now, what is the date of  
16 that advisory committee meeting?

17 **A. September 29, 1993.**

18 Q. Okay. And does that document in  
19 anyway say anything about promoting Paxil  
20 for use in patients under 18?

21 THE WITNESS: This entire  
22 document?

23 MR. DAVIS: Yes. Let's turn to

1 the agenda. Let's go to the agenda. The  
2 draft agenda that is described there.

3 (BY MR. DAVIS):

4 Q. Okay. If you can look through  
5 the agenda. Does it say anything about  
6 promoting Paxil for use in pediatric  
7 patients?

8 **A. Pediatric patients are not  
9 mentioned.**

10 Q. Okay. Does it say anything about  
11 seeking input from others about promoting  
12 Paxil for any off label or unapproved  
13 use?

14 **A. No.**

15 Q. Is it your recollection that this  
16 Advisory Board meeting in 1993 was  
17 dominated by discussions of scientific  
18 data?

19 MR. BRASLOW: Objection.

20 THE WITNESS: It's hard to  
21 remember this meeting. It's a long time  
22 ago. My recollection is that the  
23 scientists at the meeting wanted to talk

1 about the data. They wanted to talk  
2 about science. They wanted to talk about  
3 studies.

4 (BY MR. DAVIS):

5 Q. For other Advisory Board  
6 meetings, if you had other Advisory Board  
7 meetings that you attended, was that also  
8 true?

9 MR. BRASLOW: Objection.

10 THE WITNESS: It's hard for me to  
11 remember. Distinguish Advisory Board  
12 meetings one from the other. But my  
13 overall recollection is that I do  
14 remember from this someone said we don't  
15 care about colors or pretty colors. I  
16 want to talk about the data. And that is  
17 my overriding recollection of the  
18 scientific Advisory Board that I was  
19 involved with.

20 MR. DAVIS: Okay. Let's turn to  
21 Plaintiff's Exhibit three.

22 (BY MR. DAVIS):

1 Q. This is a single-page slide. Do  
2 you see that?

3 A. Yes.

4 Q. And does this document say  
5 anything about using medical literature  
6 or posters to promote Paxil for off label  
7 or unapproved uses?

8 A. No.

9 Q. Does this document say anything  
10 about using medical literature or posters  
11 for the purpose of promoting Paxil in  
12 pediatric patients under 18?

13 A. No.

14 Q. Any time that you worked on a  
15 poster for GlaxoSmithKline, did you ever  
16 get the impression that the purpose for  
17 the poster was to directly or indirectly  
18 promote for off label or unapproved  
19 uses?

20 A. **I didn't have a lot of poster  
21 experience with GlaxoSmithKline. My  
22 recollection is that the objective was to  
23 condense even more than in this  
24 manuscript, the data for presentation at  
25 a scientific meeting.**

1 Q. So did you ever get the  
2 impression that it was for the purpose of  
3 promoting Paxil either directly or  
4 indirectly for unapproved or off label  
5 uses?

6  
7 MR. BRASLOW: Objection.

8 THE WITNESS: They hired STI to  
9 help them develop a poster to present at  
10 a scientific meeting. That is what we  
11 were hired to do. That is what I know  
12 they did with it.

13  
14 (BY MR. DAVIS):

15 Q. Is it your testimony that your  
16 understanding and impression was that GSK  
17 -- the reason GSK hired STI was for the  
18 purposes of the presentation of  
19 scientific data?

20 A. Yes.

21  
22 MR. DAVIS: Let's turn to  
23 Plaintiff's Exhibit four.

24  
25 (Pause in proceedings)

1  
2 MR. DAVIS: Okay. May I see that  
3 slide, Exhibit four. I am going to turn  
4 back to the flag section on page 19 that  
5 the Plaintiff's lawyer asked you  
6 questions about.

7  
8 (BY MR. DAVIS):

9 Q. With respect to those -- you  
10 described this as kind of a brainstorming  
11 session that you had with GSK and  
12 others?

13 A. **I was invited to this session as  
14 part of other people who worked on doing  
15 other things with GSK.**

16 Q. Now with respect to the social  
17 anxiety disorder educational program that  
18 was discussed. Do you know whether or  
19 not that possible educational program was  
20 ever implemented by GlaxoSmithKline?

21 A. **Which educational program?**

22 Q. The one that -- may I see that.  
23 There is a slide her that says -- talks  
24 about school programs. And a discussion  
25 about doing educational efforts of

1 psychiatric disorders at various school  
2 programs. And do you know whether or not  
3 that was ever implemented by GSK?

4 A. **I really wasn't involved with  
5 those sales force and what the sales or  
6 whoever did that. So I don't know if  
7 they did or did not.**

8 Q. Okay. Do you know whether or not  
9 Torre Lazur ever was involved in  
10 implementing such a program?

11 A. **I don't know whether they did or  
12 did not.**

13  
14 MR. DAVIS: Let's look at I think  
15 it's Exhibit five. Plaintiff's Exhibit  
16 five. Perhaps it's the very first draft,  
17 Draft 1 of the manuscript. It's the  
18 December 18th -- it's Exhibit 6. If you  
19 can turn to the discussion of -- may I  
20 see this for a second. Thank you.

21 Okay. I want to ask you  
22 questions about pages 3 and 11 of that  
23 initial draft. Let's turn to page 3.

24  
25 (BY MR. DAVIS):

Page 450	Page 452
<p>1 Q. If can look at on page 3 the 2 article -- the draft manuscript discusses 3 8 outcome measures; right? 4 <b>A. Yes.</b> 5 Q. Okay. And then turn to page 11. 6 It describes the 8 primary outcome 7 measures; right? 8 <b>A. Yes.</b> 9 Q. Okay. And this draft, just so 10 the Jury is clear. That draft was never 11 published in that form; right? 12 <b>A. This was the first draft. My</b> 13 <b>recollection is that we went through over</b> 14 <b>10, maybe 14 drafts.</b> 15 Q. Okay. But this version where it 16 describes 8 primaries. That never found 17 it's way into the article that was 18 published in the journal; right? 19 <b>A. I would have to compare.</b> 20 Q. Okay. Look at the abstract 21 again. Does the abstract that is 22 actually in the published article 23 describe 2 primaries and not 8? 24 <b>A. The abstract in the published</b> 25 <b>paper describes 2 primaries and 5 other</b></p>	<p>1 THE WITNESS: On page 49, the 2 previous page, ends with primary efficacy 3 variables. It Continuous on page 50, and 4 I'm sorry. What was your question? 5 MR. DAVIS: Sure. 6 7 (BY MR. DAVIS): 8 Q. After there is an identification 9 at the end of page 49 about the primary 10 variables for Study 329. Is there a 11 discussion of the secondary variables for 12 Study 329? 13 <b>A. There is a paragraph that says --</b> 14 <b>they discuss other outcome measures. And</b> 15 <b>then there is a paragraph at the end of</b> 16 <b>this section. It says, The protocol</b> 17 <b>defined as secondary measures. And then</b> 18 <b>the behavioral and functional</b> 19 <b>instruments.</b> 20 Q. Okay. And does this document say 21 that prior to the opening of the blind, 22 the sponsor and the investigators 23 developed an analytical plan? 24 And later on it says that the 25 agreed analytical plan described a -- let</p>
<p>Page 451</p> <p>1 <b>depression related variables.</b> 2 Q. Okay. So does the published 3 article say anything about 8 primary 4 variables? 5 <b>A. No.</b> 6 7 MR. DAVIS: Okay. So let's look 8 at Plaintiff's Exhibit 7. That's the big 9 thick report here. Okay. 10 The Plaintiff's lawyer asked you 11 questions about page 44 of this Clinical 12 Study Report. And whether or not there 13 were any -- certain of the secondary 14 efficacy variables were identified in the 15 final paper. And I want to go through 16 and ask you questions about that. 17 18 (BY MR. DAVIS): 19 Q. Okay. Look at page 50 that I 20 have earmarked there. Does that section 21 describe efficacy -- secondary efficacy 22 variables that were assessed prior to the 23 breaking of the blind? 24 25 MR. BRASLOW: Objection.</p>	<p>Page 453</p> <p>1 me just have you read this information 2 here. It says prior to the opening of 3 the blind. 4 5 MR. MURGATROYD: What page are 6 you on, Todd? 7 THE WITNESS: 50. 8 THE WITNESS: "Prior to opening 9 the blind, the sponsor and the 10 investigators developed an analytical 11 plan. Among other issues this agreed 12 plan included a definition of a responder 13 and a remission status. 14 The intent was to provide a 15 robust definition of response, and to 16 describe a status of remission in order 17 to provide a vigorous anchor point in 18 analyzing relapses in the continuation 19 phase." . 20 MR. DAVIS: Okay. Keep going. 21 THE WITNESS: "The agreed 22 analytical plan described a responder as 23 a patient whose HAM-D score was 8 or 24 less. Or was reduced from baseline by at 25 least 50 percent. The remission status</p>

1 was defined as a HAM-D score of 8 or  
2 less."

3 MR. DAVIS: Okay. Continue.

4 THE WITNESS: "The agreed  
5 analytical plan also called for the  
6 following measures of effectiveness to be  
7 included in the analysis. The nine item  
8 depression subscale of the K-SADS-L. The  
9 depression item from both the HAM-D and  
10 the K-SADS-L. And two methodologies for  
11 analyzing the clinical global improvement  
12 score.

13 One, the means scores. And two,  
14 the proportion of patients with rating of  
15 1 or 2 (very much or much improved  
16 respectively). The initial protocol  
17 described the K-SADS-L and CGI  
18 instruments as secondary measures."

19  
20 (BY MR. DAVIS):

21 Q. Okay. Now with respect to the  
22 means score CGI, and the CGI improvement  
23 score of 1 or 2. Are those also  
24 identified as secondary variables in the  
25 Keller -- secondary efficacy variables in

1 depression subscore is also identified on  
2 page 50, and it's also identified in the  
3 abstract of the Keller article as an  
4 other depression related variable?

5 **A. This says a 9 item depression  
6 subscale of the K-SADS.**

7 Q. Okay. And is that same  
8 description reflected in the abstract of  
9 the Keller article?

10 **A. Item number two in the list of  
11 other depression related variables is  
12 depression item of the schedule for  
13 affective disorders. And schizophrenia  
14 for adolescents lifetime version  
15 (K-SADS-L).**

16  
17 MR. DAVIS: Let me see that  
18 document.

19  
20 (BY MR. DAVIS):

21 Q. And does the clinical -- the  
22 final clinical report also discuss that  
23 the depressed mood item for the HAM-D,  
24 and the depressed mood item for the  
25 K-SADS-L rating scale --

1 the Keller article?

2 **A. The two CGI 1 or 2 and means?**

3  
4 MR. DAVIS: Yes. It's right in  
5 the abstract.

6 MR. MURGATROYD: I'm sorry. The  
7 secondary variables? Is that what you  
8 said?

9 MR. DAVIS: Yes.

10 THE WITNESS: The abstract  
11 identifies two primary outcome measures.  
12 And then it lists a number of other  
13 depression related variables.

14  
15 (BY MR. DAVIS):

16 Q. And as part of the additional  
17 depression related variables, does it  
18 include the means CGI and the CGI  
19 improvement score of 1 or 2?

20 **A. Item three is the CGI improvement  
21 scores of 1 or 2. And item 5 is means  
22 CGI improvement scores.**

23 Q. Okay. And also looking back at  
24 the clinical report on page 50. Does it  
25 also describe that the K-SADS-L

1 Does the final clinical report  
2 also identify the HAM-D depressed mood  
3 item, and the K-SADS-L depressed mood  
4 item as a variable that is going to be  
5 assessed by the study report?

6 **A. Yes.**

7 Q. And are those two items also  
8 described as other variables that were  
9 analyzed in the study, and described in  
10 the Keller article?

11 **A. The abstract says item one under  
12 other depression related variables. Item  
13 one is the HAM-D depressed mood item.  
14 And number two is the depression item of  
15 the SADS -- K-SADS-L.**

16  
17 MR. DAVIS: Okay. And if you  
18 could turn back to -- you got some  
19 questioning about the -- by the  
20 Plaintiff's lawyer about the sickness  
21 impact profile, the autonomous  
22 functioning checklist, and the self  
23 perception profile.

24  
25 (BY MR. DAVIS):

Page 458	Page 460
<p>1 Q. Do you remember those 2 questions? 3 <b>A. Yes.</b> 4 Q. Okay. If you can turn to page 5 766 of the article. 6 <b>A. Okay.</b> 7 Q. Left-hand column? 8 <b>A. Okay.</b> 9 Q. And do you see a discussion there 10 about those three items? 11 <b>A. On page 766 of the published 12 article in the left-hand column?</b> 13 Q. Right-hand column. I'm sorry. 14 <b>A. Okay. I don't see them mentioned 15 by name.</b> 16 17 MR. DAVIS: Okay. Let me have 18 it. I know it's been a long day. Okay. 19 Can you read the first full paragraph. 20 THE WITNESS: On the right-hand 21 column? 22 MR. DAVIS: Yes. 23 THE WITNESS: "Although neither 24 Paroxetine or Clomipramine separated 25 statistically from placebo across the</p>	<p>1 <b>considered an efficacy evaluation. So I 2 have to assume that that what it is.</b> 3 4 MR. DAVIS: All right. And 5 then -- why don't we take a few minutes. 6 Because I think I'm pretty much wrapped 7 up. 8 MR. MURGATROYD: I only have four 9 questions. Can I ask my four questions 10 now? 11 MR. DAVIS: Why don't we change 12 the tape, and then that will give me a 13 chance to review. 14 VIDEOGRAPHER: The time is 8:38. 15 This is the end of tape number six. We 16 are off the record. 17 18 (Off the record) 19 20 (Back on the record) 21 22 VIDEOGRAPHER: We are back on the 23 record. This is tape number seven. The 24 time is 8:48. 25 MR. DAVIS: Ms. Laden, if I can</p>
<p>Page 459</p> <p>1 non-symptom measures of functioning, 2 health, and behavior. Improvements over 3 baseline were achieved for each active 4 treatment group." 5 6 (BY MR. DAVIS): 7 Q. Okay. With respect to discussion 8 about the non-symptom measures of 9 functioning health and behavior. Do you 10 see at the top of page 764 under the 11 efficacy and safety evaluation. That 12 those are described as the autonomous 13 function checklist, the self-perception 14 profile, and the sickness impact scale? 15 <b>A. Yes.</b> 16 Q. Okay. And so does that in terms 17 of what is described on page 766. Does 18 the Keller article state that the results 19 of those analyses did not reach 20 statistical significance? 21 <b>A. Yes.</b> 22 Q. Okay. And by statistical 23 significance, I mean statistical 24 significance for efficacy; right? 25 <b>A. Well that was -- I guess that was</b></p>	<p>Page 461</p> <p>1 turn your attention to Plaintiff's 2 Exhibit number 11. Which was the 3 document from FDA. 4 Let me turn your attention to the 5 page that I dog eared, that you got 6 questioned about by Plaintiff's counsel. 7 8 (BY MR. DAVIS): 9 Q. Do you see the discussion in this 10 document concerning Study 329 and it's 11 efficacy results? 12 <b>A. Yes.</b> 13 Q. Okay. Now in terms of 14 considering yourself an expert in 15 regulatory requirements for the FDA. Do 16 you believe that you're such an expert? 17 <b>A. No.</b> 18 Q. All right. And in terms of 19 the -- whether or not that 329 would meet 20 the regulatory hurdles for an approved 21 indication with FDA. Can you comment one 22 way or the other on that issue? 23 <b>A. No.</b> 24 Q. And with respect to Dr. 25 Mosholder's comment, whose the FDA</p>

1 reviewer here. Do you know -- does it  
2 say anywhere what he means by that on  
3 balance that Study 329 should be a failed  
4 study? Should be considered a failed  
5 study.

6 Does this FDA reviewer ever  
7 describe what he means by on balance this  
8 study should be considered a failed  
9 study?

10 **A. It looks like he's preferencing**  
11 **that statement with some statements at**  
12 **the beginning of the conclusion.**

13 Q. Sure. But in terms of -- what it  
14 means in terms of FDA's view of whether  
15 or not this study was a failed study or  
16 not. Does he ever describe what he means  
17 by that?

18 **A. No.**

19 Q. And in the Keller article that  
20 was published and read by physicians.  
21 Does it ever represent that the efficacy  
22 results show that Paxil -- that the  
23 efficacy results would meet the FDA  
24 requirements for efficacy?

25 **A. That -- to my recollection that**

1 **was not concluded in the paper.**

2 Q. Now with respect to an effort to  
3 try and hide your involvement with  
4 editorial assistance on the Keller  
5 article. Again, are you identified on  
6 the very first page of that article?

7 **A. Yes.**

8 Q. Was there any effort by the  
9 authors or GSK to hide your involvement  
10 in providing editorial assistance to the  
11 paper?

12 **A. Not -- I don't remember anything**  
13 **happening like that.**

14 Q. Would it make sense for the  
15 authors or GlaxoSmithKline to try to hide  
16 your involvement providing editorial  
17 assistance, and then name you by name on  
18 the first page of the article by saying  
19 that you provided editorial assistance?

21 MR. BRASLOW: Objection.

22 MR. MURGATROYD: Objection.

23 THE WITNESS: I don't know if  
24 that would make sense. It would seem  
25 contradictory.

1 MR. DAVIS: I will reserve.

2 MR. MURGATROYD: Four quick  
3 questions.

4  
5 **REDIRECT EXAMINATION**

6  
7 **BY MR. MURGATROYD:**

8 Q. You have the study -- the article  
9 in front of you; right?

10 **A. Yes.**

11 Q. Where is STI mentioned in that  
12 article?

13 **A. STI is not mentioned. My name is**  
14 **mentioned.**

15 Q. Okay. STI is not in there;  
16 right?

17 **A. No.**

18 Q. Okay. Does it say there that you  
19 prepared the manuscript? The first draft  
20 of the manuscript?

21 **A. It says editorial assistance was**  
22 **provided by Sally K. Laden, MN.**

23 Q. Okay. Nothing about you  
24 preparing the first manuscript?

25 **A. No.**

1 Q. Okay. Now in any of the  
2 documents that you have seen today or in  
3 any of the documents that were sent to  
4 you to review prior to your deposition.  
5 Did you see any comments or revisions of  
6 the 329 manuscript by Dr. Gram Emsly  
7 (Phonetic)?

8 **A. I don't recall.**

9 Q. Do you recall seeing any comments  
10 or revisions by Nancy Winners (Phonetic)?

11 **A. I don't recall.**

12 Q. Do remember them ever making any  
13 comments?

14 **A. I don't recall.**

15 Q. Have you ever seen any comments  
16 by a woman by the name of Wella  
17 (Phonetic)?

18 **A. I don't remember.**

19 Q. How about Michael Sweeney  
20 (Phonetic)?

21 **A. I don't remember.**

22 Q. Do you know who he is?

23 **A. I don't remember who a lot of**  
24 **these people are.**

25 Q. Okay. Did you ever talk to

1 Michael Sweeney (Phonetic)?  
 2 **A. I don't remember.**  
 3 Q. Okay. How about William Sack  
 4 (Phonetic)? Are there any documents that  
 5 you have seen that says that Sack  
 6 (Phonetic) made a single comment or  
 7 revision to Study 329?  
 8 **A. I don't recall.**  
 9 Q. How about -- I can't even  
 10 pronounce this guy's name, George Papa --  
 11 can you pronounce his name?  
 12 **A. I start the same way you did, and**  
 13 **I don't think I can pronounce his name.**  
 14 Q. Okay. You never talked to him,  
 15 did you?  
 16 **A. I don't remember.**  
 17 Q. Okay. Do you think you would  
 18 remember if you had to pronounce that  
 19 name?  
 20 **A. I don't remember if I spoke with**  
 21 **him or not.**  
 22 Q. Okay. Did you ever try to  
 23 pronounce his name to speak to him?  
 24 **A. I don't remember.**  
 25 Q. Did he ever give any comments, to

1 your knowledge?  
 2 **A. I don't recall.**  
 3 Q. How about David Fineburge  
 4 (Phonetic)? He's one of the co-authors;  
 5 right?  
 6 **A. Yes.**  
 7 Q. Did he ever give you any comments  
 8 or revisions for the study?  
 9 **A. I don't remember.**  
 10 Q. How about Borris Birmaher  
 11 (Phonetic). Did he ever give you any  
 12 comments or revisions?  
 13 **A. I think he did, yes.**  
 14 Q. Okay. How about Owen Haguno  
 15 (Phonetic)? Did he ever give you any  
 16 comments or revisions for the study  
 17 manuscript?  
 18 **A. I don't remember.**  
 19 Q. How about Harold Topowitz  
 20 (Phonetic)? Did he ever give you any  
 21 comments or revisions for the study?  
 22 **A. I don't remember.**  
 23 Q. Okay. How long Viviack  
 24 Kruchicabar (Phonetic)? Is that how you  
 25 pronounce his name?

1 **A. I don't know. I don't remember**  
 2 **how you pronounce his name.**  
 3 Q. Okay. Did you ever talk to  
 4 him?  
 5 **A. I don't recall.**  
 6 Q. Did you ever try to talk to  
 7 him?  
 8 **A. I don't recall.**  
 9 Q. Does he speak English?  
 10 **A. I don't recall a conversation**  
 11 **with him.**  
 12 Q. Okay. Can you pronounce his  
 13 name?  
 14 **A. I can take a stab at it.**  
 15 Q. Okay. But do you recall ever  
 16 trying to make a stab at it when you were  
 17 talking to him personally?  
 18 **A. No, I don't recall.**  
 19 Q. Okay. Would it be fair to say  
 20 that none of the names I just mentioned,  
 21 none of these people contributed anything  
 22 to the manuscript for Study 329?  
 23  
 24 MR. DAVIS: Object to the form.  
 25 THE WITNESS: My not recalling a

1 conversation with them, is not the same  
 2 as saying they didn't contribute.  
 3  
 4 (BY MR. MURGATROYD):  
 5 Q. Okay. Can you point to any  
 6 evidence in any of the documents that you  
 7 have seen today that show that any one of  
 8 those individuals we discussed, other  
 9 than Borris Birmaher (Phonetic),  
 10 contributed one comment or revision to  
 11 the Study 329 manuscript?  
 12 **A. I don't recall seeing that in the**  
 13 **documents we discussed today.**  
 14 Q. Okay. Or in the documents that  
 15 with provided for your review for this  
 16 deposition; right?  
 17 **A. Wasn't that all these?**  
 18 Q. Yes. And I think there were a  
 19 few more.  
 20 **A. I don't recall.**  
 21 Q. Okay. Why were all these -- is  
 22 the purpose of putting all these names on  
 23 a study article, is to try to make it  
 24 look impressive?  
 25

<p style="text-align: right;">Page 470</p> <p>1 MR. DAVIS: Objection to the 2 form. 3 THE WITNESS: I don't know what 4 the purpose of putting all these names 5 is. 6 7 (BY MR. MURGATROYD): 8 Q. Okay. The last question I have. 9 If you go to the article. Mr. Davis was 10 talking about the fact that the two 11 primary outcome measures are identified 12 in the abstract; correct? 13 <b>A. Yes.</b> 14 Q. And do you see what they are; 15 those two? 16 <b>A. Yes.</b> 17 Q. Okay. Now turn to table 2, if 18 you will, in the paper. Okay. Did 19 either of those primary efficacy 20 variables reach statistical significance 21 in favor of Paxil? 22 <b>A. The first one did.</b> 23 Q. It did? The HAM-D less than or 24 equal to 8. Is that a primary efficacy 25 variable?</p>	<p style="text-align: right;">Page 472</p> <p>1 item? 2 <b>A. Well HAM-D total score -- yes.</b> 3 <b>HAM-D total score is there.</b> 4 Q. Okay. And did it reach 5 statistical significance? 6 <b>A. HAM-D total score, no.</b> 7 Q. Great. So you agree that neither 8 of the primary efficacy variables reached 9 statistical significance in favor of 10 Paxil? 11 <b>A. No -- I mean yes.</b> 12 Q. You agree with that; correct? 13 <b>A. I agree with that.</b> 14 Q. Okay. Can you explain to me why 15 on page 765 under efficacy results, it 16 states, "Of the depression related 17 variables, Paxil -- I'm sorry. 18 Paroxetine separated statistically from 19 placebo at end point among four of the 20 parameters. 1) Response, i.e. primary 21 efficacy measure." 22 23 MR. DAVIS: Object to the form. 24 Mischaracterizes the statement. 25 THE WITNESS: As you read it,</p>
<p style="text-align: right;">Page 471</p> <p>1 <b>A. It's mentioned in the first</b> 2 <b>primary efficacy variable.</b> 3 Q. What is the first primary 4 efficacy variable? 5 <b>A. The abstract states two primary</b> 6 <b>outcome measures were end point response,</b> 7 <b>HAM-D score less than or equal to 8, or</b> 8 <b>greater than equal to 50 percent</b> 9 <b>reduction in baseline HAM-D.</b> 10 Q. Okay. Let's take a look at your 11 table 2. Is HAM-D less than or equal to 12 8 or 50 percent reduction in baseline 13 HAM-D listed in table 2? 14 <b>A. Yes.</b> 15 Q. Okay. And that is one of the two 16 primary efficacy variables; right? 17 <b>A. Yes.</b> 18 Q. Now, did it reach statistical 19 significance? 20 <b>A. No.</b> 21 Q. Okay. Now what is the second? 22 <b>A. Change from baseline HAM-D</b> 23 <b>score.</b> 24 Q. Okay. And is that in your table 25 2 under HAM-D total score; the last</p>	<p style="text-align: right;">Page 473</p> <p>1 that is what it says in the article. 2 3 (BY MR. MURGATROYD): 4 Q. And would you agree that's a 5 false statement? 6 7 MR. DAVIS: Object to the form of 8 the question. 9 THE WITNESS: The four parameters 10 that are mentioned in this paragraph on 11 765 didn't achieve statistical 12 significance. 13 14 (BY MR. MURGATROYD): 15 Q. It says, response i.e. primary 16 outcome measure. Didn't you just testify 17 that both of the primary efficacy 18 variables failed to reach statistical 19 significance in favor of Paxil? 20 <b>A. According to table 2, yes.</b> 21 Q. Right. They both failed; 22 correct? But yet in the body it says 23 right here that the response did reach 24 statistical significance; correct? 25</p>

1 MR. MARGOLIS: Object to the form  
2 of the question.

3 THE WITNESS: I guess I need to  
4 clarify the definition of "response".

5 MR. MURGATROYD: Well let's just  
6 take a look at the words, "i.e. primary  
7 outcome measure".

8  
9 (BY MR. MURGATROYD):

10 Q. This sentence would indicate to a  
11 reader that a primary outcome measure  
12 reached statistical significance in favor  
13 of Paxil; correct?

14  
15 MR. DAVIS: Object to the form.  
16 Calls for speculation.

17 THE WITNESS: It indicates that  
18 response.

19  
20 (BY MR. MURGATROYD):

21 Q. Okay. I.e. primary outcome  
22 measure; correct?

23 **A. That is what the document says,**  
24 **yes.**

25 Q. Okay. Did either of the primary

1 turned open to the memo that we talked  
2 about earlier that is dated February 22,  
3 1999 from Dr. Keller; right?

4 THE WITNESS: Yes.

5  
6 (BY MR. DAVIS):

7 Q. And according to this document,  
8 who was supposed to gather the input from  
9 all the other co-authors that the  
10 Plaintiff's lawyer ticked off one by one?  
11 Who was supposed to collect that  
12 information and those comments?

13 **A. This is a memo from Dr. Keller to**  
14 **the co-authors asking them to send their**  
15 **suggestions to himself, Dr. Ryan and Dr.**  
16 **Strober.**

17 Q. Okay. And according to this  
18 memo, were those comments supposed to  
19 come to you?

20 **A. No.**

21 Q. All right. So in terms of having  
22 any documents today to show the comments  
23 that went to Dr. Keller per that memo, is  
24 there any surprise that you don't have  
25 the documents?

1 outcome measures reach statistical  
2 significance in favor of Paxil?

3 **A. No.**

4  
5 MR. MURGATROYD: Thank you. I  
6 have no further questions.

7  
8 **RE-CROSS EXAMINATION**

9  
10 BY MR. DAVIS:

11 Q. Look back at Exhibit six, if you  
12 would Ms. Laden.

13 **A. Which --**

14 Q. Defendant's Exhibit six. I'm  
15 sorry.

16 **A. Yes.**

17  
18 MR. DAVIS: I'm sorry. Not  
19 Plaintiff's. It's got the blue tab on  
20 it. Let's go back to 4. This one right  
21 here. Let me find the page number for  
22 you.

23 THE WITNESS: Yes.

24 MR. DAVIS: Okay. I have handed  
25 you back Defendant's Exhibit 4. And I

1  
2 MR. MURGATROYD: Object to the  
3 form.

4 THE WITNESS: I don't know if  
5 it's a surprise or not.

6  
7 (BY MR. DAVIS):

8 Q. Well, let me just ask you a more  
9 fundamental question is that, you left  
10 STI when? How many years ago?

11 **A. 2003.**

12 Q. Okay. And so would you have any  
13 documents from STI in your possession  
14 since you're no longer there?

15 **A. No.**

16 Q. So whatever documents they may or  
17 may not have about the Keller article,  
18 those wouldn't be in your possession;  
19 right?

20 **A. No.**

21 Q. And with respect to documents  
22 that Dr. Keller may have that may show  
23 comments from the authors in response to  
24 his February, 1999 memo. You wouldn't  
25 have those either, would you?

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**A. No.**

MR. DAVIS: Thanks.

MR. MURGATROYD: That's it. We are done. Thank you.

VIDEOGRAPHER: The time is 8:58. We are off the record.

(End time: 8:58 P.M.)

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**REPORTER'S CERTIFICATE**

I, DENISE D. HARPER-FORDE, CSR No. 00133, Certified Shorthand Reporter, Certify;

That the foregoing proceedings were taken before me at the time and place therein set forth, at which time the witness was put under oath by me;

That the testimony of the witness, the questions propounded, and all objections and statements made at the time of the examination were recorded stenographically by me and were thereafter transcribed;

That the foregoing is a true and correct transcript of my shorthand notes so taken.

I further certify that I am not a relative or employee of any attorney of the parties, nor financially interested in the action.

I declare under penalty of perjury under the laws of Connecticut that the foregoing is true and correct.

Dated this     day of     , 2007.

\_\_\_\_\_  
DENISE D. HARPER-FORDE, C.S.R. NO. 00133

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