

STATE OF MINNESOTA

DISTRICT COURT

COUNTY OF HENNEPIN FOURTH JUDICIAL CIRCUIT

LEIGH ANN ENGH, DARCENE and GREG LENSING, on
behalf of the general public, themselves and
all others similarly situated

Plaintiffs

v. Court File No. PI-04-012879

SMITHKLINE BEECHAM CORPORATION, d/b/a
GLAXOSMITHKLINE, a Pennsylvania corporation

Defendant

(Captions continued on following pages.)

VOLUME I

VIDEO DEPOSITION of MARTIN B. KELLER,
M.D., a witness called by counsel for the
Plaintiffs, taken under the provisions of the
California Rules of Civil Procedure, before Jill
K. Ruggieri, Registered Merit Reporter, Certified
Realtime Reporter and Notary Public, at the
offices of Robert S. Bruzzi, Esq., 18 Imperial
Street, Providence, Rhode Island, taken on
Wednesday, September 6, 2006, commencing at
10:21 a.m.

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UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF PENNSYLVANIA

PAMELA BLAIN, individually and as personal
representative of the Estate of TREVOR KYLE
BLAIN, II, deceased, and on behalf of all those
similarly situated; TONYA D. BROOKS, individually
and on behalf of all of those similarly situated;
RONALD BLAIN, individually; LEX BROOKS,
individually; CHERYL BROOKS, individually

Plaintiffs

v. Case No. 06-1247 JD

SMITHKLINE BEECHAM CORPORATION d/b/a
GLAXOSMITHKLINE, a Pennsylvania corporation

Defendant

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THE SUPERIOR COURT OF THE STATE OF CALIFORNIA
FOR THE COUNTY OF ORANGE

BEVERLY SMITH, on behalf of herself and all
others similarly situated and on behalf of the
general public

Plaintiff

v. Case No. 04 CC 00590

SMITHKLINE BEECHAM CORPORATION, d/b/a
GLAXOSMITHKLINE, a Pennsylvania corporation, and
DOES 1-100, inclusive

Defendants

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APPEARANCES:

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and Engh

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on behalf of defendant

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James M. Green, Deputy General Counsel
Brown University, Office of the General
Counsel
110 South Main Street
Providence, Rhode Island 02912-1913
(401) 863-9977 Fax: (401) 863-1120
on behalf of the deponent

Also present: Tamar Halpern, Esq., Phillips Lytle

Videographer: Shawn Budd

1 10:15:39 P R O C E E D I N G S

2 10:21:16 THE VIDEOGRAPHER: We are on the

3 10:21:17 record. This is the video operator

4 10:21:18 speaking, Shawn Budd.

5 10:21:20 Today's date is September 6, 2006,

6 10:21:23 and the time is 10:21. We are here at the

7 10:21:28 offices of Robert S. Bruzzi, located in

8 10:21:33 Providence, Rhode Island, to take the

9 10:21:36 videotaped deposition of Dr. Martin B.

10 10:21:38 Keller in the matter of Leigh Ann Engh, et

11 10:21:43 al.; and Beverly -- Leigh Ann Engh, et al.

12 10:21:47 v. SmithKlein Beecham Corporation and

13 10:21:50 Beverly Smith, et al. v. SmithKline Beecham

14 10:21:53 Corporation d/b/a GlaxoSmithKline; and

15 10:21:58 Pamela Blain, et al. v. SmithKline Beecham

16 10:22:02 Corporation d/b/a GlaxoSmithKline.

17 10:22:06 Would counsel please introduce

18 10:22:07 themselves.

19 10:22:07 MR. MURGATROYD: My name is Skip

20 10:22:09 Murgatroyd, and I represent the plaintiffs

21 10:22:10 in the Blain and the Smith cases.

22 10:22:12 MR. COFFIN: My name is Chris Coffin.

23 10:22:13 I represent the plaintiffs in the Engh case.

24 10:22:16 MS. MENZIES: Karen Menzies. I

1 10:22:18 represent the plaintiffs in Smith, Engh and
2 10:22:20 Blain.
3 10:22:21 MR. DAVIS: Todd Davis representing
4 10:22:23 GlaxoSmithKline. And also present but not
5 10:22:24 entering an appearance is Tamar Halpern with
6 10:22:28 Phillips Lytle representing GlaxoSmithKline
7 10:22:31 as well.
8 10:22:35 MR. MURGATROYD: Jim, would you make
9 10:22:36 your presence known?
10 10:22:37 MR. GREEN: Yes.
11 10:22:37 MR. MURGATROYD: Oh.
12 10:22:37 MR. GREEN: I don't have a
13 10:22:38 microphone, but James Green, counsel for
14 10:22:40 Dr. Martin Keller.
15 10:22:48
16 10:22:48 MARTIN B. KELLER, M.D., a witness
17 10:22:48 having been duly sworn, on oath deposes and
18 10:22:48 says as follows:
19 10:22:48
20 10:22:48 EXAMINATION
21 10:22:48 BY MR. MURGATROYD:
22 10:22:49 Q Doctor, can you state and spell your full
23 10:22:50 name for the record, please.
24 10:22:52 MR. DAVIS: Before we start, Skip --

1 10:22:53 MR. MURGATROYD: Yes?

2 10:22:54 MR. DAVIS: -- let's try to get some

3 10:22:55 housekeeping issues out of the way.

4 10:22:57 MR. MURGATROYD: Sure.

5 10:22:57 MR. DAVIS: This deposition is being

6 10:22:58 taken in a number of cases in which you are

7 10:23:01 counsel representing the plaintiffs, and we

8 10:23:05 have had some discussions prior that in

9 10:23:07 terms of arranging for the deposition, that

10 10:23:11 we -- we'd get this done in two days.

11 10:23:13 I mean, that was my understanding

12 10:23:15 when we had those discussions. And I've got

13 10:23:20 to leave tomorrow by 4:45, 5:00, and I

14 10:23:24 believe I should be allowed to question

15 10:23:26 Dr. Keller, one --

16 10:23:28 Number one, that we should be able to

17 10:23:29 complete the deposition in that time frame.

18 10:23:31 You all can finish your questions of

19 10:23:33 Dr. Keller in that time frame, and that I

20 10:23:35 should be allowed several hours to question

21 10:23:38 him about GSK's defenses and other issues

22 10:23:43 that have come up that you ask him questions

23 10:23:44 or your co-counsel ask him questions about.

24 10:23:47 And I think we should be able to

1 10:23:50 finish that in that amount of time, given
2 10:23:53 the fact that the federal rules themselves,
3 10:23:54 in which one of the cases being taken,
4 10:23:57 Blain, requires -- allows for seven hours
5 10:24:00 for depositions, absent agreement of the
6 10:24:02 parties or stipulation or approval of the
7 10:24:04 court.

8 10:24:05 Two days is a lot of time for you all
9 10:24:07 to ask Dr. Keller questions you wish to ask
10 10:24:10 him about, and I implore you to -- that we
11 10:24:14 stick to those guidelines so we get this
12 10:24:17 done and we are not coming back here again
13 10:24:22 for a third or fourth day. Because at this
14 10:24:24 stage, we're reserving our right not to
15 10:24:27 agree to that and to petition the court for
16 10:24:29 relief, because we think these issues can be
17 10:24:32 adequately addressed where all counsel get a
18 10:24:34 chance to ask Dr. Keller questions that they
19 10:24:38 may have in this two-day time period.

20 10:24:40 And as I mentioned to you before the
21 10:24:42 deposition, I would think, depending upon
22 10:24:43 what you ask and what topics you and your
23 10:24:45 co-counsel cover, my examination of
24 10:24:47 Dr. Keller would last somewhere between nine

1 10:24:49 hours -- excuse me, 90 minutes and two and a
2 10:24:52 half hours. That's give or take, based upon
3 10:24:55 what you all are asking questions about.
4 10:24:57 So I'd ask that you and your
5 10:24:58 colleagues organize your questions in such a
6 10:25:00 way that allows for me to ask those
7 10:25:04 questions of Dr. Keller before the
8 10:25:06 completion of the deposition, and that we
9 10:25:08 not cover the same groundwork or the same --
10 10:25:10 same areas once you hand -- if you hand off
11 10:25:13 the questioning to either Mr. Coffin or
12 10:25:15 Ms. Menzies, because I really think that's
13 10:25:18 just not an efficient use of everyone's
14 10:25:19 time.
15 10:25:20 MR. MURGATROYD: Well, I think you
16 10:25:20 know from Jim McCaffrey's deposition two
17 10:25:23 weeks ago that he took all of three days;
18 10:25:24 and, to be honest with you, we cut out at
19 10:25:27 least a half a day of questioning, and that
20 10:25:29 was based on your representation to us you
21 10:25:32 were going to take an hour and a half with
22 10:25:34 his re -- or your cross, I guess. And that
23 10:25:38 wasn't nearly enough time.
24 10:25:41 So McCaffrey's deposition should have

1 10:25:43 been a four-day deposition.

2 10:25:45 We will try to move things along

3 10:25:46 quickly. I don't ask repetitive questions.

4 10:25:49 Chris didn't ask a single repetitive

5 10:25:52 question at Jim McCaffrey's deposition. So

6 10:25:55 that's not something we do. We do use our

7 10:25:57 time efficiently.

8 10:25:58 So I understand your situation. I

9 10:26:00 can tell you right now, I just don't know

10 10:26:03 how long it's going to take; and under

11 10:26:05 California rules, these depositions continue

12 10:26:06 from day to day will until completed.

13 10:26:08 MR. DAVIS: But it's also at the same

14 10:26:10 time a matter of reasonableness. And with

15 10:26:11 respect to Mr. McCaffrey's deposition, I

16 10:26:13 disagree that the time was used efficiently.

17 10:26:15 I disagree that repetitive questions were

18 10:26:17 not asked. They were, both by yourself and

19 10:26:20 by co-counsel, Mr. Coffin.

20 10:26:21 And if you -- if you think that

21 10:26:23 there's not adequate time that you had with

22 10:26:25 Mr. McCafferty, you have a -- you can

23 10:26:28 petition the court and ask for relief, and

24 10:26:30 we can address that at that time.

1 10:26:32 And so we're not here to dispute what
2 10:26:35 or go into what happened at
3 10:26:36 Mr. McCaffrey's -- I'm just saying
4 10:26:39 Dr. Keller, two days is plenty of time to
5 10:26:41 cover the ground -- the ground that needs to
6 10:26:42 be covered with him.
7 10:26:43 MR. MURGATROYD: Well, we -- we shall
8 10:26:45 see. Let's get started, and we'll see how
9 10:26:47 we do.
10 10:26:47 BY MR. MURGATROYD:
11 10:26:54 Q Okay. Are you ready?
12 10:26:56 So why don't we have you state and
13 10:26:58 spell your full name for the record.
14 10:27:00 A Martin B. Keller, M-A-R-T-I-N, capital B as
15 10:27:03 in boy, Keller, K-E-L-L-E-R.
16 10:27:06 Q And what is your current address?
17 10:27:07 A 22 Kirkstall Road, Newton, Massachusetts
18 10:27:11 02460.
19 10:27:12 Q Okay.
20 10:27:12 And you're represented by counsel
21 10:27:14 today, correct?
22 10:27:15 A Yes.
23 10:27:16 Q Okay.
24 10:27:17 And did you get -- have you ever been

1 10:27:20 deposited before?
2 10:27:21 A Yes.
3 10:27:22 Q Okay.
4 10:27:22 And was that a matter involving the
5 10:27:25 drug Paxil by any chance?
6 10:27:28 A No.
7 10:27:28 Q Are you familiar with the ground rules of a
8 10:27:31 deposition?
9 10:27:32 A By and large, yes. I just answer questions.
10 10:27:35 I mean, I'll just say yes, and if there's
11 10:27:39 something I'm not familiar with, I'll tell
12 10:27:41 you.
13 10:27:41 Q I just want to make sure you understand
14 10:27:43 you're under oath.
15 10:27:44 A Oh, sure.
16 10:27:45 Q And that's the same oath you would take as
17 10:27:47 if you were sitting in a court of law; do
18 10:27:49 you understand that?
19 10:27:50 A Sure.
20 10:27:50 Q Is that yes?
21 10:27:51 A Sure. Okay.
22 10:27:51 Q That's one of the key rules, is the court
23 10:27:53 reporter can't take down shrugs or nods, so
24 10:27:55 it's important that each of your answers be

1 10:27:58 out loud, okay?

2 10:28:00 A Yes.

3 10:28:00 MR. GREEN: Can I just interject?

4 10:28:02 Maybe I missed it, but did anyone

5 10:28:05 administer the oath?

6 10:28:06 MR. MURGATROYD: Yes.

7 10:28:06 MR. GREEN: Oh, I did miss it. Okay.

8 10:28:08 Good.

9 10:28:08 MR. MURGATROYD: That's fine.

10 10:28:09 Q It's important so we get a clean record that

11 10:28:11 you wait for me to completely ask a question

12 10:28:13 before you begin to answer.

13 10:28:15 Is that okay?

14 10:28:16 A Yes.

15 10:28:16 Q Okay.

16 10:28:16 Is there any reason why you can't

17 10:28:19 give your best testimony today?

18 10:28:21 A No.

19 10:28:21 Q Okay.

20 10:28:21 Now, where are you currently

21 10:28:28 employed?

22 10:28:31 A Brown University.

23 10:28:32 Q Okay.

24 10:28:32 And what's your position there?

1 10:28:34 A I'm the professor and chairman of the
2 10:28:37 Department of Psychiatry and Human Behavior.
3 10:28:42 Q And how long have you held that position?
4 10:28:44 A Started in December of 1989.
5 10:28:52 Q Okay.
6 10:28:52 And what is your actual physical
7 10:28:54 address at Brown?
8 10:28:58 A 340 -- well, my office is in Butler
9 10:29:01 Hospital, 345 Blackstone Boulevard,
10 10:29:04 Providence.
11 10:29:05 Q Okay.
12 10:29:06 And what are your -- what are your
13 10:29:08 job functions? Do you teach?
14 10:29:13 A I'm responsible for academic mission of the
15 10:29:20 Department of Psychiatry and Human Behavior,
16 10:29:25 to make it as excellent as it can possibly
17 10:29:29 be.
18 10:29:29 The two main functions of the
19 10:29:30 academic mission would be education and
20 10:29:33 research. So I'm responsible ultimately for
21 10:29:37 the training on an annual basis of
22 10:29:39 approximately 150 trainees and multiple
23 10:29:44 different types of training programs and a
24 10:29:46 research program that in its aggregate has

1 10:29:50 about \$50 million of externally funded
2 10:29:54 research.
3 10:29:55 So it's my job to figure out ways to
4 10:30:01 stimulate the research and mentor -- have
5 10:30:04 faculty mentored and to get the best
6 10:30:07 trainees to come to Brown, potential
7 10:30:10 trainees, and then when they get here, to
8 10:30:11 give them the best possible education that
9 10:30:14 they can get.
10 10:30:15 Q Let's take the training.
11 10:30:15 You say you have 150 trainees each
12 10:30:19 year; is that correct?
13 10:30:20 A Roughly.
14 10:30:21 Q Okay.
15 10:30:21 And is -- do you personally train
16 10:30:23 them?
17 10:30:24 A No.
18 10:30:24 I meet with them at various times,
19 10:30:29 but we have -- I have many different
20 10:30:32 directors for various training programs who
21 10:30:35 have an enormous amount of responsibility,
22 10:30:39 and basically I meet with them on a periodic
23 10:30:43 basis to do oversight of the training
24 10:30:46 programs. And I periodically meet with

1 10:30:51 different trainees in the group and
2 10:30:53 individually.
3 10:30:54 But I would say the lion's share of
4 10:30:56 the actual imparting of knowledge to them is
5 10:30:58 done by many other people.
6 10:31:01 Q Not yourself?
7 10:31:03 A Correct.
8 10:31:03 Q Okay.
9 10:31:04 And you say research, you're involved
10 10:31:06 in research, is that clinical research?
11 10:31:10 A Basic, translational, clinical, services,
12 10:31:15 research, outcomes research.
13 10:31:17 Q Is this where you're testing drugs on
14 10:31:20 people?
15 10:31:23 A Some of the research in the department has
16 10:31:26 to do with either randomized clinical
17 10:31:29 trials, double-blind, not double-blind,
18 10:31:32 efficacy, effectiveness, are some of what we
19 10:31:35 do, tests, those -- as of that nature.
20 10:31:38 Q Okay.
21 10:31:40 And you understand we're here today
22 10:31:42 about a study that you did involving Paxil,
23 10:31:44 also known as paroxetine, correct?
24 10:31:46 A Correct.

1 10:31:46 Q Okay.

2 10:31:47 It's known as Study 329?

3 10:31:51 A Correct.

4 10:31:51 Q Okay.

5 10:31:52 And in preparing for your deposition

6 10:31:55 today, did you review any documents that

7 10:31:57 related to that study?

8 10:32:05 A In a very cursory way.

9 10:32:07 Q Okay.

10 10:32:08 And why don't you tell me about that.

11 10:32:11 A I met twice fairly briefly with Mr. Green,

12 10:32:17 and he just reviewed with me some of the

13 10:32:24 types of questions that I might anticipate

14 10:32:37 having to do with the whole proceedings,

15 10:32:42 some of which had to do with that study; but

16 10:32:45 we didn't -- I didn't read the manuscript

17 10:32:47 from the study, didn't read things directly.

18 10:32:51 Just -- I don't actually think -- I

19 10:32:54 don't remember. I don't actually think I

20 10:32:56 read those.

21 10:32:57 Q Okay.

22 10:32:58 A I don't -- I don't remember. I don't

23 10:33:00 remember if I have -- if when Jim and I were

24 10:33:03 going over some things if I actually -- if

1 10:33:06 he -- if I actually took the article and
2 10:33:10 read paragraphs from it or not or just
3 10:33:14 talked about some of the things in it.

4 10:33:15 Q Okay.

5 10:33:16 Well, the question was, did you
6 10:33:17 review any documents?

7 10:33:18 A Yes.

8 10:33:19 Q Okay.

9 10:33:19 What documents did you review?

10 10:33:21 A I don't remember.

11 10:33:22 Q Did you -- well, I notice that -- actually,
12 10:33:25 why don't we sort this out.

13 10:33:27 MR. MURGATROYD: You produced -- I'm
14 10:33:29 talking to Mr. Green, so the record is
15 10:33:30 clear, documents on behalf of Mr. Keller,
16 10:33:32 correct?

17 10:33:33 MR. GREEN: That's correct.

18 10:33:34 MR. MURGATROYD: And I notice that
19 10:33:34 one had a confidential stamp on it.

20 10:33:36 Do you claim that some of the
21 10:33:37 documents that we requested are
22 10:33:39 confidential?

23 10:33:42 MR. GREEN: I had an understanding
24 10:33:43 with Robert Paiva, is it, with your

1 10:33:46 office --

2 10:33:48 MR. MURGATROYD: Brava-Partain.

3 10:33:51 MR. GREEN: Yes.

4 10:33:51 The records in that folder are

5 10:33:54 apparently part of a project that GSK was

6 10:34:00 working on and were sent to him in

7 10:34:04 confidence.

8 10:34:05 And I had a discussion with an

9 10:34:07 attorney from your office about the fact

10 10:34:09 that in producing them, we would like them

11 10:34:14 to be subject to the confidentiality order

12 10:34:19 that had been agreed to by the parties in

13 10:34:23 that case, and he said that that would be

14 10:34:25 fine.

15 10:34:26 MR. MURGATROYD: And which project

16 10:34:26 was that?

17 10:34:27 MR. GREEN: It was a project

18 10:34:32 involving a study compilation of 329 and two

19 10:34:41 other students.

20 10:34:42 MR. MURGATROYD: Right, 701 and 377?

21 10:34:44 MR. GREEN: I believe so.

22 10:34:44 MR. MURGATROYD: And that's the only

23 10:34:45 thing that you claim are confidential?

24 10:34:47 MR. GREEN: Yes.

1 10:34:48 MR. MURGATROYD: Okay.

2 10:34:48 And are there any documents that you

3 10:34:50 withheld under any other grounds of

4 10:34:52 confidentiality?

5 10:34:54 MR. GREEN: No.

6 10:34:55 MR. MURGATROYD: Okay.

7 10:34:55 Because there's one document that has

8 10:34:57 on it stamped "confidential."

9 10:34:58 Do you know what I'm talking about?

10 10:34:59 MR. DAVIS: I think there's a

11 10:35:00 whole -- I had a conversation with

12 10:35:02 Mr. Robert Brava-Partain as well.

13 10:35:04 He informed me that Dr. Keller's

14 10:35:06 counsel was producing documents that would

15 10:35:09 be subject to the protective order in this

16 10:35:10 case; and Mr. Robert Brava-Partain said that

17 10:35:15 he had no problem with that, that it was

18 10:35:18 fine, that plaintiffs would agree to that.

19 10:35:20 The documents at issue, I believe,

20 10:35:21 are more than one, and we believe after

21 10:35:25 having reviewed those documents, after

22 10:35:27 Dr. Keller's counsel produced them, they

23 10:35:30 are -- they should be subject to this -- the

24 10:35:32 protective order.

1 10:35:33 They're proprietary and confidential
2 10:35:35 information, and we designate any
3 10:35:37 discussions at Dr. Keller's deposition as
4 10:35:39 confidential pursuant to the protective
5 10:35:41 order.

6 10:35:44 MR. MURGATROYD: We discussed the
7 10:35:45 meta-analysis, for lack of a better word, of
8 10:35:48 the three studies for Major Depressive
9 10:35:51 Disorder in adolescents; is that what you're
10 10:35:53 talking about?

11 10:35:54 MR. DAVIS: There was a draft paper
12 10:35:55 put together concerning that, yes, and that
13 10:35:57 includes not only the draft paper but also
14 10:35:59 correspondence concerning it.

15 10:36:01 MR. MURGATROYD: Okay. That's fine.

16 10:36:03 MR. DAVIS: And just -- I know we're
17 10:36:04 doing housekeeping issues here, but the
18 10:36:08 federal judge in the Blain case --

19 10:36:13 MR. MURGATROYD: Blain case, right.

20 10:36:14 MR. DAVIS: -- has recently entered
21 10:36:16 the parties' protective -- proposed
22 10:36:17 protective order.

23 10:36:18 And as part of that, the -- counsel
24 10:36:21 have an obligation to inform Dr. Keller and

1 10:36:23 Dr. Keller's counsel that absent agreement
2 10:36:26 to sign the confidentiality agreement that
3 10:36:30 the parties agreed to, which would cover
4 10:36:33 confidential and proprietary information,
5 10:36:36 that any documents that -- or information
6 10:36:39 that is discussed in your deposition, in
7 10:36:43 Dr. Keller's deposition concerning
8 10:36:44 confidential information that has been
9 10:36:45 marked as subject to the protective order,
10 10:36:46 that neither the witness nor counsel can
11 10:36:51 take any copies of that material with them
12 10:36:53 at the end of the deposition.
13 10:36:55 Dr. Keller's counsel can -- excuse
14 10:36:59 me. The witness can review the deposition
15 10:37:02 for purposes of signing the errata sheet but
16 10:37:04 can't keep any portion of the confidential
17 10:37:08 information or portion of the transcript
18 10:37:10 that deals with the confidential information
19 10:37:12 that's designated either on the record or
20 10:37:15 afterwards unless the witness or counsel
21 10:37:18 agree to sign the nondisclosure agreement
22 10:37:22 that's part of the protective order.
23 10:37:24 That's what we have --
24 10:37:25 MR. MURGATROYD: That's right.

1 10:37:26 MR. DAVIS: We have to tell the
2 10:37:27 witness and counsel that according to the
3 10:37:28 protective order in the Blain case.
4 10:37:31 MR. MURGATROYD: And we're going to
5 10:37:32 be presenting you with a number of exhibits
6 10:37:35 today, and some are marked confidential, but
7 10:37:37 I think we have an agreement that you're
8 10:37:39 going to look at them and dedesignate them
9 10:37:41 as appropriate, correct?
10 10:37:43 MR. DAVIS: If I can.
11 10:37:44 MR. MURGATROYD: All right.
12 10:37:44 So hopefully there won't too much
13 10:37:46 confidential stuff and that by the end of
14 10:37:50 the day will be sorted out.
15 10:37:51 (Exhibit No. 1 marked for
16 10:37:51 identification.)
17 10:37:51 BY MR. MURGATROYD:
18 10:37:51 Q I marked as Exhibit 1 a document that just
19 10:37:53 has "confidential" stamped all over it.
20 10:37:55 Do you see that, Doctor? Let me show
21 10:37:57 that to your attorney also.
22 10:37:59 MR. GREEN: Mm-hmm.
23 10:38:00 Q Now, is this -- was that a document that
24 10:38:05 actually had text it on that you are

1 10:38:07 claiming is confidential, or is that just
2 10:38:08 the prelude to the study that we talked
3 10:38:11 about that we're deeming confidential?
4 10:38:13 MR. GREEN: It's the prelude.
5 10:38:14 MR. MURGATROYD: Okay.
6 10:38:14 MR. GREEN: It was done by my office
7 10:38:16 just to keep track of things.
8 10:38:18 MR. MURGATROYD: That's fine. We'll
9 10:38:18 just put that one aside. Okay.
10 10:38:20 BY MR. MURGATROYD:
11 10:38:21 Q Now, are you aware that Dr. Wagner --
12 10:38:30 Do you know Karen Wagner?
13 10:38:32 A Yes.
14 10:38:33 Q Are you aware that she's been deposed in
15 10:38:34 this case?
16 10:38:35 A Yes.
17 10:38:35 Q Have you talked to her about that?
18 10:38:36 A No.
19 10:38:37 Q Have you read her deposition?
20 10:38:38 A No.
21 10:38:38 Q Okay.
22 10:38:40 Have -- when you were served with the
23 10:38:43 subpoena in this case, did you contact
24 10:38:47 counsel or anybody at GlaxoSmithKline?

1 10:38:49 A No.

2 10:38:49 Q Okay.

3 10:38:50 Have you talked to anybody at

4 10:38:51 GlaxoSmithKline about this deposition?

5 10:38:52 A No.

6 10:38:53 Q Okay.

7 10:39:00 Are you aware that Dr. Neal Ryan will

8 10:39:02 be deposed in the next few weeks in this

9 10:39:05 case?

10 10:39:05 A No.

11 10:39:06 Q Okay.

12 10:39:06 I take it you haven't talked to him

13 10:39:10 about -- about the Study 329 recently?

14 10:39:17 A I haven't, correct.

15 10:39:18 Q Okay.

16 10:39:21 How were you aware that Karen

17 10:39:23 Wagner's deposition was taken?

18 10:39:26 A Mr. Green told me.

19 10:39:28 Q Okay.

20 10:39:29 And were you shared any of the

21 10:39:32 summaries of the -- summary of the

22 10:39:34 deposition?

23 10:39:34 MR. GREEN: I'm going to object to

24 10:39:37 asking him any questions about any

1 10:39:39 conversations we had.

2 10:39:39 MR. MURGATROYD: Oh, I don't want

3 10:39:41 conversation. I'm just looking for

4 10:39:42 documents.

5 10:39:43 Q I just want to know if you saw a summary of

6 10:39:47 her deposition.

7 10:39:47 A I don't think so.

8 10:39:48 Q Okay. Let's get back to your research.

9 10:40:01 Do you do research in

10 10:40:02 psychopharmacology?

11 10:40:04 A Yes.

12 10:40:04 Q And how do you define psychopharmacology?

13 10:40:10 A Has to do with pharmacologic agents that

14 10:40:13 involve the psychological functioning of the

15 10:40:18 mind.

16 10:40:18 Q And do you consider yourself an expert in

17 10:40:20 psychopharmacology?

18 10:40:24 A I'm knowledgeable.

19 10:40:25 Q Okay.

20 10:40:27 Do you consider yourself an expert?

21 10:40:29 MR. DAVIS: Object to the form.

22 10:40:30 Asked and answered.

23 10:40:46 A I guess how do you define "expert"? I don't

24 10:40:50 know if --

1 10:40:50 Q Well, have you ever testified as an expert
2 10:40:52 on that subject?
3 10:40:55 A No.
4 10:40:55 Q Okay.
5 10:40:55 So have you ever held yourself out to
6 10:40:59 the public as an expert in the subject of
7 10:41:01 psychopharmacology?
8 10:41:03 MR. DAVIS: Object to the form. It's
9 10:41:04 vague and ambiguous, still not defined.
10 10:41:08 A I'm trying to be straightforward. I just
11 10:41:11 don't want to overgrandize how knowledgeable
12 10:41:14 I'm considered to be.
13 10:41:15 I know a lot about it. An awful lot
14 10:41:17 of people know an awful lot more than I do,
15 10:41:20 so I'm --
16 10:41:21 Q Okay.
17 10:41:21 Have you written any books about it?
18 10:41:22 A No.
19 10:41:23 Q Have you written any medical review
20 10:41:25 articles, articles that were peer-reviewed
21 10:41:27 on the subject of psychopharmacology?
22 10:41:34 A I've written manuscripts and have been the
23 10:41:38 first author on research studies that report
24 10:41:40 the results of studies of pharmacology,

1 10:41:44 psychopharmacology.

2 10:41:45 I have not written think pieces or

3 10:41:50 review articles that -- in which I opine

4 10:41:52 about the field.

5 10:41:54 Q Okay.

6 10:41:57 Do you consider yourself an expert in

7 10:41:59 child psychiatry?

8 10:42:08 A Broadly speaking, no.

9 10:42:10 Q Okay.

10 10:42:11 Do you treat children currently?

11 10:42:13 A No.

12 10:42:14 Q Have you ever treated children in the past?

13 10:42:16 A Yes.

14 10:42:18 Q Okay.

15 10:42:20 Do you consider yourself an expert on

16 10:42:22 the drug effects on children --

17 10:42:24 MR. DAVIS: Object to the form.

18 10:42:24 Q -- such as Paxil?

19 10:42:26 MR. DAVIS: Object to the form,

20 10:42:26 still -- it's vague and ambiguous, and it's

21 10:42:30 still undefined.

22 10:42:31 A I would answer it the same way I answered

23 10:42:33 your other series of questions about

24 10:42:36 expertise in psychopharm.

1 10:42:41 Q Okay.

2 10:42:41 Well, let me ask you this: Do you

3 10:42:44 treat people currently?

4 10:42:48 A Yes.

5 10:42:50 Q How many?

6 10:43:01 A Over what time period?

7 10:43:03 Q Currently, right now.

8 10:43:06 A Now I'm not treating any, at this moment.

9 10:43:09 Q I'm sorry.

10 10:43:10 A At this moment here, I'm not treating any --

11 10:43:13 Q Obviously.

12 10:43:13 A Do you mean over the course of a week, a

13 10:43:15 month, a year?

14 10:43:17 Q Do you have current patients?

15 10:43:19 A Yes.

16 10:43:19 Q How many?

17 10:43:20 A Ten.

18 10:43:22 Q And is this a private practice or part of

19 10:43:25 your job at the university?

20 10:43:28 A Private practice.

21 10:43:31 Q Okay.

22 10:43:31 And where is your private practice?

23 10:43:35 A I see patients in one of two locations, an

24 10:43:41 office that I have in Newton, Massachusetts

1 10:43:44 and an office that I have at the location
2 10:43:49 whose address I gave you earlier in
3 10:43:50 Providence.
4 10:43:52 Q At the hospital?
5 10:43:54 A Yes.
6 10:43:55 Q Okay.
7 10:43:55 So -- and what is the address of your
8 10:43:57 office in Newton?
9 10:44:00 A 22 Kirkstall Road, Newton, Massachusetts
10 10:44:06 02460.
11 10:44:08 Q And of the ten patients that you're
12 10:44:11 currently treating, are any of those
13 10:44:13 children or adolescents?
14 10:44:14 A No.
15 10:44:17 Just to clarify who I treat, I'm
16 10:44:20 called upon to do consultations periodically
17 10:44:25 of people who have been not successfully
18 10:44:29 treated by other people.
19 10:44:32 And given the nature of how -- of the
20 10:44:35 way my life is organized professionally,
21 10:44:40 what I typically require is that the person
22 10:44:44 be currently under the care of another
23 10:44:47 psychiatrist.
24 10:44:48 And so I then do a consultation, I

1 10:44:51 give my opinion and then send that opinion
2 10:44:55 back to the person, as opposed to someone
3 10:44:58 being referred to me and saying, gee, could
4 10:45:00 you see this patient in consultation with
5 10:45:03 the possibility -- with me at the time being
6 10:45:06 the only physician.
7 So when you ask me the question, you
8 10:45:08 know, how many patients do I treat, it's --
9 10:45:12 I know -- I know I'm trying to give you a
10 10:45:15 simple, straightforward answer; but it's
11 10:45:18 hard to know whether people like that are
12 10:45:21 people who you would want me to count in my
13 10:45:24 patient cohort or people -- that's my
14 10:45:27 question back to you.
15 10:45:30 Q Well --
16 (Telephone interruption.)
17 10:45:52 Q Let me ask you -- you say that you do
18 10:45:55 consultations.
19 Do you -- do you treat them? I mean,
20 10:45:57 do you try to make them better or do you
21 10:46:00 just examine them?
22 10:46:02 A I examine them, and I make a recommendation
23 10:46:08 to them, depending upon who wants the
24 10:46:14 consultation.

1 10:46:15 Sometimes it's the person who is
2 10:46:19 suffering themselves or their family who is
3 10:46:23 saying we want a consultation, and sometimes
4 10:46:25 it's another psychiatrist who says to me I
5 10:46:28 would like you to give me consultation, you
6 10:46:30 know, I would like you to consult on my
7 10:46:32 patient.

8 10:46:33 And what I then do is I make a
9 10:46:38 recommendation, which ultimately is
10 10:46:40 available to the patient, sometimes their
11 10:46:42 family, depending, and certainly to the
12 10:46:45 other psychiatrist, as to how I would
13 10:46:48 approach treatment, be it doing the same
14 10:46:52 thing as it is already being done or perhaps
15 10:46:54 doing something differently.

16 10:46:56 I make that recommendation to the
17 10:46:59 person requesting the consultation, patient,
18 10:47:02 physician, otherwise, and then they go on
19 10:47:04 from there.

20 10:47:04 And my consultation visits can last
21 10:47:08 anywhere between one visit and several,
22 10:47:12 occasionally longer, depending upon how
23 10:47:14 complicated the case is.

24 10:47:16 Q Okay.

1 10:47:16 But the question is, do you actually
2 10:47:18 treat them to make them better? Let me ask
3 10:47:21 you that simple question.
4 10:47:23 Do you actually render treatment?
5 10:47:24 A It's not -- it's not a simple question. One
6 10:47:26 could -- I could say that when they're in my
7 10:47:29 presence, there's something about being with
8 10:47:30 me, knowing that I'm carefully reviewing
9 10:47:32 their record and questioning them that
10 10:47:34 people find helpful and therapeutic.
11 10:47:37 Oftentimes people feel better just
12 10:47:39 when I'm evaluating them.
13 10:47:41 Treatment per se, do I prescribe
14 10:47:44 something for them and they take my
15 10:47:45 prescription and come back and see me for
16 10:47:50 that, that happens rarely as part of the
17 10:47:52 consultation.
18 10:47:53 Q Well, how about psychoanalysis, do you do
19 10:47:55 any forms of psychoanalysis?
20 10:47:57 A No.
21 10:47:58 Q Of the -- do you actually see someone and
22 10:48:01 then prescribe a drug for them?
23 10:48:03 A Yes.
24 10:48:04 Q Okay.

1 10:48:04 And of the current ten patients that
2 10:48:06 you see, are all those people on drugs?
3 10:48:08 A No.
4 10:48:10 Q Okay.
5 10:48:10 Have you prescribed drugs for all ten
6 10:48:14 of those?
7 10:48:23 A I'm not sure.
8 10:48:25 Q Do you prescribe Paxil currently?
9 10:48:29 A Yes.
10 10:48:30 Q When was the last time you prescribed Paxil?
11 10:48:43 A Within the past six months, I had someone
12 10:48:48 who's on Paxil. I gave a refill for them.
13 10:48:54 So this individual was taking Paxil
14 10:48:58 on a daily basis, but the actual
15 10:49:02 prescription by me only occurred once,
16 10:49:04 because their prior prescription ran out.
17 10:49:07 Q Okay.
18 10:49:07 Well, actually, I wanted to get to
19 10:49:09 new prescription Paxil.
20 10:49:10 When was the last time you prescribed
21 10:49:12 Paxil as a new treatment for a patient?
22 10:49:19 A I can't remember.
23 10:49:19 Q Years?
24 10:49:27 A Within the past year or two.

1 10:49:30 Q Okay.

2 10:49:30 Has it been since the PDAC involving

3 10:49:34 the issue of suicidality and its

4 10:49:36 relationship to Paxil?

5 10:49:38 MR. DAVIS: Object to the form.

6 10:49:40 A I don't know what the PD -- PDAC is.

7 10:49:43 Q The 2004 PDAC that looked into the issue of

8 10:49:45 suicidality caused by antidepressants.

9 10:49:48 You don't know what that is?

10 10:49:49 A I don't know what PDAC stands for.

11 10:49:52 Q Are you familiar with the FDA looking into

12 10:49:55 the issue of antidepressants causing

13 10:49:57 suicidality --

14 10:49:59 A Yes.

15 10:49:59 Q -- in 2004? Okay.

16 10:50:01 Since that time, have you prescribed

17 10:50:02 Paxil to a patient?

18 10:50:04 A Yes.

19 10:50:05 Q Okay.

20 10:50:06 At the time that you prescribed Paxil

21 10:50:08 to a patient, did you provide them with any

22 10:50:11 warnings that the drug could cause

23 10:50:14 suicidality?

24 10:50:15 MR. DAVIS: Object to the form.

1 10:50:24 A I summarized for them my understanding of
2 10:50:35 the questions that had been raised about
3 10:50:38 Paxil and the issues that the FDA was
4 10:50:43 looking at, and so I -- that's how I
5 10:50:49 approached it.
6 10:50:50 Q Okay.
7 10:50:50 And can you tell for the jury -- tell
8 10:50:52 the jury exactly what you did? What did you
9 10:50:55 say?
10 10:50:55 A I can't remember exactly what I said.
11 10:50:56 Q Well, generally.
12 10:51:00 A Generally said that at some point in time,
13 10:51:11 there was a -- questions started, to my
14 10:51:18 knowledge, in Great Britain about Paxil and
15 10:51:21 its potential for leading to increased rates
16 10:51:24 of suicide ideation, and that then led to
17 10:51:35 investigations within the United -- within
18 10:51:38 the United States that included the Federal
19 10:51:41 Drug Administration, you know, ultimately
20 10:51:48 approves and monitors the use of drugs, that
21 10:51:50 the FDA commissioned a task force of experts
22 10:51:56 to review the data and the evidence.
23 10:51:59 And in part as a result of this
24 10:52:02 review that was conducted, a decision was

1 10:52:07 made to put some type of a warning on
2 10:52:12 prescriptions which I then -- I think pulled
3 10:52:18 out of the PDR and read to the person about
4 10:52:21 Paxil and suicide ideation.
5 10:52:25 Q Okay.
6 10:52:26 Now, when was the last time you
7 10:52:30 actually treated a child as opposed to
8 10:52:34 performed research in a clinical trial with
9 10:52:36 a child, where you had a child as an
10 10:52:43 individual patients?
11 10:52:44 And by "child," I mean a child or
12 10:52:47 adolescent 18 years or younger.
13 10:52:49 A A long time ago. I don't remember exactly
14 10:52:51 when.
15 10:52:52 Q Okay.
16 10:52:53 Well, when you say "a long time ago,"
17 10:52:55 does that mean more than ten years?
18 10:52:57 A Yes.
19 10:52:58 Q More than 20 years?
20 10:53:08 A Probably about then.
21 10:53:10 Q Okay.
22 10:53:11 A Could be more than 20, could be less than
23 10:53:13 20, but somewhere around there.
24 10:53:15 Q Okay.

1 10:53:15 Did you ever hold yourself out as a
2 10:53:17 child psychiatrist?
3 10:53:18 A No.
4 10:53:20 Q Now, getting back to the research that you
5 10:53:36 do for the university, I think you said that
6 10:53:43 the research added up to \$50 million?
7 10:53:48 A The aggregate amount of research on an
8 10:53:51 annual basis that is awarded by agencies
9 10:53:59 external to Brown University to faculty who
10 10:54:02 have a primary or secondary appointment as
11 10:54:06 faculty members in the Department of
12 10:54:08 Psychiatry and Human Behavior is roughly
13 10:54:12 \$50 million.
14 10:54:14 Q And how much of that comes from drug
15 10:54:16 companies, what percentage?
16 10:54:22 A I don't know.
17 10:54:23 Q Is it more than 50 percent, less than 50
18 10:54:25 percent?
19 10:54:25 A Less than 50 percent.
20 10:54:27 Q And was -- Study 329, that was money that
21 10:54:30 came from a drug company, correct?
22 10:54:32 A Correct.
23 10:54:33 Q And that's GlaxoSmithKline, correct?
24 10:54:37 A Yes.

1 10:54:38 Q Do you currently get -- does --
2 10:54:41 Maybe you can explain this for me.
3 10:54:43 How does it work? In 329, you solicited
4 10:54:46 that study directly to GlaxoSmithKline,
5 10:54:49 correct?
6 10:54:57 A I'm not sure how to phrase an answer to your
7 10:55:01 questions when you ask something that's
8 10:55:02 correct in which the nature of the question
9 10:55:04 is rather inexact.
10 10:55:05 So for me to say "correct" --
11 10:55:09 The short answer is no.
12 10:55:11 Q Well, you approached GlaxoSmithKline to do
13 10:55:13 Study 329?
14 10:55:15 A I don't recall whether I personally
15 10:55:19 approached GlaxoSmithKline or whether a
16 10:55:21 member of the research team other than
17 10:55:25 myself did so.
18 10:55:28 Somebody in our research group had a
19 10:55:34 conversation with SmithKline. I don't
20 10:55:36 know -- I don't remember who nor nature of
21 10:55:41 how the conversation started, but it was
22 10:55:44 about the possibility of funding the study.
23 10:55:49 Q Well, I guess we need to come back -- go
24 10:55:52 back and define what you mean by research

1 10:55:54 team.

2 10:55:54 What is research team?

3 10:56:02 A Okay. They're a group of -- a group of

4 10:56:06 somewhere between, you know, four and eight

5 10:56:08 people, people that I've worked with, had

6 10:56:12 worked with then for many years, doing child

7 10:56:17 and adolescent research studies.

8 10:56:19 And we got together, I can't tell you

9 10:56:24 the forum; I can't tell you the setting, and

10 10:56:27 I can't tell you when, but said it's about

11 10:56:31 time somebody does a study that's well

12 10:56:36 enough designed and well enough controlled

13 10:56:42 to test the efficacy of the treatment of

14 10:56:44 children -- of adolescents suffering from

15 10:56:48 depression with an antidepressant.

16 10:56:50 Because at the time that we had this

17 10:56:53 conversation, it was our judgment based on a

18 10:56:56 review of the literature that we did --

19 10:56:59 which was part of kind of our common

20 10:57:00 knowledge, but then we formally did it --

21 10:57:04 that there had not yet been any studies of

22 10:57:06 the requisite design characteristics that

23 10:57:12 would have by, you know, knowledgeable

24 10:57:14 people been judged to be a properly designed

1 10:57:19 study to give an adequate test of the
2 10:57:24 efficacy of any drug for depression in
3 10:57:28 children, in adolescents.
4 10:57:32 And we said we want to do that. It's
5 10:57:34 time. Because we believed depression was
6 10:57:36 the real -- the real onus in adolescents.
7 10:57:40 Q But you weren't treating adolescents?
8 10:57:45 A You don't have to treat -- yes is the answer
9 10:57:47 to your question.
10 10:57:48 Q Well, who were the four to eight people who
11 10:57:50 were part of this research group -- research
12 10:57:53 team. Sorry.
13 10:57:54 A I don't remember exactly who was in at the
14 10:57:58 very beginning, but it it included Neal
15 10:58:06 Ryan, Mike Strober, the three of us, and
16 10:58:15 then early on added a woman named Rachel
17 10:58:20 Gelman-Klein, someone named Stan Kutcher.
18 10:58:44 I don't remember who else were -- who
19 10:58:47 else was part of the initial discussions,
20 10:58:49 but it was at least those -- some
21 10:58:52 combination of those people.
22 10:58:54 Q And who was the head of the team? Was there
23 10:58:55 a team leader?
24 10:58:58 A Nobody was designated as team leader.

1 10:59:01 Q Okay.

2 10:59:02 And Neal Ryan, he -- he lives in

3 10:59:05 Pittsburgh, right?

4 10:59:09 A I don't know where he lives.

5 10:59:09 Q Does he work out of Pittsburgh?

6 10:59:11 A He works at the Western Psychiatric

7 10:59:14 Institute in Pittsburgh.

8 10:59:15 Q And Strober is in Los Angeles, correct?

9 10:59:20 A Mike Strober works at the University of

10 10:59:22 California in Los Angeles. I don't know

11 10:59:24 where he lives.

12 10:59:25 Q And Rachel Klein is in New York somewhere?

13 10:59:28 A Yes.

14 10:59:29 Q Where is she?

15 10:59:29 A Well, she works -- I don't know exactly.

16 10:59:32 It's a child study center affiliated with

17 10:59:36 New York University.

18 10:59:38 At the time, she worked for

19 10:59:39 Columbia -- she worked, you know, at one of

20 10:59:43 the institutions that was part of Columbia

21 10:59:47 Presbyterian.

22 10:59:48 Q Okay.

23 10:59:48 And how about Stan Kutcher, where was

24 10:59:50 he - where was he working at the time the

1 10:59:53 team was formed?

2 10:59:54 A Somewhere during the period of time when we

3 10:59:57 were discussing this, he moved from one of

4 11:00:01 the teaching hospitals in Toronto, Canada to

5 11:00:06 become chair of I believe it's called

6 11:00:15 Dalhousie Medical Center.

7 11:00:16 And I'm --

8 11:00:18 Q Can you spell that?

9 11:00:18 A No.

10 11:00:19 Q Okay.

11 11:00:20 You think phonetically it's

12 11:00:21 Dalhousie?

13 11:00:23 A D-A-L-H-O-U-I-S-I-E, and I think that's in

14 11:00:31 Halifax.

15 11:00:32 Q All right.

16 11:00:32 A Nova Scotia.

17 11:00:34 Q How is it that -- I mean obviously you're

18 11:00:36 from different parts of the country, and,

19 11:00:39 actually, two countries.

20 11:00:40 How is it that you got together? Was

21 11:00:42 this telephone conferences? Did you meet in

22 11:00:45 person, or both?

23 11:00:45 A Just to -- just to put it in context, when I

24 11:00:47 was doing my residency training, I had a

1 11:00:50 mentor who believed it was a good thing for
2 11:00:55 me to meet and collaborate with people all
3 11:00:58 over the country and the world, and he sent
4 11:01:00 me around just to meet people and get to
5 11:01:02 know them.

6 And my very first research project
7 11:01:06 was a collaborative study when I started as
8 11:01:08 a resident which involved six -- five
9 11:01:13 medical centers across the country, so I
10 11:01:17 just knew lots of people.

11 And as I developed projects and
12 11:01:21 ideas, met people, and the idea was to
13 11:01:24 somehow be put in contact with or contact
14 11:01:28 people who at least were thought -- in my
15 11:01:30 opinion and others' -- to be the best and
16 11:01:32 the brightest of researchers. And then the
17 11:01:36 other criteria was that I enjoyed their
18 11:01:39 company.

19 So when we had that combination, had
20 11:01:43 an idea, we -- somehow we'd get together.

21 Actually, the way I think I met most
22 11:01:48 of the child people, other than the ones
23 11:01:50 that I knew from my own department, was this
24 11:01:57 mentor of mine organized on an annual basis

1 11:02:02 a meeting of people who were knowledgeable
2 11:02:05 about child and adolescent psychiatry and in
3 11:02:11 particular research.
4 11:02:12 And we had an annual meeting starting
5 11:02:14 in the 1980s, two to three days a year, and
6 11:02:21 I attended all of those meetings. And the
7 11:02:26 reason was, was despite -- the reason was --
8 11:02:30 The reason was at the time I was a
9 11:02:34 coprincipal investigator on a grant
10 11:02:37 sponsored by the National Institute of
11 11:02:38 Mental Health to look at the offspring of
12 11:02:44 adults with mood disorders to see whether
13 11:02:48 they were at higher risk for developing mood
14 11:02:51 disorders than children whose parents didn't
15 11:02:57 have it.
16 11:02:57 So I was doing research on children
17 11:02:59 and adolescents, and that was my ticket of
18 11:03:03 admission to join that group and through
19 11:03:05 those meetings met each of the individuals
20 11:03:07 that I mentioned to you.
21 11:03:08 Q And let's take Neal Ryan.
22 11:03:10 Is he a child psychiatrist, to your
23 11:03:14 knowledge?
24 11:03:15 A I assume so, but I'm not -- I don't -- I

1 11:03:17 don't -- I've never studied his or anyone
2 11:03:19 else -- any the CVs of anyone you've
3 11:03:21 mentioned, so I assume that they all are.
4 11:03:24 Q Okay.
5 11:03:24 You say you assume they all are,
6 11:03:26 would that include --
7 11:03:27 A Well, Mike Strober is a Ph.D., so he would
8 11:03:29 be -- he's a psychologist.
9 11:03:32 Q Okay.
10 11:03:33 A Who -- and I don't know --
11 11:03:34 Q Does he treat children?
12 11:03:35 A He primarily treats adolescents, I believe,
13 11:03:39 not children.
14 11:03:39 Q Okay.
15 11:03:41 And Rachel Klein?
16 11:03:44 A She's a psychologist. And primarily -- I
17 11:03:49 don't know how much -- I don't know how much
18 11:03:54 of each of these individuals' times they
19 11:03:58 spend diagnosing and treating their own
20 11:04:01 patients and how much of their time they
21 11:04:02 spend doing research and teaching, but it's
22 11:04:08 in the domain of child and adolescent
23 11:04:11 psychiatry with a stronger emphasis on
24 11:04:14 adolescent than child.

1 11:04:16 Q And that includes Stan Kutcher also?

2 11:04:19 A Stan is a psychiatrist, and I would believe

3 11:04:22 the same to be true of Stan.

4 11:04:24 Q Okay.

5 11:04:29 Now, when you do the research such as

6 11:04:36 Study 329, where you were paid by

7 11:04:39 GlaxoSmithKline, does that money go to the

8 11:04:40 university, in this instance, Brown, for the

9 11:04:44 work you did?

10 11:04:49 A I don't believe I or any -- I don't believe

11 11:04:52 I or any of the investigators was paid by

12 11:04:55 GlaxoSmithKline.

13 11:04:58 Q The university was paid? Is that what

14 11:04:59 you're saying?

15 11:05:02 A Yes.

16 11:05:03 The way this grant worked, and most

17 11:05:06 that I'm aware of, is if a grant was funded,

18 11:05:12 the funding, whatever amount of money is

19 11:05:15 agreed upon, be it by the National

20 11:05:18 Institutes of Health or foundation or

21 11:05:21 pharmaceutical company, whomever might be

22 11:05:23 funding it, an individual donor, in every

23 11:05:28 instance I've ever been involved in, the

24 11:05:33 funding is a written agreement between the

1 11:05:38 funder and an institution.

2 11:05:45 And what's designated as part of the

3 11:05:49 agreement is that there's typically one

4 11:05:51 individual who is called the principal

5 11:05:54 investigator, and there are other

6 11:05:58 investigators.

7 11:05:59 And then based on, you know, how your

8 11:06:01 institution functions in relation to you,

9 11:06:04 you have as the principal investigator

10 11:06:08 varying degrees of autonomy as to how you

11 11:06:12 conduct that research within the broader,

12 11:06:16 you know, research environment of the

13 11:06:19 institution.

14 11:06:20 But it's considered an award to the

15 11:06:22 institution, not an individual.

16 11:06:23 Q Okay.

17 11:06:23 And does any of the money actually

18 11:06:26 result in your salary or in bonuses?

19 11:06:28 A Not for me.

20 11:06:29 Q You personally don't receive anything for

21 11:06:31 that?

22 11:06:32 A No.

23 11:06:31 Q For securing the study?

24 11:06:33 A No.

1 11:06:36 Q Okay.

2 11:06:38 Now -- so there's money being paid to

3 11:07:04 the university for research, but if you --

4 11:07:08 you can also be a consultant for a drug

5 11:07:10 company where you personally get paid; is

6 11:07:12 that correct?

7 11:07:13 A Yes.

8 11:07:13 Q Okay.

9 11:07:14 And have you been a consultant for

10 11:07:16 GlaxoSmithKline for any period of time in

11 11:07:19 the last 20 years?

12 11:07:20 A Yes.

13 11:07:23 Q Okay.

14 11:07:26 And what does it mean to be a

15 11:07:28 consultant?

16 11:07:35 MR. DAVIS: Object to the form of the

17 11:07:36 question.

18 11:07:38 A The word "consultant" covers the broad -- an

19 11:07:42 extremely broad range of potential

20 11:07:44 activities in a broad range of domains.

21 11:07:49 So you asked me what it meant to be a

22 11:07:51 consultant. It could mean -- I think you

23 11:07:54 have to narrow the question to be --

24 11:07:58 Q Okay, that's fine.

1 11:07:58 When did you first become a
2 11:08:01 consultant for GSK?
3 11:08:02 A I don't remember. I believe I was asked to
4 11:08:04 produce documents, which you should have,
5 11:08:05 that would state when I first did and how
6 11:08:08 much and how often.
7 11:08:09 It was sometime in the 1990s and not
8 11:08:24 since 2004.
9 11:08:25 Q Okay.
10 11:08:26 A Sometime during that period.
11 11:08:27 Q And the -- so the last time you were a
12 11:08:29 consultant for GSK was in 2004?
13 11:08:32 A Yes.
14 11:08:32 I don't remember when in 2004. I
15 11:08:36 don't remember specifically what; but as
16 11:08:37 part of producing records, I noted that the
17 11:08:44 last time I did any consulting was in 2004.
18 11:08:47 Q All right.
19 11:08:48 And -- well, let's take through --
20 11:08:52 take me through the consulting activities
21 11:08:55 that you remember doing for GSK, starting in
22 11:08:57 the 1990s through 2004.
23 11:09:00 What type of activities were you
24 11:09:01 involved in?

1 11:09:04 A In order to be precise, it would actually be
2 11:09:06 helpful if you have -- if you showed me the
3 11:09:09 stuff I produced. I could just tell you.
4 11:09:12 Q Sure. Sure.
5 11:09:13 A All right.
6 11:09:13 Q We can do it.
7 11:09:14 MR. MURGATROYD: Let's off the record
8 11:09:14 for a minute.
9 11:09:16 THE VIDEOGRAPHER: It's nine minutes
10 11:09:17 after 11:00. We're off the record.
11 11:09:21 (Discussion off the record.)
12 11:21:59 THE VIDEOGRAPHER: We are back on the
13 11:22:00 record. The time is 11:22.
14 11:22:02 BY MR. MURGATROYD:
15 11:22:03 Q Okay.
16 11:22:03 While we were off the record, did you
17 11:22:05 get a chance to go through the documents I
18 11:22:06 presented you?
19 11:22:07 A I did. And they're not nearly as
20 11:22:09 informative as I would have hoped.
21 11:22:12 Q All right.
22 11:22:12 A But go ahead.
23 11:22:12 Q Do you recognize them as being documents
24 11:22:14 that you produced in this litigation?

1 11:22:16 A Absolutely.

2 11:22:17 Q Okay.

3 11:22:18 And they all appear to be authentic?

4 11:22:20 A Yes.

5 11:22:20 Q Okay.

6 11:22:21 And were they all produced during the

7 11:22:23 course of your business --

8 11:22:24 A Yes.

9 11:22:24 Q -- by you? Okay.

10 11:22:26 Now, does it tell you a starting

11 11:22:29 date?

12 11:22:31 A Well, the earliest one I could find was

13 11:22:33 1998.

14 11:22:34 Q Okay.

15 11:22:40 Why don't we mark that as an exhibit.

16 11:22:42 Which one is that?

17 11:22:43 A Well, I don't know. Here's one that says

18 11:22:45 '99. This one says 2004.

19 11:22:53 Q Okay.

20 11:22:54 A I was trying to do them by topic.

21 11:23:01 Q Well, do you want to organize them by date

22 11:23:04 or topic? Whatever is easier for you.

23 11:23:07 A Here's three that have nothing to do with

24 11:23:10 Paxil. They have to do with a compound

1 11:23:13 called Vilazodone, which was a drug that, as
2 11:23:17 I recall -- and I don't know the
3 11:23:19 arrangements, but GSK was -- I don't know
4 11:23:25 how to say this -- had an arrangement with
5 11:23:28 the company that owned the drug, and GSK was
6 11:23:31 doing studies to decide whether they wanted
7 11:23:35 to develop this drug.

8 And I was a consultant and went to 11
9 11:23:39 see there at least three meetings to render
10 11:23:42 my opinion based on whether they should
11 11:23:45 develop it.

12 And I'm not exactly sure how it shook
13 11:23:47 out at the end, although we stopped having
14 11:23:50 meetings about it.

15 11:23:51 Q Okay.

16 11:23:51 A And I gather that they decided that it
17 11:23:53 wasn't a drug which they thought was likely
18 11:23:57 to end up being a -- approvable by the FDA,
19 11:24:02 and they gave it back, so there's a --

20 11:24:05 Q Okay.

21 So we're not going to tag these as
22 11:24:08 exhibits. We're going to take these out of
23 11:24:10 the pile.

24 11:24:10 A Yes.

1 11:24:11 MR. DAVIS: And I'll designate that
2 11:24:13 discussion by Dr. Keller about that proposed
3 11:24:15 study drug as confidential pursuant to the
4 11:24:17 protective order in the cases.
5 11:24:19 MR. MURGATROYD: That's fine.
6 11:24:32 A Now, here's a -- here's something that I
7 11:24:33 did. And I think it was related to that as
8 11:24:37 well.
9 11:24:37 It says consulting CNS pipeline.
10 11:24:40 Q Right.
11 11:24:41 A So I believe that that probably had to do
12 11:24:43 with that drug as well.
13 11:24:45 Q That's fine.
14 11:24:46 A May have been other things in the pipeline.
15 11:24:48 Q And in -- in doing these, were you paid for
16 11:24:52 the number of meetings that you attended, or
17 11:24:55 were you on a -- some kind of payroll or
18 11:24:58 were you --
19 11:24:59 A No, I was -- the answer to your question is
20 11:25:02 yes.
21 11:25:05 Q Okay.
22 11:25:06 Paid by the meeting?
23 11:25:08 A Yes.
24 11:25:08 Q And did that vary from a thousand to a

1 11:25:11 couple of thousand dollars per meeting?
2 11:25:13 MR. DAVIS: Object to the form.
3 11:25:14 A What do I do?
4 11:25:15 MR. GREEN: You can answer.
5 11:25:16 MR. DAVIS: I may make objections --
6 11:25:17 Dr. Keller, I may make objections just for
7 11:25:20 the judge to rule upon later.
8 11:25:21 THE WITNESS: Oh, okay.
9 11:25:21 MR. DAVIS: That doesn't mean you
10 11:25:22 can't answer the question, unless your
11 11:25:23 counsel instructs you not to answer.
12 11:25:26 A See, here's one that's called a Paxil
13 11:25:29 advisory meeting. Let me ask Jim to hold
14 11:25:32 that. I'll see if I can find the other
15 11:25:35 Paxil advisory one.
16 11:25:41 This is another that says Paxil
17 11:25:43 Advisory Board.. This is one in 1999. This
18 11:25:48 says Paxil Advisory Board.
19 11:25:50 This is '99, and I think this may be
20 11:25:53 the same as the other.
21 11:25:56 MR. GREEN: Mm-hmm.
22 11:26:13 (Pause.)
23 11:26:21 A This is a meeting in '99. This doesn't say.
24 11:26:23 I think this may match up with some of the

1 11:26:25 other ones.

2 11:26:26 Some of these are just like 1099s.

3 11:26:29 Q Right.

4 11:26:29 A Some have information on the meeting.

5 11:26:32 And this one -- this -- this was

6 11:26:39 another one that had nothing to do with

7 11:26:42 Paxil.

8 11:26:42 You see that number of that drug

9 11:26:43 there?

10 11:26:44 Q Yes, I'm familiar with that drug. That's

11 11:26:46 fine. We'll take this one out of it.

12 11:26:48 A You're familiar with it?

13 11:26:49 Q Yes, I've seen probably about a hundred

14 11:26:51 thousand pages related to that drug.

15 11:26:54 A There you go.

16 11:26:55 What do you think of it?

17 11:26:56 Q I think it's interesting.

18 11:26:59 A Okay.

19 11:26:59 Q We'll see it in 2010. Is that when it hits?

20 11:27:04 A So -- so there are -- I believe that I have

21 11:27:07 one, two, three -- I don't know if that's --

22 11:27:13 this is --

23 11:27:15 Okay. This is February 2003. This

24 11:27:19 is February 2004.

1 11:27:23 Q Okay. Put those in date order.

2 11:27:25 A Okay.

3 11:27:25 Q I'll mark those in a second, but let's just

4 11:27:28 get them in order.

5 11:27:29 A This is -- this is February '99.

6 11:27:30 Q Okay.

7 11:27:32 A And -- oh, this is the same meeting. This

8 11:27:35 is February '99.

9 11:27:36 Q Are those duplicates?

10 11:27:38 A Same -- same things, yes, I guess.

11 11:27:39 Q Okay.

12 11:27:41 A So -- and this -- this doesn't -- this just

13 11:27:46 has like a payment, but it doesn't track

14 11:27:51 to -- this is 1999.

15 11:27:57 Q Okay. Let's put that in the '99 pile.

16 11:28:00 A So that probably goes with '99.

17 11:28:02 Q Those --

18 11:28:03 A This has to do with something different, not

19 11:28:05 a meeting. It has to do with a manuscript

20 11:28:09 that I wrote.

21 11:28:12 Q Relating to 329?

22 11:28:13 A No.

23 11:28:14 Q Okay.

24 11:28:15 A No. Just a generic thing called the

1 11:28:18 Treatment of Major Depression.

2 11:28:20 Q Okay.

3 11:28:21 A Or --

4 11:28:21 Q Was that for -- that was STI? Was that for

5 11:28:25 GSK?

6 11:28:28 STI, so the record is clear,

7 11:28:29 is Scientific -- Scientific Therapeutics,

8 11:28:32 Inc., correct?

9 11:28:33 A Yes, right, okay. You're right. The answer

10 11:28:35 to your question is yes.

11 11:28:40 Q And so you were paid -- were you paid by GSK

12 11:28:43 or STI to do the manuscript?

13 11:28:47 A You know, it's the bane our existence when

14 11:28:49 we get the 1099s because you're never quite

15 11:28:52 sure --

16 11:28:52 Q Who's paying you?

17 11:28:53 A -- who's paying.

18 11:28:55 This one was STI.

19 11:28:58 Q Okay.

20 11:28:58 How much is that for?

21 11:28:59 A Excuse me?

22 11:29:00 Q How much was that for?

23 11:29:01 A \$2,000.

24 11:29:02 Q Okay.

1 11:29:02 MR. MURGATROYD: Let me mark that as
2 11:29:03 Exhibit 2.
3 11:29:04 (Exhibit No. 2 marked for
4 11:29:04 identification.)
5 11:29:09 A Invoice date, 2003.
6 11:29:13 Q Okay.
7 11:29:15 A Okay.
8 11:29:15 So it looks like these three have to
9 11:29:18 do with meetings which are called Paxil
10 11:29:21 Advisory Board meetings, and one was in '99
11 11:29:26 and one was in --
12 11:29:27 Q Well, let's back up for a second. Let's do
13 11:29:31 one at a time.
14 11:29:32 A Okay.
15 11:29:32 Q Let me mark Exhibit 3 that -- let me have
16 11:29:35 you identify for the record what --
17 11:29:38 Let's go back to this. For the
18 11:29:41 record, can you identify what Exhibit 2 is,
19 11:29:43 please?
20 11:29:45 A This is a letter to me saying that I was --
21 11:29:52 it contained an honorarium check for \$2,000
22 11:29:56 for editing a manuscript entitled Paroxetine
23 11:30:00 Treatment of Major Depression, which will be
24 11:30:02 included in a supplement for the June

1 11:30:06 edition of Psychopharmacology Bulletin.

2 11:30:10 Q Okay.

3 11:30:12 And we've established that STI was

4 11:30:15 doing that on behalf of GSK, correct?

5 11:30:18 A Yes.

6 11:30:18 Q Okay, good.

7 11:30:19 Let's go to Exhibit 3.

8 11:30:21 A Okay.

9 11:30:21 (Exhibit No. 3 marked for

10 11:30:21 identification.)

11 11:30:22 MR. GREEN: Could I just interject?

12 11:30:23 Exhibit 3, I think, if you look at it is a

13 11:30:26 collection of 1099s from various years, so

14 11:30:29 it's not all relating to 1999. I think just

15 11:30:33 the top page relates to 1999.

16 11:30:37 THE WITNESS: Jim is right. This

17 11:30:38 is -- this is --

18 11:30:39 BY MR. MURGATROYD:

19 11:30:39 Q Okay.

20 11:30:39 Why don't you take us -- take us

21 11:30:40 through that, and a just go through for the

22 11:30:42 record just exactly what Exhibit 3 consists

23 11:30:46 of.

24 11:30:46 A Well, it's not very informative.

1 11:30:48 So the first page says 1999. It
2 11:30:52 gives a date of February 12th to 14th, and
3 11:30:56 it says \$2,500 paid May 5, 1999.
4 11:31:01 Q Okay.
5 11:31:02 A Then the next page says 2000 and 2001, zero
6 11:31:08 income from GSK.
7 11:31:10 A Okay.
8 11:31:16 Q Okay.
9 11:31:16 A I would venture that my wife organized this.
10 11:31:19 Q Okay.
11 11:31:20 A The next one says 2002, and it says
12 11:31:26 SmithKline, you know, long name for it, and
13 11:31:29 it says nonemployee compensation, \$3,000.
14 11:31:33 Q Okay.
15 11:31:37 A Next is 2003. It's a 1099 from SmithKline
16 11:31:45 for \$2,500.
17 11:31:49 Q Okay.
18 11:31:49 A And this is 2003. I don't know if it's
19 11:31:51 another one or the same one. I can't tell.
20 11:32:00 A I don't know. It's -- you can study it.
21 11:32:03 Q Let's see if your lawyer can sort it out.
22 11:32:07 MR. GREEN: I think what you have is
23 11:32:08 Copy 2 of your 1099 and Copy B, which one is
24 11:32:11 supposed to be filed with the state and one

1 11:32:13 is supposed to be kept for your records, so
2 11:32:15 it's the same.
3 11:32:15 MR. MURGATROYD: So it's a duplicate.
4 11:32:17 That's fine.
5 11:32:18 MR. GREEN: It's a duplicate.
6 11:32:21 MR. MURGATROYD: Good.
7 11:32:21 A And then 2003, this one is from Scientific
8 11:32:24 Therapeutics, Inc. for \$2,000, probably for
9 11:32:28 what we were discussing.
10 11:32:29 Q Okay.
11 11:32:30 A This is from a travel -- this is Maritz
12 11:32:3 Travel Company, North Highway Drive, Fen ton, 3
13 11:32:39 Missouri, 2003.
14 11:32:41 Q Okay.
15 11:32:42 A \$3,000. It's not an identifier, but it's in
16 11:32:48 that -- this pile.
17 11:32:49 Q That's fine.
18 11:32:50 A So I assume it's related.
19 11:32:52 And then in 2004, also from that same
20 11:32:56 travel company, it's 2004, 1099, \$9,000.
21 11:33:05 Q Okay.
22 11:33:05 And what was that? Was that for a
23 11:33:07 GSK event, or it doesn't -- doesn't explain
24 11:33:09 it?

1 11:33:09 A No, no. Doesn't explain.

2 11:33:10 Q Okay.

3 11:33:11 A But I'm assuming that because it's in this

4 11:33:13 pile --

5 11:33:15 Q That it's related?

6 11:33:16 A -- that it's related.

7 11:33:17 Q Okay. That's fine. All right.

8 11:33:19 Let's go to the next exhibit or the

9 11:33:20 next document, and we'll mark it as

10 11:33:23 Exhibit 4.

11 11:33:25 (Exhibit No. 4 marked for

12 11:33:25 identification.)

13 11:33:31 BY MR. MURGATROYD:

14 11:33:31 Q Let me actually turn it to the first page so

15 11:33:33 it will be easy to identify

16 11:33:39 And can you identify for the record

17 11:33:40 what Exhibit 4 is?

18 11:33:50 A It's a form letter to -- doesn't have my

19 11:33:58 name on it.

20 11:34:00 It's a form letter thanking me for

21 11:34:03 being at the recent meeting. And in

22 11:34:06 handwriting on the top, it says Key West.

23 11:34:10 Doesn't say it in the letter.

24 11:34:12 Q Okay.

1 11:34:12 A It just -- It's virtually impossible for
2 11:34:17 doctors -- busy doctors to stay up to date
3 11:34:19 on new developments about pharmacology
4 11:34:21 indications, implications. You helped a
5 11:34:24 group of your colleagues learn about the
6 11:34:25 most current, up-to-date --
7 11:34:27 Q Doctor, she's got to write that.
8 11:34:29 A Oh, I'm sorry.
9 11:34:29 Q You might want to go a little slower.
10 11:34:33 MR. GREEN: And the question was,
11 11:34:33 what is it? And you said it was a --
12 11:34:34 thanking you for going to the meeting.
13 11:34:36 THE WITNESS: A thank you --
14 11:34:36 MR. GREEN: If he wants to know
15 11:34:37 anymore, he'll ask you.
16 11:34:39 A A thank-you letter for going to the meeting.
17 11:34:41 Q Okay.
18 11:34:41 And that had to do with Paxil?
19 11:34:43 A It was called the Paxil Advisory Board.
20 11:34:45 Q Okay.
21 11:34:45 And then I noticed what I'll mark
22 11:34:47 as -- actually, this is a little out of
23 11:34:51 order.
24 11:35:27 (Exhibit No. 5 marked for

1 11:35:27 identification.)

2 11:35:27 (Exhibit No. 6 marked for

3 11:35:27 identification.)

4 11:35:28 (Exhibit No. 7 marked for

5 11:35:28 identification.)

6 11:35:28 BY MR. MURGATROYD:

7 11:35:28 Q Okay.

8 11:35:28 Let me show you what we've marked as

9 11:35:30 Exhibit 5. If you can identify that for the

10 11:35:31 record, please.

11 11:35:35 A This is -- this gives logistic information

12 11:35:41 about meeting attendance, hotel

13 11:35:46 accommodations and travel.

14 11:35:48 Q Okay.

15 11:35:48 And that's for the Paxil

16 11:35:51 Psychiatric -- Psychiatry Advisory Board?

17 11:35:55 A February 12, 1999, correct.

18 11:35:57 Q Okay.

19 11:35:58 Is that a duplicate of this document?

20 11:36:00 This, I see, is dated also February 12,

21 11:36:04 1999.

22 11:36:05 A Yes.

23 11:36:05 Q So 5 and 6 are the same?

24 11:36:08 A Yes.

1 11:36:08 Q Okay.

2 11:36:08 And then what I've marked as Exhibit

3 11:36:09 7, and can you identify for the record what

4 11:36:21 that is, please?

5 11:36:23 A It's a miscellaneous expense form.

6 11:36:25 Q And does that relate to GlaxoSmithKline?

7 11:36:26 A Yes. Paxil Psychiatry Advisory Board,

8 11:36:30 February 5, 2004 to February 7, 2004.

9 11:36:36 Q Okay.

10 11:36:39 So this came from -- this originally

11 11:36:41 came from the question were you ever a

12 11:36:42 consultant for GSK.

13 11:36:44 Do you recall that?

14 11:36:45 A Yes.

15 11:36:47 Q Is being a consultant and being a member of

16 11:36:49 an advisory board, are those two different

17 11:36:51 activities or two different functions or are

18 11:36:54 they similar or the same?

19 11:36:58 A Most cases, they're similar.

20 11:37:00 Q And what do you recall doing as a member of

21 11:37:04 the advisory board for GSK?

22 11:37:07 A Sitting in a room, having certain materials

23 11:37:15 presented. Sometimes -- you know, actually,

24 11:37:20 what I'm -- what I'm remembering is --

1 11:37:22 I don't remember anything specific
2 11:37:24 about any of these meetings, but typically
3 11:37:29 what happens is there's some combination of
4 11:37:34 present -- topics that are listed and some
5 11:37:38 combination of presentations by personnel
6 11:37:40 for GSK or members of the advisory board.
7 11:37:43 These are topics we would like you to
8 11:37:45 discuss.

9 And then based on how the meeting is
10 11:37:48 run, we either spend most of our time
11 11:37:52 listening or we spend more time actually
12 11:37:59 engaging in conversation.

13 I personally -- I either spend a lot
14 11:38:05 of time listening, because there's not a lot
15 11:38:08 of time for discussion, or I spend a lot of
16 11:38:11 time discussing.

17 But since the meetings typically
18 11:38:14 average between eight and 20 people, the
19 11:38:17 amount of time that I or any one individual
20 11:38:22 would talk is minimal.

21 11:38:24 Q Okay.

22 Well, let me -- what do you
23 11:38:27 understand the purpose of the meetings are?

24 11:38:28 Is it how to better promote the drug

1 11:38:30 or better -- other indications, a
2 11:38:33 combination of both?
3 11:38:34 A It varies. I mean, the meetings I like best
4 11:38:38 are the meetings and --
5 11:38:41 It just varies enormously. The
6 11:38:43 meetings I find most appealing are the ones
7 11:38:47 when they have questions about the science
8 11:38:52 of developing a compound at its earliest
9 11:38:56 stages or after -- after a compound has
10 11:38:59 been -- say before FDA approval or after FDA
11 11:39:05 approval, trying to decide what new studies
12 11:39:08 should we do or --
13 11:39:11 Those are the things that I like
14 11:39:13 best. Sometimes you're presented with
15 11:39:16 marketing data, which has, you know, how
16 11:39:18 much of this drug -- drugs are being sold
17 11:39:21 and why do we think they are being sold.
18 11:39:25 Q Okay.
19 11:39:27 A That's --
20 11:39:28 Q Did you ever attend any Paxil Advisory Board
21 11:39:31 meetings where the main topic was how best
22 11:39:36 to get Paxil better promoted for use?
23 11:39:41 A No.
24 11:39:41 Q Okay.

1 11:39:42 Now, is there a difference between
2 11:39:43 being a member of the advisory board and
3 11:39:44 being on the GSK speakers bureau?
4 11:39:46 Do you know what that is, speakers
5 11:39:48 bureau?
6 11:40:00 A I believe I know. I've never been on the
7 11:40:05 speakers bureau, but it's my understanding
8 11:40:11 that speakers bureaus are kind of a -- a
9 11:40:14 list or a number of people who --
10 11:40:18 I don't know exactly how it works.
11 11:40:20 Either they agree generally, yes, we'd like
12 11:40:22 to give talks for GSK, or maybe they have a
13 11:40:27 specific arrangement, or maybe it's a list
14 11:40:29 of people that the -- that any given company
15 11:40:31 thinks, oh, gee, these are people who would
16 11:40:34 be good to speak.
17 11:40:35 And then when various speaker
18 11:40:37 programs are arranged, these are people that
19 11:40:39 are typically contacted.
20 11:40:41 I believe that's what a speaker
21 11:40:44 bureau is.
22 11:40:45 Q Okay.
23 11:40:45 A I've never formally been on one myself that
24 11:40:49 I'm aware of.

1 11:40:50 Q Okay.

2 11:40:50 Now, are you considered a key opinion

3 11:40:57 leader for GSK, to your knowledge?

4 11:41:01 MR. DAVIS: Object to the form.

5 11:41:05 THE WITNESS: What did you say?

6 11:41:06 MR. DAVIS: Object to the form.

7 11:41:07 I'm just making an objection for the

8 11:41:08 judge to rule on later.

9 11:41:10 A I don't know if GSK considers me a key

10 11:41:14 opinion leader for them. I do know that I'm

11 11:41:18 sort of generally referred to as an opinion

12 11:41:22 leader in the field of psychiatry

13 11:41:27 specifically having to do with depression --

14 11:41:31 with all mood disorders, and to a large

15 11:41:33 extent anxiety.

16 11:41:35 And in general, I hate to say this,

17 11:41:38 but I'm sort of becoming known as a wise old

18 11:41:41 man.

19 11:41:42 (Laughter.)

20 11:41:43 Q All right.

21 11:41:43 A So people will ask my opinion on things that

22 11:41:45 I may not know a heck of a lot about, but,

23 11:41:48 you know...

24 11:41:49 Q That was my question.

1 11:41:50 What does it mean to be an opinion
2 11:41:52 leader? Does that mean that people look up
3 11:41:53 to you and respect your opinion, to your
4 11:41:55 knowledge?

5 11:41:55 A I don't know about that. I don't know. I
6 11:41:57 don't know exactly.

7 11:42:01 I think --

8 11:42:02 Q Well, it means your opinion's respected?

9 11:42:05 A In the kindest sense of the word, I believe
10 11:42:07 it means that you're someone who is well
11 11:42:12 known by a high proportion of psychiatrists
12 11:42:16 and other mental health professionals and
13 11:42:19 that you're respected for being a -- how to
14 11:42:23 put this, an honorable person.

15 11:42:25 And therefore, when you give an
16 11:42:27 opinion about something, people tend to
17 11:42:31 listen and say, oh, this individual gave
18 11:42:34 their opinions; it's worth considering.

19 11:42:40 Q Okay, good.

20 11:42:42 A There are less kind meanings meetings, but I
21 11:42:43 don't know.

22 11:42:45 Q That's fine.

23 11:42:54 When -- when you're a member of the
24 11:42:56 Paxil Advisory Board and you said you

1 11:43:00 remembered that some of the topics may have
2 11:43:03 concerned marketing and sales figures, did
3 11:43:05 they -- did you actually see -- were
4 11:43:07 actually -- were sales numbers ever
5 11:43:08 presented to you, number of prescriptions?
6 11:43:10 A I can't remember anything specific that was
7 11:43:15 presented at any of these meetings.
8 11:43:20 I certainly do know that at some
9 11:43:22 meetings for some companies, which may have
10 11:43:25 included the GSK meetings, they will have a,
11 11:43:33 I don't know, between five minutes and a
12 11:43:35 half an hour which they present the data
13 11:43:40 about, you know, what drugs are most
14 11:43:44 prescribed and they track them, you know, in
15 11:43:49 1999 this had X percent of market share and
16 11:43:53 X percent and so on and so forth.
17 11:43:55 Q Okay.
18 11:43:55 A But --
19 11:43:56 Q Do you recall seeing that data?
20 11:43:57 A I don't recall -- I don't recall seeing that
21 11:43:59 data at any of the meetings here. What I'm
22 11:44:04 saying is that I've been to advisory board
23 11:44:07 meetings in which that's shown and often at
24 11:44:14 meetings they will show that.

1 11:44:15 I can't remember whether it was shown
2 11:44:17 at any of these meetings.
3 11:44:24 Q Okay.
4 11:44:24 Now, the -- let me -- let me look --
5 11:44:26 (Pause.)
6 11:44:26 (Exhibit No. 8 marked for
7 11:44:26 identification.)
8 11:44:26 BY MR. MURGATROYD:
9 11:45:31 Q I'm going to show you what I'm going to mark
10 11:45:34 as the next exhibit, which is Exhibit 8, and
11 11:45:52 it's from the American Psychiatric
12 11:45:52 Association Continuing Medical Education
13 11:45:58 Policy on Full Disclosure, and the pages are
14 11:46:04 actually in reverse, but you'll see that
15 11:46:11 your name is listed.
16 11:46:13 MR. DAVIS: Can I see that before you
17 11:46:14 hand it to the witness?
18 11:46:15 MR. MURGATROYD: Sure.
19 11:46:15 MR. DAVIS: Thank you.
20 11:46:16 (Counsel read document.)
21 11:46:20 MR. DAVIS: Skip, do you know what
22 11:46:21 year this is dated?
23 11:46:23 MR. MURGATROYD: I don't. I think
24 11:46:24 actually -- I think I do, actually. Let me

1 11:46:27 see. I think it was recent. I think it's
2 11:46:30 within the last year.
3 11:46:35 Maybe the doctor can identify it for
4 11:46:37 us.
5 11:46:49 (Witness read document.)
6 11:47:18 A You haven't asked me a question about this,
7 11:47:21 have you?
8 11:47:22 Q No, I was going to.
9 11:47:23 Do you recognize that document?
10 11:47:24 A No.
11 11:47:25 Q Okay.
12 11:47:25 Do you see on the second page it says
13 11:47:29 at the top that it is an American
14 11:47:33 Psychiatric Association document?
15 11:47:34 A Yes.
16 11:47:35 Q Okay.
17 11:47:35 And do you -- are you required at
18 11:47:37 times to disclose your affiliation with
19 11:47:40 manufacturers --
20 11:47:42 A Yes.
21 11:47:42 Q Okay.
22 11:47:43 And does that document disclose your
23 11:47:45 affiliation with different pharmaceutical
24 11:47:47 manufacturers?

1 11:47:48 A Yes.

2 11:47:49 Q Okay.

3 11:47:49 And can you list off -- these are all

4 11:47:52 drug companies that you've personally

5 11:47:55 received money from at some time or another

6 11:47:57 in the past?

7 11:47:58 MR. DAVIS: Object to the form.

8 11:48:02 A No.

9 11:48:05 Q Okay.

10 11:48:06 A They're not all drug companies.

11 11:48:08 Q Okay.

12 11:48:09 Are some of them medical device

13 11:48:11 companies?

14 11:48:17 A It's a little hard to read.

15 11:48:21 At least one's a device company, but

16 11:48:23 then there are other types of businesses,

17 11:48:27 companies that do other business --

18 11:48:28 companies that are neither pharmaceutical

19 11:48:30 companies nor medical device companies on

20 11:48:33 this list.

21 11:48:33 Q But companies from which you have received

22 11:48:36 money at some time in the past?

23 11:48:39 MR. DAVIS: Object to the form.

24 11:48:39 (Witness read document.)

1 11:48:55 A Yes, I've received some money from each of
2 11:48:57 these.
3 11:48:57 Q Okay.
4 11:48:57 And can you read into the record that
5 11:49:00 list of companies, please?
6 11:49:01 A Yes.
7 11:49:02 I would just say that in terms of the
8 11:49:05 way I fill these lists out, that at the
9 11:49:13 time, I list --
10 11:49:14 This was a list as complete as it
11 11:49:16 could be of any company I ever had had
12 11:49:19 contact with ever.
13 11:49:22 Q Okay.
14 11:49:23 A Since then, the policy has kind of changed
15 11:49:26 and the advice to me has changed, that what
16 11:49:30 people think is more relevant is that you
17 11:49:32 would give the companies that you've had
18 11:49:34 contact with in the past two years, to be
19 11:49:37 less inclusive.
20 11:49:39 Q Okay.
21 11:49:39 A Okay.
22 11:49:39 But if you -- do you want me to
23 11:49:41 actually read the list of everything that's
24 11:49:43 on here?

1 11:49:44 Q Yes, please.

2 11:49:46 A Are you ready? Okay.

3 11:49:49 Abbott Laboratories; Bristol-Myers

4 11:49:52 Squibb Company; Cephalon; Collegium.

5 11:50:04 There's one I can't read, so I'm

6 11:50:09 going skip the one I can't read, and if you

7 11:50:12 want to circle it and --

8 11:50:14 Q That's fine. Here, here's a pen. Why don't

9 11:50:16 you circle it.

10 11:50:17 (Witness complies.)

11 11:50:20 A Cyberonics -- if you don't mind, I'm not

12 11:50:24 reading all the Inc.'s and Ltd.'s and stuff.

13 11:50:26 Q That's fine.

14 11:50:28 A Cypress Bioscience; Eli Lilly; Forest;

15 11:50:36 GlaxoSmithKline; Janssen; Merck;

16 11:50:52 Mitsubishi -- Mitsubishi; Novartis; Organon;

17 11:51:05 Otsuka; Pfizer; PharmaStar;

18 11:51:15 Sanofi-Synthelabo; SCIREX; Sepracor;

19 11:51:22 Somerset; Vela; Wyeth.

20 11:51:36 Q That's a complete list?

21 11:51:37 MR. DAVIS: Object to the form.

22 11:51:39 Asked and answered.

23 11:51:39 Q I mean is that -- is that the complete list

24 11:51:42 of drug companies from which you have

1 11:51:44 received money from in the past?

2 11:51:46 A To the best of my knowledge, I've been

3 11:51:48 all-inclusive.

4 11:51:49 Q Okay.

5 11:51:49 Do you think that your relationship

6 11:51:51 with the drug companies has affected your

7 11:51:55 credibility with your peers?

8 11:52:08 A I think it's had a positive effect.

9 11:52:10 Q Okay.

10 11:52:10 Do you think the amount of money that

11 11:52:12 both you and the university have received

12 11:52:14 from drug companies affects your scientific

13 11:52:20 judgment about the drugs on which you do

14 11:52:22 research?

15 11:52:23 A No.

16 11:52:24 Q Okay. Can I borrow that pen back, please?

17 11:52:27 Now, we're here on a number of

18 11:52:29 different lawsuits, and I don't know if

19 11:52:33 you're aware of what they are. Let me just

20 11:52:35 go over briefly what they are.

21 11:52:36 The Engh and Smith case are both

22 11:52:39 consumer fraud cases in which it's alleged

23 11:52:44 that GSK fraudulently promoted and sold

24 11:52:47 Paxil for the use of kids and adolescents.

1 11:52:53 A Okay.

2 11:52:53 Q The Blain case is an entirely different

3 11:52:54 case.

4 11:52:54 A Say that again? They fraudulently --

5 11:52:57 Q Promoted and sold Paxil for the use --

6 11:53:01 A Okay.

7 11:53:01 Q -- of treating children and adolescents.

8 11:53:05 Okay.

9 11:53:05 The Blain case and the Brooks case,

10 11:53:07 which is in the federal district court in

11 11:53:09 Pennsylvania, arises from the wrongful death

12 11:53:12 of the 11-year-old Blain boy and the injury

13 11:53:15 to the Brooks girl from taking Paxil.

14 11:53:18 So do you understand there's two

15 11:53:24 different theories of the litigation that

16 11:53:26 we're going to be discussing today?

17 11:53:29 I just want to orient you to that.

18 11:53:32 A Mm-hmm.

19 11:53:32 Q Now, you're --

20 11:53:32 MR. MURGATROYD: I think, actually,

21 11:53:34 we need to change the type.

22 11:53:35 THE VIDEOGRAPHER: The time is 11:53.

23 11:53:37 This is the end of Tape No. 1. We are off

24 11:53:39 the record.

1 12:02:57 (Exhibit No. 9 marked for
2 12:02:57 identification.)
3 12:03:02 BY MR. MURGATROYD:
4 12:03:03 Q Doctor --
5 12:03:10 A Thank you.
6 12:03:12 (Witness read document.)
7 12:03:15 A Okay.
8 12:03:17 Q Do you recognize that document?
9 12:03:20 A No.
10 12:03:22 Q Okay.
11 12:03:22 Well, I received it from your
12 12:03:24 attorney. I need you to identify it for the
13 12:03:26 record.
14 12:03:26 A Yes. I mean, it's to me.
15 12:03:28 Q Okay.
16 12:03:28 A I couldn't -- if my name wasn't on the top,
17 12:03:31 I wouldn't remember ever having seen it,
18 12:03:33 but --
19 12:03:33 Q Okay.
20 12:03:34 A -- it's...
21 12:03:34 Q And who sent it to you?
22 12:03:36 A Neal Ryan.
23 12:03:36 Q Okay.
24 12:03:37 And does that appear to be an

1 12:03:39 authentic document?

2 12:03:40 A Yes.

3 12:03:41 Q Okay.

4 12:03:41 And you received that in the course

5 12:03:43 of your -- ordinary course of your business?

6 12:03:46 A Yes.

7 12:03:46 Q Okay.

8 12:03:47 And does it discuss the Spitzer

9 12:03:49 lawsuit in New York?

10 12:03:53 A Now you're pushing me. Yes.

11 12:03:59 Q Okay.

12 12:03:59 And does it talk about that the

13 12:04:01 lawsuit alleges deliberate concealment and

14 12:04:05 misinformation regarding Paxil and its use

15 12:04:07 in the child and adolescent population?

16 12:04:10 MR. DAVIS: Object to the form.

17 12:04:12 A Yes.

18 12:04:13 MR. DAVIS: Excuse me. I object to

19 12:04:13 the form of the question.

20 12:04:14 THE WITNESS: I'm sorry.

21 12:04:15 Q Okay.

22 12:04:15 And do you know why Neal Ryan sent

23 12:04:18 that to you?

24 12:04:19 A No.

1 12:04:19 Q Okay.

2 12:04:20 Are you aware of allegations

3 12:04:22 regarding 329 that were brought up in the

4 12:04:25 Spitzer lawsuit?

5 12:04:26 A No.

6 12:04:27 Q Okay. Put that one aside.

7 12:04:46 Have you been sued personally for

8 12:04:49 any -- any -- regarding any activities

9 12:04:51 related to Study 329?

10 12:04:53 A No.

11 12:04:54 Q Okay.

12 12:04:55 Have any of your other coauthors in

13 12:04:57 the article been sued personally, to your

14 12:05:00 knowledge?

15 12:05:00 A No.

16 12:05:01 Q Okay.

17 12:05:01 Now, let's go to --

18 12:05:46 (Exhibit No. 10 marked for

19 12:05:46 identification.)

20 12:05:47 BY MR. MURGATROYD:

21 12:05:47 Q Let's me show you what I've marked as

22 12:05:49 Exhibit 10 and ask you to take a look at

23 12:05:51 that.

24 12:05:52 (Witness read document.)

1 12:06:02 Q That may take you a minute to go through,
2 12:06:04 and there's no hurry.
3 12:06:06 MR. DAVIS: Skip, what is that
4 12:06:08 document?
5 12:06:09 MR. MURGATROYD: That is the
6 12:06:09 proposal.
7 12:06:11 MR. DAVIS: The December 5, '92
8 12:06:13 proposal?
9 12:06:13 MR. MURGATROYD: Correct.
10 12:06:28 (Witness read document.)
11 12:07:20 A Okay.
12 12:07:21 Q Okay.
13 12:07:22 Did you get a chance to look through
14 12:07:23 that?
15 12:07:24 A Yes.
16 12:07:24 Q And can you identify for the record what
17 12:07:25 that document is?
18 12:07:26 A This is the -- this is a protocol for the
19 12:07:42 study of the treatment of adolescents with
20 12:07:48 unipolar major depression, which is written
21 12:07:57 in what I'll call the NIH format, you know,
22 12:08:04 where you list the aims and background and
23 12:08:06 significance and preliminary studies and so
24 12:08:09 on.

1 12:08:10 So that's basically the rationale,
2 12:08:12 you know, what -- where the field is at and
3 12:08:15 why the study is important.

4 12:08:19 We discuss what's discussed in here,
5 12:08:22 you know, different ways one could design
6 12:08:24 the studies, since there's a lot of ways to
7 12:08:28 skin a cat.

8 12:08:31 Discuss, for example, the choice of
9 12:08:33 multiple antidepressants. So basically what
10 12:08:39 we do in here, as we would do in any NIH
11 12:08:43 grant, is take key design issues and discuss
12 12:08:48 what we might think of as the, you know, the
13 12:08:51 pros and cons of the decisions that we made
14 12:08:55 in the study that we're proposing.

15 12:08:57 Q Okay.

16 12:08:58 So am I correct in stating that this
17 12:09:02 document was prepared by you and your
18 12:09:05 research time that we described earlier --
19 12:09:07 that we talked about earlier?

20 12:09:08 A Yes.

21 12:09:08 And I noticed in my here that there
22 12:09:11 are some -- that there are names of people
23 12:09:15 that I didn't give you initially in the list
24 12:09:17 that were also --

1 12:09:18 And that as I look at their names,
2 12:09:19 they were on that -- they were on the team.
3 12:09:22 Q Okay.
4 12:09:23 And what -- which -- who did you
5 12:09:25 forget?
6 12:09:25 A Boris Birmaher, Satish Iyengar.
7 12:09:31 Q You might want to spell that one for the
8 12:09:33 court reporter, if you can.
9 12:09:34 A S-I-T-I-S-H is his first name. His last
10 12:09:39 name is I-Y-E-N-G-A-R.
11 12:09:45 Harold Koplewicz, K-O-P-L-E-W-I-C-Z,
12 12:09:53 and Philip Lavori, L-A-V-O-R-I.
13 12:09:59 And it also mentions in here after my
14 12:10:04 name that I am the permanent chair of the
15 12:10:06 steering committee. Because when you asked
16 12:10:08 me earlier if the group had a leader, I
17 12:10:14 guess to a certain extent it was me.
18 12:10:17 Q Okay.
19 12:10:17 And it identifies you as the
20 12:10:19 permanent chair in that document, correct?
21 12:10:20 A Absolutely.
22 12:10:21 Q Okay.
23 12:10:21 And does that appear to be an
24 12:10:23 authentic document?

1 12:10:25 A Yes.

2 12:10:25 Q Okay.

3 12:10:26 And, again, it was prepared by -- was

4 12:10:27 it prepared by you personally or was this

5 12:10:29 part of -- you had help from the research

6 12:10:31 team?

7 12:10:31 A Team.

8 12:10:31 Q Okay.

9 12:10:32 And this was -- I know you identified

10 12:10:36 it as a protocol, but would it also be

11 12:10:42 properly determined a proposal to do a

12 12:10:44 study?

13 12:10:44 A Yes. This is a -- we have here stamped

14 12:10:48 "draft" and -- yes.

15 12:10:53 Q Okay.

16 12:10:54 And, now, in that protocol, there is

17 12:11:02 an outcome measure that is discussed,

18 12:11:04 correct, on page 14?

19 12:11:27 (Witness read document.)

20 12:11:34 A Yes.

21 12:11:34 Q Okay.

22 12:11:34 And can you state for the record what

23 12:11:36 the original outcome measure was, please?

24 12:11:41 A Well, again, let me put it into context that

1 12:11:44 this is a draft proposal.

2 12:11:45 Q Right.

3 12:11:45 A So I'm not -- I do not know whether this was

4 12:11:48 the final proposal.

5 12:11:50 Q No, I understand.

6 12:11:52 A This was a -- you know, we make many, many

7 12:11:55 drafts.

8 12:11:55 Q Okay.

9 12:11:56 A Okay.

10 12:11:57 Definition of responder or

11 12:11:58 nonresponder at the end of eight-week acute

12 12:12:02 treatment study, and then it says, To be

13 12:12:03 classified as a responder -- which is in

14 12:12:06 quotes, responder, and continue to the

15 12:12:10 continuation phase, a subject must, and then

16 12:12:14 it lists four criteria.

17 12:12:19 Q Okay.

18 12:12:19 And can you state for the record what

19 12:12:21 those are, please?

20 12:12:22 A One: Have a Hamilton depression rating not

21 12:12:25 greater than eight.

22 12:12:27 Two: Have no more than one positive

23 12:12:29 criterion symptom for major depression as

24 12:12:32 assessed by the -- and these are capital

1 12:12:36 letters, K-SADS, S-A-D-S, -P interview.
2 12:12:46 Three: Have no present suicidal
3 12:12:48 ideation, as measured by the K-SADS-P,
4 12:12:52 that's what I just, you know, gave you a
5 12:12:54 moment ago.
6 12:12:55 And four: Have no evidence of mania
7 12:12:56 hypomania as assessed by the K-SADS-P.
8 12:13:04 Q Okay.
9 12:13:05 And at some point in time, those
10 12:13:08 endpoints were changed, correct?
11 12:13:09 MR. DAVIS: Object to the form.
12 12:13:17 A I'm not sure if they were changed or if we
13 12:13:21 added others.
14 12:13:21 Q Okay.
15 12:13:22 A In other words, I'm not sure that this
16 12:13:25 particular definition of reponder was
17 12:13:28 changed.
18 12:13:29 Q Okay.
19 12:13:29 A I just don't remember.
20 12:13:30 Q Okay.
21 12:13:30 A But I do know other endpoints were changed,
22 12:13:32 so we had multiple endpoints.
23 12:13:34 Q Okay.
24 12:13:35 You --

1 12:13:36 A Other endpoints were added.

2 12:13:37 Q Okay.

3 12:13:37 And my question is, who -- who

4 12:13:41 decided to add the additional outcome

5 12:13:48 measures?

6 12:13:53 A I don't recall exactly -- well, "exactly" is

7 12:13:55 too strong.

8 12:13:56 I don't recall the process by which

9 12:14:01 any one given aspect of this were changed,

10 12:14:04 but I do recall -- without specifics -- that

11 12:14:09 the group of us met in several ways.

12 12:14:13 Sometimes we had in-person meetings

13 12:14:14 to discuss this. I can remember two or

14 12:14:17 three in particular we met for -- at least

15 12:14:21 one we met for two days at Brown.

16 12:14:23 I remember meeting at one or two

17 12:14:25 hotels probably associated with, you know,

18 12:14:29 other meetings that we were at to be

19 12:14:31 efficient in our time.

20 12:14:33 We had quite a number of telephonic

21 12:14:36 conference calls. And during the course of

22 12:14:38 these meetings, we would discuss design

23 12:14:42 issues.

24 12:14:43 Q Okay.

1 12:14:44 A And we were regularly -- how to put this --
2 12:14:52 discussing, debating, considering changes.
3 12:14:57 And over the course of that time, you
4 12:14:59 know, changes would get made, be it
5 12:15:03 additions -- sometimes additions to what we
6 12:15:06 had. Sometimes things that we had already
7 12:15:08 decided upon we decided to do differently.
8 12:15:11 And just some of these -- some of
9 12:15:16 these were rather extended conversations
10 12:15:20 that would take hours on a particular point,
11 12:15:22 because, you know, there's no one --
12 12:15:29 There's no one -- there was no one
13 12:15:30 way to approach these issues, so it was a
14 12:15:35 matter of the best judgment that we could
15 12:15:37 collectively arrive at as to what would be
16 12:15:40 the optimal way to design the study to
17 12:15:43 accomplish our goal of properly testing the
18 12:15:45 efficacy of the treatment.
19 12:15:47 So it was a -- that kind of -- I
20 12:15:48 don't know if that gives you a feeling for
21 12:15:50 the process.
22 12:15:50 Q Yes.
23 12:15:51 Well, was it so no one person decided
24 12:15:54 on the -- the endpoint measurements?

1 12:15:58 A Correct.

2 12:15:58 Q Okay.

3 12:15:59 And was this all documented through

4 12:16:01 the -- were there minutes taken of the

5 12:16:05 conference calls?

6 12:16:07 A No.

7 12:16:08 Q Okay.

8 12:16:08 A I mean, it -- I don't remember, but I

9 12:16:13 would --

10 12:16:14 My style would occasionally to be to

11 12:16:16 say, hey, someone, could someone volunteer

12 12:16:19 to write down what we decided so when we

13 12:16:22 next talk tomorrow we remember, and usually

14 12:16:25 get someone to volunteer, but not always.

15 12:16:28 You know, it's one of those things.

16 12:16:29 It was loose.

17 12:16:30 Q Okay.

18 12:16:30 A But it was just us investigators. It wasn't

19 12:16:33 as though we had a secretary, you know, or a

20 12:16:36 research assistant who went and -- didn't

21 12:16:40 tape it.

22 12:16:40 Q Right.

23 12:16:41 A But somebody eventually would write down

24 12:16:43 what we did.

1 12:16:44 Q Okay.

2 12:16:45 And, now, you were the principal

3 12:16:48 investigator --

4 12:16:49 So it's clear, that document before

5 12:16:51 you, which we marked as Exhibit 10, was the

6 12:16:56 proposal that ultimately became Study 329,

7 12:16:58 correct?

8 12:16:59 A Yes.

9 12:16:59 Q Okay.

10 12:17:00 So the proposal was accepted by GSK

11 12:17:02 at some later point in time after -- again,

12 12:17:04 that document is dated 1992, correct, end of

13 12:17:06 '92?

14 12:17:07 A Yes.

15 12:17:07 Q So that proposal was accepted by GSK at some

16 12:17:10 later time?

17 12:17:14 A This or some, you know, further iteration of

18 12:17:18 it.

19 12:17:20 Q Right.

20 12:17:20 Well, the proposal to do 329, that's

21 12:17:24 what I mean.

22 12:17:25 A Proposal to do the research --

23 12:17:27 Q Correct.

24 12:17:27 A -- was accepted by GSK.

1 12:17:29 Q Okay.

2 12:17:29 And you were --

3 12:17:30 A I don't think I ever heard the numbers "329"

4 12:17:35 until probably more recently. I don't know

5 12:17:38 when I first heard them, but --

6 12:17:39 Q Okay.

7 12:17:40 How did -- how did you refer to the

8 12:17:42 study?

9 12:17:43 A "The study."

10 12:17:43 Q Okay. All right.

11 12:17:45 Well, so for the purposes of this

12 12:17:47 deposition, we're going to call it Study

13 12:17:49 329, because there were other studies.

14 12:17:51 Is that okay?

15 12:17:51 A That's okay.

16 12:17:52 Q Okay.

17 12:17:52 And you were the principal

18 12:17:53 investigator, though?

19 12:17:54 I mean, you were considered the

20 12:17:56 leader of the group, correct?

21 12:17:58 MR. DAVIS: Object to the form.

22 12:18:01 A Yes, I was -- yes, I was -- I was the

23 12:18:04 organizer.

24 12:18:08 Q Okay.

1 12:18:08 And was this proposal originally
2 12:18:18 submitted to Eli Lilly and rejected?
3 12:18:21 A I don't remember.
4 12:18:21 What I do remember is initially when
5 12:18:24 we came together in, you know, various
6 12:18:28 combinations, diads, triads of the
7 12:18:32 individuals involved, our plan was to submit
8 12:18:35 this to the National Institutes of Health
9 12:18:38 to -- for funding.
10 12:18:39 And at some point along the way,
11 12:18:44 somebody in the group had conversation with
12 12:18:50 at least one other company besides GSK. I
13 12:18:54 don't remember.
14 12:18:56 And the issue came up as to whether
15 12:18:59 the drug company would be interested in
16 12:19:01 funding it.
17 12:19:03 And I don't think that I was part of
18 12:19:05 those conversations, though the results of
19 12:19:08 the conversations, you know, were described
20 12:19:10 to me.
21 12:19:11 But when I say I don't think, I don't
22 12:19:13 remember, really don't remember.
23 12:19:14 And eventually, the group of us
24 12:19:22 decided that it would be faster, it would be

1 12:19:24 more expedient, and that we would get our --
2 12:19:28 we would get the funding -- the budget we
3 12:19:32 agreed to without subsequent cuts if we had
4 12:19:35 a pharmaceutical company willing to fund the
5 12:19:40 design that we wanted to do than to go
6 12:19:44 through the NIMH process, which typically
7 12:19:48 leads to at least two or three revisions
8 12:19:49 into -- in nine-month cycles.

9 So what we were weighing was, you
10 12:19:54 know, two to three years before we started
11 12:19:57 at approximately 25 percent reduction of the
12 12:20:01 budget that would be accepted by the -- that
13 12:20:02 was proposed -- accepted by the review
14 12:20:05 committee versus starting almost
15 12:20:07 immediately.

16 And we weighed it back and forth and
17 12:20:12 decided we would go with a company if they
18 12:20:17 were willing to have the design be the
19 12:20:18 design we proposed.

20 12:20:20 Q Okay.

21 And GSK turned out to be the willing
22 12:20:23 company?

23 12:20:23 A Yeah. I don't know that the other was
24 12:20:24 not -- I don't know that the others were not

1 12:20:27 willing.

2 12:20:27 Whatever -- for some -- for some

3 12:20:29 reason that I can't remember, we chose to

4 12:20:32 have GSK be the sponsor as opposed to other

5 12:20:36 potential people who were interested.

6 12:20:39 Q Okay.

7 12:20:39 A I don't -- I don't remember why, and I don't

8 12:20:41 remember who else was interested.

9 12:20:43 Q Okay. That's fine.

10 12:20:45 Now, let me just show you what I'll

11 12:20:59 mark as Exhibit 11.

12 12:21:21 (Exhibit No. 11 marked for

13 12:21:21 identification.)

14 12:21:21 BY MR. MURGATROYD:

15 12:21:21 Q Okay. Let me show you that.

16 12:21:25 MR. DAVIS: What's that, Skip?

17 12:21:26 MR. MURGATROYD: That's a letter from

18 12:21:28 Dr. Keller to GSK.

19 12:21:32 MR. DAVIS: What date is it?

20 12:21:35 MR. MURGATROYD: It's in early 1993.

21 12:21:37 I think it's March 19th.

22 12:21:46 (Witness read document.)

23 12:21:58 A Okay.

24 12:21:59 MR. DAVIS: Can I look at that real

1 12:22:00 quick before we get a question about it?

2 12:22:04 THE WITNESS: Sure.

3 12:22:05 MR. DAVIS: Thank you.

4 12:22:13 (Counsel read document.)

5 12:22:14 MR. DAVIS: Thank you.

6 12:22:15 THE WITNESS: You're welcome.

7 12:22:17 BY MR. MURGATROYD:

8 12:22:17 Q Doctor, can you identify for the record what

9 12:22:19 that document is, please?

10 12:22:21 A It's a letter written by me to a woman named

11 12:22:28 Cathy Sohn.

12 12:22:30 Q Okay.

13 12:22:31 Do you recall who she was or is?

14 12:22:34 A Well, I haven't seen or heard of her for

15 12:22:37 many years.

16 12:22:39 At the time I wrote this letter, she

17 12:22:41 worked for SmithKlein Beecham. I know she

18 12:22:46 was a Pharm. D. I don't know the position

19 12:22:48 she held at the company.

20 12:22:50 Q Okay.

21 12:22:50 A And what I was proposing in this letter was

22 12:23:03 a that we add to the efficacy study that

23 12:23:11 we've been -- what we're now referring to as

24 12:23:14 329, a prospective naturalistic phase

1 12:23:22 whereby all of the participants in the study
2 12:23:27 would after the end of the study be followed
3 12:23:34 in what's called a prospective -- a
4 12:23:36 prospective naturalistic short-interval
5 12:23:41 longitudinal follow-up design for
6 12:23:44 approximately two years.
7 12:23:47 Q That's where you follow the patients after
8 12:23:49 the study's concluded for two years?
9 12:23:52 A Yes. And we have a -- a very -- I have
10 12:23:56 developed with colleagues over the years a
11 12:23:58 very rigorous, specific approach to do this.
12 12:24:02 Q Okay.
13 12:24:05 A And just to put it in context for you, the
14 12:24:07 lion's share of the research, which I've led
15 12:24:10 people to think I have some expertise in
16 12:24:13 something, have been prospective
17 12:24:15 naturalistic studies that have not been
18 12:24:21 tied -- have not been tagged to a randomized
19 12:24:25 trial. They just gather that knowledge.
20 12:24:27 And I just thought this was a great
21 12:24:32 opportunity to learn about the life course
22 12:24:34 of adolescents with depression.
23 12:24:38 Q Is that -- well, let me ask you this:
24 12:24:41 Had your proposal been accepted and

1 12:24:43 this is something you wanted to add on to
2 12:24:45 the proposal?
3 12:24:46 A What's unclear to me now -- because at the
4 12:24:53 time, there was some ambiguity -- was sort
5 12:24:57 of when and how this component was agreed to
6 12:25:04 by SmithKline in relation to the randomized
7 12:25:11 clinical trial.
8 12:25:12 My memory -- and it's a very, very
9 12:25:16 weak memory, is that this came up, the idea
10 12:25:24 to do this, after the core efficacy study
11 12:25:27 was proposed.
12 12:25:27 Q Okay.
13 12:25:28 A This was a later proposal.
14 12:25:29 Q Right.
15 12:25:30 And was it accepted?
16 12:25:31 A Yes.
17 12:25:31 Q Okay.
18 12:25:32 And was it carried out?
19 12:25:34 A It was disappointing in that it was
20 12:25:39 eventually -- eventually the money --
21 12:25:41 It was funded, but we had a very
22 12:25:48 difficult time implementing it. So we had a
23 12:25:52 difficult time getting the participants in
24 12:25:55 the randomized trial to then participate in

1 12:26:00 the prospective follow-up study at the rate
2 12:26:05 of acceptance by the subjects that we
3 12:26:09 typically have.

4 And I believe this was the first time
5 12:26:13 that I had tried to tie together a
6 12:26:19 naturalistic study on the tail end of an
7 12:26:21 efficacy study, and I tried it once after
8 12:26:25 that, and it wasn't so successful.

9 And subsequent to that, we've stopped
10 12:26:29 trying to do it, because for a whole variety
11 12:26:32 of reasons, it's just not such an appealing
12 12:26:39 thing for either subjects or the research
13 12:26:42 sites to do.

14 So it was a -- we were disappointed
15 12:26:47 that we couldn't do it.

16 12:26:48 Q Okay.

17 And I take it -- I take it from --
18 12:26:51 and so the -- so the record's clear, that --
19 12:26:55 that is a letter from you to GSK, correct?

20 12:26:57 A Yes.

21 12:26:58 Q And it's dated March 19, 1993?

22 12:27:01 A Yes.

23 12:27:01 Q And does that appear to be an authentic
24 12:27:05 document?

1 12:27:05 A Yes.

2 12:27:05 Q And did you prepare that in the ordinary

3 12:27:07 course of your business?

4 12:27:09 A Yes.

5 12:27:09 Q Okay.

6 12:27:09 And I notice in the fourth paragraph,

7 12:27:11 you talk about the number of publications

8 12:27:12 that you would hope would result from the

9 12:27:16 study; is that correct?

10 12:27:18 A Yes.

11 12:27:18 Q And how many -- how many publications did

12 12:27:20 you project at that time?

13 12:27:23 A Twenty-five to 40.

14 12:27:26 Q Okay.

15 12:27:27 And why is the number of publications

16 12:27:32 important, if it is at all?

17 12:27:36 A Well, because in order to -- at one indici

18 12:27:40 [ph.] of why -- why -- why I would justify

19 12:27:48 doing this was referencing it to --

20 12:27:56 In other words, those -- if -- those

21 12:27:58 number of studies in the kinds of journals I

22 12:28:01 mentioned were an indication that I believe

23 12:28:04 the data that would come from this would be

24 12:28:08 were highly interesting scientifically and

1 12:28:11 make a major contribution to the field of
2 12:28:15 adolescent psychiatry, and that was my way
3 12:28:17 of -- one of my ways of explaining that,
4 12:28:20 because, indeed, this is what the case was,
5 12:28:23 is typically is, with our prospective
6 12:28:26 studies.
7 12:28:27 That would be -- you know, why do it?
8 12:28:29 Q Right.
9 12:28:29 A We call it the "so what." And when you
10 12:28:32 write a grant, they call it the significant
11 12:28:34 section. In our minds, we cross it out and
12 12:28:36 we say so what.
13 12:28:38 The "so what" is so if you do the
14 12:28:38 study, what's the big deal? And the big
15 12:28:41 deal is that this would be of interest and
16 12:28:43 people would learn a lot.
17 12:28:44 Q Okay.
18 12:28:45 And was the study also done to -- so
19 12:28:48 GSK could seek approval for a pediatric
20 12:28:51 indication for Paxil for the treatment of
21 12:28:52 depression?
22 12:28:54 MR. DAVIS: Object to the form. No
23 12:28:55 foundation.
24 12:28:59 A I -- it was never -- I was never aware that

1 12:29:06 that was something that GSK had in mind.

2 12:29:10 But these data are not the type of

3 12:29:11 data that, to my knowledge, have ever been

4 12:29:16 submitted to -- as part of -- as part of an

5 12:29:18 FDA, what would you call it, application in

6 12:29:28 support of labeling.

7 12:29:28 Q Okay.

8 12:29:28 You mean the naturalistic follow-up

9 12:29:32 phase?

10 12:29:32 A Yes.

11 12:29:32 Q Right.

12 12:29:32 A Yes.

13 12:29:33 Q But the acute phase obviously is a type

14 12:29:36 of --

15 12:29:37 A That is a type of data -- study and data

16 12:29:39 that could be used, but I was never told

17 12:29:43 that GSK intended to use that data for an

18 12:29:49 FDA filing.

19 12:29:51 Q At some point in time, you were told that,

20 12:29:53 though, correct?

21 12:29:54 MR. DAVIS: Object to the form.

22 12:29:55 A I don't remember.

23 12:29:55 Q Okay.

24 12:29:56 Do you know that -- whether or not

1 12:29:58 GSK actually sought approval for Paxil for
2 12:30:01 the treatment of pediatric depression?
3 12:30:04 A No.
4 12:30:05 Q Okay.
5 12:30:06 A I don't know, is the answer.
6 12:30:07 Q Okay.
7 12:30:07 Well, to your knowledge today, has it
8 12:30:10 been approved for the treatment of children
9 12:30:12 and adolescents with major depressive
10 12:30:15 disorder?
11 12:30:16 A No.
12 12:30:16 Q Okay.
13 12:30:17 And --
14 12:30:18 A The one thing I would say is it's not
15 12:30:22 typical -- it's very atypical -- if a
16 12:30:25 company --
17 12:30:25 In other words, I'm not aware of any
18 12:30:29 randomized controlled trial that was
19 12:30:32 designed by a group of investigators
20 12:30:34 independently, you know, carried out at a
21 12:30:36 relatively small number of sites, you know,
22 12:30:39 like this that have ever been part --
23 12:30:45 I'm just not aware of it, of an FDA
24 12:30:49 submission. Studies that are part of FDA

1 12:30:52 submissions typically are designed in-house
2 12:30:55 at pharmaceutical companies, sometimes with
3 12:30:57 a consultant -- consultation or not, and
4 12:31:01 then, you know, monitored in all sorts of
5 12:31:05 stringent ways.

6 12:31:06 So this was -- this -- were this to
7 12:31:10 have been submitted, or if it was, I know of
8 12:31:16 no other situation in which a study like
9 12:31:20 this was ever part of an FDA approval.

10 12:31:23 Q Well, let me ask you this:

11 12:31:25 Did GSK take your proposal that was
12 12:31:26 outlined in Exhibit 10 and then incorporate
13 12:31:29 it into a new protocol that was a GSK type
14 12:31:32 protocol that could be used for regulatory
15 12:31:34 purposes?

16 12:31:38 A The first part of your question is that they
17 12:31:40 did incorporate it into a GSK type protocol.
18 12:31:44 The second part, I don't know the answer to
19 12:31:46 that.

20 12:31:47 Q Okay.

21 12:31:47 A Whether -- whether it could be used for
22 12:31:50 regulatory purposes.

23 12:31:51 Q And have you reviewed the protocol as
24 12:31:55 adapted by GSK in preparing for this

1 12:32:01 deposition?
2 12:32:02 A No.
3 12:32:02 Q Okay.
4 12:32:03 When was the last time you saw it, to
5 12:32:04 your recollection?
6 12:32:10 A A long time ago.
7 12:32:12 Q Okay.
8 12:32:13 Well, let's take a look at it.
9 12:32:17 MR. MURGATROYD: Let's go off the
10 12:32:17 record for just a second.
11 12:32:18 THE VIDEOGRAPHER: It's 12:32. We
12 12:32:21 are off the record.
13 12:32:22 (Recess.)
14 12:33:25 (Exhibit No. 12 marked for
15 12:33:25 identification.)
16 12:34:13 THE VIDEOGRAPHER: Okay. we are back
17 12:34:18 on the record. The time is 12:34.
18 12:34:20 BY MR. MURGATROYD:
19 12:34:21 Q Okay.
20 12:34:21 MR. DAVIS: I think you want to wait
21 12:34:23 for Mr. Green.
22 12:34:24 MR. MURGATROYD: Oh, I -- okay.
23 12:34:26 Well, I don't think he's going to object to
24 12:34:29 anything. He never has.

1 12:34:30 MR. DAVIS: I don't know. Just as a
2 12:34:30 courtesy to him.
3 12:34:32 MR. MURGATROYD: All right. We'll go
4 12:34:32 back off the record and wait for Mr. Green.
5 12:34:35 THE VIDEOGRAPHER: The time is 12:34.
6 12:34:37 We are off the record.
7 12:34:41 (Recess.)
8 12:35:34 THE VIDEOGRAPHER: We're back on the
9 12:35:35 record. The time is 12:35.
10 12:35:38 BY MR. MURGATROYD:
11 12:35:39 Q Okay.
12 12:35:39 And, Doctor, have you had a chance to
13 12:35:41 look through what we've marked as
14 12:35:43 Exhibit 12?
15 12:35:43 A Yes.
16 12:35:44 Q And can you identify for the record what
17 12:35:46 that document is?
18 12:35:48 A It's a protocol to study -- of a
19 12:35:57 Multi-center, Double-blind, Placebo
20 12:36:00 Controlled Study of Paroxetine and
21 12:36:01 Imipramine in Adolescents with Unipolar
22 12:36:05 Major Depression.
23 12:36:06 Q Okay.
24 12:36:06 And before I get into the contents of

1 12:36:11 that document, you said that you met a
2 12:36:13 number of times with GSK concerning Study
3 12:36:16 329?
4 12:36:19 A I don't -- no, I did not say that.
5 12:36:21 Q I thought you said you had in-person
6 12:36:23 meetings, telephonic meetings --
7 12:36:25 A I was talking about meetings with my
8 12:36:29 colleagues and peers. None of those -- none
9 12:36:34 of the meetings were -- that I was -- that
10 12:36:36 were in my mind when we were talking about
11 12:36:40 involved anyone from GSK.
12 12:36:42 Q Okay.
13 12:36:42 Did you ever meet a gentleman by the
14 12:36:44 name of Jim McCafferty who worked for GSK?
15 12:36:48 A Yes.
16 12:36:48 Q Okay.
17 12:36:49 And in what context?
18 12:36:52 A In the context of implementing this study.
19 12:36:59 I don't remember when in the process I met
20 12:37:02 Jim McCafferty, but I do know that the role
21 12:37:08 that Jim played, as I would articulate it,
22 12:37:14 was the liaison, in a way, between the study
23 12:37:19 group and other individuals in GSK.
24 12:37:22 He was a GSK employee.

1 12:37:25 Q Right.

2 12:37:26 A And he was -- I don't know what his title

3 12:37:27 would be, but he was the individual, as I

4 12:37:29 understood it, from GSK that was sort of

5 12:37:32 playing the -- how to put this, the

6 12:37:35 leadership or management role within GSK for

7 12:37:40 this study, so that most of the

8 12:37:45 interactions -- there were very --

9 12:37:47 Once -- you know, once we got to a

10 12:37:52 certain point where --

11 12:37:52 See, I don't remember when it

12 12:37:54 started, but after -- but after everything

13 12:37:56 was agreed upon, the study and the budget

14 12:37:58 and so on and so forth, most of the contact

15 12:38:04 with GSK by me or colleagues in the study

16 12:38:10 was with Jim McCafferty.

17 12:38:15 And at a certain point, we did start

18 12:38:17 having regularly scheduled conference calls

19 12:38:20 to discuss perhaps the finalization of the

20 12:38:23 protocol.

21 12:38:27 And certainly once the study got

22 12:38:29 going, we would talk -- we would have

23 12:38:30 conference calls and Jim would be on the

24 12:38:33 call, not always but most of the time, along

1 12:38:35 with the principal investigators, and I
2 12:38:37 don't remember who else from GSK.
3 12:38:40 Q Okay.
4 12:38:40 Did you ever meet Mr. McCafferty's
5 12:38:43 senior in the company, Dr. David Wheaton?
6 12:38:47 MR. DAVIS: Object to the form.
7 12:38:50 A Yes.
8 12:38:51 Q Okay.
9 12:38:51 And did that have to do with Study
10 12:38:52 329 or -- or something else?
11 12:38:59 A When I first met him, it had to do with
12 12:39:04 something else. I don't recall which --
13 12:39:05 what.
14 12:39:06 But at some point, he -- at some
15 12:39:08 point, he was involved in some conversations
16 12:39:11 regarding 329.
17 12:39:14 Q Okay.
18 12:39:15 And did -- from your experience with
19 12:39:16 him, did he appear to be an intelligent
20 12:39:21 person?
21 12:39:22 A Intelligent?
22 12:39:23 Q Yes.
23 12:39:24 A Oh, yes.
24 12:39:25 Q And honest?

1 12:39:26 A Yes.

2 12:39:25 Q Okay.

3 12:39:26 And going back to that protocol, does

4 12:39:30 it set forth the efficacy variables that

5 12:39:36 were to be tested during the course of the

6 12:39:39 clinical trial?

7 12:39:48 A It's -- the pagination -- oh, I see, the

8 12:39:57 pagination is 1206 to 1207. On page 1207

9 12:40:02 and 8 -- so the answer is yes.

10 12:40:08 Q Okay.

11 12:40:09 And does it list the primary and

12 12:40:11 secondary efficacy variables?

13 12:40:14 A Yes.

14 12:40:14 Q Okay.

15 12:40:15 And is there any mention in either

16 12:40:19 the primary or secondary measures of a

17 12:40:22 change in HAM-D depression item?

18 12:40:26 A Yes.

19 12:40:26 Q And what does it say?

20 12:40:31 A And I quote, "Change in total HAM-D score

21 12:40:34 from beginning of treatment phase to the

22 12:40:36 endpoint of the acute phase, bullet two" --

23 12:40:40 Q Okay, wait. I'm actually talking about the

24 12:40:42 HAM-D depression item.

1 12:40:44 A Oh.

2 12:40:45 (Witness read document.)

3 12:41:10 A Well, not on -- not on pages 07 and 08. I

4 12:41:13 don't know whether it's mentioned elsewhere.

5 12:41:15 I do know that at some point after --

6 12:41:19 if it -- if it's not -- if it doesn't appear

7 12:41:22 later in this protocol -- because I -- you

8 12:41:25 know, I didn't --

9 12:41:27 I haven't sat here and read every

10 12:41:29 line, but if it does not appear in

11 12:41:31 subsequent pages, it is something that was

12 12:41:37 subsequently added as endpoints as we

13 12:41:40 thought about the study, which is extremely

14 12:41:46 common for us to do in studies like this.

15 12:41:49 Well, it's important. I'd like you

16 12:41:50 to take the time to look through that

17 12:41:52 protocol and see if you see any reference at

18 12:41:53 all to an endpoint or a secondary efficacy

19 12:41:56 variable being the change in HAM-D

20 12:41:58 depression.

21 12:41:59 Because I'm going to ask you -- while

22 12:42:01 you're looking, I'm going to ask you also

23 12:42:02 about remission defined as HAM-D score of

24 12:42:04 less than or equal to 8, a CGI of 1 or 2 --

1 12:42:09 that's capital C, capital G, capital I --
2 12:42:12 and a change in K-SADS-S depression.
3 12:42:18 I want to know if any -- any of those
4 12:42:21 four measures are discussed in that
5 12:42:22 protocol.
6 12:42:23 A Well, let me ask you, since you've studied
7 12:42:26 this and you seem to know these things
8 12:42:28 extremely well, to the best of your
9 12:42:30 knowledge, is it in here or not?
10 12:42:32 Q I have not been able to find it, but I
11 12:42:33 would -- I don't want to -- you're here --
12 12:42:36 you're here to testify, not me.
13 12:42:37 A I understand. Just in the spirit of --
14 12:42:40 Q Right.
15 12:42:40 A -- cooperatively --
16 12:42:41 Q There is -- there is an index.
17 12:42:43 A -- going through it.
18 12:42:44 Q I think that may help speed up the process.
19 12:42:49 A I've never been good with indexes. Let's
20 12:42:53 see.
21 12:42:54 (Witness read document.)
22 12:43:09 Q You'll see there's a Section 9.0, data
23 12:43:12 evaluation.
24 12:43:13 Do you see that?

1 12:43:14 A Yes, I was just reading that, the primary
2 12:43:16 section --
3 12:43:17 Q Correct.
4 12:43:40 (Witness read document.)
5 12:43:42 A Do you have any tabs that I could use just
6 12:43:45 for my own --
7 12:43:45 Q Yes, I do. Let me just grab them for you.
8 12:43:48 A I don't need them to be exhibit tabs,
9 12:43:51 just --
10 12:43:51 Q No, I understand. Wait a second. I'll have
11 12:43:55 to get them.
12 12:43:59 (Discussion off the record.)
13 12:44:13 Q Here you go.
14 12:44:15 A Thanks.
15 12:44:15 Q Sure.
16 12:45:00 A What's a little cumbersome is that the --
17 12:45:03 the index refers to page numbers that should
18 12:45:05 be on the top, but most of them are cut off.
19 12:45:07 Q Yes.
20 12:45:08 A So I'm having trouble --
21 12:45:10 Q Yes. You have to kind of judge where that
22 12:45:12 would be.
23 12:45:13 A Yes.
24 12:45:13 (Witness read document.)

1 12:47:16 A All right. If you don't mind, Skip, asking
2 12:47:18 me the question again?
3 12:47:19 Q Yes, that's fine.
4 12:47:20 In the original protocol that you
5 12:47:21 have in front of you, is there an efficacy
6 12:47:25 variable for the change in HAM-D depression
7 12:47:29 item?
8 12:47:30 A No.
9 12:47:30 Q Okay.
10 12:47:30 Is there an efficacy variable for
11 12:47:33 remission defined as a HAM-D score of less
12 12:47:36 than or equal to 8?
13 12:47:40 A No.
14 12:47:41 Q Is there an efficacy variable for a CGI of 1
15 12:47:45 or 2?
16 12:47:46 A No.
17 12:47:47 Q Is there an efficacy variable for a change
18 12:47:50 in K-SADS depression item?
19 12:48:06 A I don't think so. I'm just looking --
20 12:48:07 Q That's all right.
21 12:48:09 A Somewhere -- I had my finger on it. Oh,
22 12:48:15 yes, yes, changes --
23 12:48:16 Q Not the -- not the mean score, just the
24 12:48:18 depression item.

1 12:48:19 A It says secondary efficacy -- depression
2 12:48:21 items in K-SADS-P, changes from baseline.
3 12:48:28 So I guess the answer --
4 12:48:29 If I understand your question, the
5 12:48:30 answer is yes.
6 12:48:31 Q Okay.
7 12:48:32 And what page is that on? At the
8 12:48:36 bottom, use the bottom pagination.
9 12:48:39 A 1228.
10 12:48:40 Q Okay.
11 12:48:45 A Under 9. -- 9.1.2, secondary efficacy
12 12:48:50 variables.
13 12:48:51 Q What is the K-SADS-P? I asked about
14 12:48:57 K-SADS-S or K-SADS, S-A-D-S.
15 12:49:01 This is the K --
16 12:49:05 A The K-SADS.
17 12:49:06 Q This is the K-SAD-P.
18 12:49:08 A There -- what I think is --
19 12:49:14 You asked about the K-SADS?
20 12:49:16 Q Correct?
21 12:49:16 A All right. Okay.
22 12:49:17 So the K-SADS, I believe, encompasses
23 12:49:20 sort of the sub -- two interviews within it.
24 12:49:26 One is -- the K-SADS-P, I believe, is the

1 12:49:31 parent version; and the K-SADS-S, I believe,
2 12:49:35 is the subject version, but I'm not sure.
3 12:49:37 Q Okay.
4 12:49:38 A But -- but certainly -- I just -- I just
5 12:49:40 don't remember. I'd have to see them in
6 12:49:42 front of me.
7 12:49:42 Q Okay.
8 12:49:43 A You know, if you had the original
9 12:49:44 instruments.
10 12:49:45 But generically, this -- this
11 12:49:46 certainly would be referring to the K-SADS.
12 12:49:50 Q Okay.
13 12:49:50 Well, in the -- it actually says
14 12:49:52 K-SADS-P in the document, correct?
15 12:49:54 A SAD. No.
16 12:49:55 Q K-SAD-P?
17 12:49:56 A Right.
18 12:49:56 Q And that would be parent?
19 12:49:57 A I think so, but I'm not sure.
20 12:49:59 Q Okay.
21 12:50:00 A I'm just -- I'm not sure.
22 12:50:02 Q Okay.
23 12:50:02 Now, there are two primary efficacy
24 12:50:06 variables listed in this protocol, correct?

1 12:50:10 A Yes.

2 12:50:11 Q Okay.

3 12:50:13 And can you state for the record what

4 12:50:15 those are, please?

5 12:50:16 A The change in total HAM-D score from

6 12:50:19 beginning of treatment phase to the end of

7 12:50:20 the acute phase. And the second is the

8 12:50:24 proportion of respondents at the end of the

9 12:50:26 eight-week treatment -- the acute treatment

10 12:50:28 phases.

11 12:50:29 Q Okay.

12 12:50:29 Now, after the study was concluded,

13 12:50:32 how many of these measures did paroxetine

14 12:50:34 separate statistically from placebo?

15 12:50:37 A I don't remember. You'd have to show -- I'd

16 12:50:39 have to look at the article.

17 12:50:40 Q Okay.

18 12:51:10 Doctor, the exhibit before you is 12;

19 12:51:13 is that correct?

20 12:51:15 A Yes.

21 12:51:15 Q Okay.

22 12:51:17 So I'm going to mark as Exhibit 13 --

23 12:51:21 A You can come by and help me file my -- the

24 12:51:24 papers on the floor in my office any day

1 12:51:27 with your stickies.

2 12:51:30 Q There we go. There's a copy of the article.

3 12:51:32 (Exhibit No. 13 marked for

4 12:51:32 identification.)

5 12:51:32 BY MR. MURGATROYD:

6 12:51:38 Q And take your time going through.

7 12:51:40 MR. MURGATROYD: What time is it now?

8 12:51:42 MR. DAVIS: 12:45.

9 12:51:44 THE WITNESS: Lunchtime.

10 12:51:45 MR. MURGATROYD: 12:45.

11 12:51:46 Why don't we break for lunch, and you

12 12:51:46 can have -- because I want you to be

13 12:51:49 familiar with the article.

14 12:51:49 Q So if you can have a chance to review it

15 12:51:52 over lunch, it will be helpful. It will

16 12:51:54 save us some time.

17 12:51:56 A Okay.

18 12:51:56 MR. MURGATROYD: So let's go off the

19 12:51:57 record now and take a lunch break and come

20 12:51:58 back -- 45 minutes okay by you guys?

21 12:52:03 THE WITNESS: Fine.

22 12:52:04 MR. MURGATROYD: 1:30?

23 12:52:05 THE WITNESS: Yes.

24 12:52:06 MR. MURGATROYD: Okay, great.

1 12:52:06 And Bob told me there's a place
2 12:52:10 downstairs, and there's also a place around
3 12:52:12 the corner for food.
4 12:52:14 THE VIDEOGRAPHER: The time is 12:52.
5 12:52:16 We're off the record.
6 12:52:17 MR. DAVIS: Let me put something on
7 12:52:18 the -- on the transcript here.
8 12:52:18 Skip, I appreciate you turning after
9 12:52:20 the break to the issues dealing with Study
10 12:52:21 329 to push this process along, because I
11 12:52:25 think that's going to be very helpful in
12 12:52:28 order for us to see if we can get completed
13 12:52:30 by tomorrow.
14 12:52:30 MR. MURGATROYD: Right. Correct.
15 12:52:31 MR. DAVIS: So I appreciate you doing
16 12:52:32 that.
17 12:52:32 MR. MURGATROYD: No problem.
18 12:52:33 MR. DAVIS: All right.
19 12:52:33 THE WITNESS: That was a warm-fuzzy,
20 12:52:33 right?
21 12:52:33 MR. MURGATROYD: I don't know.
22 12:52:33 MR. DAVIS: It was on the record.
23 12:52:33 It was an attempt at a warm-fuzzy to
24 12:52:33 see if we can get this done, as opposed

1 12:52:33 focusing on collateral issues that don't
2 12:52:33 have any --
3 12:52:33 MR. MURGATROYD: Well, I'll do my
4 12:52:33 best to be speedy.
5 12:52:33 (Discussion off the record.)
6 12:52:37 (Luncheon recess.)
7 01:56:10 THE VIDEOGRAPHER: We are back on the
8 01:56:39 record. The time is 1:56.
9 01:56:42 BY MR. MURGATROYD:
10 01:56:42 Q Okay.
11 01:56:43 So when we broke for lunch, the
12 01:56:46 question was -- you identified the two
13 01:56:52 primary outcome variables from the protocol.
14 01:56:56 A Yes.
15 01:56:56 Q And my question was, of the two primary
16 01:57:01 outcome measures -- or how many of these --
17 01:57:06 how many of the two primary outcome measures
18 01:57:10 separated statistically from placebo?
19 01:57:16 A Okay.
20 01:57:31 (Witness read document.)
21 01:57:32 Q Now, the -- before you answer that, the
22 01:57:33 primary outcome measures are actually
23 01:57:35 mentioned in the abstract, correct, under
24 01:57:37 the second sentence, third sentence?

1 01:57:39 A Yes. That's what I was trying to get to.

2 01:57:41 The two primary outcome measures were

3 01:57:43 endpoint response, that that --

4 01:57:45 Q Right.

5 01:57:45 A And change from baseline -- and it lists the

6 01:57:48 others.

7 01:57:49 Q Right.

8 01:57:50 Now, so --

9 01:57:51 A And it gives the results the next line.

10 01:57:53 Q So the primary outcome measures, how many of

11 01:57:56 those separated statistically from placebo,

12 01:58:00 if any?

13 01:58:01 A Okay. So --

14 01:58:04 (Witness read document.)

15 01:58:31 A There -- I'm cross-referencing here. In the

16 01:58:33 abstract, neither of the two primaries did.

17 01:58:36 I'm just looking now at page 764, where it

18 01:58:40 goes over the efficacy.

19 01:58:43 Q Okay.

20 01:58:44 So in the abstract, it doesn't -- it

21 01:58:47 tells you what the two primary outcome

22 01:58:49 measures are --

23 01:58:50 A Right.

24 01:58:50 Q -- but doesn't tell you whether or not

1 01:58:52 whether they separated statistically from
2 01:58:54 placebo, correct?
3 01:58:55 MR. DAVIS: Object to the form.
4 01:58:58 THE WITNESS: What do --
5 01:59:02 MR. GREEN: You're allowed to answer,
6 01:59:03 if you --
7 01:59:04 A Correct.
8 01:59:05 Q Correct? Okay.
9 01:59:06 But later in the body of the article,
10 01:59:11 the reader is given information on the --
11 01:59:16 how -- how well the two primary outcome
12 01:59:18 measures did, correct?
13 01:59:22 MR. DAVIS: Object to the form.
14 01:59:23 A Which page, Skip? Because I'm just having
15 01:59:28 trouble -- are we talking 765?
16 01:59:30 Q No, actually, we're looking -- I'm referring
17 01:59:32 to Table 2 on 766.
18 01:59:35 A Oh, okay. Good. That's what I was looking
19 01:59:39 for.
20 01:59:51 (Witness read document.)
21 01:59:51 A Okay.
22 01:59:52 Q And do you see the two primary variables
23 01:59:55 listed as the second and third items in
24 01:59:57 Table 2?

1 01:59:58 MR. DAVIS: Object to the form.

2 01:59:59 A The second one is response, right?

3 02:00:02 Q Right. Responder.

4 02:00:04 A Responder.

5 02:00:05 Well, it's not -- it's not labeled as

6 02:00:07 responder, but it's the definition --

7 02:00:11 Q And did that separate statistically from

8 02:00:14 placebo?

9 02:00:15 Did Paxil separate statistically from

10 02:00:18 placebo with regard to that primary

11 02:00:21 endpoint?

12 02:00:23 A No.

13 02:00:24 Q Okay.

14 02:00:24 And what's the second primary

15 02:00:26 variable, outcome measure?

16 02:00:33 A It's a proportion of responders at the end

17 02:00:35 of eight weeks.

18 02:00:40 Q Well, if you go to the abstract again --

19 02:00:43 A Yes.

20 02:00:43 Q -- it says the, Two primary outcome measures

21 02:00:45 were endpoint response?

22 02:00:47 A Right.

23 02:00:47 Q Right, which we just discussed.

24 02:00:49 And you agree that that did not

1 02:00:52 separate --

2 02:00:53 A Right.

3 02:00:54 Q -- statistically from placebo?

4 02:00:55 A That's the first one in the table, isn't it?

5 02:00:58 Q No.

6 02:00:58 Look at the definition -- go back to

7 02:01:02 the abstract.

8 02:01:02 A Yes, yes.

9 02:01:03 Q And it says, The two primary outcome

10 02:01:05 measures were endpoint response.

11 02:01:08 Do you see that?

12 02:01:09 A Yes.

13 02:01:09 Q And it defines it as a score less than or

14 02:01:13 equal to 8, or greater than -- equal or less

15 02:01:17 than -- equal or greater than 50 percent

16 02:01:20 reduction of baseline HAM-D.

17 02:01:22 You take that to Table 2 --

18 02:01:25 A All right.

19 02:01:25 Q -- and which is that? Is that the second

20 02:01:27 one?

21 02:01:28 A I think it was the first and the second.

22 02:01:37 (Witness read document.)

23 02:01:41 A Looks like it's the first, isn't it?

24 02:01:44 Q Well, take -- let's go back to the abstract.

1 02:01:47 A And the second --

2 02:01:48 Q Well, actually, go to page 764.

3 02:01:52 A Yes.

4 02:01:52 Q Okay.

5 02:01:55 The section that says efficacy and

6 02:01:56 safety evaluation; do you see that?

7 02:01:58 A Right, right, right.

8 02:01:59 Q And, if you would, read the --

9 02:02:05 A Protocol defined -- described two primary

10 02:02:07 outcome measures.

11 02:02:08 Q Yes.

12 02:02:08 A Response, which was the --

13 02:02:14 The protocol described two primary

14 02:02:16 outcome measures. One: Response, which was

15 02:02:19 defined as HAM-D squared less than equal to

16 02:02:22 8 or greater than equal to 50 percent

17 02:02:24 reduction in baseline score at the end of

18 02:02:26 measurement.

19 02:02:27 Q All right. Let's stop there.

20 02:02:28 A Okay.

21 02:02:29 So --

22 02:02:30 Q Now, which is that in Table 2?

23 02:02:34 A That's the second one.

24 02:02:37 Q Okay.

1 02:02:37 Did Paxil separate statistically from
2 02:02:39 placebo with regard to that primary outcome
3 02:02:42 measure?
4 02:02:43 A No.
5 02:02:43 Q Okay. Now let's go -- now go back to 764.
6 02:02:48 What's the secondary primary
7 02:02:49 variable?
8 02:02:54 A The second primary --
9 02:02:55 Q Yes.
10 02:02:57 A That's change from baseline in HAM-D total
11 02:03:00 score.
12 02:03:00 Q Okay.
13 02:03:01 And now let's go to the Table 2
14 02:03:03 again, and which one --
15 02:03:08 A I think that's the last one, isn't it?
16 02:03:10 Q Okay.
17 02:03:13 A Am I right?
18 02:03:14 Q Yes.
19 02:03:16 And did it -- did Paxil separate
20 02:03:19 statistically from placebo with regard to
21 02:03:20 that endpoint?
22 02:03:22 A No.
23 02:03:22 Q Okay.
24 02:03:24 So am I correct in stating that

1 02:03:27 neither of the primary efficacy variables --
2 02:03:34 well, let me -- let me say that again.
3 02:03:39 Neither of the primary efficacy
4 02:03:41 variables with regard to paroxetine
5 02:03:43 separated statistically from placebo,
6 02:03:45 correct?
7 02:03:48 A Yes.
8 02:03:51 Q Okay.
9 02:03:51 Now, I want to show you what I've
10 02:03:53 marked --
11 02:03:54 Have we marked that study? We marked
12 02:03:56 that as Exhibit 13; is that correct?
13 02:03:58 MR. DAVIS: (Nods.)
14 02:03:59 MR. GREEN: (Nods.)
15 02:03:59 (Exhibit No. 14 marked for
16 02:03:59 identification.)
17 02:03:59 BY MR. MURGATROYD:
18 02:04:00 Q Let me show you what I've marked as
19 02:04:01 Exhibit 14.
20 02:04:03 A What one? Just give me one second.
21 02:04:05 Q Okay.
22 02:04:13 A Just for my own reference, because --
23 02:04:17 (Pause.)
24 02:04:17 Q No, that's fine, because we're going to come

1 02:04:19 back to the study in a certain --

2 02:04:25 A Mm-hmm.

3 02:04:25 Just -- I'm half talking to myself,

4 02:04:27 but on page 764, right after that, it talks

5 02:04:30 about -- I know this is not what you're

6 02:04:31 asking me now --

7 02:04:32 MR. GREEN: There's -- there's no

8 02:04:33 question pending.

9 02:04:34 THE WITNESS: Okay. Okay.

10 02:04:37 Q Okay.

11 02:04:37 A All right.

12 02:04:37 Q Let's go to the next exhibit --

13 02:04:39 A Okay.

14 02:04:39 Q -- which we've marked as Exhibit 14. And if

15 02:04:43 you would, take a look at that.

16 02:04:56 A This is different than 12?

17 02:04:57 Q Yes, you'll see that it's amended.

18 02:05:00 A Okay.

19 02:05:01 Q And do you see the amendment date at the

20 02:05:03 bottom?

21 02:05:03 A The last one?

22 02:05:04 Q Yes.

23 02:05:04 What's --

24 02:05:04 A October 29, 1996.

1 02:05:07 Q Okay.

2 02:05:10 A Yeah, okay.

3 02:05:10 Q All right.

4 02:05:11 Now, with regard to that amended

5 02:05:13 protocol -- and, again, I believe you -- so

6 02:05:15 the record's clear, what's the date of that

7 02:05:17 amended protocol at the bottom again?

8 02:05:24 The very bottom right --

9 02:05:25 A The Amendment No. 2 says -- there are two

10 02:05:30 dates, but the date the amendment was

11 02:05:32 approved was October 29, 1996.

12 02:05:35 Q Okay.

13 02:05:36 A It doesn't -- the protocol in itself is not

14 02:05:38 dated.

15 02:05:38 Q Okay.

16 02:05:40 Now, in that protocol, it lists the

17 02:05:44 primary and secondary efficacy variables,

18 02:05:48 correct?

19 02:05:51 And so the record's clear, an

20 02:05:52 efficacy variable and an outcome measure,

21 02:05:55 there's synonymous terms; is that correct?

22 02:05:59 MR. DAVIS: Object to the form.

23 02:06:00 A No.

24 02:06:05 Q Okay.

1 02:06:05 What's the difference between them?

2 02:06:08 A Well, there can -- can be outcome variables

3 02:06:11 which aren't efficacy, per se.

4 02:06:13 So you could be measuring outcome

5 02:06:16 in -- in psychosocial functioning. You

6 02:06:20 could be measuring a variety of outcomes

7 02:06:22 which don't fit the traditional definition

8 02:06:24 of efficacy, which, by inference, although

9 02:06:28 I'm not sure by Webster, by inference would

10 02:06:32 be having to do with the, you know, the

11 02:06:34 comparative change in the measure of

12 02:06:39 interest.

13 02:06:40 So there are a lot of outcomes you

14 02:06:43 look at.

15 02:06:43 Q Okay.

16 02:06:44 So is a better term to use "outcome

17 02:06:49 measure"? That would cover those that are

18 02:06:49 beyond efficacy?

19 02:06:51 A Yes.

20 02:06:51 Q And include efficacy and those beyond

21 02:06:54 efficacy?

22 02:06:55 A Yes.

23 02:06:55 Q Okay.

24 02:06:55 So I'm going to use the word "outcome

1 02:06:57 measure."

2 02:06:57 In terms of the documents in front of

3 02:06:58 you, I believe that it lists the secondary

4 02:07:01 outcome measures, correct?

5 02:07:03 A Which document are you referring to now,

6 02:07:05 Skip?

7 02:07:06 Q The exhibit in your hand, Exhibit 14, the

8 02:07:10 amended protocol.

9 02:07:12 MR. GREEN: If you need time to read

10 02:07:13 it, take a few minutes to read it.

11 02:07:15 (Witness read document.)

12 02:07:35 A So I -- I can find primary efficacy and

13 02:07:40 secondary efficacy on the page at the

14 02:07:44 bottom, 636.

15 02:07:45 Now I'm looking to see whether

16 02:07:47 they -- it -- it mentions other outcome

17 02:07:51 variables throughout the text of this.

18 02:07:53 Q Okay. That's fine.

19 02:07:57 A Page 24 --

20 02:08:00 (Witness read document.)

21 02:08:18 A Can we go off the record for a second?

22 02:08:20 Q Sure.

23 02:08:20 You want to go off the record to look

24 02:08:22 at it?

1 02:08:23 A Well, I want to ask you a question off the
2 02:08:25 record.
3 02:08:26 MR. MURGATROYD: Okay. That's fine.
4 02:08:27 THE VIDEOGRAPHER: The time is eight
5 02:08:28 minutes after 2:00. We are off the record.
6 02:08:31 (Discussion off the record.)
7 02:08:45 THE VIDEOGRAPHER: We're back on the
8 02:11:58 record. The time is 12 minutes after 2:00.
9 02:12:01 BY MR. MURGATROYD:
10 02:12:02 Q Okay.
11 02:12:03 So we were talking about the
12 02:12:04 secondary efficacy variables that are
13 02:12:08 contained within the amended protocol dated
14 02:12:10 1996, correct?
15 02:12:12 A Yes.
16 02:12:12 Q And can you read those into the record, what
17 02:12:15 they are?
18 02:12:19 A Secondary -- secondary efficacy variables,
19 02:12:25 page 24. Okay.
20 02:12:36 Under A: Changes from baseline to
21 02:12:38 endpoint in the following parameters:
22 02:12:42 Depression items in the K-SAD-L.
23 02:12:47 Global impressions.
24 02:12:48 Autonomic function checklist.

1 02:12:50 Self-perfection -- perception
2 02:12:50 profile.
3 02:12:51 Sickness impact scale.
4 02:12:55 B: Predictors of response
5 02:12:57 (endogenous subtypes, age, prior episodes,
6 02:13:02 duration and severity of present episode,
7 02:13:05 comorbidity with separate anxiety, attention
8 02:13:11 deficit and conduct disorder).
9 02:13:14 C: The number of patients who
10 02:13:16 relapse during maintenance phase.
11 02:13:18 Q Okay.
12 02:13:19 Now, let's take a look -- take it
13 02:13:21 from the top.
14 02:13:22 So we have the depression items in
15 02:13:24 K-SAD-L, correct?
16 02:13:26 A Yes.
17 02:13:27 Q And did that -- did paroxetine separate
18 02:13:30 statistically from placebo with regard to
19 02:13:33 that scale?
20 02:14:23 (Witness read document.)
21 02:14:25 A Yes. K-SADS-L, depressed mood item.
22 02:14:31 Q No, this is the --
23 02:14:33 A Results.
24 02:14:33 Q It says here depression items in K-SAD-L.

1 02:14:39 A Well, depression mood item would be a
2 02:14:42 depressed item in the K-SADS-L.
3 02:14:45 Q Well, what's the difference between that and
4 02:14:46 the K-SADS-L nine-item depression
5 02:14:48 subscale -- subscore?
6 02:14:55 A I believe the nine-item subscore adds up the
7 02:14:58 scores from nine items.
8 02:15:00 Q Where the other is just -- the K-SADS-L is
9 02:15:02 just one?
10 02:15:03 A Is one -- one particular item.
11 02:15:04 Q Okay.
12 02:15:05 And this -- and the protocol says
13 02:15:08 depression items in K-SAD-L, correct?
14 02:15:12 A Yes. But I think, you know, in terms of how
15 02:15:19 you read it, this -- in other words, this --
16 02:15:20 My reading of this here is that this
17 02:15:24 is not -- how to put this.
18 02:15:26 This is not definitive in being
19 02:15:29 explicit as to whether or not the
20 02:15:31 depressant -- the depression item by itself
21 02:15:36 is being intended or whether they're talking
22 02:15:39 about the subscale.
23 02:15:39 It doesn't -- it's not -- it's not
24 02:15:41 explicit from looking at this.

1 02:15:43 Q Okay.

2 02:15:43 A I think that's an open --

3 02:15:45 Q Well, let's take both of them.

4 02:15:47 According to your -- the journal

5 02:15:49 article in which you were the primary -- the

6 02:15:51 lead author, if you take the K-SADS-L

7 02:15:54 nine-item depression subscore, did

8 02:15:56 paroxetine separate statistically from

9 02:15:59 placebo?

10 02:16:00 A In the K-SADS-L depressed --

11 02:16:05 Q Nine-item depression subscore.

12 02:16:12 A No.

13 02:16:13 Q Okay.

14 02:16:15 A But it was from the K-SADS-L depressed mood

15 02:16:18 item.

16 02:16:19 Q Okay.

17 02:16:19 Now, did the change in CGI score --

18 02:16:26 mean score for -- did paroxetine or Paxil

19 02:16:30 separate statistically from placebo with

20 02:16:32 regard to the mean CGI score?

21 02:16:38 MR. DAVIS: Object to the form.

22 02:16:43 A Well, it did in the CGI score -- having a

23 02:16:45 CGI score of 1 or 2.

24 02:16:47 Q No, the question was the mean CGI score.

1 02:16:54 A No.

2 02:16:55 Q Okay.

3 02:16:57 Did -- with regard to the

4 02:17:00 autotomic -- autonomic function checklist,

5 02:17:05 can you describe for us what that is for the

6 02:17:06 record?

7 02:17:17 (Witness read document.)

8 02:17:28 A I'd have to look at the checklist to -- to

9 02:17:30 give you a precise definition of it.

10 02:17:35 Q Okay.

11 02:17:35 Do you -- do you recall from reading

12 02:17:37 your journal article whether or not placebo

13 02:17:42 separated statistically from placebo with

14 02:17:47 regard to the autonomic function checklist?

15 02:18:05 (Witness read document.)

16 02:18:16 A I don't think we reported P values for

17 02:18:20 those, unless I'm missing it.

18 02:18:23 Q It's not in Table 2, is it?

19 02:18:25 A No, no, because --

20 02:18:27 Q But it is in the -- it does mention it in

21 02:18:29 the right-hand column of page 766, correct?

22 02:18:34 A Well, I'm looking at page 764. It mentions

23 02:18:38 assessment of multiple domains of

24 02:18:41 functioning, general health and behavior

1 02:18:43 consisted of autonomic checklist, blah,
2 02:18:46 blah, blah, blah, blah, blah, blah,
3 02:18:47 self-perception, sickness impact scale.
4 02:18:50 Q And how did -- and how did Paxil do with
5 02:18:56 regard to those scales?
6 02:18:58 A I don't -- I don't see that we --
7 02:19:21 (Witness read document.)
8 02:18:58 A I don't think we reported the outcome of
9 02:19:23 those.
10 02:19:25 Q Well, actually, if you look on page 766 --
11 02:19:28 A Oh, "although neither"?
12 02:19:31 Q Yes.
13 02:19:31 A Statistically across the nonsymptom measures
14 02:19:34 of functioning.
15 02:19:35 (Witness read document.)
16 02:19:52 A Doesn't say that specifically, but --
17 02:20:01 Q Actually, why don't you read that sentence
18 02:20:03 into the record.
19 02:20:04 (Witness read document.)
20 02:20:20 A Okay. Page 766?
21 02:20:23 Q Yes, sir.
22 02:20:24 A Okay.
23 02:20:24 "Although neither paroxetine nor
24 02:20:26 imipramine separated statistically from

1 02:20:29 placebo across the nonsymptomatic measures
2 02:20:31 of functioning, health and behavior,
3 02:20:34 improvements over baseline were achieved for
4 02:20:36 each active treatment group.
5 02:20:37 Placebo-treated subjects also improved along
6 02:20:40 the behavioral measures but to a lesser
7 02:20:42 extent than patients in the active treatment
8 02:20:46 groups."
9 02:20:47 Q Okay.
10 02:20:48 So now let's take the secondary
11 02:20:49 efficacy variable that's defined in the
12 02:20:52 protocol of autonomic function checklist.
13 02:20:56 Did -- from your reading of your
14 02:20:58 study, did paroxetine separate statistically
15 02:21:00 from placebo with regard to that variable?
16 02:21:05 A No.
17 02:21:06 Q Okay.
18 02:21:06 Now, the next variable listed in the
19 02:21:09 protocol is the self-perception profile.
20 02:21:12 Do you see that?
21 02:21:14 A Yes.
22 02:21:15 Q And can you define or tell the jury what
23 02:21:16 that -- what that variable is?
24 02:21:29 Can you describe for the record what

1 02:21:30 it is?

2 02:21:31 A Yes. I mean, the general description is how

3 02:21:33 one perceives oneself.

4 02:21:35 Q Okay.

5 02:21:36 Now, is that a measure that the

6 02:21:41 patient themselves -- that the child would

7 02:21:44 fill out themselves to say whether or not

8 02:21:45 they thought they were doing better?

9 02:21:53 A It's -- it's filled out by the child, but it

10 02:21:56 has less to do with improvement and more to

11 02:22:01 do with -- how do you describe this.

12 02:22:10 Aspects of self-perception, not

13 02:22:17 symptom improvement. It's a very global

14 02:22:24 concept.

15 02:22:25 Q About how they feel about themselves?

16 02:22:27 A Right.

17 02:22:28 Q Okay.

18 02:22:28 And did Paxil separate statistically

19 02:22:32 from placebo with regard to that efficacy

20 02:22:33 variable?

21 02:22:34 A No.

22 02:22:35 Q Okay.

23 02:22:36 Now, turning to the sickness impact

24 02:22:39 scale, do you see that in -- as listed as a

1 02:22:41 secondary variable?

2 02:22:42 A Yes.

3 02:22:43 Q Okay.

4 02:22:43 Now, did -- can you describe what

5 02:22:45 that is?

6 02:22:47 A It's also very -- it's a very global measure

7 02:22:52 of the effect of the sickness or the

8 02:22:59 illness, it has on you.

9 02:23:02 So the impact of your sickness on

10 02:23:04 you. Again, a very global measure.

11 02:23:08 Q And is that filled out by the patient who is

12 02:23:10 taking the drug?

13 02:23:19 A I believe so, but I would have to see the

14 02:23:21 scale.

15 02:23:21 Q Okay.

16 02:23:22 And did Paxil separate statistically

17 02:23:24 from placebo with regard to that measure?

18 02:23:42 A Unless I'm missing it, it's not listed

19 02:23:44 specifically here, but the inference from

20 02:23:46 this paragraph would be that it's being

21 02:23:51 covered and it wasn't significant, but it's

22 02:23:53 not listed specifically.

23 02:23:55 Q Okay.

24 02:23:56 A So if it is listed specifically somewhere

1 02:23:58 else in the paper, I'd have to comb through
2 02:24:00 it.
3 02:24:01 Q All right.
4 02:24:02 So looking on the protocol that's
5 02:24:05 before you with regard to the primary
6 02:24:09 efficacy variables, we agreed that Paxil did
7 02:24:11 not separate statistically from placebo with
8 02:24:13 regard to either of those, correct?
9 02:24:17 A Yes.
10 02:24:18 Q And with regard to the secondary efficacy
11 02:24:20 variables that we just discussed, the
12 02:24:22 depression items of the K-SADS-L, global
13 02:24:26 impressions, the autonomic function
14 02:24:28 checklist, the self-perception profile and
15 02:24:30 the sickness impact scale, Paxil did not
16 02:24:35 separate statistically from any of those if
17 02:24:41 depression items of K scale -- K-SADS-L is
18 02:24:45 defined as the nine-item depression
19 02:24:47 subscore, correct?
20 02:24:50 MR. DAVIS: Object to the form.
21 02:24:51 Mischaracterizes the testimony.
22 02:24:55 A Yes, I -- I -- if you could separate those
23 02:24:58 out.
24 02:24:59 I guess I -- my -- my interpretation

1 02:25:03 and understanding of the secondary efficacy
2 02:25:08 variable, the first one listed under changes
3 02:25:12 from baseline, depression items in K-SADS-L,
4 02:25:16 my interpretation of that would be that that
5 02:25:19 would refer to the K-SADS-L depressed mood
6 02:25:24 item which did significantly separate from
7 02:25:27 placebo.
8 02:25:28 Q Okay.
9 02:25:28 So one out of the five separated?
10 02:25:31 A Then -- and then the -- the other one that I
11 02:25:42 believe separated is the clinician's global
12 02:25:47 score, which would be the second one listed
13 02:25:49 under global impression.
14 02:25:52 Q Well, actually, the -- if you go to Table 2,
15 02:25:55 the mean global score did not separate
16 02:25:58 statistically, correct?
17 02:25:59 A The mean didn't, but the actual individual
18 02:26:01 score of 1 or 2 --
19 02:26:04 Q Right.
20 02:26:05 A -- did. So that's a -- that's also a global
21 02:26:08 impression score.
22 02:26:09 Q Okay.
23 02:26:10 Well, if you take the -- all right.
24 02:26:12 So let's say the -- the secondary

1 02:26:15 variables -- you could say --

2 02:26:18 A Two.

3 02:26:19 Q -- two out of, but you'd have to add --

4 02:26:22 you'd have to add two onto this five, so it

5 02:26:26 would have to be seven, right?

6 02:26:27 MR. DAVIS: Object to the form.

7 02:26:28 I'm not sure what question is being

8 02:26:30 asked the witness.

9 02:26:31 Q Well, if you have the depression item, items

10 02:26:34 of K-SAD-L, which we have agreed could be

11 02:26:37 either the mood item or the nine-item

12 02:26:42 subscore, correct?

13 02:26:43 MR. DAVIS: Object to the form. He

14 02:26:45 said it's included within -- one is included

15 02:26:47 within the other.

16 02:26:47 Object to the form of the question.

17 02:26:50 Q Okay.

18 02:26:52 A Those are two separate -- two separate

19 02:26:53 measures, correct?

20 02:26:55 MR. DAVIS: Object to the form.

21 02:26:57 I'm not sure what is being asked of

22 02:26:58 the witness as to what are two separate

23 02:27:00 measures.

24 02:27:02 MR. MURGATROYD: Well, it's pretty

1 02:27:04 simple.

2 02:27:04 Q The HAM-D depressed mood item is different

3 02:27:07 from the -- I'm sorry.

4 02:27:11 The K-SADS-L depressed mood item is

5 02:27:14 different from the K-SADS-L nine-item

6 02:27:18 depression subscore, correct?

7 02:27:20 MR. DAVIS: Object to the form.

8 02:27:21 It's been asked and answered.

9 02:27:26 THE WITNESS: I don't know what I'm

10 02:27:26 supposed to say.

11 02:27:27 MR. GREEN: You can answer.

12 02:27:28 A Yes.

13 02:27:28 Q They're different -- two different -- two

14 02:27:29 different measures?

15 02:27:30 A Well -- yes. The depressed mood item is one

16 02:27:36 of the nine items in the nine-item

17 02:27:44 depression subscore.

18 02:27:46 Q Okay.

19 02:27:47 So it would be like a --

20 02:27:48 A So it's a subset. It's one of the items.

21 02:27:51 Q Right. Okay.

22 02:27:52 And then the CGI score of 1 or 2 --

23 02:27:55 A Would be one of the items within --

24 02:27:59 Well, actually, it's an item -- it's

1 02:28:03 not different than the CGI score. It's just
2 02:28:07 different ways of measuring it.
3 02:28:10 So that in the CGI -- the mean CGI
4 02:28:13 score would be taking the mean of all the
5 02:28:17 CGI items.
6 02:28:18 When you take the individual CGI
7 02:28:20 improvement item, there's a difference.
8 02:28:22 Q Okay.
9 02:28:22 A So I'm not, you know, in terms of sets and
10 02:28:25 subsets, it's slightly different.
11 02:28:29 Q Right, okay.
12 02:28:30 So if we're looking at this protocol
13 02:28:34 and we have the depression items of the
14 02:28:36 K-SAD-L, that could be two of the measures
15 02:28:40 that you reported upon in your journal
16 02:28:42 article, correct?
17 02:28:44 A Yes.
18 02:28:45 Q And one did -- Paxil did separate
19 02:28:47 significantly with regard to the mood item,
20 02:28:50 correct?
21 02:28:51 A Yes.
22 02:28:51 Q But it did not separate statistically --
23 02:28:54 Paxil did not separate statistically with
24 02:28:56 regard to the nine-item depression subscore,

1 02:28:58 correct?

2 02:28:58 A Yes.

3 02:28:59 Q Okay.

4 02:29:00 And if you're looking at the CGI, the

5 02:29:03 global impression, right, there are two ways

6 02:29:06 of measuring that according to your article

7 02:29:07 in Table 2.

8 02:29:09 One is the CGI score of 1 or 2,

9 02:29:11 correct?

10 02:29:12 A Correct.

11 02:29:12 Q And Paxil did separate statistically from

12 02:29:14 that?

13 02:29:15 A Correct.

14 02:29:15 Q From placebo?

15 02:29:17 But with regard to the mean CGI

16 02:29:19 score, Paxil did not separate statistically

17 02:29:22 from placebo, correct?

18 02:29:23 A Yes.

19 02:29:24 Q Okay.

20 02:29:25 So if you add them -- so we have two

21 02:29:30 primary efficacy variables that did not

22 02:29:32 achieve statistical significance and five

23 02:29:35 out of seven secondary measures that did not

24 02:29:39 achieve -- Paxil did not achieve statistical

1 02:29:42 significance.

2 02:29:44 How would you characterize the --

3 02:29:47 what would you conclude when you see

4 02:29:50 statistics such as that?

5 02:29:52 MR. DAVIS: That object to the form.

6 02:29:53 Q With regard to the success of the study.

7 02:29:57 A I wouldn't -- in other words, I wouldn't be

8 02:29:59 making a judgment about the success of the

9 02:30:01 study based on what you just described.

10 02:30:09 I would take into consideration the

11 02:30:11 other variables which were determined to be

12 02:30:15 a priori variables before the data was

13 02:30:18 analyzed.

14 02:30:19 So that variables were chosen

15 02:30:22 after --

16 02:30:25 Now, let me be careful about this so

17 02:30:27 I'm accurate.

18 02:30:28 Variables were chosen and are listed

19 02:30:32 in the article as a priori items. Either --

20 02:30:38 and either not included in this for a reason

21 02:30:41 that I could not give you or they were

22 02:30:47 chosen after this was written.

23 02:30:50 In either of those two cases, the

24 02:30:53 choice of those items was made before the

1 02:30:57 data was analyzed, which is why they're
2 02:31:00 called a priori items.
3 02:31:03 So that when the thinking and
4 02:31:07 deliberation was done by the investigators
5 02:31:11 as to what to include, we included the HAM-D
6 02:31:18 depressed mood item as well as the
7 02:31:20 comparison of improvement with placebo in
8 02:31:24 the HAM-D total score.
9 02:31:28 And those were two items --
10 02:31:35 additional items which were considered to be
11 02:31:37 extremely important with a separated
12 02:31:41 placebo, which is what led to the thinking
13 02:31:45 of the investigators that the preponderance
14 02:31:49 of the evidence was it -- well, was at the
15 02:31:52 time, is, that paroxetine separated
16 02:31:59 significantly from placebo on a number of
17 02:32:05 highly meaningful -- highly clinically
18 02:32:08 meaningful and research-relevant
19 02:32:11 depression-related measures.
20 02:32:14 Q And going back to the original protocol,
21 02:32:17 though, that's what -- that's what the
22 02:32:18 question had to do with --
23 02:32:20 A Well, I know, but --
24 02:32:21 Q I know. I understand what you're saying.

1 02:32:23 We'll get to that.

2 02:32:24 But with regard to the protocols that

3 02:32:25 are listed -- with the measures that are

4 02:32:28 listed in the protocol, would you agree that

5 02:32:31 the primary measures, both the primary

6 02:32:34 measures, Paxil did not separate

7 02:32:36 statistically from placebo?

8 02:32:38 MR. DAVIS: Objection.

9 02:32:38 Asked and answered.

10 02:32:40 A I'm sorry, Skip, you lost me on the

11 02:32:41 question.

12 02:32:43 Q Okay.

13 02:32:43 With regard to the primary efficacy

14 02:32:45 variables that are listed in that

15 02:32:46 protocol --

16 02:32:47 A Okay, now we're talking about the two

17 02:32:48 primary efficacy variables on page whatever,

18 02:32:52 64.

19 02:32:53 Q Correct.

20 02:32:54 Paxil did not separate statistically

21 02:32:55 from placebo with regard to both of those

22 02:32:59 variables?

23 02:33:00 A Correct.

24 02:33:00 Q Okay.

1 02:33:00 And now going down to the secondary
2 02:33:02 variables, I think we agreed that with
3 02:33:07 regard to the autonomic function checklist,
4 02:33:10 the self-perception profile and the sickness
5 02:33:12 impact scale, Paxil did not separate
6 02:33:14 statistically from any of -- from placebo
7 02:33:16 for any of those?
8 02:33:17 A For those three.
9 02:33:18 Q Okay.
10 02:33:18 A And the answer is -- which I assume is
11 02:33:23 appropriate -- the answer is a "yes, but."
12 02:33:25 The "yes, but" is that there's no
13 02:33:29 expectation -- there would have been no
14 02:33:31 expectation that you would -- you would see
15 02:33:35 a separation from placebo on these measures
16 02:33:41 given how global they are, nor in any
17 02:33:45 traditional -- in any study of looking at
18 02:33:49 the treatment of depression would you
19 02:33:53 include these variables as part of a measure
20 02:33:56 as to whether you've changed or improved or
21 02:34:01 worsened the person's depression.
22 02:34:04 Q That --
23 02:34:04 A These are not depression items.
24 02:34:05 Q These -- these are items where the parents

1 02:34:08 and the child get to say whether or not they
2 02:34:10 feel like they're doing better, correct?
3 02:34:17 A I would not state it that way. I would -- I
4 02:34:21 would -- I think each item has to be taken
5 02:34:25 for itself.
6 02:34:26 I wouldn't lump them, so --
7 02:34:28 Q Okay.
8 02:34:29 A -- to be precise --
9 02:34:32 Q Well, one is?
10 02:34:32 A -- it would be a splitter.
11 02:34:35 Q One is rated by the parent, correct,
12 02:34:36 perceiving their child, stating whether or
13 02:34:39 not they believe their child's doing better?
14 02:34:44 Do you know which one that is?
15 02:34:46 A The auto -- I'm not sure. Is that -- are
16 02:34:48 you referring to the autonomic function
17 02:34:50 checklist?
18 02:34:52 Q Well, I'm asking you.
19 02:34:53 A It's not -- it's not -- I'm not sure.
20 02:34:55 The self-perception is by the child.
21 02:34:57 Q Okay.
22 02:34:58 A I believe the sickness impact is by the
23 02:34:59 child. I am not sure who rated the
24 02:35:01 autonomic function.

1 02:35:03 Q Okay.

2 02:35:03 A You just have to show me the instrument, and

3 02:35:05 I can telling you. I don't remember.

4 02:35:06 Q Okay.

5 02:35:07 But these are ones that are filled

6 02:35:08 out by the people who are actually -- two of

7 02:35:10 them are filled out by the person who is

8 02:35:12 actually taking the drug --

9 02:35:13 A Right.

10 02:35:13 Q -- and the other one is the parent observing

11 02:35:15 how the child is doing?

12 02:35:16 A What I'm saying is I'm not sure which of

13 02:35:18 these three, if any, in fact, were the

14 02:35:22 parent forms.

15 02:35:23 Q Parent-rated?

16 02:35:24 A You'd have to -- I'm just not sure. You'd

17 02:35:26 have to --

18 02:35:26 Q Well, you know two out of three are

19 02:35:28 child-rated?

20 02:35:29 A Correct.

21 02:35:29 Q And the third one is either parent-rated or

22 02:35:31 child-rated?

23 02:35:33 A Correct.

24 02:35:33 Q It's not doctor-rated?

1 02:35:36 A Correct.

2 02:35:36 Q Okay.

3 02:35:36 THE VIDEOGRAPHER: We have to go off

4 02:35:37 the record to change the tapes.

5 02:35:38 MR. MURGATROYD: Okay. Stop right

6 02:35:39 there. Thanks.

7 02:35:40 THE VIDEOGRAPHER: The time is 2:35.

8 02:35:41 This is the end of Tape No. 2. We are off

9 02:35:43 the record.

10 02:35:44 (Recess.)

11 02:38:22 THE VIDEOGRAPHER: We are back on the

12 02:38:23 record. This is Tape No. 3. The time is

13 02:38:25 2:38.

14 02:38:26 THE WITNESS: See, I have a good

15 02:38:27 answer. It depends on whether you have a

16 02:38:29 question or allow me to give you the answer.

17 02:38:30 BY MR. MURGATROYD:

18 02:38:31 Q I don't think there's a question pending.

19 02:38:33 MR. GREEN: I don't either.

20 02:38:34 A I know, which is too bad.

21 02:38:35 Q All right.

22 02:38:35 Let's go to the -- now -- so you

23 02:38:45 stated that there are two other items,

24 02:38:50 measures, right? We just discussed seven.

1 02:38:55 Actually, we discussed really a total
2 02:38:57 of nine items, correct?
3 02:38:58 MR. DAVIS: Object to the form.
4 02:39:00 Q Seven secondary variables and two primary
5 02:39:02 variables?
6 02:39:04 A Yes.
7 02:39:04 Q Okay.
8 02:39:04 And then you said that two more were
9 02:39:06 added at some point in time?
10 02:39:08 MR. DAVIS: Object to the form.
11 02:39:11 THE WITNESS: I can answer that?
12 02:39:12 MR. GREEN: You can answer.
13 02:39:12 A Yes.
14 02:39:13 Q Okay.
15 02:39:13 And who --
16 02:39:15 A I'll figure this out.
17 02:39:18 Q Whose decision was it -- let's -- so the
18 02:39:21 record's clear, what were those two
19 02:39:22 additional measures that are not included in
20 02:39:24 that protocol?
21 02:39:25 A Okay.
22 02:39:25 The -- the HAM -- the depressed mood
23 02:39:36 item.
24 02:39:36 Q Okay.

1 02:39:37 A And the HAM-D total score of less than or
2 02:39:46 equal to 8.
3 02:39:50 Q Okay.
4 02:39:53 And who added -- let's take the HAM-D
5 02:39:57 depressed mood item as the first of the two.
6 02:39:59 Whose decision was it to add that
7 02:40:02 item as a --
8 02:40:03 That was added as a secondary
9 02:40:05 variable, correct?
10 02:40:08 A I would -- it -- no.
11 02:40:11 It was added as an a priori item,
12 02:40:15 which is a very critical distinction,
13 02:40:18 meaning that before the data was analyzed, a
14 02:40:24 decision was made that there were at least
15 02:40:27 two -- in this case, the ones we just
16 02:40:30 read -- very important items with regard to
17 02:40:34 depression that should be part of the
18 02:40:38 analysis, making it a priori.
19 02:40:41 Q Yes.
20 02:40:41 But neither of them were primary
21 02:40:42 efficacy variables.
22 02:40:45 We have defined what those were?
23 02:40:47 A Not primary efficacy variables as stated in
24 02:40:50 the protocol.

1 02:40:50 Q And not primary efficacy variables as stated
2 02:40:53 in your article?
3 02:40:55 A Correct.
4 02:40:55 Q Okay.
5 02:40:56 So they're a secondary?
6 02:41:00 A Because they're not primary doesn't mean
7 02:41:02 they're secondary. You don't list them as
8 02:41:08 secondary.
9 02:41:09 Q Okay.
10 02:41:09 They're not -- they're not primary?
11 02:41:11 A We didn't categorize them -- they were not
12 02:41:13 categorized --
13 02:41:15 Unless you can find where we did, my
14 02:41:17 reading and my recall is that we didn't
15 02:41:20 categorize them as primary or secondary.
16 02:41:22 We categorized them as a priori.
17 02:41:26 Q Okay.
18 02:41:26 Well, they're all a priori, right?
19 02:41:31 A No. Variables can be --
20 02:41:33 Q No.
21 02:41:33 All the ones listed in the paper were
22 02:41:35 a priori?
23 02:41:37 A Yes. There's -- there's a -- terms --
24 02:41:45 In other words, category --

1 02:41:47 categories of terms are being commingled
2 02:41:50 here, and I understand that they -- why that
3 02:41:54 would be very confusing. And -- and the
4 02:42:01 most common current paradigm is to actually
5 02:42:04 use a priori or secondary as opposed to
6 02:42:10 primary.
7 02:42:11 So -- and that conventions change
8 02:42:14 over time. So when the extra -- the items
9 02:42:20 that were not in here were chosen, we
10 02:42:22 went -- we were using the terminology of the
11 02:42:26 current convention, the extent convention at
12 02:42:30 the time that the decision was made, and
13 02:42:32 calling those a priori items.
14 02:42:35 Q Well, the -- let's take the primary efficacy
15 02:42:39 items that we've talked about, the change --
16 02:42:42 A As the --
17 02:42:43 Q The change in the HAM-D.
18 02:42:44 A The primary efficacy items -- as "primary"
19 02:42:47 was defined in this protocol -- were the two
20 02:42:50 items specified on page 664 of Exhibit 14.
21 02:42:54 Q Right.
22 02:42:55 And those --
23 02:42:55 A Those were not -- did not separate
24 02:42:57 statistics from placebo. But --

1 02:43:00 Q Okay.

2 02:43:00 And those were a priori items,

3 02:43:03 meaning they were --

4 02:43:04 A Yes.

5 02:43:04 Q They were determined before the blind was

6 02:43:05 broken?

7 02:43:06 A They were a priori --

8 02:43:07 Q Okay.

9 02:43:07 A -- using that definition.

10 02:43:10 All I'm -- what I'm trying to make a

11 02:43:11 distinction about in responding, which I

12 02:43:14 believe is a very important one, is that the

13 02:43:19 two additional items that in the judgment of

14 02:43:22 the investigators was very important were

15 02:43:24 items that were a priori because they were

16 02:43:30 chosen before we did the analyses, but

17 02:43:34 they -- neither were put into the category

18 02:43:37 of primary or secondary.

19 02:43:40 Q Well, let me ask you this:

20 02:43:41 Who --

21 02:43:41 A Which is a very legitimate --

22 02:43:43 If you were to -- if you were to read

23 02:43:45 your literature on an annual basis going

24 02:43:49 back from 1990, 1991, 1992, you'll see the

1 02:43:52 convention changing, and you'll see how now
2 02:43:55 things are much more explicit --
3 02:43:58 Q Okay.
4 02:43:58 A -- in those definitions.
5 02:44:00 Q Well, let me ask you this:
6 02:44:02 With regard to the HAM-D depressed
7 02:44:04 mood item --
8 02:44:05 A Yes.
9 02:44:05 Q -- that was a measurement that was added
10 02:44:07 after -- or it was added at some point in
11 02:44:11 time.
12 02:44:12 It's not in -- it's not in the
13 02:44:13 protocol there, right?
14 02:44:14 A No.
15 02:44:14 The measurement was always in the
16 02:44:17 protocol. The measurement was in the study
17 02:44:19 from day one.
18 02:44:19 Q Okay.
19 02:44:20 But to separate out this item was
20 02:44:22 decided -- at what -- that's the question.
21 02:44:26 At what period of time was it
22 02:44:26 decided?
23 02:44:28 A Okay. What I said before, but I can
24 02:44:31 understand we're talking about a lot of

1 02:44:32 different conversations, I don't remember
2 02:44:38 when the decision was made to add that
3 02:44:44 item --
4 02:44:45 Q Well, let me ask you this --
5 02:44:46 A -- as one of the -- let me finish, okay?
6 02:44:49 Q Okay.
7 02:44:50 A I don't remember when that decision was
8 02:44:51 made. And what I said to you was that it
9 02:44:56 could have been made before this was written
10 02:44:59 and not included for some reason, or it
11 02:45:03 could have been made after it was written,
12 02:45:05 after this was written. I just don't know
13 02:45:06 the answer.
14 02:45:07 Q Let me ask you this:
15 02:45:07 Who --
16 02:45:09 MR. DAVIS: And by written -- this
17 02:45:10 was written, you're referring to the
18 02:45:12 protocol?
19 02:45:12 THE WITNESS: Right. I'm referring
20 02:45:13 to Exhibit 14.
21 02:45:16 And what I'm saying, which I hope is
22 02:45:19 helpful in response to your question when
23 02:45:21 you asked me when, is I'm saying I don't
24 02:45:23 remember when.

1 02:45:24 But what I'm saying is, by virtue of
2 02:45:25 saying I don't remember, we could have made
3 02:45:29 that decision before Exhibit 14 was written;
4 02:45:31 and for reasons that I cannot explain, it
5 02:45:34 wasn't put in Exhibit 14, or the decision
6 02:45:37 may have been made after Exhibit 14 was
7 02:45:43 written. I don't know the answer.

8 02:45:44 Q Okay.

9 02:45:45 My next question is, who decided to
10 02:45:48 make that a measurement that was to be
11 02:45:52 analyzed?

12 02:45:55 A Okay. And my answer, I don't remember
13 02:45:58 specifically which individual of the
14 02:46:04 individuals involved in this study made that
15 02:46:07 decision.

16 02:46:11 Given the way the group functioned,
17 02:46:17 it's my belief, okay, so -- that it was
18 02:46:22 suggested by one of the investigators in the
19 02:46:27 study, brought up for discussion and then
20 02:46:31 agreed upon by the other investigators to
21 02:46:43 include it, which was the process that we
22 02:46:46 used and that I managed when things would
23 02:46:49 come up over the course of the study.

24 02:46:51 Q So you -- you can't give me the name of the

1 02:46:53 person; is that correct?

2 02:46:54 A Absolutely not.

3 02:46:55 Q Okay.

4 02:46:55 How about can you tell me exactly

5 02:46:56 when the HAM-D total score of less than or

6 02:46:58 equal to 8 was added as a measurement to be

7 02:47:02 analyzed?

8 02:47:05 A In the spirit of time, the answer would be

9 02:47:06 exactly the same, if that's acceptable, as I

10 02:47:09 gave you for Item 8.

11 02:47:11 Q Okay.

12 02:47:11 A So in other words, I would answer every

13 02:47:14 question you would have exactly the same I

14 02:47:15 did for Item 8, if that's okay.

15 02:47:18 Q With regard to who also?

16 02:47:20 A Yes.

17 02:47:20 Q Okay.

18 02:47:20 You can't give me the name?

19 02:47:21 A No.

20 02:47:21 Q Okay.

21 02:47:22 But you those were added at some

22 02:47:25 point in time, because obviously they're

23 02:47:28 reflected in your paper?

24 02:47:30 A Yes, yes.

1 02:47:30 Q Okay.

2 02:47:31 A And the most critical piece -- the most --

3 02:47:33 the most -- the most definitive thing I can

4 02:47:35 tell you about the point in time is it was

5 02:47:37 before the analyses were done, which is why

6 02:47:40 we called it a priori.

7 02:47:42 Q Okay.

8 02:47:43 Now, have you -- were you ever shown

9 02:47:44 the date when the analyses were actually

10 02:47:46 done?

11 02:47:46 Have you ever seen those documents?

12 02:47:51 A If I saw them, I don't remember.

13 02:47:53 Q Okay.

14 02:47:53 Do you know when the blind was broken

15 02:47:55 for Study 329?

16 02:47:57 A Calendar datewise?

17 02:48:00 Q Yes, approximately.

18 02:48:01 A No.

19 02:48:01 Q Okay.

20 02:48:02 Well, so the jury understands it --

21 02:48:06 understands it, what does a blinded study

22 02:48:08 mean?

23 02:48:10 A Well, the blinded study means that at least

24 02:48:18 one category of -- of participants in the

1 02:48:24 implementation of the study had no knowledge
2 02:48:29 as to some important aspect of the study.
3 02:48:34 Traditionally, you know, referring to
4 02:48:36 this, so I don't -- I don't want to get into
5 02:48:40 semantics with you --
6 02:48:41 Q Right.
7 02:48:41 A -- but traditionally referring to this, we
8 02:48:45 would typically -- a study is either
9 02:48:46 single-blind or double-blind.
10 02:48:48 And typically, the blind refers to
11 02:48:54 which treatment the study subject is
12 02:48:56 receiving.
13 02:48:57 Q Okay.
14 02:48:58 A It could be a whole host of other things,
15 02:49:00 but just to zap it right down to what's
16 02:49:05 relevant here.
17 02:49:05 Q Right.
18 02:49:06 A Now, in a double-blind study, you know, so
19 02:49:09 articles will typically say, you know,
20 02:49:10 double-blind -- I don't know what this title
21 02:49:12 is, but they typically say double-blind --
22 02:49:15 okay.
23 02:49:15 Double-blind placebo-controlled study
24 02:49:19 of -- of two drugs, so that would mean that

1 02:49:24 both the subject and the investigator doing
2 02:49:30 the ratings of how the subject -- of the
3 02:49:33 subject's depressed mood had no knowledge
4 02:49:39 about which of the three treatment
5 02:49:42 conditions the subject was receiving.
6 02:49:45 Q Okay.
7 02:49:45 So let's -- let's take it down to
8 02:49:47 this study, 329.
9 02:49:49 A Right.
10 02:49:49 Q Was that a single- or a double-blind?
11 02:49:51 A This was double-blind.
12 02:49:53 Q Which means neither the patient nor the
13 02:49:54 investigator knew which -- or whether the
14 02:49:59 patient was taking placebo, the comparator
15 02:50:02 drug or Paxil; is that correct?
16 02:50:04 A Yes.
17 02:50:04 Q Okay.
18 02:50:05 A And by extension, so certainly the subject's
19 02:50:08 parents wouldn't know, the -- basically
20 02:50:11 nobody would know.
21 02:50:12 The only person who would know, you
22 02:50:14 know -- who would theoretically have access
23 02:50:18 to that information would have been the
24 02:50:20 statistician who created the randomization

1 02:50:23 procedure, and it would be a -- an
2 02:50:31 individual designated at each of the sites
3 02:50:37 where the study is being conducted that
4 02:50:40 access to that in case there was an adverse
5 02:50:42 event or a problem or something that had to
6 02:50:44 be done.
7 02:50:46 Q Okay.
8 02:50:46 A So that information -- you know, other
9 02:50:49 than -- than the person who created the
10 02:50:51 randomization and someone who has access to
11 02:50:54 rescue, nobody would know.
12 02:50:56 Q Okay.
13 02:50:56 A Although specifically, you know, in a most
14 02:51:00 technical sense, it's the two groups I'm
15 02:51:02 referring to, but it's much broader than
16 02:51:04 that.
17 02:51:04 Q Okay.
18 02:51:05 Now, the comparator drug in your
19 02:51:07 Study 329 was a drug called imipramine; is
20 02:51:11 that correct?
21 02:51:11 A Yes.
22 02:51:12 Q And does it have an adverse event profile
23 02:51:14 that's different from Paxil?
24 02:51:16 A Yes.

1 02:51:16 Q Okay.

2 02:51:17 And what -- what -- what are the

3 02:51:18 primary differences?

4 02:51:26 A In the context of the answer, it's very

5 02:51:28 important to appreciate that the adverse

6 02:51:32 events vary extraordinarily from individual

7 02:51:37 to individual, so that a meaningful

8 02:51:40 proportion of people on imipramine do not

9 02:51:46 suffer adverse events that they find to be

10 02:51:49 troublesome, as is the case with paroxetine,

11 02:51:55 so that you could not receive any -- you

12 02:51:57 cannot have any adverse events on either of

13 02:52:01 the drugs.

14 02:52:03 A Now, then what you do is you list the

15 02:52:06 adverse events which occur, tend to occur --

16 02:52:10 which occur most frequently, you know, based

17 02:52:13 on a database; and so with imipramine, which

18 02:52:19 falls into the category of what we call a

19 02:52:23 tricyclic or norepinephrine reuptake

20 02:52:28 inhibitor, typically people on imipramine

21 02:52:31 have -- excuse me, have a higher probability

22 02:52:38 of dry mouth, for example.

23 02:52:39 Q Is that called an anticholinergic?

24 02:52:43 A Anticholinergic effects.

1 02:52:46 Q Okay.

2 02:52:47 A However, if you look at -- at the adverse

3 02:52:51 event profile for Paxil, paroxetine, SSRI,

4 02:52:58 dry mouth actually occurs greater than

5 02:53:00 placebo in a reasonably and meaningfully

6 02:53:03 higher proportion of people on paroxetine.

7 02:53:07 It just in aggregate is more common

8 02:53:11 on imipramine.

9 02:53:12 Q Okay.

10 02:53:12 And how about with regard to

11 02:53:13 cardiovascular effects?

12 02:53:17 Is imipramine known to cause

13 02:53:19 cardiovascular effects?

14 02:53:27 A It doesn't -- it's not known to cause

15 02:53:30 cardiovascular effects which a patient

16 02:53:38 taking the drug would typically be aware of.

17 02:53:41 So I'm trying to, you know, make a

18 02:53:43 distinction between a symptom and a sign,

19 02:53:45 the symptom being something that any -- you

20 02:53:47 know, you would recognize if you had a cold

21 02:53:49 or a flu, sniffles or whatever, or --

22 02:53:55 But if your electrolytes were

23 02:53:57 imbalanced because of a flu, you wouldn't

24 02:53:59 know that. That would be the sign.

1 02:54:02 So there -- there have been
2 02:54:05 reports -- and, indeed, very carefully
3 02:54:09 monitored during the course of this study --
4 02:54:12 there had been reports about problems with
5 02:54:15 hypertension in taking imipramine in --
6 02:54:21 particularly in adolescents.
7 02:54:23 So, you know, we monitored what we
8 02:54:26 called -- that's what's called a vital sign.
9 02:54:29 We monitored vital signs like blood
10 02:54:32 pressure, heart rate, so on and so forth,
11 02:54:34 very carefully in the study.
12 02:54:38 That's an example.
13 02:54:39 Q Okay.
14 02:54:39 So by monitoring the vital signs
15 02:54:41 during a study, you can actually see which
16 02:54:44 kid was taking imipramine, correct?
17 02:54:46 A No. The person -- well, I could -- you
18 02:54:48 could see; but the person doing that
19 02:54:49 monitoring was not someone that had any had
20 02:54:57 any role in rating the outcome measures.
21 02:55:01 Q Who -- who was responsible for doing the
22 02:55:03 vital signs?
23 02:55:04 A It was like a medical monitor.
24 02:55:09 Q And that was only -- they did not do any of

1 02:55:10 the medical measures -- I mean any of the
2 02:55:14 measures rating?
3 02:55:16 A No, they did -- they did not measure the --
4 02:55:16 they do any of the measure -- they did not
5 02:55:18 do any of the outcome measures.
6 02:55:20 Q Okay.
7 02:55:20 A And just, again, to avoid semantics,
8 02:55:23 we're -- let's stipulate that when we talk
9 02:55:26 about outcome measures, we're talking about
10 02:55:28 outcome measures of interest with regard to
11 02:55:30 the efficacy of the treatments.
12 02:55:32 Q Right.
13 02:55:33 A Because I did say to you before, outcome
14 02:55:35 measures could be, you know, a million
15 02:55:39 things.
16 02:55:40 Outcome measures could be costs,
17 02:55:41 anything.
18 02:55:42 Q Okay.
19 02:55:43 Well, actually, there were quite a
20 02:55:45 number of secondary variables that were
21 02:55:49 listed for this study, correct, over 20?
22 02:55:52 Do you recall that?
23 02:55:53 MR. DAVIS: Object to the form.
24 02:55:57 A You'd have to show me where they are, but it

1 02:56:00 wouldn't surprise me.

2 02:56:02 Q Let's take a look at the next document.

3 02:56:04 A We will really have to cool this room.

4 02:56:07 MR. DAVIS: It's warm, isn't it?

5 02:56:08 THE WITNESS: It's really stoking up,

6 02:56:10 yes.

7 02:56:10 MR. MURGATROYD: Yes, open up that

8 02:56:11 door. It may help.

9 02:56:13 (Exhibit No. 15 marked for

10 02:56:13 identification.)

11 02:56:13 BY MR. MURGATROYD:

12 02:56:13 Q I'm going to show you what I've marked as

13 02:56:15 Exhibit 15.

14 02:56:16 A I've got a 20-year-old boat that would hold

15 02:56:18 at least six of us, if you're game.

16 02:56:21 (Laughter.)

17 02:56:22 Q I'm going to show you this document. I'm --

18 02:56:24 we're going to be talking about page 5, but

19 02:56:27 you're absolutely free to take your time --

20 02:56:30 MR. MURGATROYD: We can go off the

21 02:56:31 record.

22 02:56:31 A Where are you? Which exhibit?

23 02:56:31 THE VIDEOGRAPHER: The time is 2:56.

24 02:56:33 We're off the record.

1 02:56:34 (Recess.)

2 03:10:43 THE VIDEOGRAPHER: We're back on the

3 03:10:51 record. The time ten minutes after 3:00.

4 03:10:57 (Discussion off the record.)

5 03:11:08 MR. MURGATROYD: Are you ready?

6 03:11:10 THE VIDEOGRAPHER: We're on the

7 03:11:12 record.

8 03:11:15 A So when you stopped, I was on --

9 03:11:17 Q Yes, we were looking at --

10 03:11:19 A -- page 2 of Exhibit 15.

11 03:11:20 Q Yes.

12 03:11:21 And you'll see that that --

13 03:11:25 A Not page 2. Page 5.

14 03:11:26 Q Okay.

15 03:11:28 That document, if you look on the

16 03:11:29 first page, is entitled Statistical

17 03:11:31 Appendix.

18 03:11:32 Do you see that on the first page?

19 03:11:38 A Yes.

20 03:11:38 Q Okay.

21 03:11:39 And it's dated in June 1998; is that

22 03:11:42 correct?

23 03:11:43 A Yes.

24 03:11:43 Q Okay.

1 03:11:43 And I ask you to turn to --

2 03:11:45 A Page 5?

3 03:11:46 Q Yes.

4 03:11:48 A Yes.

5 03:11:49 Q Actually, before I go any further, did you

6 03:11:52 participate in preparing this document, to

7 03:11:54 your knowledge?

8 03:11:58 A What I -- again, this is soft memory.

9 03:12:05 The soft memory is that all of us --

10 03:12:12 when I say "all of us," it's -- it's not

11 03:12:15 every author on the paper, but there are

12 03:12:17 about eight or ten of the authors who are

13 03:12:19 more senior people, that we participated in

14 03:12:24 the development of the statistical analysis

15 03:12:26 plan by conference calls which included

16 03:12:30 statisticians from the company and talked

17 03:12:36 about, you know, what -- what the hypotheses

18 03:12:41 were, what the variables of interest were,

19 03:12:44 you know, in order to -- in order to test

20 03:12:49 those, you know, which specific items.

21 03:12:52 So, in fact, as a group -- and I

22 03:12:54 can't -- I can't tell you exactly which role

23 03:12:59 I played.

24 03:13:01 As a group, we -- we played a

1 03:13:04 dominant role because, in other words, we
2 03:13:06 were the people that had to identify which
3 03:13:09 of the items on the whole -- in the whole
4 03:13:12 panoply of assessments that we had given to
5 03:13:15 the subjects, which of the items actually,
6 03:13:17 you know, were the variables that needed to
7 03:13:20 be pulled out to do the data -- to do the
8 03:13:25 analysis, and that's call the data
9 03:13:27 harvesting procedure.

10 03:13:28 So it's not like every single
11 03:13:30 variable in all these forms was coded. We
12 03:13:34 harvested them. And then we'd say, okay, in
13 03:13:37 order to test to see whether or not, you
14 03:13:38 know, pick one of these measures, you know,
15 03:13:42 recreational, some activity was different,
16 03:13:46 you know, which are things you would
17 03:13:46 measure, how would you measure it; and then
18 03:13:47 also, you know, we would talk about things
19 03:13:49 like --

20 03:13:50 The short answer's yes. I'll save
21 03:13:53 you some time.

22 03:13:54 Q Okay. That's fine.

23 03:13:57 And did you have -- you as being the
24 03:13:59 principal investigator, did you have veto

1 03:14:01 power over any of the measures that you --
2 03:14:03 or did you ever exercise any veto power?
3 03:14:06 A No. The biggest -- the power I would
4 03:14:07 exercise is to make sure people stayed on
5 03:14:09 task, you know; because unlike attorneys,
6 03:14:13 occasionally people like us, we sort of
7 03:14:15 waffle and daydream and start bullshitting
8 03:14:18 rather than kind of getting to it.
9 And then I would also exert myself to
10 03:14:24 make sure -- actually, now it comes back.
11 In a situation like this, you know,
12 03:14:29 for an -- for an efficiency of effort, you
13 03:14:32 know, we designated certain people who had
14 03:14:37 particular, you know, interest and expertise
15 03:14:38 in doing these things to say, well, okay,
16 03:14:41 Mike, Greg, Johnny, Sally, okay, you four
17 03:14:43 agree that you're going to do the first
18 03:14:45 draft, pulling all the stuff together.
19 03:14:48 Yeah, okay.
20 How long can is it -- how long --
21 03:14:49 when can you do it by? We want to get this
22 03:14:52 thing done. You know, we don't want to
23 03:14:53 start here in 2006 and still be writing this
24 03:14:57 paper.

1 03:14:58 That's the kind of stuff I would do.

2 03:15:01 Q Okay.

3 03:15:01 A If the group seemed to be deadlocked in

4 03:15:03 thinking something through, I would try to

5 03:15:04 figure out creative ways to kind of get

6 03:15:07 around Robin's barn and to forge a

7 03:15:11 consensus.

8 03:15:12 I can't ever remember an instance in

9 03:15:13 which I, you know, sort of went against the

10 03:15:15 tide of the group and said, Oh, you all

11 03:15:18 think that. I'm the boss; we're going to do

12 03:15:20 this.

13 03:15:21 Q Okay.

14 03:15:22 So I take it you didn't veto any

15 03:15:23 secondary measures that were -- that were

16 03:15:26 put forth by any of your coinvestigators?

17 03:15:28 A I don't, no. That's just not my style.

18 03:15:30 Q Okay.

19 03:15:31 So now turning to that exhibit --

20 03:15:34 A I do get irritable occasionally.

21 03:15:37 Q Okay.

22 03:15:39 There's a section I believe you

23 03:15:42 turned to that had the secondary outcomes

24 03:15:44 listed?

1 03:15:45 A Is that 5, page 5?
2 03:15:50 Q Yes.
3 03:15:50 Do you see that?
4 03:15:51 A Yes.
5 03:15:51 Q And can you count how many secondary
6 03:15:55 outcomes are listed there, please?
7 03:16:07 A Well, one -- you're going to want this back,
8 03:16:16 I assume, right?
9 03:16:16 Q Yes.
10 03:16:17 A One, two, three, four, five, six, seven,
11 03:16:32 eight, nine, ten, eleven, twelve, thirteen,
12 03:16:43 fourteen, fifteen, sixteen, seventeen,
13 03:16:50 eighteen, nineteen, twenty.
14 03:16:56 Q Twenty?
15 03:16:57 A You knew that.
16 03:16:58 Q I did know that. I just wanted to make sure
17 03:17:01 I was correct.
18 03:17:02 There are 20, correct?
19 03:17:04 A If I can help with that, I can help. Yes,
20 03:17:05 it was 20.
21 03:17:06 Q Okay.
22 03:17:06 And of those 20, which ones did
23 03:17:14 paroxetine separate statistically from
24 03:17:16 placebo?

1 03:17:17 MR. DAVIS: Object to the form of the
2 03:17:18 question.
3 03:17:24 A The ones that separated statistically from
4 03:17:28 placebo are the ones that are described in
5 03:17:31 the paper that we've gone over as having
6 03:17:35 separated.
7 03:17:35 What I will say, again, to the extent
8 03:17:38 that the context of this is important, there
9 03:17:44 were not hypotheses that -- where we
10 03:17:51 expected there to be a separation from
11 03:17:53 placebo.
12 03:17:56 Just as when we -- when we did an
13 03:17:59 analysis of the demographic variables of the
14 03:18:02 subjects in the various cells, we didn't
15 03:18:07 hypothesize.
16 03:18:09 Because you do an analysis, it
17 03:18:10 doesn't mean that you're hypothesizing that
18 03:18:12 there will be a difference and therefore the
19 03:18:14 lack of a difference is meaningful.
20 03:18:19 So I really would --
21 03:18:22 Q No, I -- the question was, of those 20 --
22 03:18:25 A I -- we'd have to cross-reference the paper.
23 03:18:29 Q Okay.
24 03:18:29 A And I'm assuming -- I'm assuming it would be

1 03:18:33 the four -- I'm assuming it's four.

2 03:18:36 Q Well, are the --

3 03:18:37 A I think --

4 03:18:38 Q I think we agreed that in your paper, only

5 03:18:40 four variables separated -- Paxil separated

6 03:18:43 statistically from placebo, correct?

7 03:18:45 MR. DAVIS: Object to the form.

8 03:18:46 A Yes, so --

9 03:18:46 Q Now, are those four listed as secondary

10 03:18:49 variables in Exhibit 15 in your hand?

11 03:19:00 A Well, HAM-D depressed mood item is.

12 03:19:03 Q Okay, so that's one.

13 03:19:10 A It's hard for me to follow this going

14 03:19:12 across.

15 03:19:12 Q Well, is the change in K-SADS depression

16 03:19:15 item listed among those secondary variables?

17 03:19:18 A I don't think so.

18 03:19:18 Q Okay.

19 03:19:20 A And --

20 03:19:21 Q How about CGI of 1 or 2, is that listed in

21 03:19:23 Exhibit 15 as a secondary variable?

22 03:19:25 A I don't see it. I don't see it.

23 03:19:26 Q Okay.

24 03:19:27 A Then there's one other --

1 03:19:28 Q How about the HAM-D score of less than or
2 03:19:32 equal to 8?
3 03:19:33 A I don't think so.
4 03:19:39 Q So of the 20 secondary outcomes that are
5 03:19:43 listed on that -- in that document, would
6 03:19:44 you agree that only one and only one did
7 03:19:49 Paxil separate statistically from placebo?
8 03:19:52 MR. DAVIS: Object to the form.
9 03:19:53 A Yes. But as I stated, there was not an
10 03:19:56 expectation.
11 03:19:59 Q Okay. All right.
12 03:20:00 A That was what --
13 03:20:01 Q All right.
14 03:20:06 The -- do you recall the conference
15 03:20:22 that was held in November of 1997 in which
16 03:20:33 the results were discussed among the various
17 03:20:36 researchers of Study 329?
18 03:20:41 A Could you give me more details on it?
19 03:20:43 Q Well, let me show you -- let me show you a
20 03:20:44 document. I don't want you to sit there and
21 03:20:48 guess.
22 03:21:28 (Pause.)
23 03:21:29 Q Actually, I think it's in the second pile
24 03:21:30 here. I've got a few documents here...

1 03:21:35 A I assume you had to check your luggage.
2 03:21:38 Q Yes. I did not lug this through an airport.
3 03:21:59 (Pause.)
4 03:21:59 Q Here we go.
5 03:22:05 THE WITNESS: Did you type that
6 03:22:05 statement or did you just assume it was off
7 03:22:05 the record?
8 03:22:06 MR. MURGATROYD: Okay. So I think
9 03:22:06 we're up to Exhibit --
10 03:22:13 MS. MENZIES: 16.
11 03:22:15 MR. MURGATROYD: Is it 16? Yes, 16.
12 03:22:17 (Exhibit No. 16 marked for
13 03:22:17 identification.)
14 03:22:17 (Exhibit No. 17 marked for
15 03:22:17 identification.)
16 03:22:17 BY MR. MURGATROYD:
17 03:22:18 Q I'm going to show you a collection of
18 03:22:22 documents -- well, actually, I should
19 03:22:25 probably -- I'm going to separate out the
20 03:22:26 last --
21 03:22:27 I'm going to show you Exhibits 16 and
22 03:22:30 17. I'm going to show you them together,
23 03:22:32 because I think they'll make more sense to
24 03:22:34 you in a sequence like this.

1 03:22:37 MR. MURGATROYD: For the record, 16
2 03:22:40 is a document that's signed, written by Jim
3 03:22:42 McCafferty, dated 3 November 1997; and 17
4 03:22:48 talks about a synopsis of the top-line
5 03:22:56 results of Study 329.
6 03:22:58 And then 17 is a table which lists
7 03:23:02 the top-line results of Study 329.
8 03:23:08 Q And let me just have you take a look at both
9 03:23:09 of these.
10 03:23:18 (Witness read document.)
11 03:24:34 A Okay.
12 03:24:34 Q All right.
13 03:24:35 MR. MURGATROYD: Have we got
14 03:24:36 everybody?
15 03:24:37 Todd, can we forge on or do you want
16 03:24:39 to wait for Tamar?
17 03:24:41 MR. DAVIS: Yes, I'm listening.
18 03:24:42 MR. MURGATROYD: Okay.
19 03:24:42 BY MR. MURGATROYD:
20 03:24:42 Q Now, do you recall receiving the document
21 03:24:44 which we've marked as Exhibit 16, the letter
22 03:24:46 dated 3 November 1997?
23 03:24:48 A No.
24 03:24:52 Q Do you recall attending a meeting in

1 03:25:00 Philadelphia to discuss the results of 329?

2 03:25:09 A Yes.

3 03:25:09 Q Okay.

4 03:25:09 And who attended that meeting, if you

5 03:25:12 recall?

6 03:25:16 A As many of the investigators as who were

7 03:25:18 able to attend and Jim McCafferty and

8 03:25:32 others. I just don't remember.

9 03:25:34 So --

10 03:25:34 Q Okay.

11 03:25:37 Do you remember --

12 03:25:38 A The guest list -- the guest list were the

13 03:25:40 investigators on the study, McCafferty, and

14 03:25:43 I don't know who else attended from GSK.

15 03:25:49 And I don't know which of the

16 03:25:51 investigators attended, but I seem to recall

17 03:25:55 there was a pretty good turnout of the

18 03:25:58 senior investigators.

19 03:25:59 Q Okay.

20 03:25:59 Was Neal Ryan there; do you recall?

21 03:26:06 A I just don't remember.

22 03:26:07 Q Well, do you recall that the results were

23 03:26:08 presented to you at that meeting?

24 03:26:10 A Yes.

1 03:26:10 Q Okay.

2 03:26:10 And were they the same results that

3 03:26:11 are presented in the table which is attached

4 03:26:13 or which I presented to you as -- as

5 03:26:15 Exhibit 17?

6 03:26:17 MR. DAVIS: Object to the form.

7 03:26:18 Incomplete.

8 03:26:19 A I don't remember.

9 03:26:23 Q Okay.

10 03:26:23 Well, turning to the results that are

11 03:26:31 listed in Exhibit 16; do you see those?

12 03:26:44 A Yes.

13 03:26:46 Q Okay.

14 03:26:47 Does it discuss the results of the

15 03:26:50 two primary efficacy variables that we

16 03:26:53 discussed earlier?

17 03:27:10 A What page on 14?

18 03:27:22 (Witness read document.)

19 03:27:42 A So it mentions the total HAM-D score.

20 03:27:46 Q Okay.

21 03:27:47 A Says there was a trend.

22 03:27:48 Q Okay.

23 03:27:48 Did --

24 03:27:49 A And the second one is the proportion of

1 03:27:51 responders.

2 03:28:15 (Witness read document.)

3 03:28:25 A It mentions both.

4 03:28:26 Q Okay.

5 03:28:26 And does it say whether or not

6 03:28:28 placebo -- Paxil separated statistically

7 03:28:30 from placebo with regard to those primary

8 03:28:32 measures?

9 03:28:42 A With regard to the change in total HAM-D

10 03:28:45 score, it says -- it gives the P value, and

11 03:28:47 it says -- and it says that it showed a

12 03:28:52 strong trend benefit, but it wasn't less

13 03:28:54 than .05.

14 03:28:57 Q Okay.

15 03:28:57 Which would make it statistically

16 03:28:58 significant, correct?

17 03:28:59 A Most commonly accepted definition, yes.

18 03:29:01 Q Okay.

19 03:29:02 A And it does not give the P value for the

20 03:29:06 proportion of responders.

21 03:29:08 Q Okay.

22 03:29:09 Does it give you the CGI score of

23 03:29:15 1 or 2?

24 03:29:22 A No.

1 03:29:23 Q Does it give you the change in the K-SADS
2 03:29:27 depression item?
3 03:29:41 (Witness read document.)
4 03:29:44 A It's not explicit. It mentions the K-SADS.
5 03:29:48 Q But that's the mean score, correct?
6 03:29:52 MR. DAVIS: Object.
7 03:29:52 A Doesn't say.
8 03:29:53 Q Okay.
9 03:29:53 Well, is there -- is it
10 03:29:55 statistically significant separ -- is there
11 03:29:56 a statistical --
12 03:29:57 A We're talking about 16 now, right?
13 03:29:59 Q Yes.
14 03:29:59 Is there a statistical significance
15 03:30:02 between Paxil and placebo with regard to the
16 03:30:04 K-SADS as listed in 16?
17 03:30:07 A No.
18 03:30:08 Q Okay.
19 03:30:09 Now, turning to 17, which is the
20 03:30:14 chart that lists the top-line results, do
21 03:30:16 you see that?
22 03:30:17 A Yes.
23 03:30:18 Q Do you whose handwriting that is on this
24 03:30:19 document?

1 03:30:22 A No.

2 03:30:22 Q Okay.

3 03:30:23 Now, going down this top-line

4 03:30:26 results, is there any mention of the CGI

5 03:30:35 score of 1 or 2 as a secondary endpoint?

6 03:30:47 (Witness read document.)

7 03:31:14 A The second row from the bottom has the --

8 03:31:19 has a global, which I'm assuming is the CGI.

9 03:31:23 Q Okay.

10 03:31:23 But that's not CGI score of 1 or 2,

11 03:31:26 correct?

12 03:31:27 A Doesn't say.

13 03:31:28 Q Well, is there a statistically significant

14 03:31:30 separation of Paxil from placebo with regard

15 03:31:34 to global?

16 03:31:37 A Amongst the completers, yes.

17 03:31:39 Q Okay.

18 03:31:39 How about at endpoint?

19 03:31:42 A No.

20 03:31:43 Q Okay.

21 03:31:44 Is there any reference in the

22 03:31:45 top-line results in Exhibit 17 that

23 03:31:49 reference the K-SADS depression item?

24 03:32:09 A I -- I think, but -- again, this is not

1 03:32:14 explicit, but I think the third row from the
2 03:32:17 bottom.
3 03:32:18 Q K-SADS endpoint in completers?
4 03:32:20 A Yes. The reason I say that -- but, again,
5 03:32:23 it's not, you know, totally clear, is
6 03:32:25 because the base -- on the second row from
7 03:32:30 the top, the second item which says baseline
8 03:32:34 K-SADS gives -- those numbers are mean
9 03:32:39 scores.
10 03:32:41 Q Okay.
11 03:32:42 A And so I'm -- I -- I think -- this, to me,
12 03:32:47 the third line from the bottom, given the --
13 03:32:50 given the construction of it, which it says,
14 03:32:53 you know, minus 11, minus 9, minus 6 --
15 03:32:57 Q Right.
16 03:32:57 A -- that I think it's -- well, could be the
17 03:33:02 item we're referring to, but it's not clear
18 03:33:05 from this.
19 03:33:06 Q Okay.
20 03:33:06 Well, did Paxil separate
21 03:33:08 significantly from placebo with regard to
22 03:33:11 that item that's listed here?
23 03:33:14 MR. DAVIS: Object to the form.
24 03:33:15 Which item?

1 03:33:17 MR. MURGATROYD: The -- the one he
2 03:33:18 was just talking about, third of the bottom,
3 03:33:20 change in K-SADS.
4 03:33:22 A Well, on the endpoint measure, it's -- P is
5 03:33:25 .065, which would be a strong trend.
6 03:33:28 Q But did not separate statistically, correct?
7 03:33:33 A Correct.
8 03:33:34 Q Okay.
9 03:33:42 Now, you'll see that attached to
10 03:33:43 Exhibit 16 is a consensus statement. It's
11 03:33:51 the second page.
12 03:33:53 A Mm-hmm.
13 03:33:54 Q Did -- did the group of you all at that
14 03:33:58 meeting prepare the consensus statement, or
15 03:34:00 is that something that was done before you
16 03:34:01 met?
17 03:34:05 A I don't remember.
18 03:34:07 Q Okay.
19 03:34:08 Did you vote while you were there to
20 03:34:11 approve the consensus statement?
21 03:34:13 A I don't remember.
22 03:34:14 Q Okay.
23 03:34:15 Do you recall if you personally
24 03:34:17 agreed with the consensus statement?

1 03:34:20 A You mean at the time?

2 03:34:21 Q Yes.

3 03:34:48 A No, it's -- this is -- the answer is I don't

4 03:34:56 remember. It's over nine years ago, or

5 03:35:00 almost -- yes, almost nine years ago, so I

6 03:35:02 just -- I just can't remember.

7 03:35:05 Q Okay.

8 03:35:05 A I mean, as a matter of style, it's -- I

9 03:35:13 would find it hard to believe that if

10 03:35:23 whomever was involved in writing this

11 03:35:27 would -- would purport that this was a

12 03:35:32 consensus we agreed to if it wasn't, but I

13 03:35:36 can't --

14 03:35:37 You know, that would just run so

15 03:35:39 counter to, you know, the nature of the

16 03:35:45 working relationship.

17 03:35:46 It was just very much of a group of

18 03:35:49 investigators here, company here, liaison;

19 03:35:53 and it was a pretty harmonious --

20 03:35:57 At least in, you know, in the

21 03:35:59 interactions I could observe, it was a -- it

22 03:36:02 was a harmonious and a very, you know,

23 03:36:06 positive working relationship

24 03:36:09 So it's hard for me to imagine they

1 03:36:12 would put something out there which wasn't
2 03:36:13 what we thought. But do I have any memory
3 03:36:16 of it? No.
4 03:36:17 Q Okay.
5 03:36:17 Well, has anybody -- returning to the
6 03:36:20 first page of Exhibit 16, has -- are you
7 03:36:24 aware that some of the statistical analyses
8 03:36:28 are incorrect on this page?
9 03:36:29 Have you ever been told that?
10 03:36:32 MR. DAVIS: Object to the form.
11 03:36:43 A I think the answer -- the best answer is --
12 03:36:47 the answer is I have no memory of it.
13 03:36:49 Q Okay.
14 03:36:50 A I certainly -- and just as a qualifier so I
15 03:36:55 just don't sound like someone who is saying
16 03:36:58 "I don't remember," certainly whenever we
17 03:37:01 do -- not whenever -- yes.
18 03:37:03 It's always a process. So when
19 03:37:04 you -- when you see a draft of analyses at a
20 03:37:06 meeting -- I do know that --
21 03:37:09 I do remember there was a lot of
22 03:37:10 discussion about the analyses at the
23 03:37:12 meeting. There was a lot of discussion
24 03:37:13 about whether there were other analyses that

1 03:37:16 should be done.

2 03:37:18 I seem to recall that the analyses

3 03:37:21 weren't -- what's the word -- scrubbed, if

4 03:37:26 you will; that when I said top line, that

5 03:37:29 these analyses were not -- had not been gone

6 03:37:32 over in sufficient scrutiny with all the

7 03:37:36 standard operating procedures that anyone

8 03:37:40 would have said, okay, these are ready to

9 03:37:42 put in a manuscript.

10 03:37:43 I do know that it was a -- that we --

11 03:37:46 I do --

12 03:37:46 I mean, again, this is a vague

13 03:37:49 memory, that we wanted to get a meeting done

14 03:37:50 as soon as the, you know, results were

15 03:37:54 broken as possible so we could take a look

16 03:37:56 at what we had.

17 03:37:58 But typically when we do this, in all

18 03:38:01 studies, be it NIH studies or industry or

19 03:38:04 whatever, that's your first peak.

20 03:38:07 That's far from what we call

21 03:38:09 scrubbing the data, you know, making sure

22 03:38:12 everything has been checked, double-checked,

23 03:38:14 and then also is an opportunity to suggest

24 03:38:16 other analyses which might be done.

1 03:38:18 Q Okay.

2 03:38:18 And do you recall other analyses

3 03:38:19 being specifically discussed at that

4 03:38:21 meeting?

5 03:38:22 A I recall that we -- there was a lot of

6 03:38:25 discussion about other analyses, but I can't

7 03:38:31 tell you specifically which ones were

8 03:38:33 discussed.

9 03:38:33 Q Okay.

10 03:38:34 A You know, it was basically, okay, do we got

11 03:38:37 these right, you know?

12 03:38:39 Are these all -- are these the

13 03:38:41 analyses you want to see? Are these all the

14 03:38:45 analyses you want to see? Do these make

15 03:38:47 sense?

16 03:38:47 You know, there was discussion of the

17 03:38:49 analyses, and I just can't remember in

18 03:38:50 all -- in all, you know, efforts.

19 03:38:54 It's just so long ago that --

20 03:38:57 Q Well, do you -- do you recall the analyses

21 03:38:58 of the CGI score of 1 or 2 being

22 03:39:02 specifically discussed, that was an analysis

23 03:39:04 that needed to be done?

24 03:39:06 A Yes.

1 03:39:07 Q Okay.

2 03:39:07 A That I -- I certainly recall that.

3 03:39:09 Q Okay.

4 03:39:09 And you recall that that analysis was

5 03:39:11 done about six months later?

6 03:39:13 MR. DAVIS: Object to the form.

7 03:39:15 Mischaracterizes the record.

8 03:39:18 A No.

9 03:39:19 Q You can -- no.

10 03:39:20 Do you recall the K-SADS-L depression

11 03:39:25 item being specifically discussed at that

12 03:39:28 meeting?

13 03:39:36 A I assume it's okay if I don't just say yes

14 03:39:38 or no but give a little explanation?

15 03:39:40 Q That's fine.

16 03:39:41 A Is that --

17 03:39:42 Q Yes.

18 03:39:43 A So it's not -- I can't remember, you know,

19 03:39:50 sentences which we had a discussion and what

20 03:39:54 we said about it; but given that that was

21 03:39:56 one of the critical variables, I -- I want

22 03:40:01 to say I know we discussed it, but I can't

23 03:40:04 remember the conversation.

24 03:40:06 Q Okay. That's fine. I understand.

1 03:40:09 I mean, that was a number of years
2 03:40:10 ago. I'm not going to -- that's fine. I
3 03:40:12 guess the --
4 03:40:19 I take it that meeting wasn't
5 03:40:21 recorded, to your knowledge?
6 03:40:22 A I have no idea if it was.
7 03:40:24 Q Okay.
8 03:40:24 A But, you know, certainly the spirit of the
9 03:40:28 meeting and, you know, the context was,
10 03:40:30 okay, we've been working on this -- and I
11 03:40:34 should say study which was a bear to do.
12 03:40:37 You know, it's hard to do these
13 03:40:39 studies. Any study of children and
14 03:40:40 adolescents or any study is hard to do.
15 03:40:45 It's hard to get the subjects in in a timely
16 03:40:47 fashion. It's just always difficult.
17 03:40:49 Everybody was very, very happy that
18 03:40:50 we completed the study. We were all happy.
19 03:40:53 And we were all very, very keen and
20 03:40:55 interested in knowing what our results were,
21 03:40:58 as fast as we could see them; and then we
22 03:41:01 were keen --
23 03:41:02 I do -- what I can remember of the
24 03:41:04 meeting was there was a lot of active energy

1 03:41:07 and discussion about, gee, what do we have
2 03:41:11 here? What does it look like? Do we have a
3 03:41:13 finding? You know, do we have a separation
4 03:41:15 from placebo? Did the study work, and what
5 03:41:18 manuscripts should be written?
6 03:41:21 That somehow -- and I -- I have some
7 03:41:27 memory that when we went so far as to -- as
8 03:41:30 to agree who should be the lead author on at
9 03:41:36 least three manuscripts, I can't remember
10 03:41:41 who, I'm guessing it was Ryan and Strober,
11 03:41:43 because basically, Ryan and Strober were
12 03:41:46 seen along with me as sort of the drivers of
13 03:41:49 the study.
14 03:41:50 Q Okay.
15 03:41:51 A And that's kind of the memory. I know there
16 03:41:54 was lots of discussion.
17 03:41:57 Q Okay.
18 03:41:57 A And the goal was to leave there so that --
19 03:42:00 one of the goals was to leave the meeting
20 03:42:02 with a charge, if you will -- not a charge,
21 03:42:04 you know, with a plan.
22 03:42:08 Not a plan -- not a -- you know, not
23 03:42:11 an operating plan that was a line item, you
24 03:42:14 know, do these items and this, but a plan of

1 03:42:16 what was going to happen after we left the
2 03:42:18 meeting to push the analyses forward so we
3 03:42:20 could move this to the point where then we
4 03:42:24 could -- where we could then start to write
5 03:42:26 the manuscripts of interest.
6 03:42:27 Q Okay.
7 03:42:27 A So, I mean, you know, that was the thrust of
8 03:42:30 the energies.
9 03:42:31 Q Okay.
10 03:42:31 I think I actually have a document
11 03:42:33 that -- that talks about the -- it was --
12 03:42:37 So part of the meeting had to do with
13 03:42:39 the publication plan?
14 03:42:40 A Yes, yes.
15 03:42:41 Q Okay.
16 03:42:41 Where different people could possibly
17 03:42:43 be authors of different publications arising
18 03:42:48 from the results of the trial?
19 03:42:51 A Yes.
20 03:42:51 Q Okay.
21 03:42:51 I'm going to see --
22 03:42:51 A Keller's rule of managing studies is that no
23 03:42:54 one is allowed to claim dibs on who will be
24 03:42:57 further author on which paper until the

1 03:42:58 study is completely over; that we can't
2 03:43:00 discuss it, argue about it or fight about
3 03:43:01 it.
4 03:43:02 And if you feel the need to and think
5 03:43:03 it's not fair, you can't participate in a
6 03:43:05 Keller study, because we never know until
7 03:43:08 the end who is, A, going to be still
8 03:43:10 standing, you know, who actually stayed in
9 03:43:13 the study and who did the work and deserved
10 03:43:15 it. So that discussion came up.
11 03:43:16 (Exhibit No. 18 marked for identification.)
12 03:43:18 Q Okay. No, that's all right.
13 03:43:19 And let me show you what I marked as
14 03:43:22 Exhibit 18, because I think it -- it has the
15 03:43:26 same date as the meeting, November 4, 1997,
16 03:43:29 so I assume -- and it may help refresh your
17 03:43:31 recollection on -- there's -- I'm going
18 03:43:34 to --
19 03:43:34 This is actually a two-page document
20 03:43:36 I'm going to show you. And the first page
21 03:43:39 is publication strategy, and it's dated
22 03:43:41 November 4, 1997.
23 03:43:43 That's the date you recall this
24 03:43:44 meeting taking place, correct? And then the

1 03:43:46 second one is the scientific
2 03:43:47 presentations --
3 03:43:47 A No, I don't recall the meeting taking place
4 03:43:49 on that date. I assume because it's dated
5 03:43:51 that, that's when it took place.
6 03:43:52 Q Right, yes. The date of document, correct?
7 03:43:55 A Yes.
8 03:43:55 Q Well, this -- these documents are also dated
9 03:43:57 November 4, 1997.
10 03:43:59 And the second page is a scientific
11 03:44:01 presentation/meeting strategy.
12 03:44:02 Do you see that? So let me --
13 03:44:04 A No, I didn't see it.
14 03:44:05 Q Let me show you that and see if that -- see
15 03:44:07 if that refreshes any recollections.
16 03:44:09 (Witness read document.)
17 03:44:14 (Exhibit No. marked for
18 03:44:14 identification.)
19 03:44:27 A You know, the recollection -- you said
20 03:44:29 you'll show me this to see if it refreshes
21 03:44:32 any recollections, and the answer, like my
22 03:44:36 others, is no and yes.
23 03:44:39 The -- the "no" being I can't
24 03:44:42 specifically remember doing it, but the

1 03:44:43 "yes" is that, again, to the extent that I
2 03:44:48 had a hand in -- in driving the process of
3 03:44:52 the meeting in addition to worrying about,
4 03:44:55 you know, manuscripts and thinking about it,
5 03:45:00 the idea was, okay, how can we get these
6 03:45:03 results out?

7 03:45:04 And what I can -- what I --

8 03:45:05 See, I can't remember specifically
9 03:45:07 for this, but I've done -- I've chaired
10 03:45:11 many, many collaborative studies; and what
11 03:45:14 we always do is we say, okay, what are --
12 03:45:17 what are the meetings coming up in the next
13 03:45:19 two years that would be relevant to present
14 03:45:21 these data at?

15 03:45:21 And so, you know, we know what the
16 03:45:23 meetings are, by and large. And sometimes
17 03:45:25 we even assign an individual, you know, to
18 03:45:27 actually look up when are the deadline dates
19 03:45:29 and so on and so forth.

20 03:45:30 And, actually, that was probably
21 03:45:32 done -- there's a pretty good chance -- and,
22 03:45:35 again, I'm surmising.

23 03:45:37 Q Mm-hmm.

24 03:45:37 A There's a pretty good chance that I said to

1 03:45:39 someone, Okay, in anticipation of this
2 03:45:42 meeting, would you look up the dead -- the
3 03:45:43 submission deadline dates for these
4 03:45:46 following meetings. Or it was on a
5 03:45:48 conference call and everybody contributed.
6 03:45:50 Because for the child meetings in
7 03:45:52 particular -- although as you'll notice,
8 03:45:54 most of these meetings aren't child meetings
9 03:45:57 perfect se, they're adult meetings.
10 03:45:59 Q Okay.
11 03:46:00 A You know, contribute.
12 03:46:01 So we have those dates. And then the
13 03:46:04 idea is, okay, someone is going to present
14 03:46:06 the poster, an oral thing or whatever, and
15 03:46:09 let's just divvy it up.
16 03:46:10 Q Okay.
17 03:46:11 A And --
18 03:46:11 Q Okay.
19 03:46:12 So the -- well, in terms of the first
20 03:46:13 document in that exhibit, can you identify
21 03:46:15 for the record what that is, please?
22 03:46:18 A This was a -- this is a list of a proposed
23 03:46:30 plan for which publications we thought could
24 03:46:32 be written with the data from this study and

1 03:46:36 who the authors would be.

2 03:46:39 And on the second page, it's a list

3 03:46:45 of the meetings that were coming up over the

4 03:46:48 course of the next year or so and which

5 03:46:55 individuals in our group, single or

6 03:46:57 collaboratively, would be responsible for

7 03:47:01 proposing -- for presenting -- and it's

8 03:47:03 not -- it's not specific, for presenting --

9 03:47:06 Oh, yes, it says on some either a

10 03:47:09 poster or an oral presentation on the

11 03:47:12 meetings. So it was a plan.

12 03:47:14 Q Okay.

13 03:47:15 So it was a publications plan as well

14 03:47:16 as a scientific meeting plan?

15 03:47:19 A Yes.

16 03:47:19 Q Okay.

17 03:47:19 A A publications plan and a plan for -- for

18 03:47:24 who would present at the scientific

19 03:47:27 meetings.

20 03:47:27 Q Okay.

21 03:47:28 And with regard to the publication

22 03:47:29 plans, how many -- how many publications

23 03:47:31 were proposed at that particular time?

24 03:47:34 A Well, the hope was that there would be nine

1 03:47:37 worth writing.

2 03:47:39 Q Okay.

3 03:47:39 And what -- what is the purpose of

4 03:47:41 publications of study results?

5 03:47:53 A There are multiple goals, but the core goal

6 03:47:56 is to have a mechanism to --

7 03:48:04 The core goal is to disseminate the

8 03:48:06 findings of the study to a -- to an

9 03:48:11 appropriate audience of people.

10 03:48:14 Q Which would be readers?

11 03:48:16 A Yes.

12 03:48:17 MR. DAVIS: Object to the form.

13 03:48:18 MR. MURGATROYD: Well --

14 03:48:19 Q That's a publication, right? It's the --

15 03:48:22 it's -- well, I'm just talking about

16 03:48:23 publications.

17 03:48:25 That's for somebody to read?

18 03:48:26 A Correct, an appropriate audience.

19 03:48:28 Q Right.

20 03:48:29 A Yeah, if the --

21 03:48:30 Q Okay.

22 03:48:30 And what are -- what are all the

23 03:48:31 other purposes -- the lesser purposes,

24 03:48:33 instead of --

1 03:48:34 A Well, not lesser, but they're part of it. I
2 03:48:42 mean it -- it is a --
3 03:48:50 Publications serve as a document to
4 03:48:53 define the design and the outcome of a
5 03:49:04 research project.
6 03:49:08 Distinction between that and having
7 03:49:11 something for an audience is the
8 03:49:15 documentation piece, that, you know, an
9 03:49:17 important activity took place over a period
10 03:49:21 of seven years in which ultimately, you
11 03:49:24 know, 275 or so adolescents agreed and
12 03:49:31 behaved as subjects in a study.
13 03:49:34 You know, all sorts of people were
14 03:49:36 involved, an enormous effort, a scientific
15 03:49:38 enterprise; and the right thing to do is to
16 03:49:41 document that endeavor and to do it
17 03:49:47 accurately.
18 03:49:48 So, you know, even if they're -- and
19 03:49:50 I separate that from the communications
20 03:49:52 piece.
21 03:49:53 Q Right.
22 03:49:53 A You know, the -- you can't have the
23 03:49:56 communications piece without the
24 03:49:57 documentation.

1 03:49:58 But even if there was never an intent
2 03:50:01 to communicate it, in my -- the way I view
3 03:50:05 the world of this -- this world that we're
4 03:50:09 talking about is you always need to document
5 03:50:11 it.
6 03:50:12 Q Okay.
7 03:50:13 And is it true that clinicians get
8 03:50:18 their information by clinical trials through
9 03:50:21 publications, that that's how they get their
10 03:50:23 data?
11 03:50:23 A It's one way.
12 03:50:26 Unfortunately, the reality is that
13 03:50:27 the clinicians get it less through reading
14 03:50:30 the primary publications and more through,
15 03:50:37 you know, other secondary communication
16 03:50:40 means.
17 03:50:41 Q Such as going to symposiums and --
18 03:50:43 A Yes.
19 03:50:43 I mean, the best of all worlds, you
20 03:50:45 know, you could argue all the physicians
21 03:50:47 would subscribe to all the journals that
22 03:50:50 these things would be in; but in reality,
23 03:50:52 the proportion of physicians who subscribe
24 03:50:54 to the journals, let alone read the

1 03:50:56 articles, are capable of, you know, kind of
2 03:51:00 fighting through and understanding is pretty
3 03:51:02 damn low, so that -- so there are ways that
4 03:51:04 the information gets summarized.
5 03:51:07 Q Okay.
6 03:51:08 And that -- it can get summarized
7 03:51:09 through abstracts?
8 03:51:10 A Abstracts, sure, meetings, posters and
9 03:51:13 stuff.
10 03:51:13 Q Right.
11 03:51:13 And am I correct in stating that
12 03:51:18 publications can result -- you know,
13 03:51:19 publications such as your publication for
14 03:51:22 329 can result in clinical guidelines being
15 03:51:26 drafted or being adopted?
16 03:51:27 MR. DAVIS: Object to the form.
17 03:51:33 A When -- when a -- when a committee is
18 03:51:36 appointed by an organization to establish
19 03:51:39 guidelines, one of the things that the
20 03:51:43 members of the committee are assigned to do
21 03:51:49 is to look at all the published literature
22 03:51:51 and then to analyze that public literature,
23 03:51:56 to do their own assessment and analysis of
24 03:51:58 it to then make a judgment to establish

1 03:52:00 guidelines.

2 03:52:00 Q Okay.

3 03:52:01 And clinicians can read publications,

4 03:52:04 such as your publication of 329, and decide

5 03:52:08 whether or not to prescribe a drug to

6 03:52:09 patient, correct?

7 03:52:14 A They could.

8 03:52:16 What's really happened in the past

9 03:52:18 several years is something called, you know,

10 03:52:20 kind of the quest for -- for organizing

11 03:52:25 evidence-based medicine.

12 03:52:28 So there are organizations, and these

13 03:52:30 are relatively new, Cochrane reports and

14 03:52:32 others, and they take topics. I don't know

15 03:52:34 if they've done one yet on the treatment of

16 03:52:37 depression in children, and there may be one

17 03:52:39 or two such -- two or three such groups in

18 03:52:41 the world, and --

19 03:52:42 Q What was the name --

20 03:52:43 A Well, one is called the Cochrane reports.

21 03:52:46 Q The Cochrane?

22 03:52:47 A C-O-C-H-R-A-N-E. And then there's another

23 03:52:50 one. And so they go through topics.

24 03:52:53 I don't know if they've had one yet

1 03:52:55 on children and adolescents, and they -- I
2 03:52:58 don't know who employs them, where they get
3 03:53:00 their money from, but they're well respected
4 03:53:02 and they do review of a topic and they'll
5 03:53:04 actually say -- they'll actually --
6 They'll actually -- and we're trying
7 03:53:09 to get clinicians to read these. It's a
8 03:53:12 major effort I'm involved in.
9 They actually will sort of give their
10 03:53:16 analysis of the quality of the evidence
11 03:53:18 that's in the reports and come up with their
12 03:53:21 own recommendation as to what a clinician
13 03:53:25 should do.
14 03:53:26 Q Okay.
15 In terms of prescribing --
16 03:53:27 prescribing recommendations?
17 03:53:29 A Yes, yes, because it's just too hard to
18 03:53:30 expect a clinician to --
19 03:53:33 Q Okay.
20 Now --
21 03:53:40 A And I will tell you that the informed
22 03:53:41 clinician today and medical students in
23 03:53:44 training and residents in training, which I
24 03:53:47 would include my own son, they go right

1 03:53:48 after -- they're taught now to go right
2 03:53:51 after that stuff, things that we were never
3 03:53:53 taught.
4 03:53:53 So they're taught to go over the
5 03:53:54 Cochrane reports and things like that,
6 03:53:56 rather than actually read --
7 03:53:57 You know, they read the articles for
8 03:53:59 an exercise and learning how to read a
9 03:54:02 scientific article; but in terms of how they
10 03:54:04 should practice medicine, they're trained
11 03:54:07 now to go after these evidence-based things.
12 03:54:09 It's all new, the past three or four
13 03:54:11 years.
14 03:54:11 Q So that -- that didn't exist when 329 came
15 03:54:13 out, your article came out?
16 03:54:15 A If it did, I didn't know about it.
17 03:54:17 Q Okay.
18 03:54:17 A But --
19 03:54:18 Q Now, so with regard to the Exhibit 16 -- no,
20 03:54:24 wait -- yes. No, I'm sorry, 18.
21 03:54:26 You were listed as being the author
22 03:54:29 for the publication, right?
23 03:54:30 A Correct.
24 03:54:31 Q And you were listed as -- for the primary

1 03:54:32 publication, correct?

2 03:54:36 A Yes.

3 03:54:36 Q And then --

4 03:54:37 I'm sorry?

5 03:54:37 A Yes.

6 03:54:38 Q And then there were eight others we talked

7 03:54:39 about who -- who were going to be authors

8 03:54:41 other than yourself?

9 03:54:46 A Well, there were eight other publications in

10 03:54:49 which between one and five people were

11 03:54:52 listed as proposed authors.

12 03:54:57 Q And how many of those were you listed for?

13 03:54:59 A Zero.

14 03:55:00 Q Okay.

15 03:55:00 So you were just in the primary

16 03:55:01 publication number one?

17 03:55:03 A One was enough for me.

18 03:55:05 Q And that actually was the -- resulted in the

19 03:55:07 publication that we've marked as an exhibit

20 03:55:09 here today, correct?

21 03:55:10 A Yes.

22 03:55:10 Q Okay. We're going to get into how that came

23 03:55:13 about a little bit later.

24 03:55:14 But in terms of the scientific

1 03:55:16 meetings, which is the second page of that
2 03:55:17 document, it was proposed that you -- you do
3 03:55:21 go to a scientific meeting and promulgate
4 03:55:27 the results of Study 329, correct?
5 03:55:30 A I'm not sure what you mean by "promulgate."
6 03:55:32 Q Well, present.
7 03:55:34 A Yes.
8 03:55:34 Q Right.
9 03:55:35 And, in fact,, did you do that?
10 03:55:40 A Yes.
11 03:55:44 Q And do you recall what meeting that was --
12 03:55:47 well, let me ask you this:
13 03:55:48 First of all, who asked you to be a
14 03:55:51 presenter at a scientific meeting?
15 03:55:55 A Oh, a group of us, my colleagues and I,
16 03:55:58 chose the meetings. And I don't know how
17 03:56:04 the conversation unravelled, but since I was
18 03:56:09 going to be the lead author on the primary
19 03:56:15 paper and the American Psychiatric
20 03:56:17 Association meeting was the first, you know,
21 03:56:23 major meeting, as many as, whatever, 20,000
22 03:56:27 psychiatrists show up, it was decided that I
23 03:56:33 should present the findings at that meeting.
24 03:56:37 Q Okay.

1 03:56:38 A I -- I don't think I -- I don't even know if
2 03:56:40 it came to the point --
3 03:56:41 You know, we listed it, and probably
4 03:56:44 the name Keller just blew up on the board.
5 03:56:47 I don't know if it was a discussion.
6 03:56:49 Q Okay.
7 03:56:49 Did -- did GSK participate in the
8 03:56:53 this meeting on November 4, 1997? Was Jim
9 03:56:56 McCafferty there?
10 03:56:57 A As I said, you know, it's not that I can
11 03:56:59 remember Jim being there, but I -- I'm
12 03:57:04 pretty darn sure he was.
13 03:57:05 Q Right.
14 03:57:06 I mean, who was going to present the
15 03:57:08 statistical analysis --
16 03:57:09 A Right.
17 03:57:09 Q -- if it wasn't somebody from GSK?
18 03:57:11 A Right.
19 03:57:11 So, I mean, again, I can't remember
20 03:57:15 seeing Jim there, just like I can't remember
21 03:57:17 Neal being there.
22 03:57:18 Q Right.
23 03:57:18 A But I think it likely, and I am -- I assume
24 03:57:21 that there were others from GSK, but I

1 03:57:23 couldn't name one of them.

2 03:57:24 Q Let me ask you, do you know who the

3 03:57:26 statistician was for 329, Rosemary Oakes?

4 03:57:29 A No.

5 03:57:29 Q You never met her that you recall?

6 03:57:31 A I may have met her, but I don't recall

7 03:57:35 meeting her.

8 03:57:36 Q Okay.

9 03:57:36 A I mean, don't tell that to her. I don't

10 03:57:38 want to embarrass her if she remembers,

11 03:57:40 but --

12 03:57:40 Q Okay. No, that's fine.

13 03:57:43 Now, you did -- we established you

14 03:57:46 did make a presentation at a meeting. Was

15 03:57:47 it more than one meeting or just one

16 03:57:50 meeting?

17 03:57:54 A I think I only presented at the APA. There

18 03:58:01 are -- you know, whether I presented these

19 03:58:06 results in other settings, I just can't

20 03:58:08 remember, you know?

21 03:58:09 Did I present them to my own

22 03:58:11 residents at Brown, you know, sometimes they

23 03:58:13 like to hear what the chairman has to say,

24 03:58:17 or at least make believe they like to hear

1 03:58:20 what I have to to say so I feel good about
2 03:58:23 them.
3 03:58:23 I may have, you know, was there -- I
4 03:58:26 don't recall another major meeting in which
5 03:58:29 I was a formally listed presenter.
6 03:58:32 Could someone have asked me to stand
7 03:58:34 up at some other group of peers somewhere
8 03:58:36 where we meet and say, Hey, Keller, you want
9 03:58:39 to tell us about that? It could have
10 03:58:40 happened, but I don't remember.
11 03:58:41 Q Okay.
12 03:58:43 And did -- now, you -- do you recall
13 03:58:47 when you made that presentation?
14 03:58:50 A No, except that to the extent that we made
15 03:58:54 the deadline and --
16 03:59:02 The goal was to present it in the --
17 03:59:05 at the 1998 meeting of the APA, which would
18 03:59:08 have taken place -- it typically occurs in
19 03:59:14 May.
20 03:59:16 Q Okay.
21 03:59:16 And do you think you made that?
22 03:59:17 Do you want me to show you a
23 03:59:19 document?
24 03:59:19 A Sure.

1 03:59:19 Q Okay. Let's do that.
2 03:59:23 A Why speculate when we can be certain?
3 03:59:25 Q Absolutely.
4 03:59:28 Now, let me -- did -- we're going to
5 03:59:31 get to that. I'll find it in a second, but
6 03:59:34 while I'm looking for it, did -- how does it
7 03:59:37 work when you do a presentation at the APA?
8 03:59:40 You have to fly there and spend the
9 03:59:41 night, I think, and -- or do you or -- do
10 03:59:44 you --
11 03:59:45 You have to get to wherever the city
12 03:59:47 is, right?
13 03:59:48 A Well, you're not a Star Trek fan?
14 03:59:52 Q Yes, I am, but I can't remember that
15 03:59:54 technology.
16 03:59:55 A Remember Scotty? They would just beam him
17 03:59:57 right up there.
18 03:59:58 But I, not -- unlike some of the Star
19 04:00:01 Trek characters, have to move myself
20 04:00:05 physically to the meeting. And there's
21 04:00:07 different means of transportation. There's
22 04:00:09 air, boat, plane and automobile, right?
23 04:00:12 Q Right.
24 04:00:12 And I think this was was in Toronto,

1 04:00:15 if I recall correctly.

2 04:00:16 A I would say if it was, the overwhelming

3 04:00:18 probability was I flew AirCanada, and I

4 04:00:21 actually do have a memory that I forgot to

5 04:00:23 bring my passport and they either didn't

6 04:00:26 want to let me in or out of the country,

7 04:00:27 which caused my wife to have to make a major

8 04:00:30 effort to send some picture of me.

9 04:00:34 Q Okay.

10 04:00:34 A With great disdain, the Canadians, finally

11 04:00:41 let me have my -- have my passage.

12 04:00:44 Q Okay.

13 04:00:44 How does it work when that happens?

14 04:00:45 Do you get to -- does -- who pays for that?

15 04:00:51 A Depends who you are.

16 04:00:55 First of all, the first way it works

17 04:00:58 is that it's competitive as to which -- as

18 04:01:01 to whether what you want to present gets

19 04:01:03 presented.

20 04:01:04 So I submit an application to present

21 04:01:09 it, you know, to the APA committee on the

22 04:01:19 meeting -- its committee on the meeting.

23 04:01:19 It's a very formal process. And then I get

24 04:01:24 notified, boom, boom, boom.

1 04:01:33 Now, for -- for me, the -- and the
2 04:01:35 APA is highly regulated and has been as far
3 04:01:39 as I can remember, as to how people's
4 04:01:44 transportation can get paid for and
5 04:01:49 expenses.
6 04:01:51 So there's basically one of three or
7 04:01:59 four ways that you get paid, your
8 04:02:00 transportation gets paid.
9 04:02:02 One, you pay it out of your own
10 04:02:04 pocket. That would be typical for a private
11 04:02:07 practitioner or maybe one of my -- some of
12 04:02:08 my faculty members.
13 04:02:11 On the other hand, others of my
14 04:02:12 faculty members, we have academic funds, and
15 04:02:15 they're allowed to draw on their academic
16 04:02:18 funds and pay for it.
17 04:02:19 For our residents, we send a lot of
18 04:02:21 our residents because they don't have tons
19 04:02:23 of money. Sometimes if they've exhausted
20 04:02:24 their meeting allowance, they pay
21 04:02:26 themselves.
22 04:02:27 For me, if I don't have someone who
23 04:02:29 is going to pay for it -- I'll tell you who
24 04:02:31 that might be in a moment -- then I pay for

1 04:02:36 it. But as part of my arrangement with the
2 04:02:39 university, I'm allowed to take -- I have a
3 04:02:41 travel allowance.
4 04:02:42 So if I'm going to a meeting in which
5 04:02:44 I'm presenting data and that is not paid for
6 04:02:52 by a grant that I have -- because for a lot
7 04:02:54 of grants we write in "travel to meetings"
8 04:02:59 very explicitly, NIH grants.
9 04:03:02 Q Well, I want to try to keep it down to this
10 04:03:04 particular study.
11 04:03:05 A Well, the same for this particular study.
12 04:03:06 The travel was -- my travel to that meeting
13 04:03:11 was either paid for by -- by Brown, in other
14 04:03:13 words, I paid for it and I was reimbursed;
15 04:03:15 or at APA meetings, there are things called
16 04:03:22 industry-sponsored symposium, which are
17 04:03:24 highly regulated.
18 04:03:25 Q Right.
19 04:03:25 A And currently, for many years -- you're
20 04:03:27 allowed to be on two of them. In the good
21 04:03:31 old days, you could be on 30.
22 04:03:33 And the APA gets money from
23 04:03:39 pharmaceutical companies in some sort of a
24 04:03:41 pot that they homogenize.

1 04:03:43 Q Right.

2 04:03:44 A And if you're chairing a meeting, you get

3 04:03:46 paid \$2,000. If you're just a presenter,

4 04:03:48 you get 1500.

5 04:03:49 And then you get a flat \$2,000 for

6 04:03:54 your travel reimbursement if you're a

7 04:03:56 presenter or a chair of one of these

8 04:04:01 meetings. And the check comes from the

9 04:04:04 American Psychiatric Association, and

10 04:04:05 they've created firewalls -- I don't know

11 04:04:08 how they work -- between the pharmaceutical

12 04:04:10 company and whatever

13 04:04:14 So that for every APA I've been to

14 04:04:17 for the past, I don't know, many years, I've

15 04:04:19 always both chaired and presented at an

16 04:04:23 industry-sponsored symposium. So basically,

17 04:04:26 the APA pays for my travel and gives me an

18 04:04:29 honorarium.

19 04:04:30 I would not -- if GSK wanted to give

20 04:04:32 me a check for going, I would not be

21 04:04:35 allowed -- I would be in violation of APA

22 04:04:38 rules to accept it.

23 04:04:39 Q Right.

24 04:04:39 Because the GSK would pay the APA,

1 04:04:42 which, in turn --

2 04:04:43 A Yes, but for what I was doing, for

3 04:04:45 presenting a poster, they wouldn't be

4 04:04:48 allowed to pay it.

5 04:04:51 The industry-sponsored symposium that

6 04:04:54 I'm talking about of a huge headline of

7 04:04:56 events that between 500 and 3,000 people go

8 04:05:00 to, they get enormous publicity. There's

9 04:05:02 maybe 20 of them. They're held in the big

10 04:05:04 ballrooms, and the APA actually monitors the

11 04:05:08 selection of the topic.

12 04:05:11 Q Okay.

13 04:05:11 A And who can be on it. And the company can't

14 04:05:13 talk --

15 04:05:14 If I'm going to be a chair, I put

16 04:05:16 down to do it, the company's not allowed to

17 04:05:18 talk to me about who are going to be the

18 04:05:21 presenters and what are going to be the

19 04:05:22 topics.

20 04:05:23 Q And with regard to your presentation

21 04:05:26 regarding the results of 329, was that a

22 04:05:29 major presentation in one of the ballrooms

23 04:05:32 or was that a smaller event?

24 04:05:33 A No, it was a small one.

1 04:05:35 Q Okay.

2 04:05:35 And do you ever recall giving a slide

3 04:05:37 presentation?

4 04:05:45 A Probably. I've given family eulogies with

5 04:05:47 slides, so I usually have slides.

6 04:05:49 Q Okay.

7 04:05:50 Well, let me -- actually, let me --

8 04:05:51 MR. MURGATROYD: Let's go off the

9 04:05:52 record for a minute. I want to find the

10 04:05:54 abstract.

11 04:05:55 THE VIDEOGRAPHER: The time is five

12 04:05:56 minutes after 4:00. We're off the record.

13 04:06:16 (Recess.)

14 04:20:22 (Exhibit No. 19 marked for

15 04:20:22 identification.)

16 04:20:22 (Exhibit No. 20 marked for

17 04:20:22 identification.)

18 04:23:24 THE VIDEOGRAPHER: We are back on the

19 04:24:47 record. This is Tape No. 4. The time is

20 04:24:50 4:24.

21 04:25:11 MR. DAVIS: Are we back on the

22 04:25:12 record?

23 04:25:14 MR. MURGATROYD: Yes. Are we back

24 04:25:15 on?

1 04:25:16 THE VIDEOGRAPHER: We are.

2 04:25:16 BY MR. MURGATROYD:

3 04:25:17 Q Doctor, are you ready?

4 04:25:18 A Ready.

5 04:25:18 Q Okay.

6 04:25:19 During the break, I handed you two

7 04:25:22 documents which we marked as Exhibits 19 and

8 04:25:23 20, correct?

9 04:25:24 A Yes.

10 04:25:24 Q And can you identify for the record what

11 04:25:27 Exhibit 19 is, please?

12 04:25:31 A What it appears to be to me is the summary

13 04:25:37 or I guess the abstract of the presentation

14 04:25:41 which I was scheduled to make on Tuesday,

15 04:25:46 June 2nd, between 9:00 and 10:30 a.m.

16 04:25:52 It doesn't say the year on here.

17 04:25:54 Q Okay.

18 04:25:54 A And about -- on paroxetine and imipramine

19 04:25:59 treatment for depression.

20 04:26:02 Q Okay.

21 04:26:02 Do you recall making that

22 04:26:04 presentation?

23 04:26:05 A No.

24 04:26:07 Q Okay. Well, let's just stick with abstract.

1 04:26:11 Who drafted that abstract, if you
2 04:26:13 know?
3 04:26:14 A I assume me.
4 04:26:15 Q Okay.
5 04:26:17 And in the abstract, do you state
6 04:26:20 that the paroxetine failed on the two
7 04:26:25 primary outcome measures?
8 04:26:43 (Witness read document.)
9 04:26:45 A No.
10 04:26:47 Q Does -- does the abstract state that the
11 04:26:51 scales rated by the parents and the
12 04:26:53 children, paroxetine failed to separate
13 04:26:59 statistically from placebo with regard to
14 04:27:01 those scales?
15 04:27:02 A No.
16 04:27:07 Q Okay.
17 04:27:08 A But I would say, though, the abstract does
18 04:27:10 not specifically state -- does not
19 04:27:15 specifically give the scales, you know,
20 04:27:27 rates of change or P values for any outcome
21 04:27:32 measures.
22 04:27:33 Q Okay.
23 04:27:33 A So just a -- just to round up -- round out
24 04:27:36 your question to me.

1 04:27:37 Q Okay.

2 04:27:38 But does it discuss the failure to

3 04:27:41 meet -- to separate statistically -- does it

4 04:27:43 talk about Paxil's failure to separate

5 04:27:46 statistically from placebo with regard to

6 04:27:48 any measures?

7 04:27:48 A No. But nor does it -- nor does it say that

8 04:27:52 it separated statistically from any measures

9 04:27:55 in the positive way either.

10 04:27:56 It didn't give that. It just --

11 04:27:58 Q Well, what -- what did it conclude in the

12 04:28:02 last sentence of the last paragraph?

13 04:28:05 A The results -- These results support that

14 04:28:08 paroxetine is an effective treatment for

15 04:28:10 major depression in an adolescent outpatient

16 04:28:13 population, which is absolutely accurate.

17 04:28:17 Q And does your -- and now turning to the next

18 04:28:21 exhibit, which is Exhibit 20, do you see

19 04:28:28 that that is slides?

20 04:28:30 A I do.

21 04:28:31 Q And does it concern Study 329?

22 04:28:39 A It -- it -- it also is a review. It's a

23 04:28:42 review of -- it's a review -- it's a much --

24 04:28:47 it's a --

1 04:28:50 There are many slides missing from --
2 04:28:52 you know, there are many blank pages --
3 04:28:55 Q Right.
4 04:28:55 A -- which just have titles.
5 04:28:57 But what it is is a -- it reviews the
6 04:29:04 epidemiology, comorbidity, clinical course,
7 04:29:10 clinical picture of depression in
8 04:29:13 adolescents.
9 04:29:14 It talks about, you know, efficacy of
10 04:29:17 other treatments. And after giving that
11 04:29:19 background, it goes into the study design of
12 04:29:27 329.
13 04:29:31 And then it has -- it's entitled
14 04:29:36 Results Overview, but it does not have --
15 04:29:41 it's just blank with regard to demographics
16 04:29:44 based on characteristics and so on.
17 04:29:47 So it's missing all of that. It does
18 04:29:49 give the medical history. It's blank on --
19 04:29:51 it doesn't have the results for the
20 04:29:52 depression mood item, an item which, in
21 04:29:56 fact, as which we discussed earlier was --
22 04:29:58 did separate statistically from placebo.
23 04:30:04 It -- that's vital signs. So it
24 04:30:09 doesn't have the specifics of the -- so far

1 04:30:16 in the bulk of the efficacy variables, so
2 04:30:18 it's -- it's a -- I assume --
3 04:30:22 Put it this way: It's unimaginable
4 04:30:25 to me that I presented slides that were
5 04:30:30 blank, so that this would be a working draft
6 04:30:31 of an outlined talk.
7 04:30:35 Q Okay.
8 04:30:35 Well, I found a document that
9 04:30:37 actually GSK sent me that said that -- well,
10 04:30:39 do you recall ever presenting slides at --
11 04:30:41 at any -- any presentation?
12 04:30:43 A I don't remember. That's why I said -- you
13 04:30:45 asked me that earlier.
14 04:30:46 Q Yes.
15 04:30:47 A And I said that I don't recall.
16 04:30:50 Q Well, how does it work when you present a
17 04:30:54 post -- wait.
18 04:30:55 You had -- you have an abstract. We
19 04:30:57 have an abstract there, right?
20 04:30:59 A Right.
21 04:30:59 Q And the next thing is a presentation?
22 04:31:04 I mean, the abstract's published, and
23 04:31:06 then there's a presentation at the meeting?
24 04:31:07 A Well, see, it doesn't say what type of

1 04:31:17 session. There are many different types of
2 04:31:19 communication sessions at a meeting, so that
3 04:31:23 the -- there could have --
4 04:31:24 It could have been an oral
5 04:31:26 presentation. It could have been a
6 04:31:27 discussion group, which -- in which I might
7 04:31:31 have made some remarks and then had a --
8 04:31:34 just a round table discussion.
9 04:31:37 It could have been a poster -- a
10 04:31:40 poster session.
11 04:31:42 Q What -- what is a poster session? That was
12 04:31:43 my -- that was my question.
13 04:31:45 A Well, poster -- there are lots of different
14 04:31:47 ways to run them, but basically you
15 04:31:49 designate a certain time period; and during
16 04:31:51 that time period, posters are shown.
17 04:31:53 And poster -- it would be, you know,
18 04:31:55 like a -- have you ever been to a poster
19 04:31:58 session?
20 04:30:10 Q A big poster board?
21 04:30:11 A Yes, a big poster board, and you give the
22 04:30:14 design of a study and the results and so on.
23 04:30:17 And depending upon the nature of the
24 04:30:19 meeting -- and the APA being such an

1 04:30:23 enormous meeting, I mean, there's
2 04:30:25 probably --
3 04:30:26 There are 25 to 100 or more things
4 04:30:29 going on simultaneously at this meeting, so
5 04:30:33 most people can only see one at a time.
6 04:30:36 But they try to organize them. So
7 04:30:39 there may -- there could well have been a
8 04:30:41 session -- a poster session on research
9 04:30:43 related to children and adolescents, you
10 04:30:46 know, during a block.
11 04:30:49 So at some other meetings that are
12 04:30:53 smaller, like from 5:30 to 7:00 every day,
13 04:30:57 there's a poster session. And so it just --
14 04:31:02 Q What time was your meeting, according to the
15 04:31:03 abstract?
16 04:31:04 A 9:00 to 10:30.
17 04:31:06 Q So what would that indicate to you? What
18 04:31:07 type of presentation was it?
19 04:31:08 A It's just too hard to know.
20 04:31:10 Q Okay.
21 04:31:10 A What I'm saying is, the APA is such an
22 04:31:12 enormous meeting with so many things
23 04:31:14 going --
24 04:31:16 If there are 20,000 people there,

1 04:31:17 right, theoretically there's something for
2 04:31:20 everybody at every hour, you can only
3 04:31:21 imagine how many things are going on.
4 04:31:22 And the program book, which you could
5 04:31:26 probably get somehow for a meeting, just --
6 04:31:31 if you look at it, this is -- any given
7 04:31:34 time --
8 04:31:34 You can't tell from this. In any
9 04:31:36 given time slot --
10 04:31:37 Q Okay.
11 04:31:38 Do you recall -- do you know who
12 04:31:39 Kevin Bellew, B-L -- B-E-L-L-E-W, worked
13 04:31:47 with Jim McCafferty?
14 04:31:48 A There's no recall.
15 04:31:50 Q Okay.
16 04:31:50 Have you ever seen a document where
17 04:31:53 he states that he prepared slides for you
18 04:31:55 for that presentation for the APA?
19 04:31:56 A No.
20 04:31:57 Q Okay.
21 04:31:57 A But what I can tell you is I have never in
22 04:32:00 my life shown slides that someone else
23 04:32:05 prepared where I didn't take whatever help I
24 04:32:12 was given in preparation, either the

1 04:32:16 formatting of them or whatever, and make it
2 04:32:19 uniquely mine.
3 04:32:20 I can't tell you what other people
4 04:32:21 do, but I've never in my life been handed a
5 04:32:28 slide set and shown it.
6 04:32:29 Q Okay.
7 04:32:30 Well, with regard --
8 04:32:31 A I certainly have had -- I have someone on
9 04:32:33 my -- I have someone who works for me full
10 04:32:40 time at Brown, is paid by Brown, a member of
11 04:32:43 my staff. She's titled a communications
12 04:32:46 person.
13 04:32:47 And this woman helps me put together
14 04:32:49 presentations. She doesn't know anything
15 04:32:52 about -- I mean, she doesn't have any
16 04:32:54 training, you know, as a mental health
17 04:32:58 professional or any particular education,
18 04:33:00 but she's good at formatting things. She's
19 04:33:03 good at organizing things.
20 04:33:05 So I might say, you know, Anna, could
21 04:33:07 you pull together the last five talks I gave
22 04:33:09 on this topic, blah, blah, blah, blah. And
23 04:33:12 then I'll kind of scribble them up, this and
24 04:33:14 that, and say could you fix them up, format

1 04:33:18 them, check the references. Things like
2 04:33:20 that.
3 04:33:21 So her job description is she helps
4 04:33:23 Marty with his slide presentations, and she
5 04:33:25 makes the final PowerPoint, so...
6 04:33:28 Q Yes.
7 04:33:28 My question was, do you recall a GSK
8 04:33:30 employee preparing slides for you?
9 04:33:31 A No, I -- my answer -- when I'm expanding --
10 04:33:34 I'm telling --
11 04:33:35 My answer is no, I don't. And then
12 04:33:36 you said to me that someone wrote a memo,
13 04:33:39 they said they made slides to Keller, and my
14 04:33:42 response to that is I can't -- I can't
15 04:33:43 imagine --
16 04:33:44 I don't know what role they played in
17 04:33:47 it, but if they played a role, the role had
18 04:33:51 nothing to do with driving the scientific
19 04:33:53 content of what I was presenting.
20 04:33:55 Q Okay. Now -- you can put that document
21 04:33:58 down. Let's -- the --
22 04:34:11 With regard to publishing the results
23 04:34:13 of 329, there was a company involved called
24 04:34:20 STI; do you recall that?

1 04:34:23 A Yes

2 04:34:24 Q Okay. And -- well, let me ask you this.

3 04:34:25 Actually, I want to back up.

4 04:34:31 When you were at the meeting in

5 04:34:32 November of 1997 that we talked about

6 04:34:35 earlier where you had the consensus

7 04:34:38 statement, the publication strategy and

8 04:34:39 the --

9 04:34:40 A I recall.

10 04:34:41 Q Was that at GSK, do you recall?

11 04:34:43 A Do not remember.

12 04:34:45 Q Okay.

13 04:34:49 At that meeting, was it discussed

14 04:34:55 that a medical writing organization would be

15 04:34:58 hired to write the manuscript for Study 329?

16 04:35:06 A I don't remember if it was discussed at that

17 04:35:09 meeting.

18 04:35:11 Q Okay.

19 04:35:11 When do you recall that first being

20 04:35:13 discussed?

21 04:35:16 A I don't remember it being discussed, but...

22 04:35:24 Do we have a copy of the publication,

23 04:35:27 just for my own records? I don't remember

24 04:35:28 it being discussed, but...

1 04:35:30 Q Yes. The study? I think you have it there.

2 04:35:34 A But it says on the acknowledgment, editorial

3 04:35:38 assistance was provided by Sally K. Laden,

4 04:35:42 who works for STI.

5 04:35:43 Q And you know -- you communicated with her,

6 04:35:47 correct?

7 04:35:48 A Let me finish what I was going say. Okay.

8 04:35:50 So she was provided -- so what this

9 04:35:53 tells me is that she provided editorial

10 04:35:57 assistance. I know she works for STI. I

11 04:36:00 know her quite well.

12 04:36:01 I mean, I haven't seen her in a long

13 04:36:03 time, but I used to see her more. And

14 04:36:07 though I can't recall, you know, the

15 04:36:10 interactions, she did what's stated here.

16 04:36:15 She provided editorial assistance in the

17 04:36:18 preparation of the manuscript.

18 04:36:19 Q Okay. Well, we'll get into that in a

19 04:36:21 second.

20 04:36:21 I guess -- well, let me go back to

21 04:36:23 the meeting in November of '97 when you were

22 04:36:25 looking at the results of 329.

23 04:36:27 Were you provided all the raw data at

24 04:36:30 that time?

1 04:36:30 Was the raw data available at that
2 04:36:32 meeting so you all as investigators could
3 04:36:34 examine it and determine for yourselves what
4 04:36:36 the results were of the study?
5 04:36:38 A I don't recall.
6 04:36:45 If raw data was provided at that
7 04:36:47 meeting, it would have been incomplete for
8 04:36:49 the reasons I stated to you earlier, that we
9 04:36:53 had that meeting as fast as we could --
10 04:36:57 You know, we had that meeting occur
11 04:37:01 as soon as possible after the blind was
12 04:37:04 broken, and there was an expression that you
13 04:37:07 saw somewhere along there, top-line results.
14 04:37:09 Q Right.
15 04:37:10 A And that's shorthand for meaning, you know,
16 04:37:12 these are the P values of the major
17 04:37:16 variables of interest.
18 04:37:16 But certainly it -- we didn't have,
19 04:37:19 as I described to you that would need to be
20 04:37:22 done, we didn't have a document --
21 04:37:24 I don't remember this, but I would be
22 04:37:25 very surprised if we had the -- the raw --
23 04:37:29 you know, any meaningful amount of raw data
24 04:37:33 analysis that would have led to those

1 04:37:37 results.

2 04:37:38 Q Have you -- have you ever had -- personally

3 04:37:40 had the opportunity to review the raw data

4 04:37:42 of Study 329?

5 04:37:49 A I've reviewed data analytic tables. I don't

6 04:37:57 recall how raw it was, and I'm not trying to

7 04:38:01 be facetious, but what I mean is that, you

8 04:38:05 know, there are different levels of -- how

9 04:38:11 to put this -- of organizing data that

10 04:38:15 statisticians do.

11 04:38:16 So, you know, the most primary level,

12 04:38:19 the huge printouts that, you know, that list

13 04:38:22 items by item number, you know, item numbers

14 04:38:25 and variable numbers and don't even have

15 04:38:28 words on them, I tend not to look at those.

16 04:38:31 I -- I do better with words than I do with

17 04:38:33 symbols.

18 04:38:34 And so that at -- that at some -- you

19 04:38:38 know, at some level of organizing, at

20 04:38:42 some -- at some point after the data was

21 04:38:45 organized in a way that I could read tables,

22 04:38:49 you know, and so it might -- it might have

23 04:38:51 been a --

24 04:38:53 It might have been a compilation of

1 04:38:56 papers this thick (indicating). I could
2 04:38:58 have seen the tables, you know, with the
3 04:39:00 analyses and statistical tests, what was
4 04:39:03 done and the P value and the confidence
5 04:39:05 intervals and so on and so forth.
6 04:39:08 Given my style, that's highly
7 04:39:10 probable. I cannot specifically remember,
8 04:39:15 you know, doing that with these data.
9 04:39:18 But --
10 04:39:19 Q Well, if you had the -- if you had done
11 04:39:21 that, would you have kept the documents that
12 04:39:25 show the statistical analysis?
13 04:39:29 A I'm not big on saving paper, so not
14 04:39:32 necessarily.
15 04:39:32 Q Okay.
16 04:39:33 A I would have -- I would have looked at them.
17 04:39:34 I would have done what was relevant, and I
18 04:39:36 would have said -- I might have said, gee,
19 04:39:39 we need to do more analyses; or I might have
20 04:39:41 said, I don't understand this; or I might
21 04:39:43 have said, This looks fine.
22 04:39:46 Then there would be a process for
23 04:39:47 harvesting what's most important from that,
24 04:39:50 and then there would be a process on my part

1 04:39:52 of putting it in a paper file and getting
2 04:39:56 rid of it.
3 04:39:57 Q Yes.
4 04:39:57 Well, I just want to know what
5 04:39:58 specifically you did with regard to 329,
6 04:40:00 though.
7 04:40:00 A I can't -- I can't -- I can't remember,
8 04:40:02 except to tell you that I've written -- I've
9 04:40:08 been an author on hundreds of manuscripts,
10 04:40:12 and never as the first author of the
11 04:40:14 manuscript have I just taken, you know, what
12 04:40:18 you would -- what would be, say, this table,
13 04:40:24 you know, Table 1 or Table 2, and someone
14 04:40:27 said, oh, here are the tables and I said,
15 04:40:30 oh, great, and put them in the paper, you
16 04:40:33 know?
17 04:40:33 I would go back to levels to look at
18 04:40:36 the types of analyses, how they were done,
19 04:40:41 because I always analyze data.
20 04:40:46 But I can't tell you at what level,
21 04:40:47 you know, what point in the analytic process
22 04:40:50 I engaged.
23 04:40:51 Q All right.
24 04:40:51 Now, with regard to 329, were you

1 04:40:56 ever shown the contract that was entered
2 04:40:59 between GSK and STI to write the
3 04:41:02 manuscript for --
4 04:41:03 A No.
5 04:41:03 Q -- the article that was ultimately published
6 04:41:06 under your name?
7 04:41:07 A No.
8 04:41:08 Q Okay.
9 04:41:08 But you do know that Sally Laden was
10 04:41:12 hired by GSK to prepare the manuscript,
11 04:41:17 correct?
12 04:41:17 MR. DAVIS: Object to the form.
13 04:41:20 A I know that Sally Laden was hired by GSK to
14 04:41:25 provide editorial assistance in the writing
15 04:41:29 of the manuscript.
16 04:41:30 Q Well, she actually prepared the original
17 04:41:35 manuscript, correct?
18 04:41:36 MR. DAVIS: Object to the form.
19 04:41:39 A I don't know that that's correct, because if
20 04:41:43 Sally were working with me, what's likely is
21 04:41:51 that she and I would have had conversations
22 04:41:57 and discussions about what should be in the
23 04:42:01 manuscript.
24 04:42:01 I might have written an outline in

1 04:42:03 the manuscript, so there would be a process
2 04:42:06 that would have taken place before a draft
3 04:42:10 would be produced.
4 04:42:12 Q Do you recall in this instance with Sally
5 04:42:14 Laden, she, in fact, drafted the original
6 04:42:17 manuscript and then presented it to you for
7 04:42:19 review?
8 04:42:21 A I don't recall that.
9 04:42:23 Q Okay.
10 04:42:23 A And that would be -- if that -- I don't
11 04:42:25 recall that, and I -- let me say it to you
12 04:42:33 this way:
13 Not only don't I recall that, but I
14 04:42:36 never recall a -- I can't recall any
15 04:42:38 instance in which someone handed me a
16 04:42:42 document that wasn't preceded by a
17 04:42:45 meaningful amount of interchange by myself
18 04:42:48 and the person, the assistant, as to what
19 04:42:52 would be in the document.
20 04:42:54 Q Let's take a look at the next exhibit, which
21 04:42:57 is --
22 MR. COFFIN: 21.
23 04:43:01 Q -- 21.
24 04:43:04 (Exhibit No. 21 marked for

1 04:43:04 identification.).

2 04:43:17 BY MR. MURGATROYD:

3 04:43:18 Q If you would take a look at that.

4 04:43:19 (Witness read document.)

5 04:43:32 A Okay.

6 04:43:32 Q Okay.

7 04:43:34 You've had a chance to look at that?

8 04:43:35 Can you tell the jury what that do you mean

9 04:43:36 is, please?

10 04:43:44 A That is draft of a manuscript on the

11 04:43:49 efficacy of 369, Draft 3, in fact, of that.

12 04:43:57 Q Okay.

13 04:43:57 And does it identify Sally Laden on

14 04:44:00 the cover page of that document?

15 04:44:03 A Yes.

16 04:44:04 Q Okay.

17 04:44:05 And what does it state under her?

18 04:44:06 A It says, Manuscript prepared by Sally Laden,

19 04:44:09 MS.

20 04:44:12 Q Okay.

21 04:44:12 A But, as I said to you, and I want to make

22 04:44:15 sure that this is clear and what I'm -- what

23 04:44:21 the reality is isn't distorted by being cut

24 04:44:24 off, is the fact that it says that she

1 04:44:25 prepared it does not in any way mean that
2 04:44:33 she and I didn't have a meaningful amount of
3 04:44:37 exchange as to what I wanted to be in it --
4 04:44:40 Q So you --
5 04:44:40 A -- before the words were typed.
6 04:44:42 Q So do you recall as you sit here and can
7 04:44:46 state under oath that you and Sally Laden
8 04:44:51 spoke before you were presented with the
9 04:44:52 manuscript that was prepared by her for 329?
10 04:44:57 A As I've answered many of your questions
11 04:45:00 today, given that the date on this is 1999
12 04:45:04 for the third draft, which is over seven and
13 04:45:09 a half years ago, I cannot recall, you know,
14 04:45:12 under or out of specific conversations.
15 04:45:18 But what I can say to you is in any
16 04:45:22 instance in which I've been the first author
17 04:45:25 and which there have been editorial
18 04:45:27 assistants, I've had a meaningful role in
19 04:45:30 interacting with the individual as to what
20 04:45:33 will be in the document before a printed
21 04:45:38 copy of the document was prepared for me.
22 04:45:40 Q Let me ask you this:
23 04:45:42 How soon after the study was
24 04:45:44 completed were you presented with the full

1 04:45:46 final report -- the complete final report of
2 04:45:48 Study 329 as prepared by GSK?
3 04:45:51 A No idea.
4 04:45:52 Q Do you recall if you were ever -- you know,
5 04:45:54 it's a couple -- it's over a thousand pages
6 04:45:55 long.
7 04:45:56 Have you ever been presented with
8 04:45:57 that complete report, to your knowledge?
9 04:46:01 A I don't remember.
10 04:46:02 Q Okay.
11 04:46:02 Do you know if Sally Laden used that
12 04:46:04 report in which to draft the manuscript --
13 04:46:06 the first -- the first draft of the
14 04:46:07 manuscript for 329?
15 04:46:08 A I don't know.
16 04:46:16 Q Let me see if I can --
17 04:46:18 MR. MURGATROYD: Let's go off the
18 04:46:18 record for a minute, please.
19 04:46:20 THE VIDEOGRAPHER: The time is 4:48.
20 04:46:21 We are off the record.
21 04:46:22 (Recess.)
22 04:46:22 (Discussion off the record.)
23 04:50:56 (Exhibit No. 22 marked for
24 04:50:56 identification.)

1 04:50:59 MR. MURGATROYD: Let me just identify
2 04:50:59 it.
3 04:50:59 Exhibit 22 is the proposal for a
4 04:51:02 journal article on the adolescent depression
5 04:51:03 Study 329 that was proposed by Sally Laden
6 04:51:09 of STI, which is Scientific Therapeutics
7 04:51:11 Information, Inc., dated April 3, 1998.
8 04:51:15 And on page 5, it lists the services
9 04:51:18 that they, meaning Sally Laden/STI, will
10 04:51:22 perform with regard to the manuscript for
11 04:51:23 329.
12 04:51:26 BY MR. MURGATROYD:
13 04:51:27 Q Doctor, I'd like to just show that to you.
14 04:52:28 (Witness read document.)
15 04:52:48 A Okay.
16 04:52:48 Q Okay.
17 04:52:48 Do you see on page 5 it lists
18 04:52:50 services that --
19 04:52:51 THE VIDEOGRAPHER: Did you want to go
20 04:52:52 back on the record?
21 04:52:53 MR. MURGATROYD: Yes, please.
22 04:52:54 THE VIDEOGRAPHER: Okay. Stand by.
23 04:52:58 Okay. We are back on the record.
24 04:53:00 The time is 4:54.

1 04:53:02 A Actually, could -- could you hand me the
2 04:53:04 draft of the article you -- we were
3 04:53:05 discussing before just for one second?
4 04:53:08 Q Yes, I think it's right here, as a matter of
5 04:53:10 fact. Yes, there you go.
6 04:53:18 A Okay. Okay.
7 04:53:22 Q Okay.
8 04:53:22 So with regard to Exhibit 22, do you
9 04:53:25 see where it says, Services that STI will
10 04:53:27 perform with regard to Study 329?
11 04:53:32 A Which page?
12 04:53:37 Q Page 5.
13 04:53:37 (Witness read document.)
14 04:53:44 A It says services.
15 04:53:45 Q Right.
16 04:53:46 And you see -- can I see the document
17 04:53:47 for a second, sir?
18 04:53:49 A Yes.
19 04:53:52 Q Do you see the third paragraph?
20 04:53:55 A Yes.
21 04:53:55 Q Can you read the first paragraph -- that
22 04:53:58 first sentence into the record, please,
23 04:54:00 the third paragraph of that document.
24 04:54:01 A "STI will develop up to six drafts. Draft 1

1 04:54:05 is the initial draft that will be reviewed
2 04:54:07 by the sponsor."
3 04:54:08 Q Okay.
4 04:54:09 And the next sentence?
5 04:54:10 A "Comments on draft form will be incorporated
6 04:54:13 into Draft 2, which will be sent to the
7 04:54:14 primary author and sponsors for comments."
8 04:54:19 Q Okay.
9 04:54:20 So according to that document, who --
10 04:54:20 who is responsible for drafting -- for
11 04:54:22 creating the -- preparing the first draft?
12 04:54:28 A Well, according to this document, STI.
13 04:54:33 Q Okay.
14 04:54:33 A However, that is perfectly consistent with
15 04:54:38 what I told you before. Writing, typing a
16 04:54:46 manuscript, typing the words follows
17 04:54:49 discussion as to what words will be typed,
18 04:54:53 so that the preparation of the written
19 04:54:56 document by STI as -- by no means -- by no
20 04:55:06 means precludes the fact that I as the first
21 04:55:09 author have interacted with, quotes, STI --
22 04:55:14 in this case, Sally Laden -- as to what the
23 04:55:16 content will be.
24 04:55:17 So --

1 04:55:18 MR. DAVIS: Just a second.

2 04:55:19 Doctor Keller, I know it's been a

3 04:55:20 long day, but your paper is blocking the

4 04:55:23 view of the video, so --

5 04:55:26 THE WITNESS: And I just freshened my

6 04:55:29 hair, too.

7 04:55:29 MR. DAVIS: Yes, I know.

8 04:55:30 THE VIDEOGRAPHER: Don't forget your

9 04:55:31 microphone.

10 04:55:32 MR. DAVIS: Just so -- just so if the

11 04:55:33 jury hears this, at least they won't be

12 04:55:35 distracted.

13 04:55:37 THE WITNESS: Okay.

14 04:55:37 A I was responding to Skip. I don't know his

15 04:55:39 last name, so I can't call him mister.

16 04:55:42 Q That's fine.

17 04:55:44 A Something. But Mr. Skip. And -- oh. Thank

18 04:55:47 you, Karen.

19 04:55:53 In response to Skip's query to me as

20 04:55:59 to the meaning of the fact or the inference

21 04:56:08 that STI was developing the first initial

22 04:56:11 draft, my response is that that is in no way

23 04:56:19 inconsistent at all with the process I

24 04:56:24 described earlier, that prior to writing the

1 04:56:32 words, prior to typing out what would be in
2 04:56:34 the first draft, that I would be having
3 04:56:38 conversations with STI following multiple
4 04:56:42 conversations with my peers and colleagues
5 04:56:45 about what the content would be and the
6 04:56:50 theme would be and the message would be of
7 04:56:53 the article.

8 There is nothing that's inconsistent
9 04:56:56 about that.

10 04:56:57 Q Well, do you recall specifically having such
11 04:56:59 conversations with Sally Laden prior to her
12 04:57:01 preparing the manuscript?

13 04:57:04 A What I recall is on multiple instances over
14 04:57:07 the course of this afternoon and the morning
15 04:57:09 telling you, that I don't have specific
16 04:57:12 recall over events which occurred between
17 04:57:17 April 3rd -- you know, April of 1998, eight
18 04:57:22 years, over -- over eight years ago and the
19 04:57:24 present.

20 But what I recall, what I know, is
21 04:57:27 that every time I have engaged in a process
22 04:57:32 like this, and I -- to help you understand
23 04:57:36 it, because I want to make sure you really
24 04:57:39 comprehend it, given the importance of this,

1 04:57:42 from my perspective for how medical
2 04:57:44 knowledge is communicated, and specifically
3 04:57:47 with regard to Study 329, I follow the same
4 04:57:50 process with my own staff.
5 04:57:53 With my own staff, we have a meeting.
6 04:57:54 We look at the top-line results. We have a
7 04:57:57 conversation in depth.
8 04:57:59 If I'm going to be the first author,
9 04:58:01 it is what do I want the paper to basically
10 04:58:04 say; what do I believe the message to be;
11 04:58:06 what do I believe the findings are; roughly
12 04:58:09 what should be incorporated.
13 04:58:10 And then one of my staff goes ahead
14 04:58:13 and drafts and puts together a draft for me
15 04:58:17 to then review and work on.
16 04:58:18 So that same process is a process
17 04:58:20 that I have used for every paper on which I
18 04:58:26 have been the first author, and it's no
19 04:58:28 different here.
20 04:58:29 Q According --
21 04:58:31 A I cannot recall, Skip, I cannot recall the
22 04:58:37 nature of the conversations I've had with my
23 04:58:40 staff on the last five articles that I've
24 04:58:43 written that have occurred in the past

1 04:58:45 five -- few years.

2 04:58:46 Q Okay.

3 04:58:47 A But that's the process that I follow, and

4 04:58:49 there's nothing in here which is

5 04:58:50 inconsistent with that.

6 04:58:52 Q Okay.

7 04:58:52 Well, according to that contract, at

8 04:58:53 what draft does the draft get presented to

9 04:58:57 the author?

10 04:58:58 A I'm not a contract attorney, and I --

11 04:59:00 Q No.

12 04:59:00 What's it say?

13 04:59:02 A I already read what it says.

14 04:59:03 Q Right.

15 04:59:04 A But what I'm telling you is that what it

16 04:59:07 says in this contract, I've already -- I

17 04:59:10 think I've already answered the question,

18 04:59:12 but I'll repeat the answer.

19 04:59:17 What it says in here, which you asked

20 04:59:19 me to read, is that Draft 1 is the initial

21 04:59:21 draft that will be reviewed by the sponsor.

22 04:59:24 Q Okay.

23 04:59:25 Now, in this case, who --

24 04:59:26 A It didn't actually say, but let me be clear

1 04:59:28 with you.

2 04:59:29 It said Draft 1 is the initial draft

3 04:59:31 that will be reviewed by the sponsor.

4 04:59:33 Q Okay.

5 04:59:33 A It says nothing about the -- the input that

6 04:59:39 will occur between the author and the writer

7 04:59:44 or the person who is actually typing out

8 04:59:47 that draft.

9 04:59:49 So...

10 04:59:52 Q Well, if Sally Laden were to testify that

11 04:59:54 she had no contact with you prior to the

12 04:59:55 first draft, you would disagree with that?

13 04:59:57 A Absolutely.

14 04:59:58 Q Okay.

15 05:00:00 Now, according to that contract,

16 05:00:01 though, when does the author get to see the

17 05:00:03 manuscript, which draft?

18 05:00:09 A Well, this contract does not say when the

19 05:00:18 author will initially get to see the first

20 05:00:22 draft.

21 05:00:24 It merely says Draft 2 will be sent

22 05:00:28 to the primary author. It doesn't say that

23 05:00:30 Draft 1 will not be sent to the primary

24 05:00:32 author.

1 05:00:33 Q Well, it says where Draft 1 gets sent,
2 05:00:37 though, right?
3 05:00:38 A No.
4 05:00:38 It says Draft 1 will be reviewed by
5 05:00:40 the sponsor.
6 05:00:42 Q Right.
7 05:00:43 And in this case, who's the sponsor?
8 05:00:45 A The sponsor is SmithKline. But it doesn't
9 05:00:48 say that Draft 1 will be sent to the sponsor
10 05:00:51 before it's sent to the author.
11 05:00:53 And I have to say, Skip, that the
12 05:00:54 reason that this is so important is that the
13 05:00:58 attention that it's been given to the media
14 05:01:00 and other places about, you know, the
15 05:01:02 conduct and the reporting of scientific
16 05:01:07 experiments has been extensive, as you know
17 05:01:09 as well as I do.
18 05:01:10 If you read The Wall Street Journal,
19 05:01:11 The New York Post, Science Magazine -- and
20 05:01:14 it's been particularly intense over this
21 05:01:16 past year and the past couple of months and
22 05:01:18 the past month, and I want to be crystal
23 05:01:26 clear that I, and I can't speak for other
24 05:01:28 people, but the process that I follow, and

1 05:01:30 I've followed for my entire career, is one
2 05:01:35 that is as I've described to you; and that
3 05:01:38 the language in here is interpretable and
4 05:01:41 totally consistent with how I've proceeded.
5 05:01:48 Q Let me ask you this:
6 05:01:49 How is the -- what number manuscript
7 05:01:51 is the one that you first recall receiving
8 05:01:52 from Sally Laden?
9 05:01:54 A The first one I received from her would be
10 05:01:57 the No. 1 one, the first one I received from
11 05:01:59 her.
12 05:01:59 Q Okay.
13 05:02:00 And you recall that?
14 05:02:00 A No.
15 05:02:01 What I'm saying is just by -- just by
16 05:02:03 deductive reasoning, the first one I
17 05:02:05 received from her is the first one I
18 05:02:07 received from her.
19 05:02:08 Q So you don't know if the -- well --
20 05:02:12 A Skip, I would have no way of knowing -- I
21 05:02:16 would have no way of knowing if Sally Laden
22 05:02:21 had written other drafts and never sent them
23 05:02:24 to me.
24 05:02:25 I have no way of knowing that.

1 05:02:26 Q Well, it would -- that has a draft number on
2 05:02:28 it, right?
3 05:02:29 A Draft numbers are meaningless.
4 05:02:31 Q Does that document that I showed you before
5 05:02:32 have a draft number on it?
6 05:02:33 Not that one but the other one.
7 05:02:35 A This?
8 05:02:36 Q It has Draft 3, correct?
9 05:02:37 A Right.
10 05:02:38 But this doesn't say that -- number
11 05:02:39 one, the fact that this says Draft No. 3
12 05:02:41 doesn't mean that I received -- did not
13 05:02:43 receive Draft No. 1.
14 05:02:45 There's nothing in here which
15 05:02:48 suggests in any way that this is the first
16 05:02:50 draft that I received.
17 05:02:51 Q Okay.
18 05:02:51 A Can you see me, my face here now? Okay.
19 05:02:55 There's nothing in here that suggests
20 05:02:57 in any way that this is the first draft I
21 05:03:02 received; and nor is there nothing that
22 05:03:04 suggests that I didn't have a major role in
23 05:03:06 shaping the content of the first draft that
24 05:03:08 was written.

1 05:03:09 Q Okay.

2 05:03:10 Let's take a look at the next

3 05:03:12 exhibit.

4 05:03:14 (Exhibit No. 23 marked for

5 05:03:14 identification.)

6 05:03:21 (Witness read document.)

7 05:03:47 THE WITNESS: I have viewed the

8 05:03:48 Exhibit 23.

9 05:03:48 BY MR. MURGATROYD:

10 05:03:49 Q Okay.

11 05:03:49 And can you identify for the record

12 05:03:50 what that exhibit is?

13 05:03:53 A It is a letter from me to Sally Laden.

14 05:03:55 Q Okay.

15 05:03:55 Does it appear to be authentic?

16 05:03:59 A Yes.

17 05:03:59 Q And did you prepare that in the ordinary

18 05:04:00 course of your business?

19 05:04:02 A Yes.

20 05:04:03 Q And can you please read into the record the

21 05:04:05 contents of that letter?

22 05:04:06 MR. DAVIS: Can I have the date of

23 05:04:07 the letter, please?

24 05:04:09 THE WITNESS: It's dated February 11,

1 05:04:10 1999.

2 05:04:14 A "Dear Sally" --

3 05:04:15 Do you want me to read the letter?

4 05:04:17 Q Yes, please.

5 05:04:17 A "You did a superb job with this. Thank you

6 05:04:20 very much. It is excellent. Enclosed are

7 05:04:23 rather minor changes for me, Neal and Mike

8 05:04:25 and a cover memo from me to all coauthors.

9 05:04:28 If it's agreeable to you, I would ask you to

10 05:04:30 take my cover memo and send the revisions

11 05:04:33 which incorporates the comments I am sending

12 05:04:35 you directly to all coauthors, even before I

13 05:04:38 see you again, so that they may review this

14 05:04:41 as quickly as possible. Please let me know

15 05:04:43 if you'd like to discuss or handle

16 05:04:44 differently. Thanks, Marty -- Marty. Cc:

17 05:04:46 Jim McCafferty."

18 05:04:49 And I would say to you, Skip, once --

19 05:04:51 MR. GREEN: You've done what he's

20 05:04:52 asked you to do. There's no question

21 05:04:54 pending.

22 05:04:55 THE WITNESS: Okay.

23 05:04:55 Q The question I have, was the process for

24 05:04:57 creating the manuscript for 329 such that

1 05:05:02 Sally Laden would send you a copy of the
2 05:05:06 manuscript which you and your coauthors
3 05:05:09 would then comment on, according to this
4 05:05:11 letter, and then send back to her, which
5 05:05:12 then she would incorporate into the
6 05:05:14 manuscript itself?
7 05:05:15 MR. DAVIS: Objection.
8 05:05:16 Q Is that the process you went through --
9 05:05:17 MR. DAVIS: Objection.
10 05:05:17 Q -- in creating the manuscript?
11 05:05:19 MR. DAVIS: Objection.
12 05:05:19 Asked and answered several times now.
13 05:05:21 MR. GREEN: You can answer.
14 05:05:26 Q Again, I'm just looking for the process.
15 05:05:29 What was the process of the creation
16 05:05:30 of the manuscript?
17 05:05:31 A Your statement of the process is not
18 05:05:33 necessarily correct.
19 05:05:35 Q Okay. That's what I'm trying to get to.
20 05:05:38 Was the process -- was the process
21 05:05:40 that --
22 05:05:41 Wasn't Sally Laden the holder of the
23 05:05:43 manuscript to which all the corrections came
24 05:05:45 to?

1 05:05:46 MR. DAVIS: Object to the form.

2 05:05:47 A Not necessarily.

3 05:05:49 Q Okay.

4 05:05:49 Did you have a copy where you

5 05:05:51 actually changed the hard -- the computer

6 05:05:56 copy, or did you handwrite your changes?

7 05:06:03 A Well, in case you ever have the opportunity

8 05:06:05 to correspond with me in handwriting, you

9 05:06:07 would know that that would be a highly

10 05:06:08 ineffective means of communications since

11 05:06:10 neither you nor I would ever be able to read

12 05:06:14 what I wrote.

13 05:06:14 However, sometimes I handwrote;

14 05:06:15 sometimes I typed. But what was -- what the

15 05:06:18 process was, and you stated this

16 05:06:22 incorrectly, but I actually state it in

17 05:06:27 here, is --

18 05:06:27 Let me read to you from Exhibit 23,

19 05:06:29 the first sentence.

20 05:06:31 Q Okay.

21 05:06:31 A And then explain it. The first sentence of

22 05:06:33 the second paragraph:

23 05:06:34 "Enclosed are changes from me, Neal

24 05:06:37 and Mike and a cover memo to all coauthors."

1 05:06:40 Okay. What's pretty clear from what
2 05:06:43 I stated is that I received changes from
3 05:06:49 Neal and Mike in this instance. I had my
4 05:06:54 own changes.
5 05:06:56 I -- though it doesn't say it, but
6 05:06:59 it's clearly by inference, I then decided
7 05:07:02 which of the changes I received I wanted to
8 05:07:05 then pass on to her, and I passed them on to
9 05:07:08 her.
10 05:07:09 That's different than what you said,
11 05:07:10 because you made it appear as though, you
12 05:07:12 know, any change that anyone made went to
13 05:07:15 Sally Laden.
14 05:07:16 Q No, no, through you. That's what I meant to
15 05:07:19 say?
16 05:07:19 A Yes.
17 05:07:20 Q Yes.
18 05:07:20 A But in this case, I cannot tell you whether
19 05:07:23 I typed it or I handwrote it.
20 05:07:28 Q Well, do you have the drafts of the
21 05:07:32 manuscript still in your possession, to your
22 05:07:35 knowledge?
23 05:07:35 A No.
24 05:07:36 Any -- anything -- I believe that I

1 05:07:38 was asked to produce all documents that I
2 05:07:43 had, and --
3 05:07:46 MR. GREEN: I think what you'll see,
4 05:07:47 I -- to answer the question, since I've been
5 05:07:49 through the documents, I don't recall that
6 05:07:51 there were drafts of this article, other
7 05:07:54 than discussions in some emails that I think
8 05:08:00 you got.
9 05:08:01 Where there is a draft that he had
10 05:08:03 worked on, there's a -- there's a -- the
11 05:08:06 materials that we discussed this morning
12 05:08:08 that were marked as confidential, he was
13 05:08:10 sent a draft --
14 05:08:12 MR. MURGATROYD: I saw them.
15 05:08:13 MR. GREEN: -- of an article, and
16 05:08:14 he -- he had happened to save a few pages.
17 05:08:14 We produced those.
18 05:08:16 MR. MURGATROYD: Correct.
19 05:08:21 MR. MURGATROYD: Right.
20 05:08:22 MR. GREEN: But there were no similar
21 05:08:23 pages in his papers relating specifically to
22 05:08:24 this.
23 05:08:26 THE WITNESS: If I can borrow two
24 05:08:27 pages of Jim's papers, which aren't part of

1 05:08:30 your files, I'll show you, is that a write
2 05:08:33 on something or type on it, send it off, rip
3 05:08:36 it up and discard it (gesturing).
4 05:08:40 It's pointless to save it.
5 05:08:42 BY MR. MURGATROYD:
6 05:08:42 Q Okay.
7 05:08:43 But we know in some cases you don't
8 05:08:45 do that, because I do have your handwritten
9 05:08:46 notes.
10 05:08:48 A Some cases I don't --
11 05:08:49 Q Right.
12 05:08:49 A -- but most cases I do, because I only have
13 05:08:51 a limited storage capacity.
14 05:08:52 Q Okay.
15 05:08:54 Now --
16 05:08:57 A We don't need to mark that exhibit unless
17 05:08:59 you want to.
18 05:08:59 Q No, we don't need to mark that exhibit.
19 05:09:01 That's --
20 05:09:01 A Okay.
21 05:09:02 Q We're going to give that to the trash can.
22 05:09:11 Let me go back to -- do you recall
23 05:09:15 that you and I guess --
24 05:09:21 Let me ask you this: Who -- who

1 05:09:22 decided what journal the manuscript would be
2 05:09:25 ultimately or originally sent to?
3 05:09:28 Who -- whose decision was that?
4 05:09:30 A Again, I can't recall the specifics of a
5 05:09:36 conversation for this article. But what I
6 05:09:40 always do when I chair research programs is
7 05:09:45 I have a conversation with the other lead
8 05:09:48 investigators.
9 05:09:50 Typically, the first author makes a
10 05:09:55 suggestion to -- suggests a couple of
11 05:09:57 journals that they'd like to send it to, or
12 05:10:00 sometimes if they're just totally fired up
13 05:10:04 and has one journal in mind, they'll say,
14 05:10:06 gee, I want to send this one to the Journal
15 05:10:08 of Obscure Results. And everyone says
16 05:10:11 fantastic. It's the most boring article
17 05:10:13 I've ever seen. Let's send it there. And
18 05:10:16 they go along with it.
19 05:10:17 But other times I say, well, look,
20 05:10:20 you know, is this something which is of
21 05:10:22 enough general interest that we'll send it
22 05:10:24 to JAMA, General Medical Journal, or do we
23 05:10:27 this it's a specialty psychiatry journal,
24 05:10:29 or -- and if we think it's specialty

1 05:10:31 psychiatry, should we go for a child journal
2 05:10:34 or should we go for, you know, an adult
3 05:10:34 journal, since there are many more adult
4 05:10:37 than child psychiatrists.

5 That -- that's the process -- you
6 05:10:40 know, it's any number of those things, Skip,
7 05:10:42 that could have gone; and I don't remember
8 05:10:44 how it would have gone with this one

9 Frankly, with this one, since the
10 05:10:47 other lead investigators are child
11 05:10:51 psychiatrists, I am sure I solicited their
12 05:10:54 input, you know, before --

13 You know, before I said, Here's my
14 05:10:57 one, two, three, four choice, what do you
15 05:10:59 think, I'm sure I solicited people's input.

16 05:11:02 Q Did -- do you recall which journal you
17 05:11:05 originally submitted the manuscript to?

18 05:11:07 A No.

19 05:11:07 Q Okay.

20 Do you recall that the original
21 05:11:10 submission was rejected?

22 05:11:11 A No.

23 05:11:12 Q Okay.

24 You don't recall -- did -- well, were

1 05:11:14 you ever presented with -- am I correct in
2 05:11:18 stating that when an article is submitted to
3 05:11:21 a publication, a peer-reviewed publication,
4 05:11:24 it goes out for review typically?
5 05:11:27 A Sometimes.
6 05:11:28 Sometimes the editor -- and I edit
7 05:11:32 journals -- looks at it and doesn't bother
8 05:11:34 to send it to peer review for any number of
9 05:11:37 reasons.
10 05:11:37 Q Okay.
11 05:11:38 A Sometimes they don't send it out
12 05:11:39 because they -- they don't -- it's not based
13 05:11:41 on the quality of the journal. They just
14 05:11:43 don't feel -- the quality of the -- of the
15 05:11:45 manuscript, but rather they don't think it's
16 05:11:48 appropriate for their journal.
17 05:11:49 Q Okay.
18 05:11:50 Well, let me ask you this: Did -- do
19 05:11:52 you recall seeing the reviews of your
20 05:11:56 journal article from JAMA?
21 05:12:00 A I don't recall seeing it.
22 05:12:01 Q Okay.
23 05:12:02 A But --
24 05:12:02 Q Do you recall seeing any reviews, maybe

1 05:12:05 that's an easier question, from any
2 05:12:07 submissions to peer-reviewed journals?
3 05:12:09 A For this article?
4 05:12:10 Q Yes, for this article.
5 05:12:12 A Well, like the other questions I've asked
6 05:12:14 you -- I'm not trying to be evasive.
7 05:12:20 Whenever you submit an article, you,
8 05:12:26 at the very least, get back a letter from
9 05:12:28 the editor which says, you know, this is not
10 05:12:32 going out to review or it's gone out to
11 05:12:35 review and you'll be hearing from the
12 05:12:37 reviewer, you know, whatever, in due course.
13 05:12:43 And then if it's been sent out to
14 05:12:45 review, the journal editor will send you a
15 05:12:47 cover letter with the actual reviews.
16 05:12:52 So it's unimaginable to me that I did
17 05:12:55 not get at the very least a cover letter
18 05:12:59 saying it wasn't going to be reviewed, or I
19 05:13:02 got the reviews from it.
20 05:13:04 I am -- I can't re -- I have no
21 05:13:07 memory of it.
22 05:13:09 Q Okay.
23 05:13:10 A But for that process not to have happened
24 05:13:12 would just be an -- I wouldn't accept -- it

1 05:13:16 would be such an aberration I would be on
2 05:13:18 the phone to the journal editor saying what
3 05:13:20 in the world is going on?
4 05:13:22 So I'm sure I received it, but I have
5 05:13:24 no memory of it.
6 05:13:24 Q Okay. That's fine.
7 05:13:26 Well, you know that -- I think
8 05:13:28 Mr. Coffin is going to cover that with you
9 05:13:31 tomorrow, but --
10 05:13:35 MR. MURGATROYD: Are we running out
11 05:13:36 of time again?
12 05:13:37 THE VIDEOGRAPHER: No, we're fine.
13 05:13:38 We have another half an hour.
14 05:13:40 Q Ultimately, the journal -- the -- your
15 05:13:42 article was accepted for publication, and it
16 05:13:45 was published, correct?
17 05:13:46 A I remember that.
18 05:13:47 Q Okay.
19 05:13:48 A Correct.
20 05:13:48 Q And do you recall which journal accepted
21 05:13:49 your article for publication?
22 05:13:52 A The premier journal of child and adolescent
23 05:13:56 psychiatry, which is called the -- I believe
24 05:14:03 the Journal of the American Association of

1 05:14:05 Child and Adolescent Psychiatry, JAACAP.
2 05:14:09 Q Is it "association" or "academy"?
3 05:14:11 (Laughter.)
4 05:14:11 A That's why I said "I believe." I think you
5 05:14:13 probably know the answer, Skip.
6 05:14:14 Q Well, you may want to look at the article.
7 05:14:17 A Well, how important is it? I mean, where is
8 05:14:19 it?
9 05:14:19 Q We might as well get it straight what the
10 05:14:21 journal is.
11 05:14:22 A We've already done this three times.
12 05:14:24 Please.
13 05:14:26 The Journal of the American Academy
14 05:14:27 of Child and Adolescent Psychiatry.
15 05:14:32 Q Okay.
16 05:14:33 And do you recall whether that was
17 05:14:34 published?
18 05:14:36 A No, but I'll check.
19 05:14:37 Q Okay.
20 05:14:38 A According to Exhibit 13, it was published on
21 05:14:43 July -- in July of 2001.
22 05:14:45 Q Okay.
23 05:14:46 So it's about four years after the --
24 05:14:48 the study was completed, correct?

1 05:14:57 A I don't remember when the study was
2 05:14:58 completed.
3 05:14:58 Q Okay.
4 05:14:59 Do you remember the meeting in
5 05:15:00 November of 1997, right?
6 05:15:02 A It was at least -- it was at least three and
7 05:15:07 a half years after that meeting.
8 05:15:11 Q Okay.
9 05:15:11 And you said that when you write
10 05:15:16 articles, that it's your -- that you have a
11 05:15:17 purpose or you have a stated intention or
12 05:15:19 that you have a message that you want to get
13 05:15:21 across in your articles; is that correct?
14 05:15:24 A Yes.
15 05:15:24 Q And is that true for Study 329?
16 05:15:26 A Yes.
17 05:15:26 Q And what was the -- what was your intention
18 05:15:31 or your message that you wanted to get
19 05:15:33 across with regard to Study 329?
20 05:15:35 A As stated.
21 05:15:36 Q Okay.
22 05:15:38 Is that stated in the conclusion in
23 05:15:39 the abstract?
24 05:15:41 A It should be in the abstract.

1 05:15:44 (Witness read document.)

2 05:15:50 A The conclusion, which would be the message,

3 05:15:53 is paroxetine is generally well tolerated

4 05:15:59 and effective for major depression in

5 05:16:02 adolescents, which I believe to be

6 05:16:05 absolutely accurate.

7 05:16:07 Generally well tolerated and

8 05:16:11 generally effective.

9 05:16:14 Q In the treatment of adolescent depression?

10 05:16:20 A No. Generally effective for major

11 05:16:23 depression in adolescents.

12 05:16:31 Q So your study only looked at -- 329 only

13 05:16:33 looked at what's called MDD, Major

14 05:16:35 Depressive Disorder?

15 05:16:38 A Yes.

16 05:16:38 Q Okay.

17 05:16:38 And -- and you believe that your

18 05:16:40 studies showed that paroxetine or Paxil is

19 05:16:43 effective for treating kids with Major

20 05:16:46 Depressive Disorder?

21 05:16:47 A Is generally effective.

22 05:16:48 Q Okay. Generally effective.

23 05:16:55 And do you agree that GSK disagrees

24 05:16:57 with that statement, meaning

1 05:16:58 GlaxoSmithKline?

2 05:16:58 A I have no idea --

3 05:17:00 MR. DAVIS: Object to the form of the

4 05:17:01 question.

5 05:17:01 Mischaracterizes GSK's position.

6 05:17:03 A I have no idea what their position is.

7 05:17:06 Q Have you -- you haven't seen --

8 05:17:08 Are you aware -- we talked about

9 05:17:09 Dr. Wheaton earlier, remember, Jim

10 05:17:12 McCafferty's boss?

11 05:17:13 A Yes.

12 05:17:13 Q Okay.

13 05:17:14 Are you aware that he testified

14 05:17:15 before Congress?

15 05:17:16 A No.

16 05:17:18 Q Okay.

17 05:17:19 Were you aware that Congress looked

18 05:17:21 into the issue of GSK presenting incomplete

19 05:17:25 or misinformation regarding the use of Paxil

20 05:17:29 in adolescents and children?

21 05:17:34 A Not -- not specifically. I mean, I know --

22 05:17:37 I don't --

23 05:17:37 I don't specifically know what

24 05:17:42 Congress looked into with regard to GSK,

1 05:17:51 Paxil in children. I don't -- in fact,
2 05:17:52 I'm -- no.
3 05:17:53 Q You're aware that they -- Congress did look
4 05:17:56 into it, though; is that correct?
5 05:17:58 Have you heard that?
6 05:18:08 A It's entirely possible that I saw emails or
7 05:18:13 reports in the newspapers describing
8 05:18:16 Congress's interest.
9 05:18:17 I can't specifically recall seeing
10 05:18:21 that.
11 05:18:21 Q Okay.
12 05:18:22 A I'm not saying that I didn't.
13 05:18:23 Q Okay.
14 05:18:23 A But I don't -- it's not like I can tell you
15 05:18:26 that, yes, on, you know, September --
16 05:18:29 between September and December of 2004 I
17 05:18:32 read an article in The New York Times or I
18 05:18:36 got an email from some watchdog agency that
19 05:18:41 Congress was investigating.
20 05:18:44 I have no memory of that, but I'm not
21 05:18:46 saying that I didn't see it.
22 05:18:47 Q Okay.
23 05:18:47 Well, if GSK were to say that Paxil
24 05:18:49 is not effective for the use in kids, that

1 05:18:52 would be a statement inconsistent with the
2 05:18:54 message you have in your journal article,
3 05:18:55 correct?
4 05:18:55 MR. DAVIS: Objection to the form.
5 05:18:56 Mischaracterizes the record.
6 05:18:58 A Yes. Actually, your statement was
7 05:18:59 incomplete and doesn't address this article.
8 05:19:01 Your statement was, and perhaps the
9 05:19:04 court can read it back --
10 05:19:05 THE WITNESS: Would you mind reading
11 05:19:06 back Skip's statement?
12 05:19:07 (Record read as requested.)
13 05:19:22 A Okay. Stop right there.
14 05:19:23 Skip's statement was "not effective
15 05:19:24 for the use in kids." You didn't specify
16 05:19:26 for the use of what in kids.
17 05:19:28 You could have meant for the use of
18 05:19:29 having kids become better baseball players.
19 05:19:32 Q Okay.
20 05:19:32 For the treatment of depression.
21 05:19:37 A Treatment of -- still that's still too
22 05:19:38 vague.
23 05:19:38 Q All right. Well, let me make it more exact.
24 05:19:40 If GSK has stated publicly that Paxil

1 05:19:43 is ineffective for the treatment of
2 05:19:46 depression of children and adolescents, that
3 05:19:51 statement would be inconsistent with the
4 05:19:52 message that you wanted to get across in the
5 05:19:54 journal article that's before you, correct?
6 05:19:57 MR. DAVIS: Object to the form.
7 05:19:58 Mischaracterizes the record.
8 05:20:02 MR. GREEN: You can answer.
9 05:20:06 A Skip, would you just mind saying that again?
10 05:20:08 Q Sure.
11 05:20:09 Want me to --
12 05:20:10 A You can say it the same way.
13 05:20:11 Q You want me to say it again?
14 05:20:12 A Yes, just say it again.
15 05:20:14 Q Yes, that's fine.
16 05:20:16 If GSK has stated publicly that Paxil
17 05:20:18 was ineffective for the treatment of
18 05:20:22 depression in children and adolescents, that
19 05:20:24 statement would be inconsistent with the
20 05:20:26 message that you have put forth in the
21 05:20:28 article that is in your hand right there,
22 05:20:29 correct?
23 05:20:31 MR. DAVIS: Object to the form of the
24 05:20:32 question.

1 05:20:32 It's vague and ambiguous as to time,
2 05:20:34 scope, and also mischaracterizes the record.
3 05:20:36 Q You can answer.
4 05:20:37 A Okay.
5 05:20:37 So the answer is yes. The but --
6 05:20:42 MR. GREEN: No but. That's -- yes.
7 05:20:43 A Yes.
8 05:20:44 Q Okay.
9 05:20:44 Now, have -- I don't know if -- has
10 05:20:48 GSK shown you the various documents where
11 05:20:51 they state that the pediatric trials of
12 05:20:59 Paxil for the treatment of depression in
13 05:21:00 kids failed to show efficacy?
14 05:21:03 MR. DAVIS: Object to the form of the
15 05:21:03 question.
16 05:21:05 Q Have you seen those?
17 05:21:06 A No.
18 05:21:10 Q Have you seen the documents where GSK says
19 05:21:14 that the trials involving Paxil in children
20 05:21:20 and adolescents showed a definite risk of
21 05:21:23 increased suicidality?
22 05:21:26 MR. DAVIS: Object to the form.
23 05:21:27 Mischaracterizes the record.
24 05:21:29 A No.

1 05:21:31 Q If, in fact --
2 05:21:32 A Let --
3 05:21:33 Q Let me just ask the question.
4 05:21:34 A Okay, because I was --
5 05:21:35 Q If, in fact, Paxil does definitely cause an
6 05:21:38 increased risk of suicidality in kids who
7 05:21:42 take Paxil, would you agree that the drug is
8 05:21:43 not safe?
9 05:21:44 MR. DAVIS: Object to the form of the
10 05:21:45 question.
11 05:21:46 It's vague and ambiguous. No
12 05:21:48 foundation has been laid either for the
13 05:21:52 question.
14 05:21:55 A Well, I don't -- I don't know what -- what
15 05:22:00 it is appropriate for me to say with these
16 05:22:02 various objections.
17 05:22:03 Q You can answer the question.
18 05:22:04 MR. GREEN: You can answer.
19 05:22:05 Q His objections make no difference. You can
20 05:22:08 answer the question.
21 05:22:09 A They make a difference to him.
22 05:22:10 So --
23 05:22:11 MR. DAVIS: My objection is for
24 05:22:12 purposes of you if you want to correct your

1 05:22:14 question, because it's an inappropriate
2 05:22:15 question because it assumes certain things
3 05:22:17 that are not in the record of this case, nor
4 05:22:19 will they ever be.
5 But so it's to put you on notice that
6 05:22:22 you can fix your question.
7 MR. MURGATROYD: Oh, okay. Well,
8 05:22:24 here, let's -- we're going to take a --
9 What time is it now?
10 05:22:27 MR. GREEN: It's almost 5:30. I
11 05:22:29 suggest we break for the day.
12 MR. MURGATROYD: After -- let me get
13 05:22:30 one thing. I just want to lay the
14 05:22:30 foundation for what the discussion is.
15 It will take me two seconds.
16 THE VIDEOGRAPHER: Would you like to
17 05:22:36 go off the record?
18 MR. MURGATROYD: Yes, just for a
19 05:22:37 second.
20 THE VIDEOGRAPHER: The time is 5:24.
21 05:22:41 We'll go off the record.
22 (Recess.)
23 05:22:43 (Discussion off the record.)
24 05:22:49 (Exhibit No. 24 marked for

1 05:22:49 identification.)

2 05:25:14 MR. MURGATROYD: Why don't you take a

3 05:25:16 look at the last exhibit for the day so we

4 05:25:18 can wrap up.

5 05:25:20 (Witness read document.)

6 05:26:07 MR. DAVIS: I think you've got to

7 05:26:08 make a foundation for this document under

8 05:26:10 the terms of the protective order before you

9 05:26:12 can show it to Dr. Keller.

10 05:26:14 MR. MURGATROYD: No, I don't.

11 05:26:15 MR. DAVIS: Yes, you do.

12 05:26:16 MR. MURGATROYD: No, I don't. I've

13 05:26:16 already shown it to him. I'm going to put

14 05:26:16 it in the record.

15 05:26:18 MR. DAVIS: No, no.

16 05:26:19 In fairness, in fairness, Judge

17 05:26:20 Savage -- the discussions with Judge Savage

18 05:26:24 that resulted in revisions to the protective

19 05:26:26 order in Blain require certain foundations

20 05:26:29 to be established with the witness before

21 05:26:34 confidential documents can be shown to him.

22 05:26:36 This is --

23 05:26:36 MR. MURGATROYD: I believe I've

24 05:26:37 already established the foundation.

1 05:26:38 MR. DAVIS: No, you haven't. No.
2 05:26:39 You have to establish that he's -- no.
3 05:26:41 Excuse me. I'm objecting.
4 05:26:43 MR. MURGATROYD: I'm going to give it
5 05:26:43 to him to read.
6 05:26:45 MR. DAVIS: I'm objecting.
7 05:26:46 MR. MURGATROYD: Okay, fine.
8 05:26:48 THE WITNESS: I'm going wait until
9 05:26:48 you guys fight it out.
10 05:26:50 MR. DAVIS: You have to establish a
11 05:26:51 foundation.
12 05:26:52 MR. MURGATROYD: I did establish
13 05:26:52 foundation.
14 05:26:53 MR. DAVIS: You have not established
15 05:26:54 a foundation.
16 05:26:54 MR. MURGATROYD: I asked him whether
17 05:26:56 or not he was aware that GSK had said the
18 05:26:58 drug does not work for major depressive
19 05:26:59 disorder in kids, and I asked him whether or
20 05:27:01 not the -- there is a definition risk of
21 05:27:05 suicidality in that age group who are
22 05:27:09 treated with Paxil.
23 05:27:10 There's the foundation.
24 05:27:11 MR. DAVIS: No, it's not.

1 05:27:11 Under the terms of the protective
2 05:27:13 order, you've actually removed him from
3 05:27:15 being able to answer questions about that
4 05:27:16 document, because he doesn't know anything
5 05:27:17 about it.
6 05:27:18 And under the terms of the protective
7 05:27:20 order, you've got to establish that he's got
8 05:27:22 firsthand knowledge of information that's
9 05:27:25 reflected in the documents. He doesn't.
10 05:27:26 He's not copied on it.
11 05:27:27 You've yet to show that he was --
12 05:27:29 either received a correspondence or was sent
13 05:27:32 the correspondence. He's not on that
14 05:27:35 document, and so you have not established a
15 05:27:38 foundation.
16 05:27:38 That -- that relates to an internal
17 05:27:40 discussion at GlaxoSmithKline concerning
18 05:27:43 deliberations with the global safety board,
19 05:27:48 and that discussion Dr. Keller wasn't a part
20 05:27:52 of, didn't have anything to do with.
21 05:27:54 And nowhere does that article or that
22 05:27:55 document say anything about Study 329. It
23 05:27:58 doesn't.
24 05:27:58 MR. MURGATROYD: That's -- that --

1 05:28:00 Todd, I understand what you're saying, but I
2 05:28:02 think that foundation will be established
3 05:28:03 through the course of this deposition, that
4 05:28:04 he was sent documents from GSK asking about
5 05:28:08 the suicidality risk related to Paxil, which
6 05:28:11 we're going to get into tomorrow.

7 You asked me about the -- the
8 05:28:14 foundation for the question I asked him.
9 05:28:17 This document lays a foundation. This is
10 05:28:18 the document I'm going to show him, and you
11 05:28:20 can object. That's fine. It's duly noted.

12 05:28:22 MR. DAVIS: No, no, I'm --

13 05:28:24 MR. MURGATROYD: Let me show you --

14 05:28:26 MR. DAVIS: We should break for the
15 05:28:27 day and get this ironed out, because we're
16 05:28:29 not going to get it ironed out.

17 MR. MURGATROYD: No, I want to ask
18 05:28:31 the question I started with.

19 THE VIDEOGRAPHER: Would you like to
20 05:28:33 go back on the record?

21 05:28:34 MR. MURGATROYD: Yes, I want to
22 05:28:35 finish the question I started with.

23 05:28:36 MR. DAVIS: You're violating the
24 05:28:37 terms of the protective order in Blain that

1 05:28:39 was agreed to by our office and your office.
2 05:28:43 MR. MURGATROYD: I disagree.
3 05:28:45 THE VIDEOGRAPHER: I'm not on the
4 05:28:45 record yet.
5 05:28:46 MR. MURGATROYD: That's fine. Go
6 05:28:46 ahead.
7 05:28:47 MR. GREEN: Is there some judge who
8 05:28:48 can be called to resolve this? Because I've
9 05:28:50 gotten into situations like this where I've
10 05:28:52 sat and listened to two attorneys yell at
11 05:28:55 each other about what something means, and
12 05:28:58 we've had to go to a magistrate.
13 05:28:59 I mean, I --
14 05:29:01 MR. MURGATROYD: There's no --
15 05:29:01 There's no judge that we can call right now.
16 05:29:03 MR. GREEN: Okay.
17 05:29:04 THE WITNESS: Well, let me say this,
18 05:29:06 just because it's late.
19 05:29:07 It's 5:30, which is when we agreed to
20 05:29:10 stop, so I -- I need to stop, and then
21 05:29:14 hopefully when we -- I would implore you
22 05:29:18 guys, since I'm being as cooperative and as
23 05:29:24 civic-minded as I can, I'd implore you that
24 05:29:26 when we start tomorrow at 9:15 a.m., you

1 05:29:31 will have worked it out, and I can then
2 05:29:34 answer it.
3 05:29:35 MR. MURGATROYD: That's fine.
4 05:29:37 THE WITNESS: That's all I'm asking
5 05:29:39 out of just respect and dignity for time.
6 05:29:41 MR. MURGATROYD: That's fine. Why
7 05:29:41 don't we do this. I need you to -- is there
8 05:29:44 any way you can print out anything and fax
9 05:29:46 it to me tonight?
10 05:29:47 I just want to know what his
11 05:29:48 statement was.
12 05:29:49 MR. DAVIS: I'll give you a copy --
13 05:29:51 THE WITNESS: Guys, one second. One
14 05:29:52 second. If you don't need me anymore --
15 05:29:55 MR. MURGATROYD: We'll let you guys
16 05:29:56 go, absolutely. Thank you.
17 05:29:57 THE WITNESS: And as far as tomorrow,
18 05:29:58 I would just like to establish this as a
19 05:30:00 ground rule.
20 05:30:02 If -- if we can finish -- if we're
21 05:30:05 going to finish tomorrow --
22 05:30:07 MR. MURGATROYD: We are going to try.
23 05:30:08 THE WITNESS: Okay. Then I'm willing
24 05:30:10 to work late.

1 05:30:11 MR. MURGATROYD: Okay.

2 05:30:12 THE WITNESS: But if we're not going

3 05:30:13 to finish tomorrow, I mean, I'm not -- I

4 05:30:15 don't want to get --

5 05:30:16 I'm not going to get into arguments

6 05:30:19 with what's right or wrong.

7 05:30:20 MR. MURGATROYD: Yes.

8 05:30:21 THE WITNESS: All I'm saying is as a

9 05:30:22 descriptive matter, if we're not going to

10 05:30:24 finish tomorrow -- this is my first day back

11 05:30:25 after being off for three weeks -- then I

12 05:30:28 really want to stop at 4:00.

13 05:30:30 MR. MURGATROYD: That's fine.

14 05:30:31 THE WITNESS: Because if we have to

15 05:30:32 come -- you know what I'm saying? If we

16 05:30:34 have to come back --

17 05:30:36 MR. GREEN: Because he has to fly out

18 05:30:37 the next day to go to a conference.

19 05:30:38 MR. MURGATROYD: That's fine. I

20 05:30:39 agree. Absolutely fine.

21 05:30:40 THE WITNESS: Is that fair?

22 05:30:42 MR. MURGATROYD: Yes.

23 05:30:42 MR. GREEN: There is also on the

24 05:30:43 table an offer the doctor to have this

1 05:30:46 tomorrow in his conference room at Butler,
2 05:30:49 which has air conditioning.
3 05:30:50 And I would -- I personally would
4 05:30:54 strongly suggest that we take him up on his
5 05:30:56 offer.
6 05:30:56 MR. DAVIS: That's agreeable.
7 05:30:57 MR. MURGATROYD: The only problem I
8 05:30:58 have is I need to have documents copied. I
9 05:31:00 need to have documents Xeroxed -- I mean
10 05:31:02 printed out off computers.
11 05:31:04 I mean, I need to have that facility.
12 05:31:07 I mean I need to hook into a printer.
13 05:31:10 THE WITNESS: My staff is really
14 05:31:11 good. In other words, my staff would be
15 05:31:12 willing to copy things.
16 05:31:13 What else do you need?
17 05:31:14 MR. MURGATROYD: I need to have
18 05:31:15 access to a printer. Like this document I
19 05:31:17 have to print off --
20 05:31:20 THE WITNESS: We have a printer.
21 05:31:21 MR. MURGATROYD: No, let's have it
22 05:31:22 here. What I'll do is I'll try have Bob air
23 05:31:24 condition it down and get it cool.
24 05:31:25 MR. DAVIS: I'll tell you, it's

1 05:31:26 really uncomfortable. The doctor has had to
2 05:31:28 loosen his tie. He's had to roll up his
3 05:31:31 sleeves. It's hot.
4 05:31:32 MR. MURGATROYD: I just said I'm
5 05:31:34 going try to get a cooler.
6 05:31:35 MR. DAVIS: Why don't we just do it
7 05:31:37 over there?
8 05:31:37 MR. MURGATROYD: Because I need the
9 05:31:38 facility. I need the -- this doesn't have
10 05:31:41 to be on the record.
11 05:31:43 (Discussion off the record.)
12 05:32:20 (Proceedings adjourned at 5:32 p.m.)
13 05:32:22

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I N D E X

WITNESS:

MARTIN B. KELLER, M.D.

Examination by Mr. Murgatroyd 7

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