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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FILE NO.: A00466C

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

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

APPEARANCES:

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on behalf of the deponent

Also present: Tamar Halpern, Esq., Phillips Lytle

Videographer: Shawn Budd

PROCEEDINGS 10:15:39

THE VIDEOGRAPHER: We are on the 10:21:16
record. This is the video operator 10:21:17
speaking, Shawn Budd. 10:21:18
Today's date is September 6, 2006, 10:21:20
and the time is 10:21. We are here at the 10:21:23
offices of Robert S. Bruzzi, located in 10:21:28
Providence, Rhode Island, to take the 10:21:33
videotaped deposition of Dr. Martin B. 10:21:36
Keller in the matter of Leigh Ann Engh, et 10:21:38
al.; and Beverly -- Leigh Ann Engh, et al. 10:21:43
v. SmithKlein Beecham Corporation and 10:21:47
Beverly Smith, et al. v. SmithKline Beecham 10:21:50
Corporation d/b/a GlaxoSmithKline; and 10:21:53
Pamela Blain, et al. v. SmithKline Beecham 10:21:58
Corporation d/b/a GlaxoSmithKline. 10:22:02
Would counsel please introduce 10:22:06
themselves. 10:22:07
MR. MURGATROYD: My name is Skip 10:22:07
Murgatroyd, and I represent the plaintiffs 10:22:09
in the Blain and the Smith cases. 10:22:10
MR. COFFIN: My name is Chris Coffin. 10:22:12
I represent the plaintiffs in the Engh case. 10:22:13
MS. MENZIES: Karen Menzies. I 10:22:16

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

MR. MURGATROYD: Yes? 10:22:53
MR. DAVIS: -- let's try to get some 10:22:54
housekeeping issues out of the way. 10:22:55
MR. MURGATROYD: Sure. 10:22:57
MR. DAVIS: This deposition is being 10:22:57
taken in a number of cases in which you are 10:22:58
counsel representing the plaintiffs, and we 10:23:01
have had some discussions prior that in 10:23:05
terms of arranging for the deposition, that 10:23:07
we -- we'd get this done in two days. 10:23:11
I mean, that was my understanding 10:23:13
when we had those discussions. And I've got 10:23:15
to leave tomorrow by 4:45, 5:00, and I 10:23:20
believe I should be allowed to question 10:23:24
Dr. Keller, one -- 10:23:26
Number one, that we should be able to 10:23:28
complete the deposition in that time frame. 10:23:29
You all can finish your questions of 10:23:31
Dr. Keller in that time frame, and that I 10:23:33
should be allowed several hours to question 10:23:35
him about GSK's defenses and other issues 10:23:38
that have come up that you ask him questions 10:23:43
or your co-counsel ask him questions about. 10:23:44
And I think we should be able to 10:23:47

finish that in that amount of time, given the fact that the federal rules themselves, in which one of the cases being taken, Blain, requires -- allows for seven hours for depositions, absent agreement of the parties or stipulation or approval of the court. 10:24:04

Two days is a lot of time for you all to ask Dr. Keller questions you wish to ask him about, and I implore you to -- that we stick to those guidelines so we get this done and we are not coming back here again for a third or fourth day. Because at this stage, we're reserving our right not to agree to that and to petition the court for relief, because we think these issues can be adequately addressed where all counsel get a chance to ask Dr. Keller questions that they may have in this two-day time period.

And as I mentioned to you before the deposition, I would think, depending upon what you ask and what topics you and your co-counsel cover, my examination of Dr. Keller would last somewhere between nine

hours -- excuse me, 90 minutes and two and a half hours. That's give or take, based upon what you all are asking questions about.

So I'd ask that you and your colleagues organize your questions in such a way that allows for me to ask those questions of Dr. Keller before the completion of the deposition, and that we not cover the same groundwork or the same -- same areas once you hand -- if you hand off the questioning to either Mr. Coffin or Ms. Menzies, because I really think that's just not an efficient use of everyone's time. 10:25:19

MR. MURGATROYD: Well, I think you know from Jim McCaffrey's deposition two weeks ago that he took all of three days; and, to be honest with you, we cut out at least a half a day of questioning, and that was based on your representation to us you were going to take an hour and a half with his re -- or your cross, I guess. And that wasn't nearly enough time.

So McCaffrey's deposition should have

been a four-day deposition.

We will try to move things along quickly. I don't ask repetitive questions. Chris didn't ask a single repetitive question at Jim McCaffrey's deposition. So that's not something we do. We do use our time efficiently. 10:25:57

So I understand your situation. I can tell you right now, I just don't know how long it's going to take; and under California rules, these depositions continue from day to day will until completed.

MR. DAVIS: But it's also at the same time a matter of reasonableness. And with respect to Mr. McCaffrey's deposition, I disagree that the time was used efficiently. I disagree that repetitive questions were not asked. They were, both by yourself and by co-counsel, Mr. Coffin.

And if you -- if you think that there's not adequate time that you had with Mr. McCafferty, you have a -- you can petition the court and ask for relief, and we can address that at that time.

And so we're not here to dispute what or go into what happened at Mr. McCaffrey's -- I'm just saying Dr. Keller, two days is plenty of time to cover the ground -- the ground that needs to be covered with him.

MR. MURGATROYD: Well, we -- we shall see. Let's get started, and we'll see how we do. 10:26:47

BY MR. MURGATROYD:

Q Okay. Are you ready?

So why don't we have you state and spell your full name for the record.

A Martin B. Keller, M-A-R-T-I-N, capital B as in boy, Keller, K-E-L-L-E-R.

Q And what is your current address?

A 22 Kirkstall Road, Newton, Massachusetts 02460.

Q Okay.

And you're represented by counsel today, correct?

A Yes.

Q Okay.

And did you get -- have you ever been

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

out loud, okay? 10:27:58
A Yes. 10:28:00
MR. GREEN: Can I just interject? 10:28:00
Maybe I missed it, but did anyone 10:28:02
administer the oath? 10:28:05
MR. MURGATROYD: Yes. 10:28:06
MR. GREEN: Oh, I did miss it. Okay. 10:28:06
Good. 10:28:08
MR. MURGATROYD: That's fine. 10:28:08
Q It's important so we get a clean record that 10:28:09
you wait for me to completely ask a question 10:28:11
before you begin to answer. 10:28:13
Is that okay? 10:28:15
A Yes. 10:28:16
Q Okay. 10:28:16
Is there any reason why you can't 10:28:16
give your best testimony today? 10:28:19
A No. 10:28:21
Q Okay. 10:28:21
Now, where are you currently 10:28:21
employed? 10:28:28
A Brown University. 10:28:31
Q Okay. 10:28:32
And what's your position there? 10:28:32

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

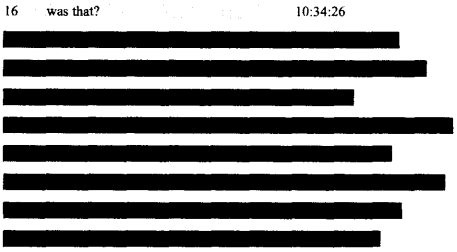
about $50 million of externally funded 10:29:50
research. 10:29:54
So it's my job to figure out ways to 10:29:55
stimulate the research and mentor -- have 10:30:01
faculty mentored and to get the best 10:30:04
trainees to come to Brown, potential 10:30:07
trainees, and then when they get here, to 10:30:10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

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

Q Okay. 10:31:46
It's known as Study 329? 10:31:47
A Correct. 10:31:51
Q Okay. 10:31:51
And in preparing for your deposition 10:31:52
today, did you review any documents that 10:31:55
related to that study? 10:31:57
A In a very cursory way. 10:32:05
Q Okay. 10:32:07
And why don't you tell me about that. 10:32:08
A I met twice fairly briefly with Mr. Green, 10:32:11
and he just reviewed with me some of the 10:32:17
types of questions that I might anticipate 10:32:24
having to do with the whole proceedings, 10:32:37
some of which had to do with that study; but 10:32:42
we didn't -- I didn't read the manuscript 10:32:45
from the study, didn't read things directly. 10:32:47
Just -- I don't actually think -- I 10:32:51
don't remember. I don't actually think I 10:32:54
read those. 10:32:56
Q Okay. 10:32:57
A I don't -- I don't remember. I don't 10:32:58
remember if I have -- if when Jim and I were 10:33:00
going over some things if I actually -- if 10:33:03

he -- if I actually took the article and 10:33:06
read paragraphs from it or not or just 10:33:10
talked about some of the things in it. 10:33:14
Q Okay. 10:33:15
Well, the question was, did you 10:33:16
review any documents? 10:33:17
A Yes. 10:33:18
Q Okay. 10:33:19
What documents did you review? 10:33:19
A I don't remember. 10:33:21
Q Did you -- well, I notice that -- actually, 10:33:22
why don't we sort this out. 10:33:25
MR. MURGATROYD: You produced -- I'm 10:33:27
talking to Mr. Green, so the record is 10:33:29
clear, documents on behalf of Mr. Keller, 10:33:30
correct? 10:33:32
MR. GREEN: That's correct. 10:33:33
MR. MURGATROYD: And I notice that 10:33:34
one had a confidential stamp on it. 10:33:34
Do you claim that some of the 10:33:36
documents that we requested are 10:33:37
confidential? 10:33:39
MR. GREEN: I had an understanding 10:33:42
with Robert Paiva, is it, with your 10:33:43

office -- 10:33:46
MR. MURGATROYD: Brava-Partain. 10:33:48
MR. GREEN: Yes. 10:33:51
The records in that folder are 10:33:51
apparently part of a project that GSK was 10:33:54
working on and were sent to him in 10:34:00
confidence. 10:34:04
And I had a discussion with an 10:34:05
attorney from your office about the fact 10:34:07
that in producing them, we would like them 10:34:09
to be subject to the confidentiality order 10:34:14
that had been agreed to by the parties in 10:34:19
that case, and he said that that would be 10:34:23
fine. 10:34:25
MR. MURGATROYD: And which project 10:34:26
was that? 10:34:26



MR. MURGATROYD: Okay. 10:34:48
And are there any documents that you 10:34:48
withheld under any other grounds of 10:34:50
confidentiality? 10:34:52
MR. GREEN: No. 10:34:54
MR. MURGATROYD: Okay. 10:34:55
Because there's one document that has 10:34:55
on it stamped "confidential." 10:34:57
Do you know what I'm talking about? 10:34:58
MR. DAVIS: I think there's a 10:34:59
whole -- I had a conversation with 10:35:00
Mr. Robert Brava-Partain as well. 10:35:02
He informed me that Dr. Keller's 10:35:04
counsel was producing documents that would 10:35:06
be subject to the protective order in this 10:35:09
case; and Mr. Robert Brava-Partain said that 10:35:10
he had no problem with that, that it was 10:35:15
fine, that plaintiffs would agree to that. 10:35:18
The documents at issue, I believe, 10:35:20
are more than one, and we believe after 10:35:21
having reviewed those documents, after 10:35:25
Dr. Keller's counsel produced them, they 10:35:27
are -- they should be subject to this -- the 10:35:30
protective order. 10:35:32

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

[redacted]

MR. MURGATROYD: Okay. That's fine. 10:36:01
MR. DAVIS: And just -- I know we're 10:36:03
doing housekeeping issues here, but the 10:36:04
federal judge in the Blain case -- 10:36:08
MR. MURGATROYD: Blain case, right. 10:36:13
MR. DAVIS: -- has recently entered 10:36:14
the parties' protective -- proposed 10:36:16
protective order. 10:36:17
And as part of that, the -- counsel 10:36:18
have an obligation to inform Dr. Keller and 10:36:21

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

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

claiming is confidential, or [redacted] 10:38:13

MR. MURGATROYD: Okay. 10:38:14

MR. GREEN: It was done by my office just to keep track of things. 10:38:14 10:38:16

MR. MURGATROYD: That's fine. We'll just put that one aside. Okay. 10:38:18 10:38:18

BY MR. MURGATROYD: 10:38:20

Q Now, are you aware that Dr. Wagner -- 10:38:21

Do you know Karen Wagner? 10:38:30

A Yes. 10:38:32

Q Are you aware that she's been deposed in this case? 10:38:33 10:38:34

A Yes. 10:38:35

Q Have you talked to her about that? 10:38:35

A No. 10:38:36

Q Have you read her deposition? 10:38:37

A No. 10:38:38

Q Okay. 10:38:38

Have -- when you were served with the subpoena in this case, did you contact counsel or anybody at GlaxoSmithKline? 10:38:40 10:38:43 10:38:47

A No. 10:38:49

Q Okay. 10:38:49

Have you talked to anybody at GlaxoSmithKline about this deposition? 10:38:50 10:38:51

A No. 10:38:52

Q Okay. 10:38:53

Are you aware that Dr. Neal Ryan will be deposed in the next few weeks in this case? 10:39:00 10:39:02 10:39:05

A No. 10:39:05

Q Okay. 10:39:06

I take it you haven't talked to him about -- about the Study 329 recently? 10:39:06 10:39:10

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

Q Okay. 10:39:18

How were you aware that Karen Wagner's deposition was taken? 10:39:21 10:39:23

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

Q Okay. 10:39:28

And were you shared any of the summaries of the -- summary of the deposition? 10:39:29 10:39:32 10:39:34

MR. GREEN: I'm going to object to asking him any questions about any 10:39:34 10:39:37

conversations we had. 10:39:39

MR. MURGATROYD: Oh, I don't want conversation. I'm just looking for documents. 10:39:39 10:39:41 10:39:42

Q I just want to know if you saw a summary of her deposition. 10:39:43 10:39:47

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

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

Do you do research in psychopharmacology? 10:40:01 10:40:02

A Yes. 10:40:04

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

A Has to do with pharmacologic agents that involve the psychological functioning of the mind. 10:40:10 10:40:13 10:40:18

Q And do you consider yourself an expert in psychopharmacology? 10:40:18 10:40:20

A I'm knowledgeable. 10:40:24

Q Okay. 10:40:25

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

MR. DAVIS: Object to the form. Asked and answered. 10:40:29 10:40:30

A I guess how do you define "expert"? I don't know if -- 10:40:46 10:40:50

Q Well, have you ever testified as an expert on that subject? 10:40:50 10:40:52

A No. 10:40:55

Q Okay. 10:40:55

So have you ever held yourself out to the public as an expert in the subject of psychopharmacology? 10:40:55 10:40:59 10:41:01

MR. DAVIS: Object to the form. It's vague and ambiguous, still not defined. 10:41:03 10:41:04

A I'm trying to be straightforward. I just don't want to overgrandize how knowledgeable I'm considered to be. 10:41:08 10:41:11 10:41:14

I know a lot about it. An awful lot of people know an awful lot more than I do, so I'm -- 10:41:15 10:41:17 10:41:20

Q Okay. 10:41:21

Have you written any books about it? 10:41:21

A No. 10:41:22

Q Have you written any medical review articles, articles that were peer-reviewed on the subject of psychopharmacology? 10:41:23 10:41:25 10:41:27

A I've written manuscripts and have been the first author on research studies that report the results of studies of pharmacology, 10:41:34 10:41:38 10:41:40

psychopharmacology. 10:41:44
I have not written think pieces or 10:41:45
review articles that -- in which I opine 10:41:50
about the field. 10:41:52
Q Okay. 10:41:54
Do you consider yourself an expert in 10:41:57
child psychiatry? 10:41:59
A Broadly speaking, no. 10:42:08
Q Okay. 10:42:10
Do you treat children currently? 10:42:11
A No. 10:42:13
Q Have you ever treated children in the past? 10:42:14
A Yes. 10:42:16
Q Okay. 10:42:18
Do you consider yourself an expert on 10:42:20
the drug effects on children -- 10:42:22
MR. DAVIS: Object to the form. 10:42:24
Q -- such as Paxil? 10:42:24
MR. DAVIS: Object to the form, 10:42:26
still -- it's vague and ambiguous, and it's 10:42:26
still undefined. 10:42:30
A I would answer it the same way I answered 10:42:31
your other series of questions about 10:42:33
expertise in psychopharm. 10:42:36

Q Okay. 10:42:41
Well, let me ask you this: Do you 10:42:41
treat people currently? 10:42:44
A Yes. 10:42:48
Q How many? 10:42:50
A Over what time period? 10:43:01
Q Currently, right now. 10:43:03
A Now I'm not treating any, at this moment. 10:43:06
Q I'm sorry. 10:43:09
A At this moment here, I'm not treating any -- 10:43:10
Q Obviously. 10:43:13
A Do you mean over the course of a week, a 10:43:13
month, a year? 10:43:15
Q Do you have current patients? 10:43:17
A Yes. 10:43:19
Q How many? 10:43:19
A Ten. 10:43:20
Q And is this a private practice or part of 10:43:22
your job at the university? 10:43:25
A Private practice. 10:43:28
Q Okay. 10:43:31
And where is your private practice? 10:43:31
A I see patients in one of two locations, an 10:43:35
office that I have in Newton, Massachusetts 10:43:41

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

give my opinion and then send that opinion 10:44:51
back to the person, as opposed to someone 10:44:55
being referred to me and saying, gee, could 10:44:58
you see this patient in consultation with 10:45:00
the possibility -- with me at the time being 10:45:03
the only physician. 10:45:06
So when you ask me the question, you 10:45:07
know, how many patients do I treat, it's -- 10:45:08
I know -- I know I'm trying to give you a 10:45:12
simple, straightforward answer; but it's 10:45:15
hard to know whether people like that are 10:45:18
people who you would want me to count in my 10:45:21
patient cohort or people -- that's my 10:45:24
question back to you. 10:45:27
Q Well -- 10:45:30
(Telephone interruption.) 10:45:32
Q Let me ask you -- you say that you do 10:45:52
consultations. 10:45:55
Do you -- do you treat them? I mean, 10:45:55
do you try to make them better or do you 10:45:57
just examine them? 10:46:00
A I examine them, and I make a recommendation 10:46:02
to them, depending upon who wants the 10:46:08
consultation. 10:46:14

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

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

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

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

Q Okay. 10:47:16

But the question is, do you actually treat them to make them better? Let me ask you that simple question. 10:47:16 10:47:18 10:47:21

Do you actually render treatment? 10:47:23

A It's not -- it's not a simple question. One could -- I could say that when they're in my presence, there's something about being with me, knowing that I'm carefully reviewing their record and questioning them that people find helpful and therapeutic. 10:47:24 10:47:26 10:47:29 10:47:30 10:47:32 10:47:34

Oftentimes people feel better just when I'm evaluating them. 10:47:37 10:47:39

Treatment per se, do I prescribe something for them and they take my prescription and come back and see me for that, that happens rarely as part of the consultation. 10:47:41 10:47:44 10:47:45 10:47:50 10:47:52

Q Well, how about psychoanalysis, do you do any forms of psychoanalysis? 10:47:53 10:47:55

A No. 10:47:57

Q Of the -- do you actually see someone and then prescribe a drug for them? 10:47:58 10:48:01

A Yes. 10:48:03

Q Okay. 10:48:04

And of the current ten patients that you see, are all those people on drugs? 10:48:04 10:48:06

A No. 10:48:08

Q Okay. 10:48:10

Have you prescribed drugs for all ten of those? 10:48:10 10:48:14

A I'm not sure. 10:48:23

Q Do you prescribe Paxil currently? 10:48:25

A Yes. 10:48:29

Q When was the last time you prescribed Paxil? 10:48:30

A Within the past six months, I had someone who's on Paxil. I gave a refill for them. 10:48:43 10:48:48

So this individual was taking Paxil on a daily basis, but the actual prescription by me only occurred once, because their prior prescription ran out. 10:48:54 10:48:58 10:49:02 10:49:04

Q Okay. 10:49:07

Well, actually, I wanted to get to new prescription Paxil. 10:49:07 10:49:09

When was the last time you prescribed Paxil as a new treatment for a patient? 10:49:10 10:49:12

A I can't remember. 10:49:19

Q Years? 10:49:19

A Within the past year or two. 10:49:27

Q Okay. 10:49:30

Has it been since the PDAC involving the issue of suicidality and its relationship to Paxil? 10:49:30 10:49:34 10:49:36

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

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

Q The 2004 PDAC that looked into the issue of suicidality caused by antidepressants. 10:49:43 10:49:45

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

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

Q Are you familiar with the FDA looking into the issue of antidepressants causing suicidality -- 10:49:52 10:49:55 10:49:57

A Yes. 10:49:59

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

Since that time, have you prescribed Paxil to a patient? 10:50:01 10:50:02

A Yes. 10:50:04

Q Okay. 10:50:05

At the time that you prescribed Paxil to a patient, did you provide them with any warnings that the drug could cause suicidality? 10:50:06 10:50:08 10:50:11 10:50:14

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

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

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

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

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

team. 10:55:54
What is research team? 10:55:54
A Okay. They're a group of -- a group of 10:56:02
somewhere between, you know, four and eight 10:56:06
people, people that I've worked with, had 10:56:08
worked with then for many years, doing child 10:56:12
and adolescent research studies. 10:56:17
And we got together, I can't tell you 10:56:19
the forum; I can't tell you the setting, and 10:56:24
I can't tell you when, but said it's about 10:56:27
time somebody does a study that's well 10:56:31
enough designed and well enough controlled 10:56:36
to test the efficacy of the treatment of 10:56:42
children -- of adolescents suffering from 10:56:44
depression with an antidepressant. 10:56:48
Because at the time that we had this 10:56:50
conversation, it was our judgment based on a 10:56:53
review of the literature that we did -- 10:56:56
which was part of kind of our common 10:56:59
knowledge, but then we formally did it -- 10:57:00
that there had not yet been any studies of 10:57:04
the requisite design characteristics that 10:57:06
would have by, you know, knowledgeable 10:57:12
people been judged to be a properly designed 10:57:14

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

Q Okay. 10:59:01
And Neal Ryan, he -- he lives in 10:59:02
Pittsburgh, right? 10:59:05
A I don't know where he lives. 10:59:09
Q Does he work out of Pittsburgh? 10:59:09
A He works at the Western Psychiatric 10:59:11
Institute in Pittsburgh. 10:59:14
Q And Strober is in Los Angeles, correct? 10:59:15
A Mike Strober works at the University of 10:59:20
California in Los Angeles. I don't know 10:59:22
where he lives. 10:59:24
Q And Rachel Klein is in New York somewhere? 10:59:25
A Yes. 10:59:28
Q Where is she? 10:59:29
A Well, she works -- I don't know exactly. 10:59:29
It's a child study center affiliated with 10:59:32
New York University. 10:59:36
At the time, she worked for 10:59:38
Columbia -- she worked, you know, at one of 10:59:39
the institutions that was part of Columbia 10:59:43
Presbyterian. 10:59:47
Q Okay. 10:59:48
And how about Stan Kutcher, where was 10:59:48
he - where was he working at the time the 10:59:50

team was formed? 10:59:53
A Somewhere during the period of time when we 10:59:54
were discussing this, he moved from one of 10:59:57
the teaching hospitals in Toronto, Canada to 11:00:01
become chair of I believe it's called 11:00:06
Dalhousie Medical Center. 11:00:15
And I'm -- 11:00:16
Q Can you spell that? 11:00:18
A No. 11:00:18
Q Okay. 11:00:19
You think phonetically it's 11:00:20
Dalhousie? 11:00:21
A D-A-L-H-O-U-I-S-I-E, and I think that's in 11:00:23
Halifax. 11:00:31
Q All right. 11:00:32
A Nova Scotia. 11:00:32
Q How is it that -- I mean obviously you're 11:00:34
from different parts of the country, and, 11:00:36
actually, two countries. 11:00:39
How is it that you got together? Was 11:00:40
this telephone conferences? Did you meet in 11:00:42
person, or both? 11:00:45
A Just to -- just to put it in context, when I 11:00:45
was doing my residency training, I had a 11:00:47

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

And my very first research project was a collaborative study when I started as a resident which involved six -- five medical centers across the country, so I just knew lots of people. 11:01:03 11:01:06 11:01:08 11:01:13 11:01:17

And as I developed projects and ideas, met people, and the idea was to somehow be put in contact with or contact people who at least were thought -- in my opinion and others' -- to be the best and the brightest of researchers. And then the other criteria was that I enjoyed their company. 11:01:19 11:01:21 11:01:24 11:01:28 11:01:30 11:01:32 11:01:36 11:01:39

So when we had that combination, had an idea, we -- somehow we'd get together. 11:01:41 11:01:43

Actually, the way I think I met most of the child people, other than the ones that I knew from my own department, was this mentor of mine organized on an annual basis 11:01:45 11:01:48 11:01:50 11:01:57

a meeting of people who were knowledgeable about child and adolescent psychiatry and in particular research. 11:02:02 11:02:05 11:02:11

And we had an annual meeting starting in the 1980s, two to three days a year, and I attended all of those meetings. And the reason was, was despite -- the reason was -- 11:02:12 11:02:14 11:02:21 11:02:26

The reason was at the time I was a coprincipal investigator on a grant sponsored by the National Institute of Mental Health to look at the offspring of adults with mood disorders to see whether they were at higher risk for developing mood disorders than children whose parents didn't have it. 11:02:30 11:02:34 11:02:37 11:02:38 11:02:44 11:02:48 11:02:51 11:02:57

So I was doing research on children and adolescents, and that was my ticket of admission to join that group and through those meetings met each of the individuals that I mentioned to you. 11:02:57 11:02:59 11:03:03 11:03:05 11:03:07

Q And let's take Neal Ryan. 11:03:08

Is he a child psychiatrist, to your knowledge? 11:03:10 11:03:14

A I assume so, but I'm not -- I don't -- I 11:03:15

don't -- I've never studied his or anyone else -- any the CV's of anyone you've mentioned, so I assume that they all are. 11:03:17 11:03:19 11:03:21

Q Okay. 11:03:24

You say you assume they all are, would that include -- 11:03:24 11:03:26

A Well, Mike Strober is a Ph.D., so he would be -- he's a psychologist. 11:03:27 11:03:29

Q Okay. 11:03:32

A Who -- and I don't know -- 11:03:33

Q Does he treat children? 11:03:34

A He primarily treats adolescents, I believe, not children. 11:03:35 11:03:39

Q Okay. 11:03:39

And Rachel Klein? 11:03:41

A She's a psychologist. And primarily -- I don't know how much -- I don't know how much of each of these individuals' times they spend diagnosing and treating their own patients and how much of their time they spend doing research and teaching, but it's in the domain of child and adolescent psychiatry with a stronger emphasis on adolescent than child. 11:03:44 11:03:49 11:03:54 11:03:58 11:04:01 11:04:02 11:04:08 11:04:11 11:04:14

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

A Stan is a psychiatrist, and I would believe the same to be true of Stan. 11:04:19 11:04:22

Q Okay. 11:04:24

Now, when you do the research such as Study 329, where you were paid by GlaxoSmithKline, does that money go to the university, in this instance, Brown, for the work you did? 11:04:29 11:04:36 11:04:39 11:04:40 11:04:44

A I don't believe I or any -- I don't believe I or any of the investigators was paid by GlaxoSmithKline. 11:04:49 11:04:52 11:04:55

Q The university was paid? Is that what you're saying? 11:04:58 11:04:59

A Yes. 11:05:02

The way this grant worked, and most that I'm aware of, is if a grant was funded, the funding, whatever amount of money is agreed upon, be it by the National Institutes of Health or foundation or pharmaceutical company, whomever might be funding it, an individual donor, in every instance I've ever been involved in, the funding is a written agreement between the 11:05:03 11:05:06 11:05:12 11:05:15 11:05:18 11:05:21 11:05:23 11:05:28 11:05:33

funder and an institution. 11:05:38
And what's designated as part of the 11:05:45
agreement is that there's typically one 11:05:49
individual who is called the principal 11:05:51
investigator, and there are other 11:05:54
investigators. 11:05:58
And then based on, you know, how your 11:05:59
institution functions in relation to you, 11:06:01
you have as the principal investigator 11:06:04
varying degrees of autonomy as to how you 11:06:08
conduct that research within the broader, 11:06:12
you know, research environment of the 11:06:16
institution. 11:06:19
But it's considered an award to the 11:06:20
institution, not an individual. 11:06:22
Q Okay. 11:06:23
And does any of the money actually 11:06:23
result in your salary or in bonuses? 11:06:26
A Not for me. 11:06:28
Q You personally don't receive anything for 11:06:29
that? 11:06:31
A No. 11:06:32
Q For securing the study? 11:06:31
A No. 11:06:33

Q Okay. 11:06:36
Now -- so there's money being paid to 11:06:38
the university for research, but if you -- 11:07:04
you can also be a consultant for a drug 11:07:08
company where you personally get paid; is 11:07:10
that correct? 11:07:12
A Yes. 11:07:13
Q Okay. 11:07:13
And have you been a consultant for 11:07:14
GlaxoSmithKline for any period of time in 11:07:16
the last 20 years? 11:07:19
A Yes. 11:07:20
Q Okay. 11:07:23
And what does it mean to be a 11:07:26
consultant? 11:07:28
MR. DAVIS: Object to the form of the 11:07:35
question. 11:07:36
A The word "consultant" covers the broad -- an 11:07:38
extremely broad range of potential 11:07:42
activities in a broad range of domains. 11:07:44
So you asked me what it meant to be a 11:07:49
consultant. It could mean -- I think you 11:07:51
have to narrow the question to be -- 11:07:54
Q Okay, that's fine. 11:07:58

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

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

A Absolutely. 11:22:16
Q Okay. 11:22:17
And they all appear to be authentic? 11:22:18
A Yes. 11:22:20
Q Okay. 11:22:20
And were they all produced during the 11:22:21
course of your business -- 11:22:23
A Yes. 11:22:24
Q -- by you? Okay. 11:22:24
Now, does it tell you a starting 11:22:26
date? 11:22:29
A Well, the earliest one I could find was 11:22:31
1998. 11:22:33
Q Okay. 11:22:34
Why don't we mark that as an exhibit. 11:22:40
Which one is that? 11:22:42
A Well, I don't know. Here's one that says 11:22:43
'99. This one says 2004. 11:22:45
Q Okay. 11:22:53
A I was trying to do them by topic. 11:22:54
Q Well, do you want to organize them by date 11:23:01
or topic? Whatever is easier for you. 11:23:04

MR. DAVIS: And I'll designate that 11:24:11
discussion by Dr. Keller about that proposed 11:24:13
study drug as confidential pursuant to the 11:24:15
protective order in the cases. 11:24:17

Q And in -- in doing these, were you paid for 11:24:48
the number of meetings that you attended, or 11:24:52
were you on a -- some kind of payroll or 11:24:55
were you -- 11:24:58
A No, I was -- the answer to your question is 11:24:59
yes. 11:25:02
Q Okay. 11:25:05
Paid by the meeting? 11:25:06
A Yes. 11:25:08
Q And did that vary from a thousand to a 11:25:08

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

other ones. 11:26:25
Some of these are just like 1099s. 11:26:26
Q Right. 11:26:29
A Some have information on the meeting. 11:26:29
And this one -- this -- this was 11:26:32
another one that had nothing to do with 11:26:39
Paxil. 11:26:42
You see that number of that drug 11:26:42
there? 11:26:43
Q Yes, I'm familiar with that drug. That's 11:26:44
fine. We'll take this one out of it. 11:26:46
A You're familiar with it? 11:26:48
Q Yes, I've seen probably about a hundred 11:26:49
thousand pages related to that drug. 11:26:51
A There you go. 11:26:54
What do you think of it? 11:26:55
Q I think it's interesting. 11:26:56
A Okay. 11:26:59
Q We'll see it in 2010. Is that when it hits? 11:26:59
A So -- so there are -- I believe that I have 11:27:04
one, two, three -- I don't know if that's -- 11:27:07
this is -- 11:27:13
Okay. This is February 2003. This 11:27:15
is February 2004. 11:27:19

Q Okay. Put those in date order. 11:27:23
A Okay. 11:27:25
Q I'll mark those in a second, but let's just 11:27:25
get them in order. 11:27:28
A This is -- this is February '99. 11:27:29
Q Okay. 11:27:30
A And -- oh, this is the same meeting. This 11:27:32
is February '99. 11:27:35
Q Are those duplicates? 11:27:36
A Same -- same things, yes, I guess. 11:27:38
Q Okay. 11:27:39
A So -- and this -- this doesn't -- this just 11:27:41
has like a payment, but it doesn't track 11:27:46
to -- this is 1999. 11:27:51
Q Okay. Let's put that in the '99 pile. 11:27:57
A So that probably goes with '99. 11:28:00
Q Those -- 11:28:02
A This has to do with something different, not 11:28:03
a meeting. It has to do with a manuscript 11:28:05
that I wrote. 11:28:09
Q Relating to 329? 11:28:12
A No. 11:28:13
Q Okay. 11:28:14
A No. Just a generic thing called the 11:28:15

Treatment of Major Depression. 11:28:18
Q Okay. 11:28:20
A Or -- 11:28:21
Q Was that for -- that was STI? Was that for 11:28:21
GSK? 11:28:25
STI, so the record is clear, 11:28:28
is Scientific -- Scientific Therapeutics, 11:28:29
Inc., correct? 11:28:32
A Yes, right, okay. You're right. The answer 11:28:33
to your question is yes. 11:28:35
Q And so you were paid -- were you paid by GSK 11:28:40
or STI to do the manuscript? 11:28:43
A You know, it's the bane our existence when 11:28:47
we get the 1099s because you're never quite 11:28:49
sure -- 11:28:52
Q Who's paying you? 11:28:52
A -- who's paying. 11:28:53
This one was STI. 11:28:55
Q Okay. 11:28:58
How much is that for? 11:28:58
A Excuse me? 11:28:59
Q How much was that for? 11:29:00
A $2,000. 11:29:01
Q Okay. 11:29:02

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

edition of Psychopharmacology Bulletin. 11:30:06
Q Okay. 11:30:10
And we've established that STI was 11:30:12
doing that on behalf of GSK, correct? 11:30:15
A Yes. 11:30:18
Q Okay, good. 11:30:18
Let's go to Exhibit 3. 11:30:19
A Okay. 11:30:21
(Exhibit No. 3 marked for 11:30:21
identification.) 11:30:21
MR. GREEN: Could I just interject? 11:30:22
Exhibit 3, I think, if you look at it is a 11:30:23
collection of 1099s from various years, so 11:30:26
it's not all relating to 1999. I think just 11:30:29
the top page relates to 1999. 11:30:33
THE WITNESS: Jim is right. This 11:30:37
is -- this is -- 11:30:38
BY MR. MURGATROYD: 11:30:39
Q Okay. 11:30:39
Why don't you take us -- take us 11:30:39
through that, and a just go through for the 11:30:40
record just exactly what Exhibit 3 consists 11:30:42
of. 11:30:46
A Well, it's not very informative. 11:30:46

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

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

A No, no. Doesn't explain. 11:33:09
Q Okay. 11:33:10
A But I'm assuming that because it's in this 11:33:11
pile -- 11:33:13
Q That it's related? 11:33:15
A -- that it's related. 11:33:16
Q Okay. That's fine. All right. 11:33:17
Let's go to the next exhibit or the 11:33:19
next document, and we'll mark it as 11:33:20
Exhibit 4. 11:33:23
(Exhibit No. 4 marked for 11:33:25
identification.) 11:33:25
BY MR. MURGATROYD: 11:33:31
Q Let me actually turn it to the first page so 11:33:31
it will be easy to identify 11:33:33
And can you identify for the record 11:33:39
what Exhibit 4 is? 11:33:40
A It's a form letter to -- doesn't have my 11:33:50
name on it. 11:33:58
It's a form letter thanking me for 11:34:00
being at the recent meeting. And in 11:34:03
handwriting on the top, it says Key West. 11:34:06
Doesn't say it in the letter. 11:34:10
Q Okay. 11:34:12

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

identification.) 11:35:27
(Exhibit No. 6 marked for 11:35:27
identification.) 11:35:27
(Exhibit No. 7 marked for 11:35:28
identification.) 11:35:28
BY MR. MURGATROYD: 11:35:28
Q Okay. 11:35:28
Let me show you what we've marked as 11:35:28
Exhibit 5. If you can identify that for the 11:35:30
record, please. 11:35:31
A This is -- this gives logistic information 11:35:35
about meeting attendance, hotel 11:35:41
accommodations and travel. 11:35:46
Q Okay. 11:35:48
And that's for the Paxil 11:35:48
Psychiatric -- Psychiatry Advisory Board? 11:35:51
A February 12, 1999, correct. 11:35:55
Q Okay. 11:35:57
Is that a duplicate of this document? 11:35:58
This, I see, is dated also February 12, 11:36:00
1999. 11:36:04
A Yes. 11:36:05
Q So 5 and 6 are the same? 11:36:05
A Yes. 11:36:08

Q Okay. 11:36:08
And then what I've marked as Exhibit 11:36:08
7, and can you identify for the record what 11:36:09
that is, please? 11:36:21
A It's a miscellaneous expense form. 11:36:23
Q And does that relate to GlaxoSmithKline? 11:36:25
A Yes. Paxil Psychiatry Advisory Board, 11:36:26
February 5, 2004 to February 7, 2004. 11:36:30
Q Okay. 11:36:36
So this came from -- this originally 11:36:39
came from the question were you ever a 11:36:41
consultant for GSK. 11:36:42
Do you recall that? 11:36:44
A Yes. 11:36:45
Q Is being a consultant and being a member of 11:36:47
an advisory board, are those two different 11:36:49
activities or two different functions or are 11:36:51
they similar or the same? 11:36:54
A Most cases, they're similar. 11:36:58
Q And what do you recall doing as a member of 11:37:00
the advisory board for GSK? 11:37:04
A Sitting in a room, having certain materials 11:37:07
presented. Sometimes -- you know, actually, 11:37:15
what I'm -- what I'm remembering is -- 11:37:20

I don't remember anything specific 11:37:22
about any of these meetings, but typically 11:37:24
what happens is there's some combination of 11:37:29
present -- topics that are listed and some 11:37:34
combination of presentations by personnel 11:37:38
for GSK or members of the advisory board. 11:37:40
These are topics we would like you to 11:37:43
discuss. 11:37:45
And then based on how the meeting is 11:37:47
run, we either spend most of our time 11:37:48
listening or we spend more time actually 11:37:52
engaging in conversation. 11:37:59
I personally -- I either spend a lot 11:38:03
of time listening, because there's not a lot 11:38:05
of time for discussion, or I spend a lot of 11:38:08
time discussing. 11:38:11
But since the meetings typically 11:38:12
average between eight and 20 people, the 11:38:14
amount of time that I or any one individual 11:38:17
would talk is minimal. 11:38:22
Q Okay. 11:38:24
Well, let me -- what do you 11:38:24
understand the purpose of the meetings are? 11:38:27
Is it how to better promote the drug 11:38:28

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

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

Q Okay. 11:40:50
Now, are you considered a key opinion 11:40:50
leader for GSK, to your knowledge? 11:40:57
MR. DAVIS: Object to the form. 11:41:01
THE WITNESS: What did you say? 11:41:05
MR. DAVIS: Object to the form. 11:41:06
I'm just making an objection for the 11:41:07
judge to rule on later. 11:41:08
A I don't know if GSK considers me a key 11:41:10
opinion leader for them. I do know that I'm 11:41:14
sort of generally referred to as an opinion 11:41:18
leader in the field of psychiatry 11:41:22
specifically having to do with depression -- 11:41:27
with all mood disorders, and to a large 11:41:31
extent anxiety. 11:41:33
And in general, I hate to say this, 11:41:35
but I'm sort of becoming known as a wise old 11:41:38
man. 11:41:41
(Laughter.) 11:41:42
Q All right. 11:41:43
A So people will ask my opinion on things that 11:41:43
I may not know a heck of a lot about, but, 11:41:45
you know... 11:41:48
Q That was my question. 11:41:49

What does it mean to be an opinion 11:41:50
leader? Does that mean that people look up 11:41:52
to you and respect your opinion, to your 11:41:53
knowledge? 11:41:55
A I don't know about that. I don't know. I 11:41:55
don't know exactly. 11:41:57
I think -- 11:42:01
Q Well, it means your opinion's respected? 11:42:02
A In the kindest sense of the word, I believe 11:42:05
it means that you're someone who is well 11:42:07
known by a high proportion of psychiatrists 11:42:12
and other mental health professionals and 11:42:16
that you're respected for being a -- how to 11:42:19
put this, an honorable person. 11:42:23
And therefore, when you give an 11:42:25
opinion about something, people tend to 11:42:27
listen and say, oh, this individual gave 11:42:31
their opinions; it's worth considering. 11:42:34
Q Okay, good. 11:42:40
A There are less kind meanings meetings, but I 11:42:42
don't know. 11:42:43
Q That's fine. 11:42:45
When -- when you're a member of the 11:42:54
Paxil Advisory Board and you said you 11:42:56

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

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

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

A Yes. 11:47:48
Q Okay. 11:47:49
And can you list off -- these are all 11:47:49
drug companies that you've personally 11:47:52
received money from at some time or another 11:47:55
in the past? 11:47:57
MR. DAVIS: Object to the form. 11:47:58
A No. 11:48:02
Q Okay. 11:48:05
A They're not all drug companies. 11:48:06
Q Okay. 11:48:08
Are some of them medical device 11:48:09
companies? 11:48:11
A It's a little hard to read. 11:48:17
At least one's a device company, but 11:48:21
then there are other types of businesses, 11:48:23
companies that do other business -- 11:48:27
companies that are neither pharmaceutical 11:48:28
companies nor medical device companies on 11:48:30
this list. 11:48:33
Q But companies from which you have received 11:48:33
money at some time in the past? 11:48:36
MR. DAVIS: Object to the form. 11:48:39
(Witness read document.) 11:48:39

A Yes, I've received some money from each of these. 11:48:55 11:48:57

Q Okay. 11:48:57

And can you read into the record that list of companies, please? 11:48:57 11:49:00

A Yes. 11:49:01

I would just say that in terms of the way I fill these lists out, that at the time, I list -- 11:49:02 11:49:05 11:49:13

This was a list as complete as it could be of any company I ever had had contact with ever. 11:49:14 11:49:16 11:49:19

Q Okay. 11:49:22

A Since then, the policy has kind of changed and the advice to me has changed, that what people think is more relevant is that you would give the companies that you've had contact with in the past two years, to be less inclusive. 11:49:23 11:49:26 11:49:30 11:49:32 11:49:34 11:49:37

Q Okay. 11:49:39

A Okay. 11:49:39

But if you -- do you want me to actually read the list of everything that's on here? 11:49:39 11:49:41 11:49:43

Q Yes, please. 11:49:44

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

Abbott Laboratories; Bristol-Myers Squibb Company; Cephalon; Collegium. 11:49:49 11:49:52

There's one I can't read, so I'm going skip the one I can't read, and if you want to circle it and -- 11:50:04 11:50:09 11:50:12

Q That's fine. Here, here's a pen. Why don't you circle it. 11:50:14 11:50:16

(Witness complies.) 11:50:17

A Cyberonics -- if you don't mind, I'm not reading all the Inc.'s and Ltd.'s and stuff. 11:50:20 11:50:24

Q That's fine. 11:50:26

A Cypress Bioscience; Eli Lilly; Forest; GlaxoSmithKline; Janssen; Merck; Mitsubishi -- Mitsubishi; Novartis; Organon; Otsuka; Pfizer; PharmaStar; Sanofi-Synthelabo; SCIREX; Sepracor; Somerset; Vela; Wyeth. 11:50:28 11:50:36 11:50:52 11:51:05 11:51:15 11:51:22

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

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

Asked and answered. 11:51:39

Q I mean is that -- is that the complete list of drug companies from which you have 11:51:39 11:51:42

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

A To the best of my knowledge, I've been all-inclusive. 11:51:46 11:51:48

Q Okay. 11:51:49

Do you think that your relationship with the drug companies has affected your credibility with your peers? 11:51:49 11:51:51 11:51:55

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

Q Okay. 11:52:10

Do you think the amount of money that both you and the university have received from drug companies affects your scientific judgment about the drugs on which you do research? 11:52:10 11:52:12 11:52:14 11:52:20 11:52:22

A No. 11:52:23

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

Now, we're here on a number of different lawsuits, and I don't know if you're aware of what they are. Let me just go over briefly what they are. 11:52:27 11:52:29 11:52:33 11:52:35

The Engh and Smith case are both consumer fraud cases in which it's alleged that GSK fraudulently promoted and sold Paxil for the use of kids and adolescents. 11:52:36 11:52:39 11:52:44 11:52:47

A Okay. 11:52:53

Q The Blain case is an entirely different case. 11:52:53 11:52:54

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

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

A Okay. 11:53:01

Q -- of treating children and adolescents. Okay. 11:53:01 11:53:05

The Blain case and the Brooks case, which is in the federal district court in Pennsylvania, arises from the wrongful death of the 11-year-old Blain boy and the injury to the Brooks girl from taking Paxil. 11:53:05 11:53:07 11:53:09 11:53:12 11:53:15

So do you understand there's two different theories of the litigation that we're going to be discussing today? 11:53:18 11:53:24 11:53:26

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

A Mm-hmm. 11:53:32

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

MR. MURGATROYD: I think, actually, we need to change the type. 11:53:32 11:53:34

THE VIDEOGRAPHER: The time is 11:53. This is the end of Tape No. 1. We are off the record. 11:53:35 11:53:37 11:53:39

(Recess.) 11:57:57
THE VIDEOGRAPHER: We are back on the 12:02:13
record. This is Tape No. 2. The time is 12:02:14
two minutes after 12:00. 12:02:16
BY MR. MURGATROYD: 12:02:17
Q Okay. 12:02:20
So we were talking about before we 12:02:21
went off the record the allegations that are 12:02:23
made in the different cases, and the -- 12:02:25
So it's clear, the Engh and the Smith 12:02:27
case, the allegations are similar to those 12:02:29
made by Attorney General Spitzer in New 12:02:33
York, which I believe you're familiar with 12:02:36
because I saw one of your emails talking 12:02:38
about that lawsuit. 12:02:41
Do you want me to show this to you to 12:02:43
refresh your recollection? 12:02:45
A Yes. 12:02:46
MR. MURGATROYD: Are we up to 10? 12:02:47
MR. DAVIS: I just object to the form 12:02:49
of the question. 12:02:49
MR. COFFIN: 9, I think. 12:02:52
MR. MURGATROYD: 9? Is it 9? 12:02:53
MR. COFFIN: As far as I know. 12:02:56

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

authentic document? 12:03:39
A Yes. 12:03:40
Q Okay. 12:03:41
And you received that in the course 12:03:41
of your -- ordinary course of your business? 12:03:43
A Yes. 12:03:46
Q Okay. 12:03:46
And does it discuss the Spitzer 12:03:47
lawsuit in New York? 12:03:49
A Now you're pushing me. Yes. 12:03:53
Q Okay. 12:03:59
And does it talk about that the 12:03:59
lawsuit alleges deliberate concealment and 12:04:01
misinformation regarding Paxil and its use 12:04:05
in the child and adolescent population? 12:04:07
MR. DAVIS: Object to the form. 12:04:10
A Yes. 12:04:12
MR. DAVIS: Excuse me. I object to 12:04:13
the form of the question. 12:04:13
THE WITNESS: I'm sorry. 12:04:14
Q Okay. 12:04:15
And do you know why Neal Ryan sent 12:04:15
that to you? 12:04:18
A No. 12:04:19

Q Okay. 12:04:19
Are you aware of allegations 12:04:20
regarding 329 that were brought up in the 12:04:22
Spitzer lawsuit? 12:04:25
A No. 12:04:26
Q Okay. Put that one aside. 12:04:27
Have you been sued personally for 12:04:46
any -- any -- regarding any activities 12:04:49
related to Study 329? 12:04:51
A No. 12:04:53
Q Okay. 12:04:54
Have any of your other coauthors in 12:04:55
the article been sued personally, to your 12:04:57
knowledge? 12:05:00
A No. 12:05:00
Q Okay. 12:05:01
Now, let's go to -- 12:05:01
(Exhibit No. 10 marked for 12:05:46
identification.) 12:05:46
BY MR. MURGATROYD: 12:05:47
Q Let's me show you what I've marked as 12:05:47
Exhibit 10 and ask you to take a look at 12:05:49
that. 12:05:51
(Witness read document.) 12:05:52

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

So that's basically the rationale, 12:08:10
you know, what -- where the field is at and 12:08:12
why the study is important. 12:08:15
We discuss what's discussed in here, 12:08:19
you know, different ways one could design 12:08:22
the studies, since there's a lot of ways to 12:08:24
skin a cat. 12:08:28
Discuss, for example, the choice of 12:08:31
multiple antidepressants. So basically what 12:08:33
we do in here, as we would do in any NIH 12:08:39
grant, is take key design issues and discuss 12:08:43
what we might think of as the, you know, the 12:08:48
pros and cons of the decisions that we made 12:08:51
in the study that we're proposing. 12:08:55
Q Okay. 12:08:57
So am I correct in stating that this 12:08:58
document was prepared by you and your 12:09:02
research time that we described earlier -- 12:09:05
that we talked about earlier? 12:09:07
A Yes. 12:09:08
And I noticed in my here that there 12:09:08
are some -- that there are names of people 12:09:11
that I didn't give you initially in the list 12:09:15
that were also -- 12:09:17

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

A Yes. 12:10:25
Q Okay. 12:10:25
And, again, it was prepared by -- was 12:10:26
it prepared by you personally or was this 12:10:27
part of -- you had help from the research 12:10:29
team? 12:10:31
A Team. 12:10:31
Q Okay. 12:10:31
And this was -- I know you identified 12:10:32
it as a protocol, but would it also be 12:10:36
properly determined a proposal to do a 12:10:42
study? 12:10:44
A Yes. This is a -- we have here stamped 12:10:44
"draft" and -- yes. 12:10:48
Q Okay. 12:10:53
And, now, in that protocol, there is 12:10:54
an outcome measure that is discussed, 12:11:02
correct, on page 14? 12:11:04
(Witness read document.) 12:11:27
A Yes. 12:11:34
Q Okay. 12:11:34
And can you state for the record what 12:11:34
the original outcome measure was, please? 12:11:36
A Well, again, let me put it into context that 12:11:41

this is a draft proposal. 12:11:44
Q Right. 12:11:45
A So I'm not -- I do not know whether this was 12:11:45
the final proposal. 12:11:48
Q No, I understand. 12:11:50
A This was a -- you know, we make many, many 12:11:52
drafts. 12:11:55
Q Okay. 12:11:55
A Okay. 12:11:56
Definition of responder or 12:11:57
nonresponder at the end of eight-week acute 12:11:58
treatment study, and then it says, To be 12:12:02
classified as a responder -- which is in 12:12:03
quotes, responder, and continue to the 12:12:06
continuation phase, a subject must, and then 12:12:10
it lists four criteria. 12:12:14
Q Okay. 12:12:19
And can you state for the record what 12:12:19
those are, please? 12:12:21
A One: Have a Hamilton depression rating not 12:12:22
greater than eight. 12:12:25
Two: Have no more than one positive 12:12:27
criterion symptom for major depression as 12:12:29
assessed by the -- and these are capital 12:12:32

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

A Other endpoints were added. 12:13:36
Q Okay. 12:13:37
And my question is, who -- who 12:13:37
decided to add the additional outcome 12:13:41
measures? 12:13:48
A I don't recall exactly -- well, "exactly" is 12:13:53
too strong. 12:13:55
I don't recall the process by which 12:13:56
any one given aspect of this were changed, 12:14:01
but I do recall -- without specifics -- that 12:14:04
the group of us met in several ways. 12:14:09
Sometimes we had in-person meetings 12:14:13
to discuss this. I can remember two or 12:14:14
three in particular we met for -- at least 12:14:17
one we met for two days at Brown. 12:14:21
I remember meeting at one or two 12:14:23
hotels probably associated with, you know, 12:14:25
other meetings that we were at to be 12:14:29
efficient in our time. 12:14:31
We had quite a number of telephonic 12:14:33
conference calls. And during the course of 12:14:36
these meetings, we would discuss design 12:14:38
issues. 12:14:42
Q Okay. 12:14:43

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

A Correct. 12:15:58
Q Okay. 12:15:58
And was this all documented through 12:15:59
the -- were there minutes taken of the 12:16:01
conference calls? 12:16:05
A No. 12:16:07
Q Okay. 12:16:08
A I mean, it -- I don't remember, but I 12:16:08
would -- 12:16:13
My style would occasionally to be to 12:16:14
say, hey, someone, could someone volunteer 12:16:16
to write down what we decided so when we 12:16:19
next talk tomorrow we remember, and usually 12:16:22
get someone to volunteer, but not always. 12:16:25
You know, it's one of those things. 12:16:28
It was loose. 12:16:29
Q Okay. 12:16:30
A But it was just us investigators. It wasn't 12:16:30
as though we had a secretary, you know, or a 12:16:33
research assistant who went and -- didn't 12:16:36
tape it. 12:16:40
Q Right. 12:16:40
A But somebody eventually would write down 12:16:41
what we did. 12:16:43

Q Okay. 12:16:44
And, now, you were the principal 12:16:45
investigator -- 12:16:48
So it's clear, that document before 12:16:49
you, which we marked as Exhibit 10, was the 12:16:51
proposal that ultimately became Study 329, 12:16:56
correct? 12:16:58
A Yes. 12:16:59
Q Okay. 12:16:59
So the proposal was accepted by GSK 12:17:00
at some later point in time after -- again, 12:17:02
that document is dated 1992, correct, end of 12:17:04
'92? 12:17:06
A Yes. 12:17:07
Q So that proposal was accepted by GSK at some 12:17:07
later time? 12:17:10
A This or some, you know, further iteration of 12:17:14
it. 12:17:18
Q Right. 12:17:20
Well, the proposal to do 329, that's 12:17:20
what I mean. 12:17:24
A Proposal to do the research -- 12:17:25
Q Correct. 12:17:27
A -- was accepted by GSK. 12:17:27

Q Okay. 12:17:29
And you were -- 12:17:29
A I don't think I ever heard the numbers "329" 12:17:30
until probably more recently. I don't know 12:17:35
when I first heard them, but -- 12:17:38
Q Okay. 12:17:39
How did -- how did you refer to the 12:17:40
study? 12:17:42
A "The study." 12:17:43
Q Okay. All right. 12:17:43
Well, so for the purposes of this 12:17:45
deposition, we're going to call it Study 12:17:47
329, because there were other studies. 12:17:49
Is that okay? 12:17:51
A That's okay. 12:17:51
Q Okay. 12:17:52
And you were the principal 12:17:52
investigator, though? 12:17:53
I mean, you were considered the 12:17:54
leader of the group, correct? 12:17:56
MR. DAVIS: Object to the form. 12:17:58
A Yes, I was -- yes, I was -- I was the 12:18:01
organizer. 12:18:04
Q Okay. 12:18:08

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

more expedient, and that we would get our -- 12:19:24
we would get the funding -- the budget we 12:19:28
agreed to without subsequent cuts if we had 12:19:32
a pharmaceutical company willing to fund the 12:19:35
design that we wanted to do than to go 12:19:40
through the NIMH process, which typically 12:19:44
leads to at least two or three revisions 12:19:48
into -- in nine-month cycles. 12:19:49
So what we were weighing was, you 12:19:51
know, two to three years before we started 12:19:54
at approximately 25 percent reduction of the 12:19:57
budget that would be accepted by the -- that 12:20:01
was proposed -- accepted by the review 12:20:02
committee versus starting almost 12:20:05
immediately. 12:20:07
And we weighed it back and forth and 12:20:08
decided we would go with a company if they 12:20:12
were willing to have the design be the 12:20:17
design we proposed. 12:20:18
Q Okay. 12:20:20
And GSK turned out to be the willing 12:20:21
company? 12:20:23
A Yeah. I don't know that the other was 12:20:23
not -- I don't know that the others were not 12:20:24

willing. 12:20:27
Whatever -- for some -- for some 12:20:27
reason that I can't remember, we chose to 12:20:29
have GSK be the sponsor as opposed to other 12:20:32
potential people who were interested. 12:20:36
Q Okay. 12:20:39
A I don't -- I don't remember why, and I don't 12:20:39
remember who else was interested. 12:20:41
Q Okay. That's fine. 12:20:43
Now, let me just show you what I'll 12:20:45
mark as Exhibit 11. 12:20:59
(Exhibit No. 11 marked for 12:21:21
identification.) 12:21:21
BY MR. MURGATROYD: 12:21:21
Q Okay. Let me show you that. 12:21:21
MR. DAVIS: What's that, Skip? 12:21:25
MR. MURGATROYD: That's a letter from 12:21:26
Dr. Keller to GSK. 12:21:28
MR. DAVIS: What date is it? 12:21:32
MR. MURGATROYD: It's in early 1993. 12:21:35
I think it's March 19th. 12:21:37
(Witness read document.) 12:21:46
A Okay. 12:21:58
MR. DAVIS: Can I look at that real 12:21:59

quick before we get a question about it? 12:22:00
THE WITNESS: Sure. 12:22:04
MR. DAVIS: Thank you. 12:22:05
(Counsel read document.) 12:22:13
MR. DAVIS: Thank you. 12:22:14
THE WITNESS: You're welcome. 12:22:15
BY MR. MURGATROYD: 12:22:17
Q Doctor, can you identify for the record what 12:22:17
that document is, please? 12:22:19
A It's a letter written by me to a woman named 12:22:21
Cathy Sohn. 12:22:28
Q Okay. 12:22:30
Do you recall who she was or is? 12:22:31
A Well, I haven't seen or heard of her for 12:22:34
many years. 12:22:37
At the time I wrote this letter, she 12:22:39
worked for SmithKlein Beecham. I know she 12:22:41
was a Pharm. D. I don't know the position 12:22:46
she held at the company. 12:22:48
Q Okay. 12:22:50
A And what I was proposing in this letter was 12:22:50
a that we add to the efficacy study that 12:23:03
we've been -- what we're now referring to as 12:23:11
329, a prospective naturalistic phase 12:23:14

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

this is something you wanted to add on to the proposal? 12:24:43 12:24:45

A What's unclear to me now -- because at the time, there was some ambiguity -- was sort of when and how this component was agreed to by SmithKline in relation to the randomized clinical trial. 12:24:46 12:24:53 12:24:57 12:25:04 12:25:11

My memory -- and it's a very, very weak memory, is that this came up, the idea to do this, after the core efficacy study was proposed. 12:25:12 12:25:16 12:25:24 12:25:27

Q Okay. 12:25:27

A This was a later proposal. 12:25:28

Q Right. 12:25:29

And was it accepted? 12:25:30

A Yes. 12:25:31

Q Okay. 12:25:31

And was it carried out? 12:25:32

A It was disappointing in that it was eventually -- eventually the money -- 12:25:34 12:25:39

It was funded, but we had a very difficult time implementing it. So we had a difficult time getting the participants in the randomized trial to then participate in 12:25:41 12:25:48 12:25:52 12:25:55

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

And I believe this was the first time that I had tried to tie together a naturalistic study on the tail end of an efficacy study, and I tried it once after that, and it wasn't so successful. 12:26:11 12:26:13 12:26:19 12:26:21 12:26:25

And subsequent to that, we've stopped trying to do it, because for a whole variety of reasons, it's just not such an appealing thing for either subjects or the research sites to do. 12:26:27 12:26:29 12:26:32 12:26:39 12:26:42

So it was a -- we were disappointed that we couldn't do it. 12:26:44 12:26:47

Q Okay. 12:26:48

And I take it -- I take it from -- and so the -- so the record's clear, that -- that is a letter from you to GSK, correct? 12:26:49 12:26:51 12:26:55

A Yes. 12:26:57

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

A Yes. 12:27:01

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

A Yes. 12:27:05

Q And did you prepare that in the ordinary course of your business? 12:27:05 12:27:07

A Yes. 12:27:09

Q Okay. 12:27:09

And I notice in the fourth paragraph, you talk about the number of publications that you would hope would result from the study; is that correct? 12:27:09 12:27:11 12:27:12 12:27:16

A Yes. 12:27:18

Q And how many -- how many publications did you project at that time? 12:27:18 12:27:20

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

Q Okay. 12:27:26

And why is the number of publications important, if it is at all? 12:27:27 12:27:32

A Well, because in order to -- at one indici [ph.] of why -- why -- why I would justify doing this was referencing it to -- 12:27:36 12:27:40 12:27:48

In other words, those -- if -- those number of studies in the kinds of journals I mentioned were an indication that I believe the data that would come from this would be were highly interesting scientifically and 12:27:56 12:27:58 12:28:01 12:28:04 12:28:08

make a major contribution to the field of adolescent psychiatry, and that was my way of -- one of my ways of explaining that, because, indeed, this is what the case was, is typically is, with our prospective studies. 12:28:11 12:28:15 12:28:17 12:28:20 12:28:23 12:28:26

That would be -- you know, why do it? 12:28:27

Q Right. 12:28:29

A We call it the "so what." And when you write a grant, they call it the significant section. In our minds, we cross it out and we say so what. 12:28:29 12:28:32 12:28:34 12:28:36

The "so what" is so if you do the study, what's the big deal? And the big deal is that this would be of interest and people would learn a lot. 12:28:38 12:28:38 12:28:41 12:28:43

Q Okay. 12:28:44

And was the study also done to -- so GSK could seek approval for a pediatric indication for Paxil for the treatment of depression? 12:28:45 12:28:48 12:28:51 12:28:52

MR. DAVIS: Object to the form. No foundation. 12:28:54 12:28:55

A I -- it was never -- I was never aware that 12:28:59

that was something that GSK had in mind. 12:29:06
But these data are not the type of 12:29:10
data that, to my knowledge, have ever been 12:29:11
submitted to -- as part of -- as part of an 12:29:16
FDA, what would you call it, application in 12:29:18
support of labeling. 12:29:28
Q Okay. 12:29:28
You mean the naturalistic follow-up 12:29:28
phase? 12:29:32
A Yes. 12:29:32
Q Right. 12:29:32
A Yes. 12:29:32
Q But the acute phase obviously is a type 12:29:33
of -- 12:29:36
A That is a type of data -- study and data 12:29:37
that could be used, but I was never told 12:29:39
that GSK intended to use that data for an 12:29:43
FDA filing. 12:29:49
Q At some point in time, you were told that, 12:29:51
though, correct? 12:29:53
MR. DAVIS: Object to the form. 12:29:54
A I don't remember. 12:29:55
Q Okay. 12:29:55
Do you know that -- whether or not 12:29:56

GSK actually sought approval for Paxil for 12:29:58
the treatment of pediatric depression? 12:30:01
A No. 12:30:04
Q Okay. 12:30:05
A I don't know, is the answer. 12:30:06
Q Okay. 12:30:07
Well, to your knowledge today, has it 12:30:07
been approved for the treatment of children 12:30:10
and adolescents with major depressive 12:30:12
disorder? 12:30:15
A No. 12:30:16
Q Okay. 12:30:16
And -- 12:30:17
A The one thing I would say is it's not 12:30:18
typical -- it's very atypical -- if a 12:30:22
company -- 12:30:25
In other words, I'm not aware of any 12:30:25
randomized controlled trial that was 12:30:29
designed by a group of investigators 12:30:32
independently, you know, carried out at a 12:30:34
relatively small number of sites, you know, 12:30:36
like this that have ever been part -- 12:30:39
I'm just not aware of it, of an FDA 12:30:45
submission. Studies that are part of FDA 12:30:49

submissions typically are designed in-house 12:30:52
at pharmaceutical companies, sometimes with 12:30:55
a consultant -- consultation or not, and 12:30:57
then, you know, monitored in all sorts of 12:31:01
stringent ways. 12:31:05
So this was -- this -- were this to 12:31:06
have been submitted, or if it was, I know of 12:31:10
no other situation in which a study like 12:31:16
this was ever part of an FDA approval. 12:31:20
Q Well, let me ask you this: 12:31:23
Did GSK take your proposal that was 12:31:25
outlined in Exhibit 10 and then incorporate 12:31:26
it into a new protocol that was a GSK type 12:31:29
protocol that could be used for regulatory 12:31:32
purposes? 12:31:34
A The first part of your question is that they 12:31:38
did incorporate it into a GSK type protocol. 12:31:40
The second part, I don't know the answer to 12:31:44
that. 12:31:46
Q Okay. 12:31:47
A Whether -- whether it could be used for 12:31:47
regulatory purposes. 12:31:50
Q And have you reviewed the protocol as 12:31:51
adapted by GSK in preparing for this 12:31:55

deposition? 12:32:01
A No. 12:32:02
Q Okay. 12:32:02
When was the last time you saw it, to 12:32:03
your recollection? 12:32:04
A A long time ago. 12:32:10
Q Okay. 12:32:12
Well, let's take a look at it. 12:32:13
MR. MURGATROYD: Let's go off the 12:32:17
record for just a second. 12:32:17
THE VIDEOGRAPHER: It's 12:32. We 12:32:18
are off the record. 12:32:21
(Recess.) 12:32:22
(Exhibit No. 12 marked for 12:33:25
identification.) 12:33:25
THE VIDEOGRAPHER: Okay. we are back 12:34:13
on the record. The time is 12:34. 12:34:18
BY MR. MURGATROYD: 12:34:20
Q Okay. 12:34:21
MR. DAVIS: I think you want to wait 12:34:21
for Mr. Green. 12:34:23
MR. MURGATROYD: Oh, I -- okay. 12:34:24
Well, I don't think he's going to object to 12:34:26
anything. He never has. 12:34:29

MR. DAVIS: I don't know. Just as a courtesy to him. 12:34:30

MR. MURGATROYD: All right. We'll go back off the record and wait for Mr. Green. 12:34:32

THE VIDEOGRAPHER: The time is 12:34. We are off the record. 12:34:35

(Recess.) 12:34:37

THE VIDEOGRAPHER: We're back on the record. The time is 12:35. 12:34:41

BY MR. MURGATROYD: 12:35:35

Q Okay. 12:35:38

And, Doctor, have you had a chance to look through what we've marked as Exhibit 12? 12:35:39

A Yes. 12:35:43

Q And can you identify for the record what that document is? 12:35:43

A It's a protocol to study -- of a Multi-center, Double-blind, Placebo Controlled Study of Paroxetine and Imipramine in Adolescents with Unipolar Major Depression. 12:35:46

Q Okay. 12:36:06

And before I get into the contents of 12:36:06

that document, you said that you met a number of times with GSK concerning Study 329? 12:36:11

A I don't -- no, I did not say that. 12:36:16

Q I thought you said you had in-person meetings, telephonic meetings -- . 12:36:19

A I was talking about meetings with my colleagues and peers. None of those -- none of the meetings were -- that I was -- that were in my mind when we were talking about involved anyone from GSK. 12:36:21

Q Okay. 12:36:40

Did you ever meet a gentleman by the name of Jim McCafferty who worked for GSK? 12:36:42

A Yes. 12:36:44

Q Okay. 12:36:48

And in what context? 12:36:48

A In the context of implementing this study. I don't remember when in the process I met Jim McCafferty, but I do know that the role that Jim played, as I would articulate it, was the liaison, in a way, between the study group and other individuals in GSK. 12:36:49

He was a GSK employee. 12:37:19

Q Right. 12:37:22

A And he was -- I don't know what his title would be, but he was the individual, as I understood it, from GSK that was sort of playing the -- how to put this, the leadership or management role within GSK for this study, so that most of the interactions -- there were very -- 12:37:25

Once -- you know, once we got to a certain point where -- 12:37:40

See, I don't remember when it started, but after -- but after everything was agreed upon, the study and the budget and so on and so forth, most of the contact with GSK by me or colleagues in the study was with Jim McCafferty. 12:37:47

And at a certain point, we did start having regularly scheduled conference calls to discuss perhaps the finalization of the protocol. 12:38:10

And certainly once the study got going, we would talk -- we would have conference calls and Jim would be on the call, not always but most of the time, along 12:38:15

with the principal investigators, and I don't remember who else from GSK. 12:38:23

Q Okay. 12:38:35

Did you ever meet Mr. McCafferty's senior in the company, Dr. David Wheaton? 12:38:37

MR. DAVIS: Object to the form. 12:38:40

A Yes. 12:38:43

Q Okay. 12:38:47

And did that have to do with Study 329 or -- or something else? 12:38:50

A When I first met him, it had to do with something else. I don't recall which -- what. 12:38:51

But at some point, he -- at some point, he was involved in some conversations regarding 329. 12:38:52

Q Okay. 12:38:59

And did -- from your experience with him, did he appear to be an intelligent person? 12:39:04

A Intelligent? 12:39:05

Q Yes. 12:39:06

A Oh, yes. 12:39:11

Q And honest? 12:39:14

A Yes. 12:39:26
Q Okay. 12:39:25
And going back to that protocol, does 12:39:26
it set forth the efficacy variables that 12:39:30
were to be tested during the course of the 12:39:36
clinical trial? 12:39:39
A It's -- the pagination -- oh, I see, the 12:39:48
pagination is 1206 to 1207. On page 1207 12:39:57
and 8 -- so the answer is yes. 12:40:02
Q Okay. 12:40:08
And does it list the primary and 12:40:09
secondary efficacy variables? 12:40:11
A Yes. 12:40:14
Q Okay. 12:40:14
And is there any mention in either 12:40:15
the primary or secondary measures of a 12:40:19
change in HAM-D depression item? 12:40:22
A Yes. 12:40:26
Q And what does it say? 12:40:26
A And I quote, "Change in total HAM-D score 12:40:31
from beginning of treatment phase to the 12:40:34
endpoint of the acute phase, bullet two" -- 12:40:36
Q Okay, wait. I'm actually talking about the 12:40:40
HAM-D depression item. 12:40:42

A Oh. 12:40:44
(Witness read document.) 12:40:45
A Well, not on -- not on pages 07 and 08. I 12:41:10
don't know whether it's mentioned elsewhere. 12:41:13
I do know that at some point after -- 12:41:15
if it -- if it's not -- if it doesn't appear 12:41:19
later in this protocol -- because I -- you 12:41:22
know, I didn't -- 12:41:25
I haven't sat here and read every 12:41:27
line, but if it does not appear in 12:41:29
subsequent pages, it is something that was 12:41:31
subsequently added as endpoints as we 12:41:37
thought about the study, which is extremely 12:41:40
common for us to do in studies like this. 12:41:46
Well, it's important. I'd like you 12:41:49
to take the time to look through that 12:41:50
protocol and see if you see any reference at 12:41:52
all to an endpoint or a secondary efficacy 12:41:53
variable being the change in HAM-D 12:41:56
depression. 12:41:58
Because I'm going to ask you -- while 12:41:59
you're looking, I'm going to ask you also 12:42:01
about remission defined as HAM-D score of 12:42:02
less than or equal to 8, a CGI of 1 or 2 -- 12:42:04

that's capital C, capital G, capital I -- 12:42:09
and a change in K-SADS-S depression. 12:42:12
I want to know if any -- any of those 12:42:18
four measures are discussed in that 12:42:21
protocol. 12:42:22
A Well, let me ask you, since you've studied 12:42:23
this and you seem to know these things 12:42:26
extremely well, to the best of your 12:42:28
knowledge, is it in here or not? 12:42:30
Q I have not been able to find it, but I 12:42:32
would -- I don't want to -- you're here -- 12:42:33
you're here to testify, not me. 12:42:36
A I understand. Just in the spirit of -- 12:42:37
Q Right. 12:42:40
A -- cooperatively -- 12:42:40
Q There is -- there is an index. 12:42:41
A -- going through it. 12:42:43
Q I think that may help speed up the process. 12:42:44
A I've never been good with indexes. Let's 12:42:49
see. 12:42:53
(Witness read document.) 12:42:54
Q You'll see there's a Section 9.0, data 12:43:09
evaluation. 12:43:12
Do you see that? 12:43:13

A Yes, I was just reading that, the primary 12:43:14
section -- 12:43:16
Q Correct. 12:43:17
(Witness read document.) 12:43:40
A Do you have any tabs that I could use just 12:43:42
for my own -- 12:43:45
Q Yes, I do. Let me just grab them for you. 12:43:45
A I don't need them to be exhibit tabs, 12:43:48
just -- 12:43:51
Q No, I understand. Wait a second. I'll have 12:43:51
to get them. 12:43:55
(Discussion off the record.) 12:43:59
Q Here you go. 12:44:13
A Thanks. 12:44:15
Q Sure. 12:44:15
A What's a little cumbersome is that the -- 12:45:00
the index refers to page numbers that should 12:45:03
be on the top, but most of them are cut off. 12:45:05
Q Yes. 12:45:07
A So I'm having trouble -- 12:45:08
Q Yes. You have to kind of judge where that 12:45:10
would be. 12:45:12
A Yes. 12:45:13
(Witness read document.) 12:45:13

A All right. If you don't mind, Skip, asking me the question again? 12:47:16 12:47:18

Q Yes, that's fine. In the original protocol that you have in front of you, is there an efficacy variable for the change in HAM-D depression item? 12:47:19 12:47:20 12:47:21 12:47:25 12:47:29

A No. 12:47:30

Q Okay. Is there an efficacy variable for remission defined as a HAM-D score of less than or equal to 8? 12:47:30 12:47:30 12:47:33 12:47:36

A No. 12:47:40

Q Is there an efficacy variable for a CGI of 1 or 2? 12:47:41 12:47:45

A No. 12:47:46

Q Is there an efficacy variable for a change in K-SADS depression item? 12:47:47 12:47:50

A I don't think so. I'm just looking -- 12:48:06

Q That's all right. 12:48:07

A Somewhere -- I had my finger on it. Oh, yes, yes, changes -- 12:48:09 12:48:15

Q Not the -- not the mean score, just the depression item. 12:48:16 12:48:18

A It says secondary efficacy -- depression items in K-SADS-P, changes from baseline. So I guess the answer -- 12:48:19 12:48:21 12:48:28

If I understand your question, the answer is yes. 12:48:29 12:48:30

Q Okay. 12:48:31

And what page is that on? At the bottom, use the bottom pagination. 12:48:32 12:48:36

A 1228. 12:48:39

Q Okay. 12:48:40

A Under 9. -- 9.1.2, secondary efficacy variables. 12:48:45 12:48:50

Q What is the K-SADS-P? I asked about K-SADS-S or K-SADS, S-A-D-S. 12:48:51 12:48:57

This is the K -- 12:49:01

A The K-SADS. 12:49:05

Q This is the K-SAD-P. 12:49:06

A There -- what I think is -- 12:49:08

You asked about the K-SADS? 12:49:14

Q Correct? 12:49:16

A All right. Okay. 12:49:16

So the K-SADS, I believe, encompasses sort of the sub -- two interviews within it. One is -- the K-SADS-P, I believe, is the 12:49:17 12:49:20 12:49:26

parent version; and the K-SADS-S, I believe, is the subject version, but I'm not sure. 12:49:31 12:49:35

Q Okay. 12:49:37

A But -- but certainly -- I just -- I just don't remember. I'd have to see them in front of me. 12:49:38 12:49:40 12:49:42

Q Okay. 12:49:42

A You know, if you had the original instruments. 12:49:43 12:49:44

But generically, this -- this certainly would be referring to the K-SADS. 12:49:45 12:49:46

Q Okay. 12:49:50

Well, in the -- it actually says K-SADS-P in the document, correct? 12:49:50 12:49:52

A SAD. No. 12:49:54

Q K-SAD-P? 12:49:55

A Right. 12:49:56

Q And that would be parent? 12:49:56

A I think so, but I'm not sure. 12:49:57

Q Okay. 12:49:59

A I'm just -- I'm not sure. 12:50:00

Q Okay. 12:50:02

Now, there are two primary efficacy variables listed in this protocol, correct? 12:50:02 12:50:06

A Yes. 12:50:10

Q Okay. 12:50:11

And can you state for the record what those are, please? 12:50:13 12:50:15

A The change in total HAM-D score from beginning of treatment phase to the end of the acute phase. And the second is the proportion of respondents at the end of the eight-week treatment -- the acute treatment phases. 12:50:16 12:50:19 12:50:20 12:50:24 12:50:26 12:50:28

Q Okay. 12:50:29

Now, after the study was concluded, how many of these measures did paroxetine separate statistically from placebo? 12:50:29 12:50:32 12:50:34

A I don't remember. You'd have to show -- I'd have to look at the article. 12:50:37 12:50:39

Q Okay. 12:50:40

Doctor, the exhibit before you is 12; is that correct? 12:51:10 12:51:13

A Yes. 12:51:15

Q Okay. 12:51:15

So I'm going to mark as Exhibit 13 -- 12:51:17

A You can come by and help me file my -- the papers on the floor in my office any day 12:51:21 12:51:24

with your stickies. 12:51:27
Q There we go. There's a copy of the article. 12:51:30
(Exhibit No. 13 marked for 12:51:32
identification.) 12:51:32
BY MR. MURGATROYD: 12:51:32
Q And take your time going through. 12:51:38
MR. MURGATROYD: What time is it now? 12:51:40
MR. DAVIS: 12:45. 12:51:42
THE WITNESS: Lunchtime. 12:51:44
MR. MURGATROYD: 12:45. 12:51:45
Why don't we break for lunch, and you 12:51:46
can have -- because I want you to be 12:51:46
familiar with the article. 12:51:49
Q So if you can have a chance to review it 12:51:49
over lunch, it will be helpful. It will 12:51:52
save us some time. 12:51:54
A Okay. 12:51:56
MR. MURGATROYD: So let's go off the 12:51:56
record now and take a lunch break and come 12:51:57
back -- 45 minutes okay by you guys? 12:51:58
THE WITNESS: Fine. 12:52:03
MR. MURGATROYD: 1:30? 12:52:04
THE WITNESS: Yes. 12:52:05
MR. MURGATROYD: Okay, great. 12:52:06

And Bob told me there's a place 12:52:06
downstairs, and there's also a place around 12:52:10
the corner for food. 12:52:12
THE VIDEOGRAPHER: The time is 12:52. 12:52:14
We're off the record. 12:52:16
MR. DAVIS: Let me put something on 12:52:17
the -- on the transcript here. 12:52:18
Skip, I appreciate you turning after 12:52:18
the break to the issues dealing with Study 12:52:20
329 to push this process along, because I 12:52:21
think that's going to be very helpful in 12:52:25
order for us to see if we can get completed 12:52:28
by tomorrow. 12:52:30
MR. MURGATROYD: Right. Correct. 12:52:30
MR. DAVIS: So I appreciate you doing 12:52:31
that. 12:52:32
MR. MURGATROYD: No problem. 12:52:32
MR. DAVIS: All right. 12:52:33
THE WITNESS: That was a warm-fuzzy, 12:52:33
right? 12:52:33
MR. MURGATROYD: I don't know. 12:52:33
MR. DAVIS: It was on the record. 12:52:33
It was an attempt at a warm-fuzzy to 12:52:33
see if we can get this done, as opposed 12:52:33

focusing on collateral issues that don't 12:52:33
have any -- 12:52:33
MR. MURGATROYD: Well, I'll do my 12:52:33
best to be speedy. 12:52:33
(Discussion off the record.) 12:52:33
(Luncheon recess.) 12:52:37
THE VIDEOGRAPHER: We are back on the 01:56:10
record. The time is 1:56. 01:56:39
BY MR. MURGATROYD: 01:56:42
Q Okay. 01:56:42
So when we broke for lunch, the 01:56:43
question was -- you identified the two 01:56:46
primary outcome variables from the protocol. 01:56:52
A Yes. 01:56:56
Q And my question was, of the two primary 01:56:56
outcome measures -- or how many of these -- 01:57:01
how many of the two primary outcome measures 01:57:06
separated statistically from placebo? 01:57:10
A Okay. 01:57:16
(Witness read document.) 01:57:31
Q Now, the -- before you answer that, the 01:57:32
primary outcome measures are actually 01:57:33
mentioned in the abstract, correct, under 01:57:35
the second sentence, third sentence? 01:57:37

A Yes. That's what I was trying to get to. 01:57:39
The two primary outcome measures were 01:57:41
endpoint response, that that -- 01:57:43
Q Right. 01:57:45
A And change from baseline -- and it lists the 01:57:45
others. 01:57:48
Q Right. 01:57:49
Now, so -- 01:57:50
A And it gives the results the next line. 01:57:51
Q So the primary outcome measures, how many of 01:57:53
those separated statistically from placebo, 01:57:56
if any? 01:58:00
A Okay. So -- 01:58:01
(Witness read document.) 01:58:04
A There -- I'm cross-referencing here. In the 01:58:31
abstract, neither of the two primaries did. 01:58:33
I'm just looking now at page 764, where it 01:58:36
goes over the efficacy. 01:58:40
Q Okay. 01:58:43
So in the abstract, it doesn't -- it 01:58:44
tells you what the two primary outcome 01:58:47
measures are -- 01:58:49
A Right. 01:58:50
Q -- but doesn't tell you whether or not 01:58:50

whether they separated statistically from placebo, correct?

MR. DAVIS: Object to the form.

THE WITNESS: What do --

MR. GREEN: You're allowed to answer, if you --

A Correct.

Q Correct? Okay.

But later in the body of the article, the reader is given information on the -- how -- how well the two primary outcome measures did, correct?

MR. DAVIS: Object to the form.

A Which page, Skip? Because I'm just having trouble -- are we talking 765?

Q No, actually, we're looking -- I'm referring to Table 2 on 766.

A Oh, okay. Good. That's what I was looking for.

(Witness read document.)

A Okay.

Q And do you see the two primary variables listed as the second and third items in Table 2?

MR. DAVIS: Object to the form.

A The second one is response, right?

Q Right. Responder.

A Responder.

Well, it's not -- it's not labeled as responder, but it's the definition --

Q And did that separate statistically from placebo?

Did Paxil separate statistically from placebo with regard to that primary endpoint?

A No.

Q Okay.

And what's the second primary variable, outcome measure?

A It's a proportion of responders at the end of eight weeks.

Q Well, if you go to the abstract again --

A Yes.

Q -- it says the, Two primary outcome measures were endpoint response?

A Right.

Q Right, which we just discussed.

And you agree that that did not

separate --

A Right.

Q -- statistically from placebo?

A That's the first one in the table, isn't it?

Q No.

Look at the definition -- go back to the abstract.

A Yes, yes.

Q And it says, The two primary outcome measures were endpoint response.

Do you see that?

A Yes.

Q And it defines it as a score less than or equal to 8, or greater than -- equal or less than -- equal or greater than 50 percent reduction of baseline HAM-D.

You take that to Table 2 --

A All right.

Q -- and which is that? Is that the second one?

A I think it was the first and the second.

(Witness read document.)

A Looks like it's the first, isn't it?

Q Well, take -- let's go back to the abstract.

A And the second --

Q Well, actually, go to page 764.

A Yes.

Q Okay.

The section that says efficacy and safety evaluation; do you see that?

A Right, right, right.

Q And, if you would, read the --

A Protocol defined -- described two primary outcome measures.

Q Yes.

A Response, which was the --

The protocol described two primary outcome measures. One: Response, which was defined as HAM-D squared less than equal to 8 or greater than equal to 50 percent reduction in baseline score at the end of measurement.

Q All right. Let's stop there.

A Okay.

So --

Q Now, which is that in Table 2?

A That's the second one.

Q Okay.

Did Paxil separate statistically from placebo with regard to that primary outcome measure? 02:02:37 02:02:39 02:02:42

A No. 02:02:43

Q Okay. Now let's go -- now go back to 764. What's the secondary primary variable? 02:02:43 02:02:48 02:02:49

A The second primary -- 02:02:54

Q Yes. 02:02:55

A That's change from baseline in HAM-D total score. 02:02:57 02:03:00

Q Okay. And now let's go to the Table 2 again, and which one -- 02:03:00 02:03:01 02:03:03

A I think that's the last one, isn't it? 02:03:08

Q Okay. 02:03:10

A Am I right? 02:03:13

Q Yes. 02:03:14

And did it -- did Paxil separate statistically from placebo with regard to that endpoint? 02:03:16 02:03:19 02:03:20

A No. 02:03:22

Q Okay. 02:03:22

So am I correct in stating that 02:03:24

neither of the primary efficacy variables -- well, let me -- let me say that again. 02:03:27 02:03:34

Neither of the primary efficacy variables with regard to paroxetine separated statistically from placebo, correct? 02:03:39 02:03:41 02:03:43 02:03:45

A Yes. 02:03:48

Q Okay. 02:03:51

Now, I want to show you what I've marked -- 02:03:51 02:03:53

Have we marked that study? We marked that as Exhibit 13; is that correct? 02:03:54 02:03:56

MR. DAVIS: (Nods.) 02:03:58

MR. GREEN: (Nods.) 02:03:59

(Exhibit No. 14 marked for identification.) 02:03:59 02:03:59

BY MR. MURGATROYD: 02:03:59

Q Let me show you what I've marked as Exhibit 14. 02:04:00 02:04:01

A What one? Just give me one second. 02:04:03

Q Okay. 02:04:05

A Just for my own reference, because -- 02:04:13

(Pause.) 02:04:17

Q No, that's fine, because we're going to come 02:04:17

back to the study in a certain -- 02:04:19

A Mm-hmm. 02:04:25

Just -- I'm half talking to myself, but on page 764, right after that, it talks about -- I know this is not what you're asking me now -- 02:04:25 02:04:27 02:04:30 02:04:31

MR. GREEN: There's -- there's no question pending. 02:04:32 02:04:33

THE WITNESS: Okay. Okay. 02:04:34

Q Okay. 02:04:37

A All right. 02:04:37

Q Let's go to the next exhibit -- 02:04:37

A Okay. 02:04:39

Q -- which we've marked as Exhibit 14. And if you would, take a look at that. 02:04:39 02:04:43

A This is different than 12? 02:04:56

Q Yes, you'll see that it's amended. 02:04:57

A Okay. 02:05:00

Q And do you see the amendment date at the bottom? 02:05:01 02:05:03

A The last one? 02:05:03

Q Yes. 02:05:04

What's -- 02:05:04

A October 29, 1996. 02:05:04

Q Okay. 02:05:07

A Yeah, okay. 02:05:10

Q All right. 02:05:10

Now, with regard to that amended protocol -- and, again, I believe you -- so the record's clear, what's the date of that amended protocol at the bottom again? 02:05:11 02:05:13 02:05:15 02:05:17

The very bottom right -- 02:05:24

A The Amendment No. 2 says -- there are two dates, but the date the amendment was approved was October 29, 1996. 02:05:25 02:05:30 02:05:32

Q Okay. 02:05:35

A It doesn't -- the protocol in itself is not dated. 02:05:36 02:05:38

Q Okay. 02:05:38

Now, in that protocol, it lists the primary and secondary efficacy variables, correct? 02:05:40 02:05:44 02:05:48

And so the record's clear, an efficacy variable and an outcome measure, there's synonymous terms; is that correct? 02:05:51 02:05:52 02:05:55

MR. DAVIS: Object to the form. 02:05:59

A No. 02:06:00

Q Okay. 02:06:05

What's the difference between them? 02:06:05
A Well, there can -- can be outcome variables 02:06:08
which aren't efficacy, per se. 02:06:11
So you could be measuring outcome 02:06:13
in -- in psychosocial functioning. You 02:06:16
could be measuring a variety of outcomes 02:06:20
which don't fit the traditional definition 02:06:22
of efficacy, which, by inference, although 02:06:24
I'm not sure by Webster, by inference would 02:06:28
be having to do with the, you know, the 02:06:32
comparative change in the measure of 02:06:34
interest. 02:06:39
So there are a lot of outcomes you 02:06:40
look at. 02:06:43
Q Okay. 02:06:43
So is a better term to use "outcome 02:06:44
measure"? That would cover those that are 02:06:49
beyond efficacy? 02:06:49
A Yes. 02:06:51
Q And include efficacy and those beyond 02:06:51
efficacy? 02:06:54
A Yes. 02:06:55
Q Okay. 02:06:55
So I'm going to use the word "outcome 02:06:55

measure." 02:06:57
In terms of the documents in front of 02:06:57
you, I believe that it lists the secondary 02:06:58
outcome measures, correct? 02:07:01
A Which document are you referring to now, 02:07:03
Skip? 02:07:05
Q The exhibit in your hand, Exhibit 14, the 02:07:06
amended protocol. 02:07:10
MR. GREEN: If you need time to read 02:07:12
it, take a few minutes to read it. 02:07:13
(Witness read document.) 02:07:15
A So I -- I can find primary efficacy and 02:07:35
secondary efficacy on the page at the 02:07:40
bottom, 636. 02:07:44
Now I'm looking to see whether 02:07:45
they -- it -- it mentions other outcome 02:07:47
variables throughout the text of this. 02:07:51
Q Okay. That's fine. 02:07:53
A Page 24 -- 02:07:57
(Witness read document.) 02:08:00
A Can we go off the record for a second? 02:08:18
Q Sure. 02:08:20
You want to go off the record to look 02:08:20
at it? 02:08:22

A Well, I want to ask you a question off the 02:08:23
record. 02:08:25
MR. MURGATROYD: Okay. That's fine. 02:08:26
THE VIDEOGRAPHER: The time is eight 02:08:27
minutes after 2:00. We are off the record. 02:08:28
(Discussion off the record.) 02:08:31
THE VIDEOGRAPHER: We're back on the 02:08:45
record. The time is 12 minutes after 2:00. 02:11:58
BY MR. MURGATROYD: 02:12:01
Q Okay. 02:12:02
So we were talking about the 02:12:03
secondary efficacy variables that are 02:12:04
contained within the amended protocol dated 02:12:08
1996, correct? 02:12:10
A Yes. 02:12:12
Q And can you read those into the record, what 02:12:12
they are? 02:12:15
A Secondary -- secondary efficacy variables, 02:12:19
page 24. Okay. 02:12:25
Under A: Changes from baseline to 02:12:36
endpoint in the following parameters: 02:12:38
Depression items in the K-SAD-L. 02:12:42
Global impressions. 02:12:47
Autonomic function checklist. 02:12:48

Self-perfection -- perception 02:12:50
profile. 02:12:50
Sickness impact scale. 02:12:51
B: Predictors of response 02:12:55
(endogenous subtypes, age, prior episodes, 02:12:57
duration and severity of present episode, 02:13:02
comorbidity with separate anxiety, attention 02:13:05
deficit and conduct disorder). 02:13:11
C: The number of patients who 02:13:14
relapse during maintenance phase. 02:13:16
Q Okay. 02:13:18
Now, let's take a look -- take it 02:13:19
from the top. 02:13:21
So we have the depression items in 02:13:22
K-SAD-L, correct? 02:13:24
A Yes. 02:13:26
Q And did that -- did paroxetine separate 02:13:27
statistically from placebo with regard to 02:13:30
that scale? 02:13:33
(Witness read document.) 02:14:23
A Yes. K-SADS-L, depressed mood item. 02:14:25
Q No, this is the -- 02:14:31
A Results. 02:14:33
Q It says here depression items in K-SAD-L. 02:14:33

A Well, depression mood item would be a depressed item in the K-SADS-L. 02:14:39 02:14:42

Q Well, what's the difference between that and the K-SADS-L nine-item depression subscale -- subscore? 02:14:45 02:14:46 02:14:48

A I believe the nine-item subscore adds up the scores from nine items. 02:14:55 02:14:58

Q Where the other is just -- the K-SADS-L is just one? 02:15:00 02:15:02

A Is one -- one particular item. 02:15:03

Q Okay. 02:15:04

And this -- and the protocol says depression items in K-SAD-L, correct? 02:15:05 02:15:08

A Yes. But I think, you know, in terms of how you read it, this -- in other words, this -- 02:15:12 02:15:19

My reading of this here is that this is not -- how to put this. 02:15:20 02:15:24

This is not definitive in being explicit as to whether or not the depressant -- the depression item by itself is being intended or whether they're talking about the subscale. 02:15:26 02:15:29 02:15:31 02:15:36 02:15:39

It doesn't -- it's not -- it's not explicit from looking at this. 02:15:39 02:15:41

Q Okay. 02:15:43

A I think that's an open -- 02:15:43

Q Well, let's take both of them. 02:15:45

According to your -- the journal article in which you were the primary -- the lead author, if you take the K-SADS-L nine-item depression subscore, did paroxetine separate statistically from placebo? 02:15:47 02:15:49 02:15:51 02:15:54 02:15:56 02:15:59

A In the K-SADS-L depressed -- 02:16:00

Q Nine-item depression subscore. 02:16:05

A No. 02:16:12

Q Okay. 02:16:13

A But it was from the K-SADS-L depressed mood item. 02:16:15 02:16:18

Q Okay. 02:16:19

Now, did the change in CGI score -- mean score for -- did paroxetine or Paxil separate statistically from placebo with regard to the mean CGI score? 02:16:19 02:16:26 02:16:30 02:16:32

MR. DAVIS: Object to the form. 02:16:38

A Well, it did in the CGI score -- having a CGI score of 1 or 2. 02:16:43 02:16:45

Q No, the question was the mean CGI score. 02:16:47

A No. 02:16:54

Q Okay. 02:16:55

Did -- with regard to the autotomic -- autonomic function checklist, can you describe for us what that is for the record? 02:16:57 02:17:00 02:17:05 02:17:06

(Witness read document.) 02:17:17

A I'd have to look at the checklist to -- to give you a precise definition of it. 02:17:28 02:17:30

Q Okay. 02:17:35

Do you -- do you recall from reading your journal article whether or not placebo separated statistically from placebo with regard to the autonomic function checklist? 02:17:35 02:17:37 02:17:42 02:17:47

(Witness read document.) 02:18:05

A I don't think we reported P values for those, unless I'm missing it. 02:18:16 02:18:20

Q It's not in Table 2, is it? 02:18:23

A No, no, because -- 02:18:25

Q But it is in the -- it does mention it in the right-hand column of page 766, correct? 02:18:27 02:18:29

A Well, I'm looking at page 764. It mentions assessment of multiple domains of functioning, general health and behavior 02:18:34 02:18:38 02:18:41

consisted of autonomic checklist, blah, blah, blah, blah, blah, blah, self-perception, sickness impact scale. 02:18:43 02:18:46 02:18:47

Q And how did -- and how did Paxil do with regard to those scales? 02:18:50 02:18:56

A I don't -- I don't see that we -- 02:18:58

(Witness read document.) 02:19:21

A I don't think we reported the outcome of those. 02:18:58 02:19:23

Q Well, actually, if you look on page 766 -- 02:19:25

A Oh, "although neither"? 02:19:28

Q Yes. 02:19:31

A Statistically across the nonsymptom measures of functioning. 02:19:31 02:19:34

(Witness read document.) 02:19:35

A Doesn't say that specifically, but -- 02:19:52

Q Actually, why don't you read that sentence into the record. 02:20:01 02:20:03

(Witness read document.) 02:20:04

A Okay. Page 766? 02:20:20

Q Yes, sir. 02:20:23

A Okay. 02:20:24

"Although neither paroxetine nor imipramine separated statistically from 02:20:24 02:20:26

placebo across the nonsymptomatic measures of functioning, health and behavior, improvements over baseline were achieved for each active treatment group. Placebo-treated subjects also improved along the behavioral measures but to a lesser extent than patients in the active treatment groups." 02:20:29 02:20:31 02:20:34 02:20:36 02:20:37 02:20:40 02:20:42 02:20:46

Q. Okay. So now let's take the secondary efficacy variable that's defined in the protocol of autonomic function checklist. Did -- from your reading of your study, did paroxetine separate statistically from placebo with regard to that variable? 02:20:47 02:20:48 02:20:49 02:20:52 02:20:56 02:20:58 02:21:00

A. No. 02:21:05

Q. Okay. Now, the next variable listed in the protocol is the self-perception profile. Do you see that? 02:21:06 02:21:06 02:21:09 02:21:12

A. Yes. 02:21:14

Q. And can you define or tell the jury what that -- what that variable is? Can you describe for the record what 02:21:15 02:21:16 02:21:29

it is? 02:21:30

A. Yes. I mean, the general description is how one perceives oneself. 02:21:31 02:21:33

Q. Okay. Now, is that a measure that the patient themselves -- that the child would fill out themselves to say whether or not they thought they were doing better? 02:21:35 02:21:36 02:21:41 02:21:44 02:21:45

A. It's -- it's filled out by the child, but it has less to do with improvement and more to do with -- how do you describe this. Aspects of self-perception, not symptom improvement. It's a very global concept. 02:21:53 02:21:56 02:22:01 02:22:10 02:22:17 02:22:24

Q. About how they feel about themselves? 02:22:25

A. Right. 02:22:27

Q. Okay. And did Paxil separate statistically from placebo with regard to that efficacy variable? 02:22:28 02:22:28 02:22:32 02:22:33

A. No. 02:22:34

Q. Okay. Now, turning to the sickness impact scale, do you see that in -- as listed as a 02:22:35 02:22:36 02:22:39

secondary variable? 02:22:41

A. Yes. 02:22:42

Q. Okay. Now, did -- can you describe what that is? 02:22:43 02:22:43 02:22:45

A. It's also very -- it's a very global measure of the effect of the sickness or the illness, it has on you. So the impact of your sickness on you. Again, a very global measure. 02:22:47 02:22:52 02:22:59 02:23:02 02:23:04

Q. And is that filled out by the patient who is taking the drug? 02:23:08 02:23:10

A. I believe so, but I would have to see the scale. 02:23:19 02:23:21

Q. Okay. And did Paxil separate statistically from placebo with regard to that measure? 02:23:21 02:23:22 02:23:24

A. Unless I'm missing it, it's not listed specifically here, but the inference from this paragraph would be that it's being covered and it wasn't significant, but it's not listed specifically. 02:23:42 02:23:44 02:23:46 02:23:51 02:23:53

Q. Okay. 02:23:55

A. So if it is listed specifically somewhere 02:23:56

else in the paper, I'd have to comb through it. 02:23:58 02:24:00

Q. All right. So looking on the protocol that's before you with regard to the primary efficacy variables, we agreed that Paxil did not separate statistically from placebo with regard to either of those, correct? 02:24:01 02:24:02 02:24:05 02:24:09 02:24:11 02:24:13

A. Yes. 02:24:17

Q. And with regard to the secondary efficacy variables that we just discussed, the depression items of the K-SADS-L, global impressions, the autonomic function checklist, the self-perception profile and the sickness impact scale, Paxil did not separate statistically from any of those if depression items of K scale -- K-SADS-L is defined as the nine-item depression subscore, correct? 02:24:18 02:24:20 02:24:22 02:24:26 02:24:28 02:24:30 02:24:35 02:24:41 02:24:45 02:24:47

MR. DAVIS: Object to the form. Mischaracterizes the testimony. 02:24:50 02:24:51

A. Yes, I -- I -- if you could separate those out. I guess I -- my -- my interpretation 02:24:55 02:24:58 02:24:59

and understanding of the secondary efficacy 02:25:03
variable, the first one listed under changes 02:25:08
from baseline, depression items in K-SADS-L, 02:25:12
my interpretation of that would be that that 02:25:16
would refer to the K-SADS-L depressed mood 02:25:19
item which did significantly separate from 02:25:24
placebo. 02:25:27
Q Okay. 02:25:28
So one out of the five separated? 02:25:28
A Then -- and then the -- the other one that I 02:25:31
believe separated is the clinician's global 02:25:42
score, which would be the second one listed 02:25:47
under global impression. 02:25:49
Q Well, actually, the -- if you go to Table 2, 02:25:52
the mean global score did not separate 02:25:55
statistically, correct? 02:25:58
A The mean didn't, but the actual individual 02:25:59
score of 1 or 2 -- 02:26:01
Q Right. 02:26:04
A -- did. So that's a -- that's also a global 02:26:05
impression score. 02:26:08
Q Okay. 02:26:09
Well, if you take the -- all right. 02:26:10
So let's say the -- the secondary 02:26:12

variables -- you could say -- 02:26:15
A Two. 02:26:18
Q -- two out of, but you'd have to add -- 02:26:19
you'd have to add two onto this five, so it 02:26:22
would have to be seven, right? 02:26:26
MR. DAVIS: Object to the form. 02:26:27
I'm not sure what question is being 02:26:28
asked the witness. 02:26:30
Q Well, if you have the depression item, items 02:26:31
of K-SAD-L, which we have agreed could be 02:26:34
either the mood item or the nine-item 02:26:37
subscore, correct? 02:26:42
MR. DAVIS: Object to the form. He 02:26:43
said it's included within -- one is included 02:26:45
within the other. 02:26:47
Object to the form of the question. 02:26:47
Q Okay. 02:26:50
A Those are two separate -- two separate 02:26:52
measures, correct? 02:26:53
MR. DAVIS: Object to the form. 02:26:55
I'm not sure what is being asked of 02:26:57
the witness as to what are two separate 02:26:58
measures. 02:27:00
MR. MURGATROYD: Well, it's pretty 02:27:02

simple. 02:27:04
Q The HAM-D depressed mood item is different 02:27:04
from the -- I'm sorry. 02:27:07
The K-SADS-L depressed mood item is 02:27:11
different from the K-SADS-L nine-item 02:27:14
depression subscore, correct? 02:27:18
MR. DAVIS: Object to the form. 02:27:20
It's been asked and answered. 02:27:21
THE WITNESS: I don't know what I'm 02:27:26
supposed to say. 02:27:26
MR. GREEN: You can answer. 02:27:27
A Yes. 02:27:28
Q They're different -- two different -- two 02:27:28
different measures? 02:27:29
A Well -- yes. The depressed mood item is one 02:27:30
of the nine items in the nine-item 02:27:36
depression subscore. 02:27:44
Q Okay. 02:27:46
So it would be like a -- 02:27:47
A So it's a subset. It's one of the items. 02:27:48
Q Right. Okay. 02:27:51
And then the CGI score of 1 or 2 -- 02:27:52
A Would be one of the items within -- 02:27:55
Well, actually, it's an item -- it's 02:27:59

not different than the CGI score. It's just 02:28:03
different ways of measuring it. 02:28:07
So that in the CGI -- the mean CGI 02:28:10
score would be taking the mean of all the 02:28:13
CGI items. 02:28:17
When you take the individual CGI 02:28:18
improvement item, there's a difference. 02:28:20
Q Okay. 02:28:22
A So I'm not, you know, in terms of sets and 02:28:22
subsets, it's slightly different. 02:28:25
Q Right, okay. 02:28:29
So if we're looking at this protocol 02:28:30
and we have the depression items of the 02:28:34
K-SAD-L, that could be two of the measures 02:28:36
that you reported upon in your journal 02:28:40
article, correct? 02:28:42
A Yes. 02:28:44
Q And one did -- Paxil did separate 02:28:45
significantly with regard to the mood item, 02:28:47
correct? 02:28:50
A Yes. 02:28:51
Q But it did not separate statistically -- 02:28:51
Paxil did not separate statistically with 02:28:54
regard to the nine-item depression subscore, 02:28:56

correct? 02:28:58
A Yes. 02:28:58
Q Okay. 02:28:59
And if you're looking at the CGI, the 02:29:00
global impression, right, there are two ways 02:29:03
of measuring that according to your article 02:29:06
in Table 2. 02:29:07
One is the CGI score of 1 or 2, 02:29:09
correct? 02:29:11
A Correct. 02:29:12
Q And Paxil did separate statistically from 02:29:12
that? 02:29:14
A Correct. 02:29:15
Q From placebo? 02:29:15
But with regard to the mean CGI 02:29:17
score, Paxil did not separate statistically 02:29:19
from placebo, correct? 02:29:22
A Yes. 02:29:23
Q Okay. 02:29:24
So if you add them -- so we have two 02:29:25
primary efficacy variables that did not 02:29:30
achieve statistical significance and five 02:29:32
out of seven secondary measures that did not 02:29:35
achieve -- Paxil did not achieve statistical 02:29:39

significance. 02:29:42
How would you characterize the -- 02:29:44
what would you conclude when you see 02:29:47
statistics such as that? 02:29:50
MR. DAVIS: That object to the form. 02:29:52
Q With regard to the success of the study. 02:29:53
A I wouldn't -- in other words, I wouldn't be 02:29:57
making a judgment about the success of the 02:29:59
study based on what you just described. 02:30:01
I would take into consideration the 02:30:09
other variables which were determined to be 02:30:11
a priori variables before the data was 02:30:15
analyzed. 02:30:18
So that variables were chosen 02:30:19
after -- 02:30:22
Now, let me be careful about this so 02:30:25
I'm accurate. 02:30:27
Variables were chosen and are listed 02:30:28
in the article as a priori items. Either -- 02:30:32
and either not included in this for a reason 02:30:38
that I could not give you or they were 02:30:41
chosen after this was written. 02:30:47
In either of those two cases, the 02:30:50
choice of those items was made before the 02:30:53

data was analyzed, which is why they're 02:30:57
called a priori items. 02:31:00
So that when the thinking and 02:31:03
deliberation was done by the investigators 02:31:07
as to what to include, we included the HAM-D 02:31:11
depressed mood item as well as the 02:31:18
comparison of improvement with placebo in 02:31:20
the HAM-D total score. 02:31:24
And those were two items -- 02:31:28
additional items which were considered to be 02:31:35
extremely important with a separated 02:31:37
placebo, which is what led to the thinking 02:31:41
of the investigators that the preponderance 02:31:45
of the evidence was it -- well, was at the 02:31:49
time, is, that paroxetine separated 02:31:52
significantly from placebo on a number of 02:31:59
highly meaningful -- highly clinically 02:32:05
meaningful and research-relevant 02:32:08
depression-related measures. 02:32:11
Q And going back to the original protocol, 02:32:14
though, that's what -- that's what the 02:32:17
question had to do with -- 02:32:18
A Well, I know, but -- 02:32:20
Q I know. I understand what you're saying. 02:32:21

We'll get to that. 02:32:23
But with regard to the protocols that 02:32:24
are listed -- with the measures that are 02:32:25
listed in the protocol, would you agree that 02:32:28
the primary measures, both the primary 02:32:31
measures, Paxil did not separate 02:32:34
statistically from placebo? 02:32:36
MR. DAVIS: Objection. 02:32:38
Asked and answered. 02:32:38
A I'm sorry, Skip, you lost me on the 02:32:40
question. 02:32:41
Q Okay. 02:32:43
With regard to the primary efficacy 02:32:43
variables that are listed in that 02:32:45
protocol -- 02:32:46
A Okay, now we're talking about the two 02:32:47
primary efficacy variables on page whatever, 02:32:48
64. 02:32:52
Q Correct. 02:32:53
Paxil did not separate statistically 02:32:54
from placebo with regard to both of those 02:32:55
variables? 02:32:59
A Correct. 02:33:00
Q Okay. 02:33:00

And now going down to the secondary 02:33:00
variables, I think we agreed that with 02:33:02
regard to the autonomic function checklist, 02:33:07
the self-perception profile and the sickness 02:33:10
impact scale, Paxil did not separate 02:33:12
statistically from any of -- from placebo 02:33:14
for any of those? 02:33:16
A For those three. 02:33:17
Q Okay. 02:33:18
A And the answer is -- which I assume is 02:33:18
appropriate -- the answer is a "yes, but." 02:33:23
The "yes, but" is that there's no 02:33:25
expectation -- there would have been no 02:33:29
expectation that you would -- you would see 02:33:31
a separation from placebo on these measures 02:33:35
given how global they are, nor in any 02:33:41
traditional -- in any study of looking at 02:33:45
the treatment of depression would you 02:33:49
include these variables as part of a measure 02:33:53
as to whether you've changed or improved or 02:33:56
worsened the person's depression. 02:34:01
Q That -- 02:34:04
A These are not depression items. 02:34:04
Q These -- these are items where the parents 02:34:05

and the child get to say whether or not they 02:34:08
feel like they're doing better, correct? 02:34:10
A I would not state it that way. I would -- I 02:34:17
would -- I think each item has to be taken 02:34:21
for itself. 02:34:25
I wouldn't lump them, so -- 02:34:26
Q Okay. 02:34:28
A -- to be precise -- 02:34:29
Q Well, one is? 02:34:32
A -- it would be a splitter. 02:34:32
Q One is rated by the parent, correct, 02:34:35
perceiving their child, stating whether or 02:34:36
not they believe their child's doing better? 02:34:39
Do you know which one that is? 02:34:44
A The auto -- I'm not sure. Is that -- are 02:34:46
you referring to the autonomic function 02:34:48
checklist? 02:34:50
Q Well, I'm asking you. 02:34:52
A It's not -- it's not -- I'm not sure. 02:34:53
The self-perception is by the child. 02:34:55
Q Okay. 02:34:57
A I believe the sickness impact is by the 02:34:58
child. I am not sure who rated the 02:34:59
autonomic function. 02:35:01

Q Okay. 02:35:03
A You just have to show me the instrument, and 02:35:03
I can telling you. I don't remember. 02:35:05
Q Okay. 02:35:06
But these are ones that are filled 02:35:07
out by the people who are actually -- two of 02:35:08
them are filled out by the person who is 02:35:10
actually taking the drug -- 02:35:12
A Right. 02:35:13
Q -- and the other one is the parent observing 02:35:13
how the child is doing? 02:35:15
A What I'm saying is I'm not sure which of 02:35:16
these three, if any, in fact, were the 02:35:18
parent forms. 02:35:22
Q Parent-rated? 02:35:23
A You'd have to -- I'm just not sure. You'd 02:35:24
have to -- 02:35:26
Q Well, you know two out of three are 02:35:26
child-rated? 02:35:28
A Correct. 02:35:29
Q And the third one is either parent-rated or 02:35:29
child-rated? 02:35:31
A Correct. 02:35:33
Q It's not doctor-rated? 02:35:33

A Correct. 02:35:36
Q Okay. 02:35:36
THE VIDEOGRAPHER: We have to go off 02:35:36
the record to change the tapes. 02:35:37
MR. MURGATROYD: Okay. Stop right 02:35:38
there. Thanks. 02:35:39
THE VIDEOGRAPHER: The time is 2:35. 02:35:40
This is the end of Tape No. 2. We are off 02:35:41
the record. 02:35:43
(Recess.) 02:35:44
THE VIDEOGRAPHER: We are back on the 02:38:22
record. This is Tape No. 3. The time is 02:38:23
2:38. 02:38:25
THE WITNESS: See, I have a good 02:38:26
answer. It depends on whether you have a 02:38:27
question or allow me to give you the answer. 02:38:29
BY MR. MURGATROYD: 02:38:30
Q I don't think there's a question pending. 02:38:31
MR. GREEN: I don't either. 02:38:33
A I know, which is too bad. 02:38:34
Q All right. 02:38:35
Let's go to the -- now -- so you 02:38:35
stated that there are two other items, 02:38:45
measures, right? We just discussed seven. 02:38:50

Actually, we discussed really a total of nine items, correct? 02:38:55 02:38:57

MR. DAVIS: Object to the form. 02:38:58

Q Seven secondary variables and two primary variables? 02:39:00 02:39:02

A Yes. 02:39:04

Q Okay. 02:39:04

And then you said that two more were added at some point in time? 02:39:04 02:39:06

MR. DAVIS: Object to the form. 02:39:08

THE WITNESS: I can answer that? 02:39:11

MR. GREEN: You can answer. 02:39:12

A Yes. 02:39:12

Q Okay. 02:39:13

And who -- 02:39:13

A I'll figure this out. 02:39:15

Q Whose decision was it -- let's -- so the record's clear, what were those two additional measures that are not included in that protocol? 02:39:18 02:39:21 02:39:22 02:39:24

A Okay. 02:39:25

The -- the HAM -- the depressed mood item. 02:39:25 02:39:36

Q Okay. 02:39:36

A And the HAM-D total score of less than or equal to 8. 02:39:37 02:39:46

Q Okay. 02:39:50

And who added -- let's take the HAM-D depressed mood item as the first of the two. 02:39:53 02:39:57

Whose decision was it to add that item as a -- 02:39:59 02:40:02

That was added as a secondary variable, correct? 02:40:03 02:40:05

A I would -- it -- no. 02:40:08

It was added as an a priori item, which is a very critical distinction, meaning that before the data was analyzed, a decision was made that there were at least two -- in this case, the ones we just read -- very important items with regard to depression that should be part of the analysis, making it a priori. 02:40:11 02:40:15 02:40:18 02:40:24 02:40:27 02:40:30 02:40:34 02:40:38

Q Yes. 02:40:41

But neither of them were primary efficacy variables. 02:40:41 02:40:42

We have defined what those were? 02:40:45

A Not primary efficacy variables as stated in the protocol. 02:40:47 02:40:50

Q And not primary efficacy variables as stated in your article? 02:40:50 02:40:53

A Correct. 02:40:55

Q Okay. 02:40:55

So they're a secondary? 02:40:56

A Because they're not primary doesn't mean they're secondary. You don't list them as secondary. 02:41:00 02:41:02 02:41:08

Q Okay. 02:41:09

They're not -- they're not primary? 02:41:09

A We didn't categorize them -- they were not categorized -- 02:41:11 02:41:13

Unless you can find where we did, my reading and my recall is that we didn't categorize them as primary or secondary. 02:41:15 02:41:17 02:41:20

We categorized them as a priori. 02:41:22

Q Okay. 02:41:26

Well, they're all a priori, right? 02:41:26

A No. Variables can be -- 02:41:31

Q No. 02:41:33

All the ones listed in the paper were a priori? 02:41:33 02:41:35

A Yes. There's -- there's a -- terms -- 02:41:37

In other words, category -- 02:41:45

categories of terms are being commingled here, and I understand that they -- why that would be very confusing. And -- and the most common current paradigm is to actually use a priori or secondary as opposed to primary. 02:41:47 02:41:50 02:41:54 02:42:01 02:42:04 02:42:10

So -- and that conventions change over time. So when the extra -- the items that were not in here were chosen, we went -- we were using the terminology of the current convention, the extent convention at the time that the decision was made, and calling those a priori items. 02:42:11 02:42:14 02:42:20 02:42:22 02:42:26 02:42:30 02:42:32

Q Well, the -- let's take the primary efficacy items that we've talked about, the change -- 02:42:35 02:42:39

A As the -- 02:42:42

Q The change in the HAM-D. 02:42:43

A The primary efficacy items -- as "primary" was defined in this protocol -- were the two items specified on page 664 of Exhibit 14. 02:42:44 02:42:47 02:42:50

Q Right. 02:42:54

And those -- 02:42:55

A Those were not -- did not separate statistics from placebo. But -- 02:42:55 02:42:57

Q Okay. 02:43:00
And those were a priori items, 02:43:00
meaning they were -- 02:43:03
A Yes. 02:43:04
Q They were determined before the blind was 02:43:04
broken? 02:43:05
A They were a priori -- 02:43:06
Q Okay. 02:43:07
A -- using that definition. 02:43:07
All I'm -- what I'm trying to make a 02:43:10
distinction about in responding, which I 02:43:11
believe is a very important one, is that the 02:43:14
two additional items that in the judgment of 02:43:19
the investigators was very important were 02:43:22
items that were a priori because they were 02:43:24
chosen before we did the analyses, but 02:43:30
they -- neither were put into the category 02:43:34
of primary or secondary. 02:43:37
Q Well, let me ask you this: 02:43:40
Who -- 02:43:41
A Which is a very legitimate -- 02:43:41
If you were to -- if you were to read 02:43:43
your literature on an annual basis going 02:43:45
back from 1990, 1991, 1992, you'll see the 02:43:49

convention changing, and you'll see how now 02:43:52
things are much more explicit -- 02:43:55
Q Okay. 02:43:58
A -- in those definitions. 02:43:58
Q Well, let me ask you this: 02:44:00
With regard to the HAM-D depressed 02:44:02
mood item -- 02:44:04
A Yes. 02:44:05
Q -- that was a measurement that was added 02:44:05
after -- or it was added at some point in 02:44:07
time. 02:44:11
It's not in -- it's not in the 02:44:12
protocol there, right? 02:44:13
A No. 02:44:14
The measurement was always in the 02:44:14
protocol. The measurement was in the study 02:44:17
from day one. 02:44:19
Q Okay. 02:44:19
But to separate out this item was 02:44:20
decided -- at what -- that's the question. 02:44:22
At what period of time was it 02:44:26
decided? 02:44:26
A Okay. What I said before, but I can 02:44:28
understand we're talking about a lot of 02:44:31

different conversations, I don't remember 02:44:32
when the decision was made to add that 02:44:38
item -- 02:44:44
Q Well, let me ask you this -- 02:44:45
A -- as one of the -- let me finish, okay? 02:44:46
Q Okay. 02:44:49
A I don't remember when that decision was 02:44:50
made. And what I said to you was that it 02:44:51
could have been made before this was written 02:44:56
and not included for some reason, or it 02:44:59
could have been made after it was written, 02:45:03
after this was written. I just don't know 02:45:05
the answer. 02:45:06
Q Let me ask you this: 02:45:07
Who -- 02:45:07
MR. DAVIS: And by written -- this 02:45:09
was written, you're referring to the 02:45:10
protocol? 02:45:12
THE WITNESS: Right. I'm referring 02:45:12
to Exhibit 14. 02:45:13
And what I'm saying, which I hope is 02:45:16
helpful in response to your question when 02:45:19
you asked me when, is I'm saying I don't 02:45:21
remember when. 02:45:23

But what I'm saying is, by virtue of 02:45:24
saying I don't remember, we could have made 02:45:25
that decision before Exhibit 14 was written; 02:45:29
and for reasons that I cannot explain, it 02:45:31
wasn't put in Exhibit 14, or the decision 02:45:34
may have been made after Exhibit 14 was 02:45:37
written. I don't know the answer. 02:45:43
Q Okay. 02:45:44
My next question is, who decided to 02:45:45
make that a measurement that was to be 02:45:48
analyzed? 02:45:52
A Okay. And my answer, I don't remember 02:45:55
specifically which individual of the 02:45:58
individuals involved in this study made that 02:46:04
decision. 02:46:07
Given the way the group functioned, 02:46:11
it's my belief, okay, so -- that it was 02:46:17
suggested by one of the investigators in the 02:46:22
study, brought up for discussion and then 02:46:27
agreed upon by the other investigators to 02:46:31
include it, which was the process that we 02:46:43
used and that I managed when things would 02:46:46
come up over the course of the study. 02:46:49
Q So you -- youcan't give me the name of the 02:46:51

person; is that correct? 02:46:53
A Absolutely not. 02:46:54
Q Okay. 02:46:55
How about can you tell me exactly 02:46:55
when the HAM-D total score of less than or 02:46:56
equal to 8 was added as a measurement to be 02:46:58
analyzed? 02:47:02
A In the spirit of time, the answer would be 02:47:05
exactly the same, if that's acceptable, as I 02:47:06
gave you for Item 8. 02:47:09
Q Okay. 02:47:11
A So in other words, I would answer every 02:47:11
question you would have exactly the same I 02:47:14
did for Item 8, if that's okay. 02:47:15
Q With regard to who also? 02:47:18
A Yes. 02:47:20
Q Okay. 02:47:20
You can't give me the name? 02:47:20
A No. 02:47:21
Q Okay. 02:47:21
But you those were added at some 02:47:22
point in time, because obviously they're 02:47:25
reflected in your paper? 02:47:28
A Yes, yes. 02:47:30

Q Okay. 02:47:30
A And the most critical piece -- the most -- 02:47:31
the most -- the most definitive thing I can 02:47:33
tell you about the point in time is it was 02:47:35
before the analyses were done, which is why 02:47:37
we called it a priori. 02:47:40
Q Okay. 02:47:42
Now, have you -- were you ever shown 02:47:43
the date when the analyses were actually 02:47:44
done? 02:47:46
Have you ever seen those documents? 02:47:46
A If I saw them, I don't remember. 02:47:51
Q Okay. 02:47:53
Do you know when the blind was broken 02:47:53
for Study 329? 02:47:55
A Calendar datewise? 02:47:57
Q Yes, approximately. 02:48:00
A No. 02:48:01
Q Okay. 02:48:01
Well, so the jury understands it -- 02:48:02
understands it, what does a blinded study 02:48:06
mean? 02:48:08
A Well, the blinded study means that at least 02:48:10
one category of -- of participants in the 02:48:18

implementation of the study had no knowledge 02:48:24
as to some important aspect of the study. 02:48:29
Traditionally, you know, referring to 02:48:34
this, so I don't -- I don't want to get into 02:48:36
semantics with you -- 02:48:40
Q Right. 02:48:41
A -- but traditionally referring to this, we 02:48:41
would typically -- a study is either 02:48:45
single-blind or double-blind. 02:48:46
And typically, the blind refers to 02:48:48
which treatment the study subject is 02:48:54
receiving. 02:48:56
Q Okay. 02:48:57
A It could be a whole host of other things, 02:48:58
but just to zap it right down to what's 02:49:00
relevant here. 02:49:05
Q Right. 02:49:05
A Now, in a double-blind study, you know, so 02:49:06
articles will typically say, you know, 02:49:09
double-blind -- I don't know what this title 02:49:10
is, but they typically say double-blind -- 02:49:12
okay. 02:49:15
Double-blind placebo-controlled study 02:49:15
of -- of two drugs, so that would mean that 02:49:19

both the subject and the investigator doing 02:49:24
the ratings of how the subject -- of the 02:49:30
subject's depressed mood had no knowledge 02:49:33
about which of the three treatment 02:49:39
conditions the subject was receiving. 02:49:42
Q Okay. 02:49:45
So let's -- let's take it down to 02:49:45
this study, 329. 02:49:47
A Right. 02:49:49
Q Was that a single- or a double-blind? 02:49:49
A This was double-blind. 02:49:51
Q Which means neither the patient nor the 02:49:53
investigator knew which -- or whether the 02:49:54
patient was taking placebo, the comparator 02:49:59
drug or Paxil; is that correct? 02:50:02
A Yes. 02:50:04
Q Okay. 02:50:04
A And by extension, so certainly the subject's 02:50:05
parents wouldn't know, the -- basically 02:50:08
nobody would know. 02:50:11
The only person who would know, you 02:50:12
know -- who would theoretically have access 02:50:14
to that information would have been the 02:50:18
statistician who created the randomization 02:50:20

procedure, and it would be a -- an 02:50:23
individual designated at each of the sites 02:50:31
where the study is being conducted that 02:50:37
access to that in case there was an adverse 02:50:40
event or a problem or something that had to 02:50:42
be done. 02:50:44
Q Okay. 02:50:46
A So that information -- you know, other 02:50:46
than -- than the person who created the 02:50:49
randomization and someone who has access to 02:50:51
rescue, nobody would know. 02:50:54
Q Okay. 02:50:56
A Although specifically, you know, in a most 02:50:56
technical sense, it's the two groups I'm 02:51:00
referring to, but it's much broader than 02:51:02
that. 02:51:04
Q Okay. 02:51:04
Now, the comparator drug in your 02:51:05
Study 329 was a drug called imipramine; is 02:51:07
that correct? 02:51:11
A Yes. 02:51:11
Q And does it have an adverse event profile 02:51:12
that's different from Paxil? 02:51:14
A Yes. 02:51:16

Q Okay. 02:51:16
And what -- what -- what are the 02:51:17
primary differences? 02:51:18
A In the context of the answer, it's very 02:51:26
important to appreciate that the adverse 02:51:28
events vary extraordinarily from individual 02:51:32
to individual, so that a meaningful 02:51:37
proportion of people on imipramine do not 02:51:40
suffer adverse events that they find to be 02:51:46
troublesome, as is the case with paroxetine, 02:51:49
so that you could not receive any -- you 02:51:55
cannot have any adverse events on either of 02:51:57
the drugs. 02:52:01
A Now, then what you do is you list the 02:52:03
adverse events which occur, tend to occur -- 02:52:06
which occur most frequently, you know, based 02:52:10
on a database; and so with imipramine, which 02:52:13
falls into the category of what we call a 02:52:19
tricyclic or norepinephrine reuptake 02:52:23
inhibitor, typically people on imipramine 02:52:28
have -- excuse me, have a higher probability 02:52:31
of dry mouth, for example. 02:52:38
Q Is that called and anticholinergic? 02:52:39
A Anticholinergic effects. 02:52:43

Q Okay. 02:52:46
A However, if you look at -- at the adverse 02:52:47
event profile for Paxil, paroxetine, SSRI, 02:52:51
dry mouth actually occurs greater than 02:52:58
placebo in a reasonably and meaningfully 02:53:00
higher proportion of people on paroxetine. 02:53:03
It just in aggregate is more common 02:53:07
on imipramine. 02:53:11
Q Okay. 02:53:12
And how about with regard to 02:53:12
cardiovascular effects? 02:53:13
Is imipramine known to cause 02:53:17
cardiovascular effects? 02:53:19
A It doesn't -- it's not known to cause 02:53:27
cardiovascular effects which a patient 02:53:30
taking the drug would typically be aware of. 02:53:38
So I'm trying to, you know, make a 02:53:41
distinction between a symptom and a sign, 02:53:43
the symptom being something that any -- you 02:53:45
know, you would recognize if you had a cold 02:53:47
or a flu, sniffles or whatever, or -- 02:53:49
But if your electrolytes were 02:53:55
imbalanced because of a flu, you wouldn't 02:53:57
know that. That would be the sign. 02:53:59

So there -- there have been 02:54:02
reports -- and, indeed, very carefully 02:54:05
monitored during the course of this study -- 02:54:09
there had been reports about problems with 02:54:12
hypertension in taking imipramine in -- 02:54:15
particularly in adolescents. 02:54:21
So, you know, we monitored what we 02:54:23
called -- that's what's called a vital sign. 02:54:26
We monitored vital signs like blood 02:54:29
pressure, heart rate, so on and so forth, 02:54:32
very carefully in the study. 02:54:34
That's an example. 02:54:38
Q Okay. 02:54:39
So by monitoring the vital signs 02:54:39
during a study, you can actually see which 02:54:41
kid was taking imipramine, correct? 02:54:44
A No. The person -- well, I could -- you 02:54:46
could see; but the person doing that 02:54:48
monitoring was not someone that had any had 02:54:49
any role in rating the outcome measures. 02:54:57
Q Who -- who was responsible for doing the 02:55:01
vital signs? 02:55:03
A It was like a medical monitor. 02:55:04
Q And that was only -- they did not do any of 02:55:09

the medical measures -- I mean any of the 02:55:10
measures rating? 02:55:14
A No, they did -- they did not measure the -- 02:55:16
they do any of the measure -- they did not 02:55:16
do any of the outcome measures. 02:55:18
Q Okay. 02:55:20
A And just, again, to avoid semantics, 02:55:20
we're -- let's stipulate that when we talk 02:55:23
about outcome measures, we're talking about 02:55:26
outcome measures of interest with regard to 02:55:28
the efficacy of the treatments. 02:55:30
Q Right. 02:55:32
A Because I did say to you before, outcome 02:55:33
measures could be, you know, a million 02:55:35
things. 02:55:39
Outcome measures could be costs, 02:55:40
anything. 02:55:41
Q Okay. 02:55:42
Well, actually, there were quite a 02:55:43
number of secondary variables that were 02:55:45
listed for this study, correct, over 20? 02:55:49
Do you recall that? 02:55:52
MR. DAVIS: Object to the form. 02:55:53
A You'd have to show me where they are, but it 02:55:57

wouldn't surprise me. 02:56:00
Q Let's take a look at the next document. 02:56:02
A We will really have to cool this room. 02:56:04
MR. DAVIS: It's warm, isn't it? 02:56:07
THE WITNESS: It's really stoking up, 02:56:08
yes. 02:56:10
MR. MURGATROYD: Yes, open up that 02:56:10
door. It may help. 02:56:11
(Exhibit No. 15 marked for 02:56:13
identification.) 02:56:13
BY MR. MURGATROYD: 02:56:13
Q I'm going to show you what I've marked as 02:56:13
Exhibit 15. 02:56:15
A I've got a 20-year-old boat that would hold 02:56:16
at least six of us, if you're game. 02:56:18
(Laughter.) 02:56:21
Q I'm going to show you this document. I'm -- 02:56:22
we're going to be talking about page 5, but 02:56:24
you're absolutely free to take your time -- 02:56:27
MR. MURGATROYD: We can go off the 02:56:30
record. 02:56:31
A Where are you? Which exhibit? 02:56:31
THE VIDEOGRAPHER: The time is 2:56. 02:56:31
We're off the record. 02:56:33

(Recess.) 02:56:34
THE VIDEOGRAPHER: We're back on the 03:10:43
record. The time ten minutes after 3:00. 03:10:51
(Discussion off the record.) 03:10:57
MR. MURGATROYD: Are you ready? 03:11:08
THE VIDEOGRAPHER: We're on the 03:11:10
record. 03:11:12
A So when you stopped, I was on -- 03:11:15
Q Yes, we were looking at -- 03:11:17
A -- page 2 of Exhibit 15. 03:11:19
Q Yes. 03:11:20
And you'll see that that -- 03:11:21
A Not page 2. Page 5. 03:11:25
Q Okay. 03:11:26
That document, if you look on the 03:11:28
first page, is entitled Statistical 03:11:29
Appendix. 03:11:31
Do you see that on the first page? 03:11:32
A Yes. 03:11:38
Q Okay. 03:11:38
And it's dated in June 1998; is that 03:11:39
correct? 03:11:42
A Yes. 03:11:43
Q Okay. 03:11:43

And I ask you to turn to -- 03:11:43
A Page 5? 03:11:45
Q Yes. 03:11:46
A Yes. 03:11:48
Q Actually, before I go any further, did you 03:11:49
participate in preparing this document, to 03:11:52
your knowledge? 03:11:54
A What I -- again, this is soft memory. 03:11:58
The soft memory is that all of us -- 03:12:05
when I say "all of us," it's -- it's not 03:12:12
every author on the paper, but there are 03:12:15
about eight or ten of the authors who are 03:12:17
more senior people, that we participated in 03:12:19
the development of the statistical analysis 03:12:24
plan by conference calls which included 03:12:26
statisticians from the company and talked 03:12:30
about, you know, what -- what the hypotheses 03:12:36
were, what the variables of interest were, 03:12:41
you know, in order to -- in order to test 03:12:44
those, you know, which specific items. 03:12:49
So, in fact, as a group -- and I 03:12:52
can't -- I can't tell you exactly which role 03:12:54
I played. 03:12:59
As a group, we -- we played a 03:13:01

dominant role because, in other words, we 03:13:04
were the people that had to identify which 03:13:06
of the items on the whole -- in the whole 03:13:09
panoply of assessments that we had given to 03:13:12
the subjects, which of the items actually, 03:13:15
you know, were the variables that needed to 03:13:17
be pulled out to do the data -- to do the 03:13:20
analysis, and that's call the data 03:13:25
harvesting procedure. 03:13:27
So it's not like every single 03:13:28
variable in all these forms was coded. We 03:13:30
harvested them. And then we'd say, okay, in 03:13:34
order to test to see whether or not, you 03:13:37
know, pick one of these measures, you know, 03:13:38
recreational, some activity was different, 03:13:42
you know, which are things you would 03:13:46
measure, how would you measure it; and then 03:13:46
also, you know, we would talk about things 03:13:47
like -- 03:13:49
The short answer's yes. I'll save 03:13:50
you some time. 03:13:53
Q Okay. That's fine. 03:13:54
And did you have -- you as being the 03:13:57
principal investigator, did you have veto 03:13:59

power over any of the measures that you -- 03:14:01
or did you ever exercise any veto power? 03:14:03
A No. The biggest -- the power I would 03:14:06
exercise is to make sure people stayed on 03:14:07
task, you know; because unlike attorneys, 03:14:09
occasionally people like us, we sort of 03:14:13
waffle and daydream and start bullshitting 03:14:15
rather than kind of getting to it. 03:14:18
And then I would also exert myself to 03:14:19
make sure -- actually, now it comes back. 03:14:24
In a situation like this, you know, 03:14:27
for an -- for an efficiency of effort, you 03:14:29
know, we designated certain people who had 03:14:32
particular, you know, interest and expertise 03:14:37
in doing these things to say, well, okay, 03:14:38
Mike, Greg, Johnny, Sally, okay, you four 03:14:41
agree that you're going to do the first 03:14:43
draft, pulling all the stuff together. 03:14:45
Yeah, okay. 03:14:48
How long can is it -- how long -- 03:14:48
when can you do it by? We want to get this 03:14:49
thing done. You know, we don't want to 03:14:52
start here in 2006 and still be writing this 03:14:53
paper. 03:14:57

That's the kind of stuff I would do. 03:14:58
Q Okay. 03:15:01
A If the group seemed to be deadlocked in 03:15:01
thinking something through, I would try to 03:15:03
figure out creative ways to kind of get 03:15:04
around Robin's barn and to forge a 03:15:07
consensus. 03:15:11
I can't ever remember an instance in 03:15:12
which I, you know, sort of went against the 03:15:13
tide of the group and said, Oh, you all 03:15:15
think that. I'm the boss; we're going to do 03:15:18
this 03:15:20
Q Okay. 03:15:21
So I take it you didn't veto any 03:15:22
secondary measures that were -- that were 03:15:23
put forth by any of your coinvestigators? 03:15:26
A I don't, no. That's just not my style. 03:15:28
Q Okay. 03:15:30
So now turning to that exhibit -- 03:15:31
A I do get irritable occasionally. 03:15:34
Q Okay. 03:15:37
There's a section I believe you 03:15:39
turned to that had the secondary outcomes 03:15:42
listed? 03:15:44

A Is that 5, page 5? 03:15:45
Q Yes. 03:15:50
Do you see that? 03:15:50
A Yes. 03:15:51
Q And can you count how many secondary 03:15:51
outcomes are listed there, please? 03:15:55
A Well, one -- you're going to want this back, 03:16:07
I assume, right? 03:16:16
Q Yes. 03:16:16
A One, two, three, four, five, six, seven, 03:16:17
eight, nine, ten, eleven, twelve, thirteen, 03:16:32
fourteen, fifteen, sixteen, seventeen, 03:16:43
eighteen, nineteen, twenty. 03:16:50
Q Twenty? 03:16:56
A You knew that. 03:16:57
Q I did know that. I just wanted to make sure 03:16:58
I was correct. 03:17:01
There are 20, correct? 03:17:02
A If I can help with that, I can help. Yes, 03:17:04
it was 20. 03:17:05
Q Okay. 03:17:06
And of those 20, which ones did 03:17:06
paroxetine separate statistically from 03:17:14
placebo? 03:17:16

MR. DAVIS: Object to the form of the question. 03:17:17 03:17:18

A The ones that separated statistically from placebo are the ones that are described in the paper that we've gone over as having separated. 03:17:24 03:17:28 03:17:31 03:17:35

What I will say, again, to the extent that the context of this is important, there were not hypotheses that -- where we expected there to be a separation from placebo. 03:17:35 03:17:38 03:17:44 03:17:51 03:17:53

Just as when we -- when we did an analysis of the demographic variables of the subjects in the various cells, we didn't hypothesize. 03:17:56 03:17:59 03:18:02 03:18:07

Because you do an analysis, it doesn't mean that you're hypothesizing that there will be a difference and therefore the lack of a difference is meaningful. 03:18:09 03:18:10 03:18:12 03:18:14

So I really would -- 03:18:19

Q No, I -- the question was, of those 20 -- 03:18:22

A I -- we'd have to cross-reference the paper. 03:18:25

Q Okay. 03:18:29

A And I'm assuming -- I'm assuming it would be 03:18:29

the four -- I'm assuming it's four. 03:18:33

Q Well, are the -- 03:18:36

A I think -- 03:18:37

Q I think we agreed that in your paper, only four variables separated -- Paxil separated statistically from placebo, correct? 03:18:38 03:18:40 03:18:43

MR. DAVIS: Object to the form. 03:18:45

A Yes, so -- 03:18:46

Q Now, are those four listed as secondary variables in Exhibit 15 in your hand? 03:18:46 03:18:49

A Well, HAM-D depressed mood item is. 03:19:00

Q Okay, so that's one. 03:19:03

A It's hard for me to follow this going across. 03:19:10 03:19:12

Q Well, is the change in K-SADS depression item listed among those secondary variables? 03:19:12 03:19:15

A I don't think so. 03:19:18

Q Okay. 03:19:18

A And -- 03:19:20

Q How about CGI of 1 or 2, is that listed in Exhibit 15 as a secondary variable? 03:19:21 03:19:23

A I don't see it. I don't see it. 03:19:25

Q Okay. 03:19:26

A Then there's one other -- 03:19:27

Q How about the HAM-D score of less than or equal to 8? 03:19:28 03:19:32

A I don't think so. 03:19:33

Q So of the 20 secondary outcomes that are listed on that -- in that document, would you agree that only one and only one did Paxil separate statistically from placebo? 03:19:39 03:19:43 03:19:44 03:19:49

MR. DAVIS: Object to the form. 03:19:52

A Yes. But as I stated, there was not an expectation. 03:19:53 03:19:56

Q Okay. All right. 03:19:59

A That was what -- 03:20:00

Q All right. 03:20:01

The -- do you recall the conference that was held in November of 1997 in which the results were discussed among the various researchers of Study 329? 03:20:06 03:20:22 03:20:33 03:20:36

A Could you give me more details on it? 03:20:41

Q Well, let me show you -- let me show you a document. I don't want you to sit there and guess. 03:20:43 03:20:44 03:20:48

(Pause.) 03:21:28

Q Actually, I think it's in the second pile here. I've got a few documents here... 03:21:29 03:21:30

A I assume you had to check your luggage. 03:21:35

Q Yes. I did not lug this through an airport. 03:21:38

(Pause.) 03:21:59

Q Here we go. 03:21:59

THE WITNESS: Did you type that statement or did you just assume it was off the record? 03:22:05 03:22:05 03:22:05

MR. MURGATROYD: Okay. So I think we're up to Exhibit -- 03:22:06 03:22:06

MS. MENZIES: 16. 03:22:13

MR. MURGATROYD: Is it 16? Yes, 16. 03:22:15

(Exhibit No. 16 marked for identification.) 03:22:17 03:22:17

(Exhibit No. 17 marked for identification.) 03:22:17 03:22:17

BY MR. MURGATROYD: 03:22:17

Q I'm going to show you a collection of documents -- well, actually, I should probably -- I'm going to separate out the last -- 03:22:18 03:22:22 03:22:25 03:22:26

I'm going to show you Exhibits 16 and 17. I'm going to show you them together, because I think they'll make more sense to you in a sequence like this. 03:22:27 03:22:30 03:22:32 03:22:34

MR. MURGATROYD: For the record, 16 is a document that's signed, written by Jim McCafferty, dated 3 November 1997; and 17 talks about a synopsis of the top-line results of Study 329. 03:22:37 03:22:40 03:22:42 03:22:48 03:22:56

And then 17 is a table which lists the top-line results of Study 329. 03:22:58 03:23:02

Q And let me just have you take a look at both of these. 03:23:08 03:23:09

(Witness read document.) 03:23:18

A Okay. 03:24:34

Q All right. 03:24:34

MR. MURGATROYD: Have we got everybody? 03:24:35 03:24:36

Todd, can we forge on or do you want to wait for Tamar? 03:24:37 03:24:39

MR. DAVIS: Yes, I'm listening. 03:24:41

MR. MURGATROYD: Okay. 03:24:42

BY MR. MURGATROYD: 03:24:42

Q Now, do you recall receiving the document which we've marked as Exhibit 16, the letter dated 3 November 1997? 03:24:42 03:24:44 03:24:46

A No. 03:24:48

Q Do you recall attending a meeting in 03:24:52

Philadelphia to discuss the results of 329? 03:25:00

A Yes. 03:25:09

Q Okay. 03:25:09

And who attended that meeting, if you recall? 03:25:09 03:25:12

A As many of the investigators as who were able to attend and Jim McCafferty and others. I just don't remember. 03:25:16 03:25:18 03:25:32

So -- 03:25:34

Q Okay. 03:25:34

Do you remember -- 03:25:37

A The guest list -- the guest list were the investigators on the study, McCafferty, and I don't know who else attended from GSK. 03:25:38 03:25:40 03:25:43

And I don't know which of the investigators attended, but I seem to recall there was a pretty good turnout of the senior investigators. 03:25:49 03:25:51 03:25:55 03:25:58

Q Okay. 03:25:59

Was Neal Ryan there; do you recall? 03:25:59

A I just don't remember. 03:26:06

Q Well, do you recall that the results were presented to you at that meeting? 03:26:07 03:26:08

A Yes. 03:26:10

Q Okay. 03:26:10

And were they the same results that are presented in the table which is attached or which I presented to you as -- as Exhibit 17? 03:26:10 03:26:11 03:26:13 03:26:15

MR. DAVIS: Object to the form. Incomplete. 03:26:17 03:26:18

A I don't remember. 03:26:19

Q Okay. 03:26:23

Well, turning to the results that are listed in Exhibit 16: do you see those? 03:26:23 03:26:31

A Yes. 03:26:44

Q Okay. 03:26:46

Does it discuss the results of the two primary efficacy variables that we discussed earlier? 03:26:47 03:26:50 03:26:53

A What page on 14? 03:27:10

(Witness read document.) 03:27:22

A So it mentions the total HAM-D score. 03:27:42

Q Okay. 03:27:46

A Says there was a trend. 03:27:47

Q Okay. 03:27:48

Did -- 03:27:48

A And the second one is the proportion of 03:27:49

responders. 03:27:51

(Witness read document.) 03:28:15

A It mentions both. 03:28:25

Q Okay. 03:28:26

And does it say whether or not placebo -- Paxil separated statistically from placebo with regard to those primary measures? 03:28:26 03:28:28 03:28:30 03:28:32

A With regard to the change in total HAM-D score, it says -- it gives the P value, and it says -- and it says that it showed a strong trend benefit, but it wasn't less than .05. 03:28:42 03:28:45 03:28:47 03:28:52 03:28:54

Q Okay. 03:28:57

Which would make it statistically significant, correct? 03:28:57 03:28:58

A Most commonly accepted definition, yes. 03:28:59

Q Okay. 03:29:01

A And it does not give the P value for the proportion of responders. 03:29:02 03:29:06

Q Okay. 03:29:08

Does it give you the CGI score of 1 or 2? 03:29:09 03:29:15

A No. 03:29:22

Q Does it give you the change in the K-SADS depression item? 03:29:23 03:29:27

(Witness read document.) 03:29:41

A It's not explicit. It mentions the K-SADS. 03:29:44

Q But that's the mean score, correct? 03:29:48

MR. DAVIS: Object. 03:29:52

A Doesn't say. 03:29:52

Q Okay. 03:29:53

Well, is there -- is it statistically significant separ -- is there a statistical -- 03:29:53 03:29:55 03:29:56

A We're talking about 16 now, right? 03:29:57

Q Yes. 03:29:59

Is there a statistical significance between Paxil and placebo with regard to the K-SADS as listed in 16? 03:29:59 03:30:02 03:30:04

A No. 03:30:07

Q Okay. 03:30:08

Now, turning to 17, which is the chart that lists the top-line results, do you see that? 03:30:09 03:30:14 03:30:16

A Yes. 03:30:17

Q Do you whose handwriting that is on this document? 03:30:18 03:30:19

A No. 03:30:22

Q Okay. 03:30:22

Now, going down this top-line results, is there any mention of the CGI score of 1 or 2 as a secondary endpoint? 03:30:23 03:30:26 03:30:35

(Witness read document.) 03:30:47

A The second row from the bottom has the -- has a global, which I'm assuming is the CGI. 03:31:14 03:31:19

Q Okay. 03:31:23

But that's not CGI score of 1 or 2, correct? 03:31:23 03:31:26

A Doesn't say. 03:31:27

Q Well, is there a statistically significant separation of Paxil from placebo with regard to global? 03:31:28 03:31:30 03:31:34

A Amongst the completers, yes. 03:31:37

Q Okay. 03:31:39

How about at endpoint? 03:31:39

A No. 03:31:42

Q Okay. 03:31:43

Is there any reference in the top-line results in Exhibit 17 that reference the K-SADS depression item? 03:31:44 03:31:45 03:31:49

A I -- I think, but -- again, this is not 03:32:09

explicit, but I think the third row from the bottom. 03:32:14 03:32:17

Q K-SADS endpoint in completers? 03:32:18

A Yes. The reason I say that -- but, again, it's not, you know, totally clear, is because the base -- on the second row from the top, the second item which says baseline K-SADS gives -- those numbers are mean scores. 03:32:20 03:32:23 03:32:25 03:32:30 03:32:34 03:32:39

Q Okay. 03:32:41

A And so I'm -- I -- I think -- this, to me, the third line from the bottom, given the -- given the construction of it, which it says, you know, minus 11, minus 9, minus 6 -- 03:32:42 03:32:47 03:32:50 03:32:53

Q Right. 03:32:57

A -- that I think it's -- well, could be the item we're referring to, but it's not clear from this. 03:32:57 03:33:02 03:33:05

Q Okay. 03:33:06

Well, did Paxil separate significantly from placebo with regard to that item that's listed here? 03:33:06 03:33:08 03:33:11

MR. DAVIS: Object to the form. 03:33:14

Which item? 03:33:15

MR. MURGATROYD: The -- the one he was just talking about, third of the bottom, change in K-SADS. 03:33:17 03:33:18 03:33:20

A Well, on the endpoint measure, it's -- P is .065, which would be a strong trend. 03:33:22 03:33:25

Q But did not separate statistically, correct? 03:33:28

A Correct. 03:33:33

Q Okay. 03:33:34

Now, you'll see that attached to Exhibit 16 is a consensus statement. It's the second page. 03:33:42 03:33:43 03:33:51

A Mm-hmm. 03:33:53

Q Did -- did the group of you all at that meeting prepare the consensus statement, or is that something that was done before you met? 03:33:54 03:33:58 03:34:00 03:34:01

A I don't remember. 03:34:05

Q Okay. 03:34:07

Did you vote while you were there to approve the consensus statement? 03:34:08 03:34:11

A I don't remember. 03:34:13

Q Okay. 03:34:14

Do you recall if you personally agreed with the consensus statement? 03:34:15 03:34:17

A You mean at the time? 03:34:20
Q Yes. 03:34:21
A No, it's -- this is -- the answer is I don't 03:34:48
remember. It's over nine years ago, or 03:34:56
almost -- yes, almost nine years ago, so I 03:35:00
just -- I just can't remember. 03:35:02
Q Okay. 03:35:05
A I mean, as a matter of style, it's -- I 03:35:05
would find it hard to believe that if 03:35:13
whomever was involved in writing this 03:35:23
would -- would purport that this was a 03:35:27
consensus we agreed to if it wasn't, but I 03:35:32
can't -- 03:35:36
You know, that would just run so 03:35:37
counter to, you know, the nature of the 03:35:39
working relationship. 03:35:45
It was just very much of a group of 03:35:46
investigators here, company here, liaison; 03:35:49
and it was a pretty harmonious -- 03:35:53
At least in, you know, in the 03:35:57
interactions I could observe, it was a -- it 03:35:59
was a harmonious and a very, you know, 03:36:02
positive working relationship 03:36:06
So it's hard for me to imagine they 03:36:09

would put something out there which wasn't 03:36:12
what we thought. But do I have any memory 03:36:13
of it? No. 03:36:16
Q Okay. 03:36:17
Well, has anybody -- returning to the 03:36:17
first page of Exhibit 16, has -- are you 03:36:20
aware that some of the statistical analyses 03:36:24
are incorrect on this page? 03:36:28
Have you ever been told that? 03:36:29
MR. DAVIS: Object to the form. 03:36:32
A I think the answer -- the best answer is -- 03:36:43
the answer is I have no memory of it. 03:36:47
Q Okay. 03:36:49
A I certainly -- and just as a qualifier so I 03:36:50
just don't sound like someone who is saying 03:36:55
"I don't remember," certainly whenever we 03:36:58
do -- not whenever -- yes. 03:37:01
It's always a process. So when 03:37:03
you -- when you see a draft of analyses at a 03:37:04
meeting -- I do know that -- 03:37:06
I do remember there was a lot of 03:37:09
discussion about the analyses at the 03:37:10
meeting. There was a lot of discussion 03:37:12
about whether there were other analyses that 03:37:13

should be done. 03:37:16
I seem to recall that the analyses 03:37:18
weren't -- what's the word -- scrubbed, if 03:37:21
you will; that when I said top line, that 03:37:26
these analyses were not -- had not been gone 03:37:29
over in sufficient scrutiny with all the 03:37:32
standard operating procedures that anyone 03:37:36
would have said, okay, these are ready to 03:37:40
put in a manuscript. 03:37:42
I do know that it was a -- that we -- 03:37:43
I do -- 03:37:46
I mean, again, this is a vague 03:37:46
memory, that we wanted to get a meeting done 03:37:49
as soon as the, you know, results were 03:37:50
broken as possible so we could take a look 03:37:54
at what we had. 03:37:56
But typically when we do this, in all 03:37:58
studies, be it NIH studies or industry or 03:38:01
whatever, that's your first peak. 03:38:04
That's far from what we call 03:38:07
scrubbing the data, you know, making sure 03:38:09
everything has been checked, double-checked, 03:38:12
and then also is an opportunity to suggest 03:38:14
other analyses which might be done. 03:38:16

Q Okay. 03:38:18
And do you recall other analyses 03:38:18
being specifically discussed at that 03:38:19
meeting? 03:38:21
A I recall that we -- there was a lot of 03:38:22
discussion about other analyses, but I can't 03:38:25
tell you specifically which ones were 03:38:31
discussed. 03:38:33
Q Okay. 03:38:33
A You know, it was basically, okay, do we got 03:38:34
these right, you know? 03:38:37
Are these all -- are these the 03:38:39
analyses you want to see? Are these all the 03:38:41
analyses you want to see? Do these make 03:38:45
sense? 03:38:47
You know, there was discussion of the 03:38:47
analyses, and I just can't remember in 03:38:49
all -- in all, you know, efforts. 03:38:50
It's just so long ago that -- 03:38:54
Q Well, do you -- do you recall the analyses 03:38:57
of the CGI score of 1 or 2 being 03:38:58
specifically discussed, that was an analysis 03:39:02
that needed to be done? 03:39:04
A Yes. 03:39:06

Q Okay. 03:39:07
A That I -- I certainly recall that. 03:39:07
Q Okay. 03:39:09
And you recall that that analysis was 03:39:09
done about six months later? 03:39:11
MR. DAVIS: Object to the form. 03:39:13
Mischaracterizes the record. 03:39:15
A No. 03:39:18
Q You can -- no. 03:39:19
Do you recall the K-SADS-L depression 03:39:20
item being specifically discussed at that 03:39:25
meeting? 03:39:28
A I assume it's okay if I don't just say yes 03:39:36
or no but give a little explanation? 03:39:38
Q That's fine. 03:39:40
A Is that -- 03:39:41
Q Yes. 03:39:42
A So it's not -- I can't remember, you know, 03:39:43
sentences which we had a discussion and what 03:39:50
we said about it; but given that that was 03:39:54
one of the critical variables, I -- I want 03:39:56
to say I know we discussed it, but I can't 03:40:01
remember the conversation. 03:40:04
Q Okay. That's fine. I understand. 03:40:06

I mean, that was a number of years 03:40:09
ago. I'm not going to -- that's fine. I 03:40:10
guess the -- 03:40:12
I take it that meeting wasn't 03:40:19
recorded, to your knowledge? 03:40:21
A I have no idea if it was. 03:40:22
Q Okay. 03:40:24
A But, you know, certainly the spirit of the 03:40:24
meeting and, you know, the context was, 03:40:28
okay, we've been working on this -- and I 03:40:30
should say study which was a bear to do. 03:40:34
You know, it's hard to do these 03:40:37
studies. Any study of children and 03:40:39
adolescents or any study is hard to do. 03:40:40
It's hard to get the subjects in in a timely 03:40:45
fashion. It's just always difficult. 03:40:47
Everybody was very, very happy that 03:40:49
we completed the study. We were all happy. 03:40:50
And we were all very, very keen and 03:40:53
interested in knowing what our results were, 03:40:55
as fast as we could see them; and then we 03:40:58
were keen -- 03:41:01
I do -- what I can remember of the 03:41:02
meeting was there was a lot of active energy 03:41:04

and discussion about, gee, what do we have 03:41:07
here? What does it look like? Do we have a 03:41:11
finding? You know, do we have a separation 03:41:13
from placebo? Did the study work, and what 03:41:15
manuscripts should be written? 03:41:18
That somehow -- and I -- I have some 03:41:21
memory that when we went so far as to -- as 03:41:27
to agree who should be the lead author on at 03:41:30
least three manuscripts, I can't remember 03:41:36
who, I'm guessing it was Ryan and Strober, 03:41:41
because basically, Ryan and Strober were 03:41:43
seen along with me as sort of the drivers of 03:41:46
the study. 03:41:49
Q Okay. 03:41:50
A And that's kind of the memory. I know there 03:41:51
was lots of discussion. 03:41:54
Q Okay. 03:41:57
A And the goal was to leave there so that -- 03:41:57
one of the goals was to leave the meeting 03:42:00
with a charge, if you will -- not a charge, 03:42:02
you know, with a plan. 03:42:04
Not a plan -- not a -- you know, not 03:42:08
an operating plan that was a line item, you 03:42:11
know, do these items and this, but a plan of 03:42:14

what was going to happen after we left the 03:42:16
meeting to push the analyses forward so we 03:42:18
could move this to the point where then we 03:42:20
could -- where we could then start to write 03:42:24
the manuscripts of interest. 03:42:26
Q Okay. 03:42:27
A So, I mean, you know, that was the thrust of 03:42:27
the energies. 03:42:30
Q Okay. 03:42:31
I think I actually have a document 03:42:31
that -- that talks about the -- it was -- 03:42:33
So part of the meeting had to do with 03:42:37
the publication plan? 03:42:39
A Yes, yes. 03:42:40
Q Okay. 03:42:41
Where different people could possibly 03:42:41
be authors of different publications arising 03:42:43
from the results of the trial? 03:42:48
A Yes. 03:42:51
Q Okay. 03:42:51
I'm going to see -- 03:42:51
A Keller's rule of managing studies is that no 03:42:51
one is allowed to claim dibs on who will be 03:42:54
further author on which paper until the 03:42:57

study is completely over; that we can't discuss it, argue about it or fight about it. 03:42:58 03:43:00 03:43:01

And if you feel the need to and think it's not fair, you can't participate in a Keller study, because we never know until the end who is, A, going to be still standing, you know, who actually stayed in the study and who did the work and deserved it. So that discussion came up. 03:43:02 03:43:03 03:43:05 03:43:08 03:43:10 03:43:13 03:43:15

(Exhibit No. 18 marked for identification.) 03:43:16

Q Okay. No, that's all right. 03:43:18

And let me show you what I marked as Exhibit 18, because I think it -- it has the same date as the meeting, November 4, 1997, so I assume -- and it may help refresh your recollection on -- there's -- I'm going to -- 03:43:19 03:43:22 03:43:26 03:43:29 03:43:31 03:43:34

This is actually a two-page document I'm going to show you. And the first page is publication strategy, and it's dated November 4, 1997. 03:43:34 03:43:36 03:43:39 03:43:41

That's the date you recall this meeting taking place, correct? And then the 03:43:43 03:43:44

second one is the scientific presentations -- 03:43:46 03:43:47

A No, I don't recall the meeting taking place on that date. I assume because it's dated that, that's when it took place. 03:43:47 03:43:49 03:43:51

Q Right, yes. The date of document, correct? 03:43:52

A Yes. 03:43:55

Q Well, this -- these documents are also dated November 4, 1997. 03:43:55 03:43:57

And the second page is a scientific presentation/meeting strategy. 03:43:59 03:44:01

Do you see that? So let me -- 03:44:02

A No, I didn't see it. 03:44:04

Q Let me show you that and see if that -- see if that refreshes any recollections. 03:44:05 03:44:07

(Witness read document.) 03:44:09

(Exhibit No. marked for identification.) 03:44:14 03:44:14

A You know, the recollection -- you said you'll show me this to see if it refreshes any recollections, and the answer, like my others, is no and yes. 03:44:27 03:44:29 03:44:32 03:44:36

The -- the "no" being I can't specifically remember doing it, but the 03:44:39 03:44:42

"yes" is that, again, to the extent that I had a hand in -- in driving the process of the meeting in addition to worrying about, you know, manuscripts and thinking about it, the idea was, okay, how can we get these results out? 03:44:43 03:44:48 03:44:52 03:44:55 03:45:00 03:45:03

And what I can -- what I -- 03:45:04

See, I can't remember specifically for this, but I've done -- I've chaired many, many collaborative studies; and what we always do is we say, okay, what are -- what are the meetings coming up in the next two years that would be relevant to present these data at? 03:45:05 03:45:07 03:45:11 03:45:14 03:45:17 03:45:19 03:45:21

And so, you know, we know what the meetings are, by and large. And sometimes we even assign an individual, you know, to actually look up when are the deadline dates and so on and so forth. 03:45:21 03:45:23 03:45:25 03:45:27 03:45:29

And, actually, that was probably done -- there's a pretty good chance -- and, again, I'm surmising. 03:45:30 03:45:32 03:45:35

Q Mm-hmm. 03:45:37

A There's a pretty good chance that I said to 03:45:37

someone, Okay, in anticipation of this meeting, would you look up the dead -- the submission deadline dates for these following meetings. Or it was on a conference call and everybody contributed. 03:45:39 03:45:42 03:45:43 03:45:46 03:45:48

Because for the child meetings in particular -- although as you'll notice, most of these meetings aren't child meetings perfect se, they're adult meetings. 03:45:50 03:45:52 03:45:54 03:45:57

Q Okay. 03:45:59

A You know, contribute. 03:46:00

So we have those dates. And then the idea is, okay, someone is going to present the poster, an oral thing or whatever, and let's just divvy it up. 03:46:01 03:46:04 03:46:06 03:46:09

Q Okay. 03:46:10

A And -- 03:46:11

Q Okay. 03:46:11

So the -- well, in terms of the first document in that exhibit, can you identify for the record what that is, please? 03:46:12 03:46:13 03:46:15

A This was a -- this is a list of a proposed plan for which publications we thought could be written with the data from this study and 03:46:18 03:46:30 03:46:32

who the authors would be. 03:46:36
And on the second page, it's a list 03:46:39
of the meetings that were coming up over the 03:46:45
course of the next year or so and which 03:46:48
individuals in our group, single or 03:46:55
collaboratively, would be responsible for 03:46:57
proposing -- for presenting -- and it's 03:47:01
not -- it's not specific, for presenting -- 03:47:03
Oh, yes, it says on some either a 03:47:06
poster or an oral presentation on the 03:47:09
meetings. So it was a plan. 03:47:12
Q Okay. 03:47:14
So it was a publications plan as well 03:47:15
as a scientific meeting plan? 03:47:16
A Yes. 03:47:19
Q Okay. 03:47:19
A A publications plan and a plan for -- for 03:47:19
who would present at the scientific 03:47:24
meetings. 03:47:27
Q Okay. 03:47:27
And with regard to the publication 03:47:28
plans, how many -- how many publications 03:47:29
were proposed at that particular time? 03:47:31
A Well, the hope was that there would be nine 03:47:34

worth writing. 03:47:37
Q Okay. 03:47:39
And what -- what is the purpose of 03:47:39
publications of study results? 03:47:41
A There are multiple goals, but the core goal 03:47:53
is to have a mechanism to -- 03:47:56
The core goal is to disseminate the 03:48:04
findings of the study to a -- to an 03:48:06
appropriate audience of people. 03:48:11
Q Which would be readers? 03:48:14
A Yes. 03:48:16
MR. DAVIS: Object to the form. 03:48:17
MR. MURGATROYD: Well -- 03:48:18
Q That's a publication, right? It's the -- 03:48:19
it's -- well, I'm just talking about 03:48:22
publications. 03:48:23
That's for somebody to read? 03:48:25
A Correct, an appropriate audience. 03:48:26
Q Right. 03:48:28
A Yeah, if the -- 03:48:29
Q Okay. 03:48:30
And what are -- what are all the 03:48:30
other purposes -- the lesser purposes, 03:48:31
instead of -- 03:48:33

A Well, not lesser, but they're part of it. I 03:48:34
mean it -- it is a -- 03:48:42
Publications serve as a document to 03:48:50
define the design and the outcome of a 03:48:53
research project. 03:49:04
Distinction between that and having 03:49:08
something for an audience is the 03:49:11
documentation piece, that, you know, an 03:49:15
important activity took place over a period 03:49:17
of seven years in which ultimately, you 03:49:21
know, 275 or so adolescents agreed and 03:49:24
behaved as subjects in a study. 03:49:31
You know, all sorts of people were 03:49:34
involved, an enormous effort, a scientific 03:49:36
enterprise; and the right thing to do is to 03:49:38
document that endeavor and to do it 03:49:41
accurately. 03:49:47
So, you know, even if they're -- and 03:49:48
I separate that from the communications 03:49:50
piece. 03:49:52
Q Right. 03:49:53
A You know, the -- you can't have the 03:49:53
communications piece without the 03:49:56
documentation. 03:49:57

But even if there was never an intent 03:49:58
to communicate it, in my -- the way I view 03:50:01
the world of this -- this world that we're 03:50:05
talking about is you always need to document 03:50:09
it. 03:50:11
Q Okay. 03:50:12
And is it true that clinicians get 03:50:13
their information by clinical trials through 03:50:18
publications, that that's how they get their 03:50:21
data? 03:50:23
A It's one way. 03:50:23
Unfortunately, the reality is that 03:50:26
the clinicians get it less through reading 03:50:27
the primary publications and more through, 03:50:30
you know, other secondary communication 03:50:37
means. 03:50:40
Q Such as going to symposiums and -- 03:50:41
A Yes. 03:50:43
I mean, the best of all worlds, you 03:50:43
know, you could argue all the physicians 03:50:45
would subscribe to all the journals that 03:50:47
these things would be in; but in reality, 03:50:50
the proportion of physicians who subscribe 03:50:52
to the journals, let alone read the 03:50:54

articles, are capable of, you know, kind of 03:50:56
fighting through and understanding is pretty 03:51:00
damn low, so that -- so there are ways that 03:51:02
the information gets summarized. 03:51:04
Q Okay. 03:51:07
And that -- it can get summarized 03:51:08
through abstracts? 03:51:09
A Abstracts, sure, meetings, posters and 03:51:10
stuff. 03:51:13
Q Right. 03:51:13
And am I correct in stating that 03:51:13
publications can result -- you know, 03:51:18
publications such as your publication for 03:51:19
329 can result in clinical guidelines being 03:51:22
drafted or being adopted? 03:51:26
MR. DAVIS: Object to the form. 03:51:27
A When -- when a -- when a committee is 03:51:33
appointed by an organization to establish 03:51:36
guidelines, one of the things that the 03:51:39
members of the committee are assigned to do 03:51:43
is to look at all the published literature 03:51:49
and then to analyze that public literature, 03:51:51
to do their own assessment and analysis of 03:51:56
it to then make a judgment to establish 03:51:58

guidelines. 03:52:00
Q Okay. 03:52:00
And clinicians can read publications, 03:52:01
such as your publication of 329, and decide 03:52:04
whether or not to prescribe a drug to 03:52:08
patient, correct? 03:52:09
A They could. 03:52:14
What's really happened in the past 03:52:16
several years is something called, you know, 03:52:18
kind of the quest for -- for organizing 03:52:20
evidence-based medicine. 03:52:25
So there are organizations, and these 03:52:28
are relatively new, Cochrane reports and 03:52:30
others, and they take topics. I don't know 03:52:32
if they've done one yet on the treatment of 03:52:34
depression in children, and there may be one 03:52:37
or two such -- two or three such groups in 03:52:39
the world, and -- 03:52:41
Q What was the name -- 03:52:42
A Well, one is called the Cochrane reports. 03:52:43
Q The Cochrane? 03:52:46
A C-O-C-H-R-A-N-E. And then there's another 03:52:47
one. And so they go through topics. 03:52:50
I don't know if they've had one yet 03:52:53

on children and adolescents, and they -- I 03:52:55
don't know who employs them, where they get 03:52:58
their money from, but they're well respected 03:53:00
and they do review of a topic and they'll 03:53:02
actually say -- they'll actually -- 03:53:04
They'll actually -- and we're trying 03:53:06
to get clinicians to read these. It's a 03:53:09
major effort I'm involved in. 03:53:12
They actually will sort of give their 03:53:14
analysis of the quality of the evidence 03:53:16
that's in the reports and come up with their 03:53:18
own recommendation as to what a clinician 03:53:21
should do. 03:53:25
Q Okay. 03:53:26
In terms of prescribing -- 03:53:26
prescribing recommendations? 03:53:27
A Yes, yes, because it's just too hard to 03:53:29
expect a clinician to -- 03:53:30
Q Okay. 03:53:33
Now -- 03:53:39
A And I will tell you that the informed 03:53:40
clinician today and medical students in 03:53:41
training and residents in training, which I 03:53:44
would include my own son, they go right 03:53:47

after -- they're taught now to go right 03:53:48
after that stuff, things that we were never 03:53:51
taught. 03:53:53
So they're taught to go over the 03:53:53
Cochrane reports and things like that, 03:53:54
rather than actually read -- 03:53:56
You know, they read the articles for 03:53:57
an exercise and learning how to read a 03:53:59
scientific article; but in terms of how they 03:54:02
should practice medicine, they're trained 03:54:04
now to go after these evidence-based things. 03:54:07
It's all new, the past three or four 03:54:09
years. 03:54:11
Q So that -- that didn't exist when 329 came 03:54:11
out, your article came out? 03:54:13
A If it did, I didn't know about it. 03:54:15
Q Okay. 03:54:17
A But -- 03:54:17
Q Now, so with regard to the Exhibit 16 -- no, 03:54:18
wait -- yes. No, I'm sorry, 18. 03:54:24
You were listed as being the author 03:54:26
for the publication, right? 03:54:29
A Correct. 03:54:30
Q And you were listed as -- for the primary 03:54:31

publication, correct? 03:54:32
A Yes. 03:54:36
Q And then -- 03:54:36
I'm sorry? 03:54:37
A Yes. 03:54:37
Q And then there were eight others we talked 03:54:38
about who -- who were going to be authors 03:54:39
other than yourself? 03:54:41
A Well, there were eight other publications in 03:54:46
which between one and five people were 03:54:49
listed as proposed authors. 03:54:52
Q And how many of those were you listed for? 03:54:57
A Zero. 03:54:59
Q Okay. 03:55:00
So you were just in the primary 03:55:00
publication number one? 03:55:01
A One was enough for me. 03:55:03
Q And that actually was the -- resulted in the 03:55:05
publication that we've marked as an exhibit 03:55:07
here today, correct? 03:55:09
A Yes. 03:55:10
Q Okay. We're going to get into how that came 03:55:10
about a little bit later. 03:55:13
But in terms of the scientific 03:55:14

meetings, which is the second page of that 03:55:16
document, it was proposed that you -- you do 03:55:17
go to a scientific meeting and promulgate 03:55:21
the results of Study 329, correct? 03:55:27
A I'm not sure what you mean by "promulgate." 03:55:30
Q Well, present. 03:55:32
A Yes. 03:55:34
Q Right. 03:55:34
And, in fact,, did you do that? 03:55:35
A Yes. 03:55:40
Q And do you recall what meeting that was -- 03:55:44
well, let me ask you this: 03:55:47
First of all, who asked you to be a 03:55:48
presenter at a scientific meeting? 03:55:51
A Oh, a group of us, my colleagues and I, 03:55:55
chose the meetings. And I don't know how 03:55:58
the conversation unravelled, but since I was 03:56:04
going to be the lead author on the primary 03:56:09
paper and the American Psychiatric 03:56:15
Association meeting was the first, you know, 03:56:17
major meeting, as many as, whatever, 20,000 03:56:23
psychiatrists show up, it was decided that I 03:56:27
should present the findings at that meeting. 03:56:33
Q Okay. 03:56:37

A I -- I don't think I -- I don't even know if 03:56:38
it came to the point -- 03:56:40
You know, we listed it, and probably 03:56:41
the name Keller just blew up on the board. 03:56:44
I don't know if it was a discussion. 03:56:47
Q Okay. 03:56:49
Did -- did GSK participate in the 03:56:49
this meeting on November 4, 1997? Was Jim 03:56:53
McCafferty there? 03:56:56
A As I said, you know, it's not that I can 03:56:57
remember Jim being there, but I -- I'm 03:56:59
pretty darn sure he was. 03:57:04
Q Right. 03:57:05
I mean, who was going to present the 03:57:06
statistical analysis -- 03:57:08
A Right. 03:57:09
Q -- if it wasn't somebody from GSK? 03:57:09
A Right. 03:57:11
So, I mean, again, I can't remember 03:57:11
seeing Jim there, just like I can't remember 03:57:15
Neal being there. 03:57:17
Q Right. 03:57:18
A But I think it likely, and I am -- I assume 03:57:18
that there were others from GSK, but I 03:57:21

couldn't name one of them. 03:57:23
Q Let me ask you, do you know who the 03:57:24
statistician was for 329, Rosemary Oakes? 03:57:26
A No. 03:57:29
Q You never met her that you recall? 03:57:29
A I may have met her, but I don't recall 03:57:31
meeting her. 03:57:35
Q Okay. 03:57:36
A I mean, don't tell that to her. I don't 03:57:36
want to embarrass her if she remembers, 03:57:38
but -- 03:57:40
Q Okay. No, that's fine. 03:57:40
Now, you did -- we established you 03:57:43
did make a presentation at a meeting. Was 03:57:46
it more than one meeting or just one 03:57:47
meeting? 03:57:50
A I think I only presented at the APA. There 03:57:54
are -- you know, whether I presented these 03:58:01
results in other settings, I just can't 03:58:06
remember, you know? 03:58:08
Did I present them to my own 03:58:09
residents at Brown, you know, sometimes they 03:58:11
like to hear what the chairman has to say, 03:58:13
or at least make believe they like to hear 03:58:17

what I have to to say so I feel good about them. I may have, you know, was there -- I don't recall another major meeting in which I was a formally listed presenter. Could someone have asked me to stand up at some other group of peers somewhere where we meet and say, Hey, Keller, you want to tell us about that? It could have happened, but I don't remember. 03:58:20 03:58:23 03:58:23 03:58:26 03:58:29 03:58:32 03:58:34 03:58:36 03:58:39 03:58:40

Q Okay. And did -- now, you -- do you recall when you made that presentation? 03:58:41 03:58:43 03:58:47

A No, except that to the extent that we made the deadline and -- The goal was to present it in the -- at the 1998 meeting of the APA, which would have taken place -- it typically occurs in May. 03:58:50 03:58:54 03:59:02 03:59:05 03:59:08 03:59:14

Q Okay. And do you think you made that? Do you want me to show you a document? 03:59:16 03:59:16 03:59:17 03:59:19

A Sure. 03:59:19

Q Okay. Let's do that. 03:59:19

A Why speculate when we can be certain? 03:59:23

Q Absolutely. Now, let me -- did -- we're going to get to that. I'll find it in a second, but while I'm looking for it, did -- how does it work when you do a presentation at the APA? You have to fly there and spend the night, I think, and -- or do you or -- do you -- You have to get to wherever the city is, right? 03:59:25 03:59:28 03:59:31 03:59:34 03:59:37 03:59:40 03:59:41 03:59:44 03:59:45 03:59:47

A Well, you're not a Star Trek fan? 03:59:48

Q Yes, I am, but I can't remember that technology. 03:59:52 03:59:54

A Remember Scotty? They would just beam him right up there. 03:59:55 03:59:57

But I, not -- unlike some of the Star Trek characters, have to move myself physically to the meeting. And there's different means of transportation. There's air, boat, plane and automobile, right? 03:59:58 04:00:01 04:00:05 04:00:07 04:00:09

Q Right. And I think this was was in Toronto, 04:00:12 04:00:12

if I recall correctly. 04:00:15

A I would say if it was, the overwhelming probability was I flew AirCanada, and I actually do have a memory that I forgot to bring my passport and they either didn't want to let me in or out of the country, which caused my wife to have to make a major effort to send some picture of me. 04:00:16 04:00:18 04:00:21 04:00:23 04:00:26 04:00:27 04:00:30

Q Okay. 04:00:34

A With great disdain, the Canadians, finally let me have my -- have my passage. 04:00:34 04:00:41

Q Okay. How does it work when that happens? Do you get to -- does -- who pays for that? 04:00:44 04:00:44 04:00:45

A Depends who you are. First of all, the first way it works is that it's competitive as to which -- as to whether what you want to present gets presented. 04:00:51 04:00:55 04:00:58 04:01:01 04:01:03

So I submit an application to present it, you know, to the APA committee on the meeting -- its committee on the meeting. It's a very formal process. And then I get notified, boom, boom, boom. 04:01:04 04:01:09 04:01:19 04:01:19 04:01:24

Now, for -- for me, the -- and the APA is highly regulated and has been as far as I can remember, as to how people's transportation can get paid for and expenses. 04:01:33 04:01:35 04:01:39 04:01:44 04:01:49

So there's basically one of three or four ways that you get paid, your transportation gets paid. 04:01:51 04:01:59 04:02:00

One, you pay it out of your own pocket. That would be typical for a private practitioner or maybe one of my -- some of my faculty members. 04:02:02 04:02:04 04:02:07 04:02:08

On the other hand, others of my faculty members, we have academic funds, and they're allowed to draw on their academic funds and pay for it. 04:02:11 04:02:12 04:02:15 04:02:18

For our residents, we send a lot of our residents because they don't have tons of money. Sometimes if they've exhausted their meeting allowance, they pay themselves. 04:02:19 04:02:21 04:02:23 04:02:24 04:02:26

For me, if I don't have someone who is going to pay for it -- I'll tell you who that might be in a moment -- then I pay for 04:02:27 04:02:29 04:02:31

it. But as part of my arrangement with the university, I'm allowed to take -- I have a travel allowance. 04:02:36 04:02:39 04:02:41

So if I'm going to a meeting in which I'm presenting data and that is not paid for by a grant that I have -- because for a lot of grants we write in "travel to meetings" very explicity, NIH grants. 04:02:42 04:02:44 04:02:52 04:02:54 04:02:59

Q Well, I want to try to keep it down to this particular study. 04:03:02 04:03:04

A Well, the same for this particular study. The travel was -- my travel to that meeting was either paid for by -- by Brown, in other words, I paid for it and I was reimbursed; or at APA meetings, there are things called industry-sponsored symposium, which are highly regulated. 04:03:05 04:03:06 04:03:11 04:03:13 04:03:15 04:03:22 04:03:24

Q Right. 04:03:25

A And currently, for many years -- you're allowed to be on two of them. In the good old days, you could be on 30. 04:03:25 04:03:27 04:03:31

And the APA gets money from pharmaceutical companies in some sort of a pot that they homogenize. 04:03:33 04:03:39 04:03:41

Q Right. 04:03:43

A And if you're chairing a meeting, you get paid $2,000. If you're just a presenter, you get 1500. 04:03:44 04:03:46 04:03:48

And then you get a flat $2,000 for your travel reimbursement if you're a presenter or a chair of one of these meetings. And the check comes from the American Psychiatric Association, and they've created firewalls -- I don't know how they work -- between the pharmaceutical company and whatever 04:03:49 04:03:54 04:03:56 04:04:01 04:04:04 04:04:05 04:04:08 04:04:10

So that for every APA I've been to for the past, I don't know, many years, I've always both chaired and presented at an industry-sponsored symposium. So basically, the APA pays for my travel and gives me an honorarium. 04:04:14 04:04:17 04:04:19 04:04:23 04:04:26 04:04:29

I would not -- if GSK wanted to give me a check for going, I would not be allowed -- I would be in violation of APA rules to accept it. 04:04:30 04:04:32 04:04:35 04:04:38

Q Right. 04:04:39

Because the GSK would pay the APA, 04:04:39

which, in turn -- 04:04:42

A Yes, but for what I was doing, for presenting a poster, they wouldn't be allowed to pay it. 04:04:43 04:04:45 04:04:48

The industry-sponsored symposium that I'm talking about of a huge headline of events that between 500 and 3,000 people go to, they get enormous publicity. There's maybe 20 of them. They're held in the big ballrooms, and the APA actually monitors the selection of the topic. 04:04:51 04:04:54 04:04:56 04:05:00 04:05:02 04:05:04 04:05:08

Q Okay. 04:05:11

A And who can be on it. And the company can't talk -- 04:05:11 04:05:13

If I'm going to be a chair, I put down to do it, the company's not allowed to talk to me about who are going to be the presenters and what are going to be the topics. 04:05:14 04:05:16 04:05:18 04:05:21 04:05:22

Q And with regard to your presentation regarding the results of 329, was that a major presentation in one of the ballrooms or was that a smaller event? 04:05:23 04:05:26 04:05:29 04:05:32

A No, it was a small one. 04:05:33

Q Okay. 04:05:35

And do you ever recall giving a slide presentation? 04:05:35 04:05:37

A Probably. I've given family eulogies with slides, so I usually have slides. 04:05:45 04:05:47

Q Okay. 04:05:49

Well, let me -- actually, let me -- 04:05:50

MR. MURGATROYD: Let's go off the record for a minute. I want to find the abstract. 04:05:51 04:05:52 04:05:54

THE VIDEOGRAPHER: The time is five minutes after 4:00. We're off the record. 04:05:55 04:05:56

(Recess.) 04:06:16

(Exhibit No. 19 marked for identification.) 04:20:22 04:20:22

(Exhibit No. 20 marked for identification.) 04:20:22 04:20:22

THE VIDEOGRAPHER: We are back on the record. This is Tape No. 4. The time is 4:24. 04:23:24 04:24:47 04:24:50

MR. DAVIS: Are we back on the record? 04:25:11 04:25:12

MR. MURGATROYD: Yes. Are we back on? 04:25:14 04:25:15

THE VIDEOGRAPHER: We are. 04:25:16
BY MR. MURGATROYD: 04:25:16
Q Doctor, are you ready? 04:25:17
A Ready. 04:25:18
Q Okay. 04:25:18
During the break, I handed you two 04:25:19
documents which we marked as Exhibits 19 and 04:25:22
20, correct? 04:25:23
A Yes. 04:25:24
Q And can you identify for the record what 04:25:24
Exhibit 19 is, please? 04:25:27
A What it appears to be to me is the summary 04:25:31
or I guess the abstract of the presentation 04:25:37
which I was scheduled to make on Tuesday, 04:25:41
June 2nd, between 9:00 and 10:30 a.m. 04:25:46
It doesn't say the year on here. 04:25:52
Q Okay. 04:25:54
A And about -- on paroxetine and imipramine 04:25:54
treatment for depression. 04:25:59
Q Okay. 04:26:02
Do you recall making that 04:26:02
presentation? 04:26:04
A No. 04:26:05
Q Okay. Well, let's just stick with abstract. 04:26:07

Who drafted that abstract, if you 04:26:11
know? 04:26:13
A I assume me. 04:26:14
Q Okay. 04:26:15
And in the abstract, do you state 04:26:17
that the paroxetine failed on the two 04:26:20
primary outcome measures? 04:26:25
(Witness read document.) 04:26:43
A No. 04:26:45
Q Does -- does the abstract state that the 04:26:47
scales rated by the parents and the 04:26:51
children, paroxetine failed to separate 04:26:53
statistically from placebo with regard to 04:26:59
those scales? 04:27:01
A No. 04:27:02
Q Okay. 04:27:07
A But I would say, though, the abstract does 04:27:08
not specifically state -- does not 04:27:10
specifically give the scales, you know, 04:27:15
rates of change or P values for any outcome 04:27:27
measures. 04:27:32
Q Okay. 04:27:33
A So just a -- just to round up -- round out 04:27:33
your question to me. 04:27:36

Q Okay. 04:27:37
But does it discuss the failure to 04:27:38
meet -- to separate statistically -- does it 04:27:41
talk about Paxil's failure to separate 04:27:43
statistically from placebo with regard to 04:27:46
any measures? 04:27:48
A No. But nor does it -- nor does it say that 04:27:48
it separated statistically from any measures 04:27:52
in the positive way either. 04:27:55
It didn't give that. It just -- 04:27:56
Q Well, what -- what did it conclude in the 04:27:58
last sentence of the last paragraph? 04:28:02
A The results -- These results support that 04:28:05
paroxetine is an effective treatment for 04:28:08
major depression in an adolescent outpatient 04:28:10
population, which is absolutely accurate. 04:28:13
Q And does your -- and now turning to the next 04:28:17
exhibit, which is Exhibit 20, do you see 04:28:21
that that is slides? 04:28:28
A I do. 04:28:30
Q And does it concern Study 329? 04:28:31
A It -- it -- it also is a review. It's a 04:28:39
review of -- it's a review -- it's a much -- 04:28:42
it's a -- 04:28:47

There are many slides missing from -- 04:28:50
you know, there are many blank pages -- 04:28:52
Q Right. 04:28:55
A -- which just have titles. 04:28:55
But what it is is a -- it reviews the 04:28:57
epidemiology, comorbidity, clinical course, 04:29:04
clinical picture of depression in 04:29:10
adolescents. 04:29:13
It talks about, you know, efficacy of 04:29:14
other treatments. And after giving that 04:29:17
background, it goes into the study design of 04:29:19
329. 04:29:27
And then it has -- it's entitled 04:29:31
Results Overview, but it does not have -- 04:29:36
it's just blank with regard to demographics 04:29:41
based on characteristics and so on. 04:29:44
So it's missing all of that. It does 04:29:47
give the medical history. It's blank on -- 04:29:49
it doesn't have the results for the 04:29:51
depression mood item, an item which, in 04:29:52
fact, as which we discussed earlier was -- 04:29:56
did separate statistically from placebo. 04:29:58
It -- that's vital signs. So it 04:30:04
doesn't have the specifics of the -- so far 04:30:09

in the bulk of the efficacy variables, so 04:30:16
it's -- it's a -- I assume -- 04:30:18
Put it this way: It's unimaginable 04:30:22
to me that I presented slides that were 04:30:25
blank, so that this would be a working draft 04:30:30
of an outlined talk. 04:30:31
Q Okay. 04:30:35
Well, I found a document that 04:30:35
actually GSK sent me that said that -- well, 04:30:37
do you recall ever presenting slides at -- 04:30:39
at any -- any presentation? 04:30:41
A I don't remember. That's why I said -- you 04:30:43
asked me that earlier. 04:30:45
Q Yes. 04:30:46
A And I said that I don't recall. 04:30:47
Q Well, how does it work when you present a 04:30:50
post -- wait. 04:30:54
You had -- you have an abstract. We 04:30:55
have an abstract there, right? 04:30:57
A Right. 04:30:59
Q And the next thing is a presentation? 04:30:59
I mean, the abstract's published, and 04:31:04
then there's a presentation at the meeting? 04:31:06
A Well, see, it doesn't say what type of 04:31:07

session. There are many different types of 04:31:17
communication sessions at a meeting, so that 04:31:19
the -- there could have -- 04:31:23
It could have been an oral 04:31:24
presentation. It could have been a 04:31:26
discussion group, which -- in which I might 04:31:27
have made some remarks and then had a -- 04:31:31
just a round table discussion. 04:31:34
It could have been a poster -- a 04:31:37
poster session. 04:31:40
Q What -- what is a poster session? That was 04:31:42
my -- that was my question. 04:31:43
A Well, poster -- there are lots of different 04:31:45
ways to run them, but basically you 04:31:47
designate a certain time period; and during 04:31:49
that time period, posters are shown. 04:31:51
And poster -- it would be, you know, 04:31:53
like a -- have you ever been to a poster 04:31:55
session? 04:31:58
Q A big poster board? 04:30:10
A Yes, a big poster board, and you give the 04:30:11
design of a study and the results and so on. 04:30:14
And depending upon the nature of the 04:30:17
meeting -- and the APA being such an 04:30:19

enormous meeting, I mean, there's 04:30:23
probably -- 04:30:25
There are 25 to 100 or more things 04:30:26
going on simultaneously at this meeting, so 04:30:29
most people can only see one at a time. 04:30:33
But they try to organize them. So 04:30:36
there may -- there could well have been a 04:30:39
session -- a poster session on research 04:30:41
related to children and adolescents, you 04:30:43
know, during a block. 04:30:46
So at some other meetings that are 04:30:49
smaller, like from 5:30 to 7:00 every day, 04:30:53
there's a poster session. And so it just -- 04:30:57
Q What time was your meeting, according to the 04:31:02
abstract? 04:31:03
A 9:00 to 10:30. 04:31:04
Q So what would that indicate to you? What 04:31:06
type of presentation was it? 04:31:07
A It's just too hard to know. 04:31:08
Q Okay. 04:31:10
A What I'm saying is, the APA is such an 04:31:10
enormous meeting with so many things 04:31:12
going -- 04:31:14
If there are 20,000 people there, 04:31:16

right, theoretically there's something for 04:31:17
everybody at every hour, you can only 04:31:20
imagine how many things are going on. 04:31:21
And the program book, which you could 04:31:22
probably get somehow for a meeting, just -- 04:31:26
if youlook at it, this is -- any given 04:31:31
time -- 04:31:34
You can't tell from this. In any 04:31:34
given time slot -- 04:31:36
Q Okay. 04:31:37
Do you recall -- do you know who 04:31:38
Kevin Bellew, B-L -- B-E-L-L-E-W, worked 04:31:39
with Jim McCafferty? 04:31:47
A There's no recall. 04:31:48
Q Okay. 04:31:50
Have you ever seen a document where 04:31:50
he states that he prepared slides for you 04:31:53
for that presentation for the APA? 04:31:55
A No. 04:31:56
Q Okay. 04:31:57
A But what I can tell you is I have never in 04:31:57
my life shown slides that someone else 04:32:00
prepared where I didn't take whatever help I 04:32:05
was given in preparation, either the 04:32:12

formating of them or whatever, and make it 04:32:16
uniquely mine. 04:32:19
I can't tell you what other people 04:32:20
do, but I've never in my life been handed a 04:32:21
slide set and shown it. 04:32:28
Q Okay. 04:32:29
Well, with regard -- 04:32:30
A I certainly have had -- I have someone on 04:32:31
my -- I have someone who works for me full 04:32:33
time at Brown, is paid by Brown, a member of 04:32:40
my staff. She's titled a communications 04:32:43
person. 04:32:46
And this woman helps me put together 04:32:47
presentations. She doesn't know anything 04:32:49
about -- I mean, she doesn't have any 04:32:52
training, you know, as a mental health 04:32:54
professional or any particular education, 04:32:58
but she's good at formatting things. She's 04:33:00
good at organizing things. 04:33:03
So I might say, you know, Anna, could 04:33:05
you pull together the last five talks I gave 04:33:07
on this topic, blah, blah, blah, blah. And 04:33:09
then I'll kind of scribble them up, this and 04:33:12
that, and say could you fix them up, format 04:33:14

them, check the references. Things like 04:33:18
that. 04:33:20
So her job description is she helps 04:33:21
Marty with his slide presentations, and she 04:33:23
makes the final PowerPoint, so... 04:33:25
Q Yes. 04:33:28
My question was, do you recall a GSK 04:33:28
employee preparing slides for you? 04:33:30
A No, I -- my answer -- when I'm expanding -- 04:33:31
I'm telling -- 04:33:34
My answer is no, I don't. And then 04:33:35
you said to me that someone wrote a memo, 04:33:36
they said they made slides to Keller, and my 04:33:39
response to that is I can't -- I can't 04:33:42
imagine -- 04:33:43
I don't know what role they played in 04:33:44
it, but if they played a role, the role had 04:33:47
nothing to do with driving the scientific 04:33:51
content of what I was presenting. 04:33:53
Q Okay. Now -- you can put that document 04:33:55
down. Let's -- the -- 04:33:58
With regard to publishing the results 04:34:11
of 329, there was a company involved called 04:34:13
STI; do you recall that? 04:34:20

A Yes 04:34:23
Q Okay. And -- well, let me ask you this. 04:34:24
Actually, I want to back up. 04:34:25
When you were at the meeting in 04:34:31
November of 1997 that we talked about 04:34:32
earlier where you had the consensus 04:34:35
statement, the publication strategy and 04:34:38
the -- 04:34:39
A I recall. 04:34:40
Q Was that at GSK, do you recall? 04:34:41
A Do not remember. 04:34:43
Q Okay. 04:34:45
At that meeting, was it discussed 04:34:49
that a medical writing organization would be 04:34:55
hired to write the manuscript for Study 329? 04:34:58
A I don't remember if it was discussed at that 04:35:06
meeting. 04:35:09
Q Okay. 04:35:11
When do you recall that first being 04:35:11
discussed? 04:35:13
A I don't remember it being discussed, but... 04:35:16
Do we have a copy of the publication, 04:35:24
just for my own records? I don't remember 04:35:27
it being discussed, but... 04:35:28

Q Yes. The study? I think you have it there. 04:35:30
A But it says on the acknowledgment, editorial 04:35:34
assistance was provided by Sally K. Laden, 04:35:38
who works for STI. 04:35:42
Q And you know -- you communicated with her, 04:35:43
correct? 04:35:47
A Let me finish what I was going say. Okay. 04:35:48
So she was provided -- so what this 04:35:50
tells me is that she provided editorial 04:35:53
assistance. I know she works for STI. I 04:35:57
know her quite well. 04:36:00
I mean, I haven't seen her in a long 04:36:01
time, but I used to see her more. And 04:36:03
though I can't recall, you know, the 04:36:07
interactions, she did what's stated here. 04:36:10
She provided editorial assistance in the 04:36:15
preparation of the manuscript. 04:36:18
Q Okay. Well, we'll get into that in a 04:36:19
second. 04:36:21
I guess -- well, let me go back to 04:36:21
the meeting in November of '97 when you were 04:36:23
looking at the results of 329. 04:36:25
Were you provided all the raw data at 04:36:27
that time? 04:36:30

Was the raw data available at that 04:36:30
meeting so you all as investigators could 04:36:32
examine it and determine for yourselves what 04:36:34
the results were of the study? 04:36:36
A I don't recall. 04:36:38
If raw data was provided at that 04:36:45
meeting, it would have been incomplete for 04:36:47
the reasons I stated to you earlier, that we 04:36:49
had that meeting as fast as we could -- 04:36:53
You know, we had that meeting occur 04:36:57
as soon as possible after the blind was 04:37:01
broken, and there was an expression that you 04:37:04
saw somewhere along there, top-line results. 04:37:07
Q Right. 04:37:09
A And that's shorthand for meaning, you know, 04:37:10
these are the P values of the major 04:37:12
variables of interest. 04:37:16
But certainly it -- we didn't have, 04:37:16
as I described to you that would need to be 04:37:19
done, we didn't have a document -- 04:37:22
I don't remember this, but I would be 04:37:24
very surprised if we had the -- the raw -- 04:37:25
you know, any meaningful amount of raw data 04:37:29
analysis that would have led to those 04:37:33

results. 04:37:37
Q Have you -- have you ever had -- personally 04:37:38
had the opportunity to review the raw data 04:37:40
of Study 329? 04:37:42
A I've reviewed data analytic tables. I don't 04:37:49
recall how raw it was, and I'm not trying to 04:37:57
be facetious, but what I mean is that, you 04:38:01
know, there are different levels of -- how 04:38:05
to put this -- of organizing data that 04:38:11
statisticians do. 04:38:15
So, you know, the most primary level, 04:38:16
the huge printouts that, you know, that list 04:38:19
items by item number, you know, item numbers 04:38:22
and variable numbers and don't even have 04:38:25
words on them, I tend not to look at those. 04:38:28
I -- I do better with words than I do with 04:38:31
symbols. 04:38:33
And so that at -- that at some -- you 04:38:34
know, at some level of organizing, at 04:38:38
some -- at some point after the data was 04:38:42
organized in a way that I could read tables, 04:38:45
you know, and so it might -- it might have 04:38:49
been a -- 04:38:51
It might have been a compilation of 04:38:53

papers this thick (indicating). I could 04:38:56
have seen the tables, you know, with the 04:38:58
analyses and statistical tests, what was 04:39:00
done and the P value and the confidence 04:39:03
intervals and so on and so forth. 04:39:05
Given my style, that's highly 04:39:08
probable. I cannot specifically remember, 04:39:10
you know, doing that with these data. 04:39:15
But -- 04:39:18
Q Well, if you had the -- if you had done 04:39:19
that, would you have kept the documents that 04:39:21
show the statistical analysis? 04:39:25
A I'm not big on saving paper, so not 04:39:29
necessarily. 04:39:32
Q Okay. 04:39:32
A I would have -- I would have looked at them. 04:39:33
I would have done what was relevant, and I 04:39:34
would have said -- I might have said, gee, 04:39:36
we need to do more analyses; or I might have 04:39:39
said, I don't understand this; or I might 04:39:41
have said, This looks fine. 04:39:43
Then there would be a process for 04:39:46
harvesting what's most important from that, 04:39:47
and then there would be a process on my part 04:39:50

of putting it in a paper file and getting 04:39:52
rid of it. 04:39:56
Q Yes. 04:39:57
Well, I just want to know what 04:39:57
specifically you did with regard to 329, 04:39:58
though. 04:40:00
A I can't -- I can't -- I can't remember, 04:40:00
except to tell you that I've written -- I've 04:40:02
been an author on hundreds of manuscripts, 04:40:08
and never as the first author of the 04:40:12
manuscript have I just taken, you know, what 04:40:14
you would -- what would be, say, this table, 04:40:18
you know, Table 1 or Table 2, and someone 04:40:24
said, oh, here are the tables and I said, 04:40:27
oh, great, and put them in the paper, you 04:40:30
know? 04:40:33
I would go back to levels to look at 04:40:33
the types of analyses, how they were done, 04:40:36
because I always analyze data. 04:40:41
But I can't tell you at what level, 04:40:46
you know, what point in the analytic process 04:40:47
I engaged. 04:40:50
Q All right. 04:40:51
Now, with regard to 329, were you 04:40:51

ever shown the contract that was entered 04:40:56
between GSK and STI to write the 04:40:59
manuscript for -- 04:41:02
A No. 04:41:03
Q -- the article that was ultimately published 04:41:03
under your name? 04:41:06
A No. 04:41:07
Q Okay. 04:41:08
But you do know that Sally Laden was 04:41:08
hired by GSK to prepare the manuscript, 04:41:12
correct? 04:41:17
MR. DAVIS: Object to the form. 04:41:17
A I know that Sally Laden was hired by GSK to 04:41:20
provide editorial assistance in the writing 04:41:25
of the manuscript. 04:41:29
Q Well, she actually prepared the original 04:41:30
manuscript, correct? 04:41:35
MR. DAVIS: Object to the form. 04:41:36
A I don't know that that's correct, because if 04:41:39
Sally were working with me, what's likely is 04:41:43
that she and I would have had conversations 04:41:51
and discussions about what should be in the 04:41:57
manuscript. 04:42:01
I might have written an outline in 04:42:01

the manuscript, so there would be a process 04:42:03
that would have taken place before a draft 04:42:06
would be produced. 04:42:10
Q Do you recall in this instance with Sally 04:42:12
Laden, she, in fact, drafted the original 04:42:14
manuscript and then presented it to you for 04:42:17
review? 04:42:19
A I don't recall that. 04:42:21
Q Okay. 04:42:23
A And that would be -- if that -- I don't 04:42:23
recall that, and I -- let me say it to you 04:42:25
this way: 04:42:33
Not only don't I recall that, but I 04:42:34
never recall a -- I can't recall any 04:42:36
instance in which someone handed me a 04:42:38
document that wasn't preceded by a 04:42:42
meaningful amount of interchange by myself 04:42:45
and the person, the assistant, as to what 04:42:48
would be in the document. 04:42:52
Q Let's take a look at the next exhibit, which 04:42:54
is -- 04:42:57
MR. COFFIN: 21. 04:43:00
Q -- 21. 04:43:01
(Exhibit No. 21 marked for 04:43:04

identification.). 04:43:04
BY MR. MURGATROYD: 04:43:17
Q If you would take a look at that. 04:43:18
(Witness read document.) 04:43:19
A Okay. 04:43:32
Q Okay. 04:43:32
You've had a chance to look at that? 04:43:34
Can you tell the jury what that do you mean 04:43:35
is, please? 04:43:36
A That is draft of a manuscript on the 04:43:44
efficacy of 369, Draft 3, in fact, of that. 04:43:49
Q Okay. 04:43:57
And does it identify Sally Laden on 04:43:57
the cover page of that document? 04:44:00
A Yes. 04:44:03
Q Okay. 04:44:04
And what does it state under her? 04:44:05
A It says, Manuscript prepared by Sally Laden, 04:44:06
MS. 04:44:09
Q Okay. 04:44:12
A But, as I said to you, and I want to make 04:44:12
sure that this is clear and what I'm -- what 04:44:15
the reality is isn't distorted by being cut 04:44:21
off, is the fact that it says that she 04:44:24

prepared it does not in any way mean that 04:44:25
she and I didn't have a meaningful amount of 04:44:33
exchange as to what I wanted to be in it -- 04:44:37
Q So you -- 04:44:40
A -- before the words were typed. 04:44:40
Q So do you recall as you sit here and can 04:44:42
state under oath that you and Sally Laden 04:44:46
spoke before you were presented with the 04:44:51
manuscript that was prepared by her for 329? 04:44:52
A As I've answered many of your questions 04:44:57
today, given that the date on this is 1999 04:45:00
for the third draft, which is over seven and 04:45:04
a half years ago, I cannot recall, you know, 04:45:09
under or out of specific conversations. 04:45:12
But what I can say to you is in any 04:45:18
instance in which I've been the first author 04:45:22
and which there have been editorial 04:45:25
assistants, I've had a meaningful role in 04:45:27
interacting with the individual as to what 04:45:30
will be in the document before a printed 04:45:33
copy of the document was prepared for me. 04:45:38
Q Let me ask you this: 04:45:40
How soon after the study was 04:45:42
completed were you presented with the full 04:45:44

final report -- the complete final report of 04:45:46
Study 329 as prepared by GSK? 04:45:48
A No idea. 04:45:51
Q Do you recall if you were ever -- you know, 04:45:52
it's a couple -- it's over a thousand pages 04:45:54
long. 04:45:55
Have you ever been presented with 04:45:56
that complete report, to your knowledge? 04:45:57
A I don't remember. 04:46:01
Q Okay. 04:46:02
Do you know if Sally Laden used that 04:46:02
report in which to draft the manuscript -- 04:46:04
the first -- the first draft of the 04:46:06
manuscript for 329? 04:46:07
A I don't know. 04:46:08
Q Let me see if I can -- 04:46:16
MR. MURGATROYD: Let's go off the 04:46:18
record for a minute, please. 04:46:18
THE VIDEOGRAPHER: The time is 4:48. 04:46:20
We are off the record. 04:46:21
(Recess.) 04:46:22
(Discussion off the record.) 04:46:22
(Exhibit No. 22 marked for 04:50:56
identification.) 04:50:56

MR. MURGATROYD: Let me just identify 04:50:59
it. 04:50:59
Exhibit 22 is the proposal for a 04:50:59
journal article on the adolescent depression 04:51:02
Study 329 that was proposed by Sally Laden 04:51:03
of STI, which is Scientific Therapeutics 04:51:09
Information, Inc., dated April 3, 1998. 04:51:11
And on page 5, it lists the services 04:51:15
that they, meaning Sally Laden/STI, will 04:51:18
perform with regard to the manuscript for 04:51:22
329. 04:51:23
BY MR. MURGATROYD: 04:51:26
Q Doctor, I'd like to just show that to you. 04:51:27
(Witness read document.) 04:52:28
A Okay. 04:52:48
Q Okay. 04:52:48
Do you see on page 5 it lists 04:52:48
services that -- 04:52:50
THE VIDEOGRAPHER: Did you want to go 04:52:51
back on the record? 04:52:52
MR. MURGATROYD: Yes, please. 04:52:53
THE VIDEOGRAPHER: Okay. Stand by. 04:52:54
Okay. We are back on the record. 04:52:58
The time is 4:54. 04:53:00

A Actually, could -- could you hand me the 04:53:02
draft of the article you -- we were 04:53:04
discussing before just for one second? 04:53:05
Q Yes, I think it's right here, as a matter of 04:53:08
fact. Yes, there you go. 04:53:10
A Okay. Okay. 04:53:18
Q Okay. 04:53:22
So with regard to Exhibit 22, do you 04:53:22
see where it says, Services that STI will 04:53:25
perform with regard to Study 329? 04:53:27
A Which page? 04:53:32
Q Page 5. 04:53:37
(Witness read document.) 04:53:37
A It says services. 04:53:44
Q Right. 04:53:45
And you see -- can I see the document 04:53:46
for a second, sir? 04:53:47
A Yes. 04:53:49
Q Do you see the third paragraph? 04:53:52
A Yes. 04:53:55
Q Can you read the first paragraph -- that 04:53:55
first sentence into the record, please, 04:53:58
the third paragraph of that document. 04:54:00
A "STI will develop up to six drafts. Draft 1 04:54:01

is the initial draft that will be reviewed 04:54:05
by the sponsor." 04:54:07
Q Okay. 04:54:08
And the next sentence? 04:54:09
A "Comments on draft form will be incorporated 04:54:10
into Draft 2, which will be sent to the 04:54:13
primary author and sponsors for comments." 04:54:14
Q Okay. 04:54:19
So according to that document, who -- 04:54:20
who is responsible for drafting -- for 04:54:20
creating the -- preparing the first draft? 04:54:22
A Well, according to this document, STI. 04:54:28
Q Okay. 04:54:33
A However, that is perfectly consistent with 04:54:33
what I told you before. Writing, typing a 04:54:38
manuscript, typing the words follows 04:54:46
discussion as to what words will be typed, 04:54:49
so that the preparation of the written 04:54:53
document by STI as -- by no means -- by no 04:54:56
means precludes the fact that I as the first 04:55:06
author have interacted with, quotes, STI -- 04:55:09
in this case, Sally Laden -- as to what the 04:55:14
content will be. 04:55:16
So -- 04:55:17

MR. DAVIS: Just a second. 04:55:18
Doctor Keller, I know it's been a 04:55:19
long day, but your paper is blocking the 04:55:20
view of the video, so -- 04:55:23
THE WITNESS: And I just freshened my 04:55:26
hair, too. 04:55:29
MR. DAVIS: Yes, I know. 04:55:29
THE VIDEOGRAPHER: Don't forget your 04:55:30
microphone. 04:55:31
MR. DAVIS: Just so -- just so if the 04:55:32
jury hears this, at least they won't be 04:55:33
distracted. 04:55:35
THE WITNESS: Okay. 04:55:37
A I was responding to Skip. I don't know his 04:55:37
last name, so I can't call him mister. 04:55:39
Q That's fine. 04:55:42
A Something. But Mr. Skip. And -- oh. Thank 04:55:44
you, Karen. 04:55:47
In response to Skip's query to me as 04:55:53
to the meaning of the fact or the inference 04:55:59
that STI was developing the first initial 04:56:08
draft, my response is that that is in no way 04:56:11
inconsistent at all with the process I 04:56:19
described earlier, that prior to writing the 04:56:24

words, prior to typing out what would be in 04:56:32
the first draft, that I would be having 04:56:34
conversations with STI following multiple 04:56:38
conversations with my peers and colleagues 04:56:42
about what the content would be and the 04:56:45
theme would be and the message would be of 04:56:50
the article. 04:56:53
There is nothing that's inconsistent 04:56:54
about that. 04:56:56
Q Well, do you recall specifically having such 04:56:57
conversations with Sally Laden prior to her 04:56:59
preparing the manuscript? 04:57:01
A What I recall is on multiple instances over 04:57:04
the course of this afternoon and the morning 04:57:07
telling you, that I don't have specific 04:57:09
recall over events which occurred between 04:57:12
April 3rd -- you know, April of 1998, eight 04:57:17
years, over -- over eight years ago and the 04:57:22
present. 04:57:24
But what I recall, what I know, is 04:57:25
that every time I have engaged in a process 04:57:27
like this, and I -- to help you understand 04:57:32
it, because I want to make sure you really 04:57:36
comprehend it, given the importance of this, 04:57:39

from my perspective for how medical 04:57:42
knowledge is communicated, and specifically 04:57:44
with regard to Study 329, I follow the same 04:57:47
process with my own staff. 04:57:50
With my own staff, we have a meeting. 04:57:53
We look at the top-line results. We have a 04:57:54
conversation in depth. 04:57:57
If I'm going to be the first author, 04:57:59
it is what do I want the paper to basically 04:58:01
say; what do I believe the message to be; 04:58:04
what do I believe the findings are; roughly 04:58:06
what should be incorporated. 04:58:09
And then one of my staff goes ahead 04:58:10
and drafts and puts together a draft for me 04:58:13
to then review and work on. 04:58:17
So that same process is a process 04:58:18
that I have used for every paper on which I 04:58:20
have been the first author, and it's no 04:58:26
different here. 04:58:28
Q According -- 04:58:29
A I cannot recall, Skip, I cannot recall the 04:58:31
nature of the conversations I've had with my 04:58:37
staff on the last five articles that I've 04:58:40
written that have occurred in the past 04:58:43

five -- few years. 04:58:45
Q Okay. 04:58:46
A But that's the process that I follow, and 04:58:47
there's nothing in here which is 04:58:49
inconsistent with that. 04:58:50
Q Okay. 04:58:52
Well, according to that contract, at 04:58:52
what draft does the draft get presented to 04:58:53
the author? 04:58:57
A I'm not a contract attorney, and I -- 04:58:58
Q No. 04:59:00
What's it say? 04:59:00
A I already read what it says. 04:59:02
Q Right. 04:59:03
A But what I'm telling you is that what it 04:59:04
says in this contract, I've already -- I 04:59:07
think I've already answered the question, 04:59:10
but I'll repeat the answer. 04:59:12
What it says in here, which you asked 04:59:17
me to read, is that Draft 1 is the initial 04:59:19
draft that will be reviewed by the sponsor. 04:59:21
Q Okay. 04:59:24
Now, in this case, who -- 04:59:25
A It didn't actually say, but let me be clear 04:59:26

with you. 04:59:28
It said Draft 1 is the initial draft 04:59:29
that will be reviewed by the sponsor. 04:59:31
Q Okay. 04:59:33
A It says nothing about the -- the input that 04:59:33
will occur between the author and the writer 04:59:39
or the person who is actually typing out 04:59:44
that draft. 04:59:47
So... 04:59:49
Q Well, if Sally Laden were to testify that 04:59:52
she had no contact with you prior to the 04:59:54
first draft, you would disagree with that? 04:59:55
A Absolutely. 04:59:57
Q Okay. 04:59:58
Now, according to that contract, 05:00:00
though, when does the author get to see the 05:00:01
manuscript, which draft? 05:00:03
A Well, this contract does not say when the 05:00:09
author will initially get to see the first 05:00:18
draft. 05:00:22
It merely says Draft 2 will be sent 05:00:24
to the primary author. It doesn't say that 05:00:28
Draft 1 will not be sent to the primary 05:00:30
author. 05:00:32

Q Well, it says where Draft 1 gets sent, 05:00:33
though, right? 05:00:37
A No. 05:00:38
It says Draft 1 will be reviewed by 05:00:38
the sponsor. 05:00:40
Q Right. 05:00:42
And in this case, who's the sponsor? 05:00:43
A The sponsor is SmithKline. But it doesn't 05:00:45
say that Draft 1 will be sent to the sponsor 05:00:48
before it's sent to the author. 05:00:51
And I have to say, Skip, that the 05:00:53
reason that this is so important is that the 05:00:54
attention that it's been given to the media 05:00:58
and other places about, you know, the 05:01:00
conduct and the reporting of scientific 05:01:02
experiments has been extensive, as you know 05:01:07
as well as I do. 05:01:09
If you read The Wall Street Journal, 05:01:10
The New York Post, Science Magazine -- and 05:01:11
it's been particularly intense over this 05:01:14
past year and the past couple of months and 05:01:16
the past month, and I want to be crystal 05:01:18
clear that I, and I can't speak for other 05:01:26
people, but the process that I follow, and 05:01:28

I've followed for my entire career, is one 05:01:30
that is as I've described to you; and that 05:01:35
the language in here is interpretable and 05:01:38
totally consistent with how I've proceeded. 05:01:41
Q Let me ask you this: 05:01:48
How is the -- what number manuscript 05:01:49
is the one that you first recall receiving 05:01:51
from Sally Laden? 05:01:52
A The first one I received from her would be 05:01:54
the No. 1 one, the first one I received from 05:01:57
her. 05:01:59
Q Okay. 05:01:59
And you recall that? 05:02:00
A No. 05:02:00
What I'm saying is just by -- just by 05:02:01
deductive reasoning, the first one I 05:02:03
received from her is the first one I 05:02:05
received from her. 05:02:07
Q So you don't know if the -- well -- 05:02:08
A Skip, I would have no way of knowing -- I 05:02:12
would have no way of knowing if Sally Laden 05:02:16
had written other drafts and never sent them 05:02:21
to me. 05:02:24
I have no way of knowing that. 05:02:25

Q Well, it would -- that has a draft number on 05:02:26
it, right? 05:02:28
A Draft numbers are meaningless. 05:02:29
Q Does that document that I showed you before 05:02:31
have a draft number on it? 05:02:32
Not that one but the other one. 05:02:33
A This? 05:02:35
Q It has Draft 3, correct? 05:02:36
A Right. 05:02:37
But this doesn't say that -- number 05:02:38
one, the fact that this says Draft No. 3 05:02:39
doesn't mean that I received -- did not 05:02:41
receive Draft No. 1. 05:02:43
There's nothing in here which 05:02:45
suggests in any way that this is the first 05:02:48
draft that I received. 05:02:50
Q Okay. 05:02:51
A Can you see me, my face here now? Okay. 05:02:51
There's nothing in here that suggests 05:02:55
in any way that this is the first draft I 05:02:57
received; and nor is there nothing that 05:03:02
suggests that I didn't have a major role in 05:03:04
shaping the content of the first draft that 05:03:06
was written. 05:03:08

Q Okay. 05:03:09
Let's take a look at the next 05:03:10
exhibit. 05:03:12
(Exhibit No. 23 marked for 05:03:14
identification.) 05:03:14
(Witness read document.) 05:03:21
THE WITNESS: I have viewed the 05:03:47
Exhibit 23. 05:03:48
BY MR. MURGATROYD: 05:03:48
Q Okay. 05:03:49
And can you identify for the record 05:03:49
what that exhibit is? 05:03:50
A It is a letter from me to Sally Laden. 05:03:53
Q Okay. 05:03:55
Does it appear to be authentic? 05:03:55
A Yes. 05:03:59
Q And did you prepare that in the ordinary 05:03:59
course of your business? 05:04:00
A Yes. 05:04:02
Q And can you please read into the record the 05:04:03
contents of that letter? 05:04:05
MR. DAVIS: Can I have the date of 05:04:06
the letter, please? 05:04:07
THE WITNESS. It's dated February 11, 05:04:09

1999. 05:04:10
A "Dear Sally" -- 05:04:14
Do you want me to read the letter? 05:04:15
Q Yes, please. 05:04:17
A "You did a superb job with this. Thank you 05:04:17
very much. It is excellent. Enclosed are 05:04:20
rather minor changes for me, Neal and Mike 05:04:23
and a cover memo from me to all coauthors. 05:04:25
If it's agreeable to you, I would ask you to 05:04:28
take my cover memo and send the revisions 05:04:30
which incorporates the comments I am sending 05:04:33
you directly to all coauthors, even before I 05:04:35
see you again, so that they may review this 05:04:38
as quickly as possible. Please let me know 05:04:41
if you'd like to discuss or handle 05:04:43
differently. Thanks, Marty -- Marty. Cc: 05:04:44
Jim McCafferty." 05:04:46
And I would say to you, Skip, once -- 05:04:49
MR. GREEN: You've done what he's 05:04:51
asked you to do. There's no question 05:04:52
pending. 05:04:54
THE WITNESS: Okay. 05:04:55
Q The question I have, was the process for 05:04:55
creating the manuscript for 329 such that 05:04:57

Sally Laden would send you a copy of the 05:05:02
manuscript which you and your coauthors 05:05:06
would then comment on, according to this 05:05:09
letter, and then send back to her, which 05:05:11
then she would incorporate into the 05:05:12
manuscript itself? 05:05:14
MR. DAVIS: Objection. 05:05:15
Q Is that the process you went through -- 05:05:16
MR. DAVIS: Objection. 05:05:17
Q -- in creating the manuscript? 05:05:17
MR. DAVIS: Objection. 05:05:19
Asked and answered several times now. 05:05:19
MR. GREEN: You can answer. 05:05:21
Q Again, I'm just looking for the process. 05:05:26
What was the process of the creation 05:05:29
of the manuscript? 05:05:30
A Your statement of the process is not 05:05:31
necessarily correct. 05:05:33
Q Okay. That's what I'm trying to get to. 05:05:35
Was the process -- was the process 05:05:38
that -- 05:05:40
Wasn't Sally Laden the holder of the 05:05:41
manuscript to which all the corrections came 05:05:43
to? 05:05:45

MR. DAVIS: Object to the form. 05:05:46
A Not necessarily. 05:05:47
Q Okay. 05:05:49
Did you have a copy where you 05:05:49
actually changed the hard -- the computer 05:05:51
copy, or did you handwrite your changes? 05:05:56
A Well, in case you ever have the opportunity 05:06:03
to correspond with me in handwriting, you 05:06:05
would know that that would be a highly 05:06:07
ineffective means of communications since 05:06:08
neither you nor I would ever be able to read 05:06:10
what I wrote. 05:06:14
However, sometimes I handwrote; 05:06:14
sometimes I typed. But what was -- what the 05:06:15
process was, and you stated this 05:06:18
incorrectly, but I actually state it in 05:06:22
here, is -- 05:06:27
Let me read to you from Exhibit 23, 05:06:27
the first sentence. 05:06:29
Q Okay. 05:06:31
A And then explain it. The first sentence of 05:06:31
the second paragraph: 05:06:33
"Enclosed are changes from me, Neal 05:06:34
and Mike and a cover memo to all coauthors." 05:06:37

Okay. What's pretty clear from what 05:06:40
I stated is that I received changes from 05:06:43
Neal and Mike in this instance. I had my 05:06:49
own changes. 05:06:54
I -- though it doesn't say it, but 05:06:56
it's clearly by inference, I then decided 05:06:59
which of the changes I received I wanted to 05:07:02
then pass on to her, and I passed them on to 05:07:05
her. 05:07:08
That's different than what you said, 05:07:09
because you made it appear as though, you 05:07:10
know, any change that anyone made went to 05:07:12
Sally Laden. 05:07:15
Q No, no, through you. That's what I meant to 05:07:16
say? 05:07:19
A Yes. 05:07:19
Q Yes. 05:07:20
A But in this case, I cannot tell you whether 05:07:20
I typed it or I handwrote it. 05:07:23
Q Well, do you have the drafts of the 05:07:28
manuscript still in your possession, to your 05:07:32
knowledge? 05:07:35
A No. 05:07:35
Any -- anything -- I believe that I 05:07:36

was asked to produce all documents that I 05:07:38
had, and -- 05:07:43
MR. GREEN: I think what you'll see, 05:07:46
I -- to answer the question, since I've been 05:07:47
through the documents, I don't recall that 05:07:49
there were drafts of this article, other 05:07:51
than discussions in some emails that I think 05:07:54
you got. 05:08:00

MR. MURGATROYD: I saw them. 05:08:12
MR. GREEN: -- of an article, and 05:08:13
he -- he had happened to save a few pages. 05:08:14
We produced those. 05:08:14
MR. MURGATROYD: Correct. 05:08:16
MR. MURGATROYD: Right. 05:08:21
MR. GREEN: But there were no similar 05:08:22
pages in his papers relating specifically to 05:08:23
this. 05:08:24
THE WITNESS: If I can borrow two 05:08:26
pages of Jim's papers, which aren't part of 05:08:27

your files, I'll show you, is that a write 05:08:30
on something or type on it, send it off, rip 05:08:33
it up and discard it (gesturing). 05:08:36
It's pointless to save it. 05:08:40
BY MR. MURGATROYD: 05:08:42
Q Okay. 05:08:42
But we know in some cases you don't 05:08:43
do that, because I do have your handwritten 05:08:45
notes. 05:08:46
A Some cases I don't -- 05:08:48
Q Right. 05:08:49
A -- but most cases I do, because I only have 05:08:49
a limited storage capacity. 05:08:51
Q Okay. 05:08:52
Now -- 05:08:54
A We don't need to mark that exhibit unless 05:08:57
you want to. 05:08:59
Q No, we don't need to mark that exhibit. 05:08:59
That's -- 05:09:01
A Okay. 05:09:01
Q We're going to give that to the trash can. 05:09:02
Let me go back to -- do you recall 05:09:11
that you and I guess -- 05:09:15
Let me ask you this: Who -- who 05:09:21

decided what journal the manuscript would be 05:09:22
ultimately or originally sent to? 05:09:25
Who -- whose decision was that? 05:09:28
A Again, I can't recall the specifics of a 05:09:30
conversation for this article. But what I 05:09:36
always do when I chair research programs is 05:09:40
I have a conversation with the other lead 05:09:45
investigators. 05:09:48
Typically, the first author makes a 05:09:50
suggestion to -- suggests a couple of 05:09:55
journals that they'd like to send it to, or 05:09:57
sometimes if they're just totally fired up 05:10:00
and has one journal in mind, they'll say, 05:10:04
gee, I want to send this one to the Journal 05:10:06
of Obscure Results. And everyone says 05:10:08
fantastic. It's the most boring article 05:10:11
I've ever seen. Let's send it there. And 05:10:13
they go along with it. 05:10:16
But other times I say, well, look, 05:10:17
you know, is this something which is of 05:10:20
enough general interest that we'll send it 05:10:22
to JAMA, General Medical Journal, or do we 05:10:24
this it's a specialty psychiatry journal, 05:10:27
or -- and if we think it's specialty 05:10:29

psychiatry, should we go for a child journal 05:10:31
or should we go for, you know, an adult 05:10:34
journal, since there are many more adult 05:10:34
than child psychiatrists. 05:10:37
That -- that's the process -- you 05:10:39
know, it's any number of those things, Skip, 05:10:40
that could have gone; and I don't remember 05:10:42
how it would have gone with this one 05:10:44
Frankly, with this one, since the 05:10:46
other lead investigators are child 05:10:47
psychiatrists, I am sure I solicited their 05:10:51
input, you know, before -- 05:10:54
You know, before I said, Here's my 05:10:55
one, two, three, four choice, what do you 05:10:57
think, I'm sure I solicited people's input. 05:10:59
Q Did -- do you recall which journal you 05:11:02
originally submitted the manuscript to? 05:11:05
A No. 05:11:07
Q Okay. 05:11:07
Do you recall that the original 05:11:07
submission was rejected? 05:11:10
A No. 05:11:11
Q Okay. 05:11:12
You don't recall -- did -- well, were 05:11:12

you ever presented with -- am I correct in 05:11:14
stating that when an article is submitted to 05:11:18
a publication, a peer-reviewed publication, 05:11:21
it goes out for review typically? 05:11:24
A Sometimes. 05:11:27
Sometimes the editor -- and I edit 05:11:28
journals -- looks at it and doesn't bother 05:11:32
to send it to peer review for any number of 05:11:34
reasons. 05:11:37
Q Okay. 05:11:37
A Sometimes they don't send it out 05:11:38
because they -- they don't -- it's not based 05:11:39
on the quality of the journal. They just 05:11:41
don't feel -- the quality of the -- of the 05:11:43
manuscript, but rather they don't think it's 05:11:45
appropriate for their journal. 05:11:48
Q Okay. 05:11:49
Well, let me ask you this: Did -- do 05:11:50
you recall seeing the reviews of your 05:11:52
journal article from JAMA? 05:11:56
A I don't recall seeing it. 05:12:00
Q Okay. 05:12:01
A But -- 05:12:02
Q Do you recall seeing any reviews, maybe 05:12:02

that's an easier question, from any 05:12:05
submissions to peer-reviewed journals? 05:12:07
A For this article? 05:12:09
Q Yes, for this article. 05:12:10
A Well, like the other questions I've asked 05:12:12
you -- I'm not trying to be evasive. 05:12:14
Whenever you submit an article, you, 05:12:20
at the very least, get back a letter from 05:12:26
the editor which says, you know, this is not 05:12:28
going out to review or it's gone out to 05:12:32
review and you'll be hearing from the 05:12:35
reviewer, you know, whatever, in due course. 05:12:37
And then if it's been sent out to 05:12:43
review, the journal editor will send you a 05:12:45
cover letter with the actual reviews. 05:12:47
So it's unimaginable to me that I did 05:12:52
not get at the very least a cover letter 05:12:55
saying it wasn't going to be reviewed, or I 05:12:59
got the reviews from it. 05:13:02
I am -- I can't re -- I have no 05:13:04
memory of it. 05:13:07
Q Okay. 05:13:09
A But for that process not to have happened 05:13:10
would just be an -- I wouldn't accept -- it 05:13:12

would be such an aberration I would be on 05:13:16
the phone to the journal editor saying what 05:13:18
in the world is going on? 05:13:20
So I'm sure I received it, but I have 05:13:22
no memory of it. 05:13:24
Q Okay. That's fine. 05:13:24
Well, you know that -- I think 05:13:26
Mr. Coffin is going to cover that with you 05:13:28
tomorrow, but -- 05:13:31
MR. MURGATROYD: Are we running out 05:13:35
of time again? 05:13:36
THE VIDEOGRAPHER: No, we're fine. 05:13:37
We have another half an hour. 05:13:38
Q Ultimately, the journal -- the -- your 05:13:40
article was accepted for publication, and it 05:13:42
was published, correct? 05:13:45
A I remember that. 05:13:46
Q Okay. 05:13:47
A Correct. 05:13:48
Q And do you recall which journal accepted 05:13:48
your article for publication? 05:13:49
A The premier journal of child and adolescent 05:13:52
psychiatry, which is called the -- I believe 05:13:56
the Journal of the American Association of 05:14:03

Child and Adolescent Psychiatry, JAACAP. 05:14:05
Q Is it "association" or "academy"? 05:14:09
(Laughter.) 05:14:11
A That's why I said "I believe." I think you 05:14:11
probably know the answer, Skip. 05:14:13
Q Well, you may want to look at the article. 05:14:14
A Well, how important is it? I mean, where is 05:14:17
it? 05:14:19
Q We might as well get it straight what the 05:14:19
journal is. 05:14:21
A We've already done this three times. 05:14:22
Please. 05:14:24
The Journal of the American Academy 05:14:26
of Child and Adolescent Psychiatry. 05:14:27
Q Okay. 05:14:32
And do you recall whether that was 05:14:33
published? 05:14:34
A No, but I'll check. 05:14:36
Q Okay. 05:14:37
A According to Exhibit 13, it was published on 05:14:38
July -- in July of 2001. 05:14:43
Q Okay. 05:14:45
So it's about four years after the -- 05:14:46
the study was completed, correct? 05:14:48

A I don't remember when the study was 05:14:57
completed. 05:14:58
Q Okay. 05:14:58
Do you remember the meeting in 05:14:59
November of 1997, right? 05:15:00
A It was at least -- it was at least three and 05:15:02
a half years after that meeting. 05:15:07
Q Okay. 05:15:11
And you said that when you write 05:15:11
articles, that it's your -- that you have a 05:15:16
purpose or you have a stated intention or 05:15:17
that you have a message that you want to get 05:15:19
across in your articles; is that correct? 05:15:21
A Yes. 05:15:24
Q And is that true for Study 329? 05:15:24
A Yes. 05:15:26
Q And what was the -- what was your intention 05:15:26
or your message that you wanted to get 05:15:31
across with regard to Study 329? 05:15:33
A As stated. 05:15:35
Q Okay. 05:15:36
Is that stated in the conclusion in 05:15:38
the abstract? 05:15:39
A It should be in the abstract. 05:15:41

(Witness read document.) 05:15:44
A The conclusion, which would be the message, 05:15:50
is paroxetine is generally well tolerated 05:15:53
and effective for major depression in 05:15:59
adolescents, which I believe to be 05:16:02
absolutely accurate. 05:16:05
Generally well tolerated and 05:16:07
generally effective. 05:16:11
Q In the treatment of adolescent depression? 05:16:14
A No. Generally effective for major 05:16:20
depression in adolescents. 05:16:23
Q So your study only looked at -- 329 only 05:16:31
looked at what's called MDD, Major 05:16:33
Depressive Disorder? 05:16:35
A Yes. 05:16:38
Q Okay. 05:16:38
And -- and you believe that your 05:16:38
studies showed that paroxetine or Paxil is 05:16:40
effective for treating kids with Major 05:16:43
Depressive Disorder? 05:16:46
A Is generally effective. 05:16:47
Q Okay. Generally effective. 05:16:48
And do you agree that GSK disagrees 05:16:55
with that statement, meaning 05:16:57

GlaxoSmithKline? 05:16:58
A I have no idea -- 05:16:58
MR. DAVIS: Object to the form of the 05:17:00
question. 05:17:01
Mischaracterizes GSK's position. 05:17:01
A I have no idea what their position is. 05:17:03
Q Have you -- you haven't seen -- 05:17:06
Are you aware -- we talked about 05:17:08
Dr. Wheaton earlier, remember, Jim 05:17:09
McCafferty's boss? 05:17:12
A Yes. 05:17:13
Q Okay. 05:17:13
Are you aware that he testified 05:17:14
before Congress? 05:17:15
A No. 05:17:16
Q Okay. 05:17:18
Were you aware that Congress looked 05:17:19
into the issue of GSK presenting incomplete 05:17:21
or misinformation regarding the use of Paxil 05:17:25
in adolescents and children? 05:17:29
A Not -- not specifically. I mean, I know -- 05:17:34
I don't -- 05:17:37
I don't specifically know what 05:17:37
Congress looked into with regard to GSK, 05:17:42

Paxil in children. I don't -- in fact, 05:17:51
I'm -- no. 05:17:52
Q You're aware that they -- Congress did look 05:17:53
into it, though; is that correct? 05:17:56
Have you heard that? 05:17:58
A It's entirely possible that I saw emails or 05:18:08
reports in the newspapers describing 05:18:13
Congress's interest. 05:18:16
I can't specifically recall seeing 05:18:17
that. 05:18:21
Q Okay. 05:18:21
A I'm not saying that I didn't. 05:18:22
Q Okay. 05:18:23
A But I don't -- it's not like I can tell you 05:18:23
that, yes, on, you know, September -- 05:18:26
between September and December of 2004 I 05:18:29
read an article in The New York Times or I 05:18:32
got an email from some watchdog agency that 05:18:36
Congress was investigating. 05:18:41
I have no memory of that, but I'm not 05:18:44
saying that I didn't see it. 05:18:46
Q Okay. 05:18:47
Well, if GSK were to say that Paxil 05:18:47
is not effective for the use in kids, that 05:18:49

would be a statement inconsistent with the 05:18:52
message you have in your journal article, 05:18:54
correct? 05:18:55
MR. DAVIS: Objection to the form. 05:18:55
Mischaracterizes the record. 05:18:56
A Yes. Actually, your statement was 05:18:58
incomplete and doesn't address this article. 05:18:59
Your statement was, and perhaps the 05:19:01
court can read it back -- 05:19:04
THE WITNESS: Would you mind reading 05:19:05
back Skip's statement? 05:19:06
(Record read as requested.) 05:19:07
A Okay. Stop right there. 05:19:22
Skip's statement was "not effective 05:19:23
for the use in kids." You didn't specify 05:19:24
for the use of what in kids. 05:19:26
You could have meant for the use of 05:19:28
having kids become better baseball players. 05:19:29
Q Okay. 05:19:32
For the treatment of depression. 05:19:32
A Treatment of -- still that's still too 05:19:37
vague. 05:19:38
Q All right. Well, let me make it more exact. 05:19:38
If GSK has stated publicly that Paxil 05:19:40

is ineffective for the treatment of 05:19:43
depression of children and adolescents, that 05:19:46
statement would be inconsistent with the 05:19:51
message that you wanted to get across in the 05:19:52
journal article that's before you, correct? 05:19:54
MR. DAVIS: Object to the form. 05:19:57
Mischaracterizes the record. 05:19:58
MR. GREEN: You can answer. 05:20:02
A Skip, would you just mind saying that again? 05:20:06
Q Sure. 05:20:08
Want me to -- 05:20:09
A You can say it the same way. 05:20:10
Q You want me to say it again? 05:20:11
A Yes, just say it again. 05:20:12
Q Yes, that's fine. 05:20:14
If GSK has stated publicly that Paxil 05:20:16
was ineffective for the treatment of 05:20:18
depression in children and adolescents, that 05:20:22
statement would be inconsistent with the 05:20:24
message that you have put forth in the 05:20:26
article that is in your hand right there, 05:20:28
correct? 05:20:29
MR. DAVIS: Object to the form of the 05:20:31
question. 05:20:32

It's vague and ambiguous as to time, 05:20:32
scope, and also mischaracterizes the record. 05:20:34
Q You can answer. 05:20:36
A Okay. 05:20:37
So the answer is yes. The but -- 05:20:37
MR. GREEN: No but. That's -- yes. 05:20:42
A Yes. 05:20:43
Q Okay. 05:20:44
Now, have -- I don't know if -- has 05:20:44
GSK shown you the various documents where 05:20:48
they state that the pediatric trials of 05:20:51
Paxil for the treatment of depression in 05:20:59
kids failed to show efficacy? 05:21:00
MR. DAVIS: Object to the form of the 05:21:03
question. 05:21:03
Q Have you seen those? 05:21:05
A No. 05:21:06
Q Have you seen the documents where GSK says 05:21:10
that the trials involving Paxil in children 05:21:14
and adolescents showed a definite risk of 05:21:20
increased suicidality? 05:21:23
MR. DAVIS: Object to the form. 05:21:26
Mischaracterizes the record. 05:21:27
A No. 05:21:29

Q If, in fact -- 05:21:31
A Let -- 05:21:32
Q Let me just ask the question. 05:21:33
A Okay, because I was -- 05:21:34
Q If, in fact, Paxil does definitely cause an increased risk of suicidality in kids who take Paxil, would you agree that the drug is not safe? 05:21:35 05:21:38 05:21:42 05:21:43
MR. DAVIS: Object to the form of the question. 05:21:44 05:21:45
It's vague and ambiguous. No foundation has been laid either for the question. 05:21:46 05:21:48 05:21:52
A Well, I don't -- I don't know what -- what it is appropriate for me to say with these various objections. 05:21:55 05:22:00 05:22:02
Q You can answer the question. 05:22:03
MR. GREEN: You can answer. 05:22:04
Q His objections make no difference. You can answer the question. 05:22:05 05:22:08
A They make a difference to him. 05:22:09
So -- 05:22:10
MR. DAVIS: My objection is for purposes of you if you want to correct your 05:22:11 05:22:12

question, because it's an inappropriate question because it assumes certain things that are not in the record of this case, nor will they ever be. 05:22:14 05:22:15 05:22:17 05:22:19
But so it's to put you on notice that you can fix your question. 05:22:21 05:22:22
MR. MURGATROYD: Oh, okay. Well, here, let's -- we're going to take a -- 05:22:23 05:22:24
What time is it now? 05:22:25
MR. GREEN: It's almost 5:30. I suggest we break for the day. 05:22:27 05:22:29
MR. MURGATROYD: After -- let me get one thing. I just want to lay the foundation for what the discussion is. 05:22:30 05:22:30 05:22:30
It will take me two seconds. 05:22:33
THE VIDEOGRAPHER: Would you like to go off the record? 05:22:36 05:22:36
MR. MURGATROYD: Yes, just for a second. 05:22:37 05:22:37
THE VIDEOGRAPHER: The time is 5:24. We'll go off the record. 05:22:39 05:22:41
(Recess.) 05:22:43
(Discussion off the record.) 05:22:43
(Exhibit No. 24 marked for 05:22:49

identification.) 05:22:49
MR. MURGATROYD: Why don't you take a look at the last exhibit for the day so we can wrap up. 05:25:14 05:25:16 05:25:18
(Witness read document.) 05:25:20
MR. DAVIS: I think you've got to make a foundation for this document under the terms of the protective order before you can show it to Dr. Keller. 05:26:07 05:26:08 05:26:10 05:26:12
MR. MURGATROYD: No, I don't. 05:26:14
MR. DAVIS: Yes, you do. 05:26:15
MR. MURGATROYD: No, I don't. I've already shown it to him. I'm going to put it in the record. 05:26:16 05:26:16 05:26:16
MR. DAVIS: No, no. 05:26:18
In fairness, in fairness, Judge Savage -- the discussions with Judge Savage that resulted in revisions to the protective order in Blain require certain foundations to be established with the witness before confidential documents can be shown to him. 05:26:19 05:26:20 05:26:24 05:26:26 05:26:29 05:26:34
This is -- 05:26:36
MR. MURGATROYD: I believe I've already established the foundation. 05:26:36 05:26:37

MR. DAVIS: No, you haven't. No. You have to establish that he's -- no. 05:26:38 05:26:39
Excuse me. I'm objecting. 05:26:41
MR. MURGATROYD: I'm going to give it to him to read. 05:26:43 05:26:43
MR. DAVIS: I'm objecting. 05:26:45
MR. MURGATROYD: Okay, fine. 05:26:46
THE WITNESS: I'm going wait until you guys fight it out. 05:26:48 05:26:48
MR. DAVIS: You have to establish a foundation. 05:26:50 05:26:51
MR. MURGATROYD: I did establish foundation. 05:26:52 05:26:52
MR. DAVIS: You have not established a foundation. 05:26:53 05:26:54
MR. MURGATROYD: I asked him whether or not he was aware that GSK had said the drug does not work for major depressive disorder in kids, and I asked him whether or not the -- there is a definition risk of suicidality in that age group who are treated with Paxil. 05:26:54 05:26:56 05:26:58 05:26:59 05:27:01 05:27:05 05:27:09
There's the foundation. 05:27:10
MR. DAVIS: No, it's not. 05:27:11

Under the terms of the protective order, you've actually removed him from being able to answer questions about that document, because he doesn't know anything about it. 05:27:11 05:27:13 05:27:15 05:27:16 05:27:17

And under the terms of the protective order, you've got to establish that he's got firsthand knowledge of information that's reflected in the documents. He doesn't. He's not copied on it. 05:27:18 05:27:20 05:27:22 05:27:25 05:27:26

You've yet to show that he was -- either received a correspondence or was sent the correspondence. He's not on that document, and so you have not established a foundation. 05:27:27 05:27:29 05:27:32 05:27:35 05:27:38

That -- that relates to an internal discussion at GlaxoSmithKline concerning deliberations with the global safety board, and that discussion Dr. Keller wasn't a part of, didn't have anything to do with. 05:27:38 05:27:40 05:27:43 05:27:48 05:27:52

And nowhere does that article or that document say anything about Study 329. It doesn't. 05:27:54 05:27:55 05:27:58

MR. MURGATROYD: That's -- that -- 05:27:58

Todd, I understand what you're saying, but I think that foundation will be established through the course of this deposition, that he was sent documents from GSK asking about the suicidality risk related to Paxil, which we're going to get into tomorrow. 05:28:00 05:28:02 05:28:03 05:28:04 05:28:08 05:28:11

You asked me about the -- the foundation for the question I asked him. This document lays a foundation. This is the document I'm going to show him, and you can object. That's fine. It's duly noted. 05:28:13 05:28:14 05:28:17 05:28:18 05:28:20

MR. DAVIS: No, no, I'm -- 05:28:22

MR. MURGATROYD: Let me show you -- 05:28:24

MR. DAVIS: We should break for the day and get this ironed out, because we're not going to get it ironed out. 05:28:26 05:28:27 05:28:29

MR. MURGATROYD: No, I want to ask the question I started with. 05:28:30 05:28:31

THE VIDEOGRAPHER: Would you like to go back on the record? 05:28:32 05:28:33

MR. MURGATROYD: Yes, I want to finish the question I started with. 05:28:34 05:28:35

MR. DAVIS: You're violating the terms of the protective order in Blain that 05:28:36 05:28:37

was agreed to by our office and your office. 05:28:39

MR. MURGATROYD: I disagree. 05:28:43

THE VIDEOGRAPHER: I'm not on the record yet. 05:28:45 05:28:45

MR. MURGATROYD: That's fine. Go ahead. 05:28:46 05:28:46

MR. GREEN: Is there some judge who can be called to resolve this? Because I've gotten into situations like this where I've sat and listened to two attorneys yell at each other about what something means, and we've had to go to a magistrate. 05:28:47 05:28:48 05:28:50 05:28:52 05:28:55 05:28:58

I mean, I -- 05:28:59

MR. MURGATROYD: There's no -- There's no judge that we can call right now. 05:29:01 05:29:01

MR. GREEN: Okay. 05:29:03

THE WITNESS: Well, let me say this, just because it's late. 05:29:04 05:29:06

It's 5:30, which is when we agreed to stop, so I -- I need to stop, and then hopefully when we -- I would implore you guys, since I'm being as cooperative and as civic-minded as I can, I'd implore you that when we start tomorrow at 9:15 a.m., you 05:29:07 05:29:10 05:29:14 05:29:18 05:29:24 05:29:26

will have worked it out, and I can then answer it. 05:29:31 05:29:34

MR. MURGATROYD: That's fine. 05:29:35

THE WITNESS: That's all I'm asking out of just respect and dignity for time. 05:29:37 05:29:39

MR. MURGATROYD: That's fine. Why don't we do this. I need you to -- is there any way you can print out anything and fax it to me tonight? 05:29:41 05:29:41 05:29:44 05:29:46

I just want to know what his statement was. 05:29:47 05:29:48

MR. DAVIS: I'll give you a copy -- 05:29:49

THE WITNESS: Guys, one second. One second. If you don't need me anymore -- 05:29:51 05:29:52

MR. MURGATROYD: We'll let you guys go, absolutely. Thank you. 05:29:55 05:29:56

THE WITNESS: And as far as tomorrow, I would just like to establish this as a ground rule. 05:29:57 05:29:58 05:30:00

If -- if we can finish -- if we're going to finish tomorrow -- 05:30:02 05:30:05

MR. MURGATROYD: We are going to try. 05:30:07

THE WITNESS: Okay. Then I'm willing to work late. 05:30:08 05:30:10

MR. MURGATROYD: Okay. 05:30:11
THE WITNESS: But if we're not going 05:30:12
to finish tomorrow, I mean, I'm not -- I 05:30:13
don't want to get -- 05:30:15
I'm not going to get into arguments 05:30:16
with what's right or wrong. 05:30:19
MR. MURGATROYD: Yes. 05:30:20
THE WITNESS: All I'm saying is as a 05:30:21
descriptive matter, if we're not going to 05:30:22
finish tomorrow -- this is my first day back 05:30:24
after being off for three weeks -- then I 05:30:25
really want to stop at 4:00. 05:30:28
MR. MURGATROYD: That's fine. 05:30:30
THE WITNESS: Because if we have to 05:30:31
come -- you know what I'm saying? If we 05:30:32
have to come back -- 05:30:34
MR. GREEN: Because he has to fly out 05:30:36
the next day to go to a conference. 05:30:37
MR. MURGATROYD: That's fine. I 05:30:38
agree. Absolutely fine. 05:30:39
THE WITNESS: Is that fair? 05:30:40
MR. MURGATROYD: Yes. 05:30:42
MR. GREEN: There is also on the 05:30:42
table an offer the doctor to have this 05:30:43

tomorrow in his conference room at Butler, 05:30:46
which has air conditioning. 05:30:49
And I would -- I personally would 05:30:50
strongly suggest that we take him up on his 05:30:54
offer. 05:30:56
MR. DAVIS: That's agreeable. 05:30:56
MR. MURGATROYD: The only problem I 05:30:57
have is I need to have documents copied. I 05:30:58
need to have documents Xeroxed -- I mean 05:31:00
printed out off computers. 05:31:02
I mean, I need to have that facility. 05:31:04
I mean I need to hook into a printer. 05:31:07
THE WITNESS: My staff is really 05:31:10
good. In other words, my staff would be 05:31:11
willing to copy things. 05:31:12
What else do you need? 05:31:13
MR. MURGATROYD: I need to have 05:31:14
access to a printer. Like this document I 05:31:15
have to print off -- 05:31:17
THE WITNESS: We have a printer. 05:31:20
MR. MURGATROYD: No, let's have it 05:31:21
here. What I'll do is I'll try have Bob air 05:31:22
condition it down and get it cool. 05:31:24
MR. DAVIS: I'll tell you, it's 05:31:25

really uncomfortable. The doctor has had to 05:31:26
loosen his tie. He's had to roll up his 05:31:28
sleeves. It's hot. 05:31:31
MR. MURGATROYD: I just said I'm 05:31:32
going try to get a cooler. 05:31:34
MR. DAVIS: Why don't we just do it 05:31:35
over there? 05:31:37
MR. MURGATROYD: Because I need the 05:31:37
facility. I need the -- this doesn't have 05:31:38
to be on the record. 05:31:41
(Discussion off the record.) 05:31:43
(Proceedings adjourned at 5:32 p.m.) 05:32:20
05:32:22

INDEX

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 2, VIDEO DEPOSITION of MARTIN B. 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 Thursday, September 7, 2006, commencing at 10:18 a.m.

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FILE NO.: A00640A

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

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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Also present: Tamar Halpern, Esq., Phillips Lytle

Videographer: Shawn Budd

PROCEEDINGS 10:05:04

THE VIDEOGRAPHER: We are back on the record. Today's date is September 7, 2006, and this is the continuation of the deposition of Dr. Martin B. Keller, and the time is approximately 10:18. 10:16:24 10:16:26 10:16:31 10:16:32 10:16:35

You may continue. 10:16:38

MR. DAVIS: Just a couple of housekeeping issues concerning the deposition exhibits that have presently been marked. 10:16:39 10:16:40 10:16:42 10:16:44

None of those have -- are subject to the protective order that's been entered into the cases, with the exception of Exhibit 24, which was marked, and we had a discussion about it at the end of yesterday's deposition. That is -- that document is subject to the protective order in the case. 10:16:45 10:16:49 10:16:52 10:16:54 10:16:59 10:17:01 10:17:04 10:17:05

In addition, we've had conversations with counsel for plaintiffs and counsel for Dr. Keller off the record, and the plaintiffs have informed the other participants that they will not complete 10:17:06 10:17:08 10:17:11 10:17:15 10:17:17

their questioning of Dr. Keller today, and so we have agreed to reconvene for a third day to finish the deposition. 10:17:19 10:17:23 10:17:26

And at that time, the plaintiffs will finish their questioning. GSK will be entitled to have time with Dr. Keller to ask him questions concerning the issues raised in the lawsuit and the issues raised by plaintiffs' counsel, and then we will finish on that -- on that third day. 10:17:30 10:17:32 10:17:36 10:17:38 10:17:41 10:17:45 10:17:47

MR. GREEN: And I think we agreed that we're going to conclude at 4:00 today; is that right? 10:17:49 10:17:50 10:17:53

MR. DAVIS: That's correct, yes. 10:17:55

MR. GREEN: Okay. 10:17:57

THE WITNESS: Actually, is 3:45 possible, just so I can get to a meeting? 10:17:58 10:17:58 10:18:01

MR. COFFIN: I don't have a problem with that, considering we've all agreed to an additional day. If counsel for GSK and your counsel -- 10:18:03 10:18:04 10:18:06 10:18:09

MR. DAVIS: That's fine. 10:18:11

MR. GREEN: Do you want to put on the 10:18:12

record we signed the nondisclosure agreement as well as Exhibit 24 and that's been given to the notary and she's going to notarize it and -- 10:18:13 10:18:15 10:18:19 10:18:21

MR. MURGATROYD: We're going to make it Exhibit 25. 10:18:22 10:18:22

Do we actually have it handy? 10:18:25

MR. COFFIN: Yes, why don't we do that. 10:18:29 10:18:29

MR. MURGATROYD: Let's make it Exhibit 25. 10:18:29 10:18:29

Exhibit 24 will now be officially part of the pile, but I'm going to reserve my questions on it for when it's my turn again. 10:18:30 10:18:32 10:18:34 10:18:37

MR. GREEN: Sure. 10:18:38

(Discussion off the record.) 10:18:38

(Exhibit No. 25 marked for identification.) 10:18:38 10:18:38

MR. COFFIN: Okay. 10:18:46

So Exhibit 25 to Dr. Keller's deposition will be the agreement by Dr. Keller and his counsel to abide by the protective order specifically in the Blam 10:18:46 10:18:49 10:18:51 10:18:55

case, but also applying to protective orders 10:18:59
in Engh and -- 10:19:04
MR. MURGATROYD: Smith. 10:19:07
MR. COFFIN: -- Smith. Thank you. 10:19:07
MR. MURGATROYD: Did we go through 10:19:11
the dedesignation of all the documents 10:19:12
except for 24? 10:19:14
MR. COFFIN: Yes. Todd just -- 10:19:16
Mr. Davis stated that on the record. 10:19:17
MR. MURGATROYD: Okay. Excellent. 10:19:19
MR. COFFIN: Todd, do you have 10:19:20
anything else before we get started? 10:19:21
10:19:22
MARTIN B. KELLER, M.D., a witness 10:19:22
having been previously duly sworn, on oath 10:19:22
deposes and says as follows: 10:19:22
10:19:22
EXAMINATION 10:19:22
BY MR. COFFIN: 10:19:23
Q Dr. Keller, my name is Chris Coffin. I 10:19:24
represent the plaintiffs in the case 10:19:26
entitled Engh, et al. versus 10:19:28
GlaxoSmithKline. It's in the state court in 10:19:30
Minnesota. 10:19:32

I have, obviously, a number of 10:19:34
questions to ask you, and some of them I'm 10:19:37
going to begin with are some follow-up 10:19:40
questions to some that Mr. Murgatroyd asked 10:19:44
you yesterday. 10:19:46
The first thing is, after the 10:19:46
deposition concluded yesterday, you stepped 10:19:48
out in the hallway and had some discussions 10:19:51
with counsel for GlaxoSmithKline, correct? 10:19:53
Mr. Davis? 10:19:55
MR. DAVIS: Incorrect, but you can 10:19:57
answer the question -- the witness can 10:19:58
answer the question for himself. 10:20:00
A No. 10:20:01
Q You didn't speak to him after the 10:20:02
deposition? 10:20:04
A Well, I just said goodbye, and I asked him 10:20:05
where is he going to eat dinner. I don't 10:20:07
remember -- I don't actually remember if we 10:20:12
spoke. 10:20:12
Q You don't remember stepping out in the hall 10:20:13
and talking to him? 10:20:15
A Actually, I didn't. 10:20:16
Q Okay. 10:20:17

A I didn't. I mean, I do remember and I 10:20:17
didn't speak to him. 10:20:19
Q Okay. 10:20:20
Were you present when he was 10:20:21
speaking -- did Mr. Davis speak to your 10:20:22
counsel? 10:20:25
A I don't know. I went down -- I went 10:20:25
downstairs, and these two gentlemen stayed 10:20:27
upstairs. 10:20:30
I have no idea what they did. 10:20:31
Q Okay. 10:20:32
You testified yesterday that you've 10:20:33
given a deposition in the past, correct? 10:20:35
A Yes. 10:20:39
Q Okay. 10:20:40
And how many times have you given a 10:20:40
deposition, other than in this case or these 10:20:41
cases? 10:20:43
MR. DAVIS: Object to the form. 10:20:50
A I think either -- either once or twice. 10:20:51
Q Okay. 10:20:54
And do you recall what the substance 10:20:54
of the case was in which -- 10:20:57
A Yes. 10:20:58

Q -- you were giving a deposition? 10:20:59
Wait until I'm finished with my 10:21:01
question. 10:21:04
A Oh, I'm sorry. 10:21:05
Q That's okay. It's a new day, so it takes 10:21:05
some time. 10:21:07
A Yes. 10:21:07
(Laughter.) 10:21:07
Q Do you recall the substance of the case in 10:21:08
with you provided a deposition? 10:21:10
A Yes. 10:21:11
Q And what was the substance of that case? 10:21:12
A Could we go off record? 10:21:15
Q Well, not when there's a question pending. 10:21:18
That's the only -- 10:21:20
A I'm not -- it was something that was under a 10:21:22
grand jury, and I don't know whether I'm 10:21:28
allowed to say so. 10:21:31
It was a highly confidential matter. 10:21:33
Q Okay. 10:21:36
A I can say it had nothing to do -- I mean, it 10:21:37
was a very -- had to do -- 10:21:40
I was -- how to put this. I was -- I 10:21:42
was represented -- I was -- I was an expert 10:21:47

witness for the United States of America, 10:21:50
who was the plaintiff in a very high-profile 10:21:53
lawsuit having to do with -- with nothing 10:21:58
basically related to what we're doing here. 10:22:02
Q Okay. 10:22:04
A Twice I was the plaintiff for the United 10:22:05
States of America, and they seem to have me 10:22:06
shredding everything as soon as I read it, 10:22:10
so I don't know whether I -- 10:22:12
Q That's fine. 10:22:13
A I mean, you tell me. I don't know whether 10:22:14
I'm allowed to say. 10:22:15
Q No, we don't need to get into that. 10:22:17
Can you tell me -- first of all, you 10:22:19
weren't a party in either of those cases? 10:22:21
A No. 10:22:23
Q Okay. 10:22:23
And was -- was the -- what was your 10:22:26
testimony as -- what were you qualified -- 10:22:29
Were you qualified as an expert in 10:22:31
that case? Let me ask that first. 10:22:33
A Yes. 10:22:35
Q Okay. 10:22:35
And what was the area you were 10:22:36

qualified as an expert in? 10:22:37
A Had to do with a liability of a company 10:22:41
based on a -- what's the word -- based on 10:22:58
the performance of a wholly owned subsidiary 10:23:06
medical company that they had which would -- 10:23:09
which performed medical and psychiatric 10:23:11
examination of one of their employees. 10:23:16
And my expertise had to do with the 10:23:22
quality of the performance of their wholly 10:23:25
owned subsidiary and the conclusion they 10:23:29
made as to the mental state of the employee 10:23:32
and the implications of that for an action 10:23:36
which led to great distress for the United 10:23:40
States of America. 10:23:45
Q Okay. 10:23:46
You -- have you ever been qualified 10:23:46
as an expert in any other cases other than 10:23:49
those that we don't need to talk about that 10:23:51
you mentioned? 10:23:54
A No. 10:23:55
Q Okay. 10:23:56
You've never been qualified as an 10:23:58
expert in child psychiatry, correct? 10:23:59
A Never been qualified -- correct. 10:24:03

Q Do you hold yourself out to be an expert in 10:24:08
child psychiatry? 10:24:10
A I'm an expert in the design and 10:24:17
implementation of certain types of clinical 10:24:24
research related to child and adolescent 10:24:30
psychiatry; and based on the fact that I've 10:24:35
been a coprincipal investigator and 10:24:39
principal investigator on at least, you 10:24:42
know, on many -- on at least four or five 10:24:45
National Institutes of Health funded 10:24.51
research grants since 1980s, so I assume I'm 10:24:54
an expert, because it's hard to get grants 10:24:59
funded, and they funded them and I did the 10:25:02
work. 10:25:04
Q Okay. 10:25:04
Let me go back to the question, and 10:25:05
I'll state it a little differently, more 10:25:06
specific. 10:25:09
Do you hold yourself out to be an 10:25:09
expert in the treatment of children and 10:25:10
adolescents in the field of psychiatry? 10:25:13
MR. DAVIS: Objection. 10:25:15
Asked and answered. 10:25:16
A I know an enormous amount about the 10:25:23

treatment of children and adolescents with 10:25:34
mood disorders based on the literature and 10:25:37
performing and designing trials, not based 10:25:47
on my own personal treatment in a clinical 10:25:51
setting of these individuals. 10:25:57
Q Right. 10:25:59
And I think yesterday you testified 10:25:59
you hadn't actually treated a child or 10:26:01
adolescent in at least 20 years, correct? 10:26:04
A Correct. 10:26:08
Q Okay. 10:26:08
So any of your knowledge or 10:26:09
information you have about treatment with 10:26:13
children at least within the last 20 years 10:26:16
has to do with research and/or literature, 10:26:19
correct? 10:26:22
A No. 10:26:24
Q Okay. 10:26:25
Let me say it this way: Any of your 10:26:26
knowledge regarding treatment of children 10:26:29
and adolescents in the field of psychiatry 10:26:33
at least within the last 20 years is not 10:26:36
gained by your personal treatment of 10:26:39
children or adolescents, correct? 10:26:42

A The -- not in -- that's not entirely correct. 10:26:45 10:26:49

Q All right. 10:26:51

A I also have -- sit in on a periodic basis on case conferences that involve our trainees, residents, psychologists, in which cases are presented and discussed; and I'll often be one of the discussants so that the -- the patient being discussed for supervision by senior people, which would include myself, would be that of a child or an adolescent. 10:26:52 10:27:00 10:27:05 10:27:10 10:27:14 10:27:17 10:27:22 10:27:24

And my expertise is brought in based on the knowledge that I have both from the treatment of adults and also from research, because there is considered to be some carryover. So I do hear the presentation of clinical cases in that type of venue. 10:27:28 10:27:31 10:27:33 10:27:37 10:27:39 10:27:42

Q Okay. 10:27:46

Do you recall anymore clearly when the last time you treated a child or adolescent in psychiatry was, other than the broader answer you've given sometime after the last or prior to the last 20 years? 10:27:50 10:27:55 10:27:57 10:28:01 10:28:06

A Could you please repeat the question? 10:28:12

Q Yes, I'm sorry. That was a difficult question. 10:28:14 10:28:15

The question is, can you say any more specifically when the last time you treated a child or adolescent for a psychiatric issue was? 10:28:16 10:28:19 10:28:21 10:28:24

A When you say treated, if you could just clarify what you mean by treated? 10:28:27 10:28:29

Q Sure. 10:28:31

Evaluated and prescribed some kind of treatment, either psychotherapy and/or pharmacotherapy. 10:28:32 10:28:38 10:28:42

A Okay. 10:28:45

So -- and the question is very -- could you -- 10:28:46 10:28:48

Do you mind just repeating the question? 10:28:50 10:28:52

Q Sure. 10:28:52

The question is, do you recall any more specifically how many years ago it was since you've treated a child or adolescent in the field of psychiatry? 10:28:53 10:28:54 10:28:58 10:29:01

A No. 10:29:02

Q Okay. 10:29:04

So your best answer is sometime over 20 years ago? 10:29:04 10:29:06

A Yes. 10:29:07

Q Okay. All right. 10:29:08

Yesterday there was some -- excuse me. There was some questions about the advisory board meetings that you had with regard to Study 329; do you recall that? 10:29:12 10:29:13 10:29:15 10:29:17

A Yes. 10:29:20

Q Do you recall those questions? 10:29:20

A In generality. 10:29:25

Q Good. That's all I'm looking for. 10:29:27

You attended multiple advisory board meetings that addressed the Study 329, correct? 10:29:30 10:29:33 10:29:37

A No. 10:29:37

Q You did not? 10:29:38

A No. 10:29:38

Q Okay. 10:29:39

Were you involved in a group of investigators that met to discuss the results of -- or, excuse me, the methodology of Study 329? 10:29:41 10:29:44 10:29:46 10:29:50

A Please repeat that. 10:29:56

Q Were you involved in meetings that discussed the design, implementation, methodology of Study 329? 10:29:58 10:30:01 10:30:07

A Yes, but -- 10:30:08

Q And what did you -- 10:30:09

A But just to make sure that your question isn't linked to your previous one, these were not advisory board meetings. These meetings were not sponsored by a third party. 10:30:10 10:30:11 10:30:14 10:30:17 10:30:19

These meetings were meetings that were organized by myself and my peers and colleagues. 10:30:19 10:30:21 10:30:28

Q Okay. 10:30:29

Were those the -- the meetings that you're discussing right now that you said you and your peers and colleagues had, did they include Jim McCafferty from GlaxoSmithKline? 10:30:29 10:30:32 10:30:33 10:30:36 10:30:40

A I don't recall whether he was ever present at any of these meetings. If he was present at any of the meetings, it might have been a meeting or two very long after, you know, well -- well more than a year after we 10:30:41 10:30:44 10:30:49 10:30:50 10:30:59

started meeting and discussing and after we 10:31:02
basically had a protocol set and written. 10:31:05
I'm not saying that happened. I'm 10:31:07
saying it's possible that it happened; but 10:31:09
if it did happen, it happened long after the 10:31:12
study was discussed and designed and we had 10:31:16
written our own internal -- our own 10:31:20
protocol. 10:31:22
Q Okay. 10:31:25
Are those meetings that you just 10:31:25
described the same meetings you were talking 10:31:28
about where you were presented with 10:31:30
prescription numbers or sales figures 10:31:34
regarding Paxil? 10:31:36
A No. 10:31:38
Q Okay. 10:31:39
What are those meetings? 10:31:40
A Which meetings? 10:31:44
Q Okay. 10:31:44
Yesterday you testified that at some 10:31:47
meetings, I don't know the title of them -- 10:31:49
advisory board, investigator meetings -- 10:31:50
there were some meetings in which you were 10:31:52
provided information from a representative 10:31:57

of GlaxoSmithKline regarding sales figures 10:32:01
for Paxil; is that correct? 10:32:04
MR. DAVIS: Object to the form. 10:32:07
Mischaracterizes the testimony. It's 10:32:08
been asked and answered. 10:32:10
A Could you just say that more succinctly, 10:32:13
please? 10:32:16
Q Have you ever been to a meeting -- have you 10:32:18
ever been to any meeting in your whole 10:32:19
entire life where the results or the sales 10:32:21
figures from Paxil sales were presented to 10:32:26
you? 10:32:30
A I don't recall if I was. 10:32:32
Q Okay. 10:32:36
At the investigator meetings that you 10:32:46
testified about -- 10:32:49
Are we clear on what investigator 10:32:50
meetings are? 10:32:52
A No. 10:32:53
Q Okay. 10:32:53
You got together with groups of 10:32:54
investigators to talk about 329, correct? 10:32:56
A To be precise, the answer is no. 10:33:04
Q Okay. 10:33:05

Did you ever meet -- did you ever 10:33:06
meet with Neal Ryan to discuss 329? 10:33:07
A The answer's no. 10:33:14
Q It's going to be a long day, Doc. 10:33:18
A Well, but you need to sharpen your 10:33:20
questions; and if you want me to tell you 10:33:22
why, it's because I -- I did meet with Neal 10:33:24
Ryan and I did meet with other peers, but 10:33:28
when we met, we didn't have -- we didn't 10:33:30
have anything called Study 329. 10:33:35
We met to talk, as I explained 10:33:37
yesterday in detail, about the fact that we 10:33:40
thought it would be important to develop a 10:33:45
research program to study the efficacy of 10:33:47
treating adolescents with antidepressants. 10:33:50
So what I'm trying to do in answering 10:33:55
you precisely is to disentangle the 10:33:57
evolution and the development of this from 10:34:01
something which has become -- became 10:34:04
codified at some point in time far after I 10:34:07
was -- you know, I have no idea when it 10:34:11
became codified as a 329. 10:34:13
The implication -- the linkage there 10:34:16
being the 329 was a number given by 10:34:19

SmithKlein Beecham to a study, you know, 10:34:25
that had been evolved. 10:34:29
I'm trying to disentangle it to make 10:34:31
it clear. 10:34:35
Q Okay. 10:34:36
A I'm not trying to be difficult. 10:34:36
Q Well, let's clarify this, because a lot of 10:34:37
my questions I'll ask you about Study 329. 10:34:39
Do you know what I'm referring to 10:34:42
when I say Study 329? 10:34:43
A Yes. 10:34:45
Q Okay. 10:34:45
And in your mind, is Study 329 the 10:34:46
same as the study that you met with 10:34:50
investigators about regarding the use of 10:34:53
paroxetine, Paxil, in children and 10:34:56
adolescents? 10:34:59
MR. DAVIS: Object to the form. 10:35:02
A At -- for a very substantial duration of 10:35:05
time of at least a year, colleagues and I 10:35:17
met to discuss research on the treatment of 10:35:20
depression in children and adolescents. 10:35:25
That resulted in us writing a 10:35:29
protocol, a copy of which I believe is one 10:35:30

of the exhibits. 10:35:32
Q Yes. 10:35:35
A And that protocol didn't have any 10:35:36
SmithKline, you know, letters or numbers or 10:35:37
anything on it. Okay. 10:35:41
At some point after the group made a 10:35:43
decision to develop -- to have a working 10:35:47
relationship with SmithKline with regard to 10:35:53
the funding and conduct of this grant, it 10:35:55
then shifted, in my mind, to, you know -- 10:35:58
I see a -- I sort of -- I see a shift 10:36:03
in that process, and then there was -- then 10:36:06
it's what I would call 329. 10:36:09
So if you want to -- just for clarity 10:36:13
of thought, I just -- I would just make that 10:36:18
distinction. 10:36:19
Q That's understandable. 10:36:20
A However you want to put that. 10:36:21
Q I hear your distinction. 10:36:23
What I'm asking is, for the purposes 10:36:26
of my questioning today, can we agree that 10:36:28
when I refer to 329 and I refer to meetings 10:36:30
involving 329, that I'm referring to any 10:36:33
time that you met with investigators and/or 10:36:37

individuals from GSK to discuss the study 10:36:42
that resulted in the publication of your 10:36:46
article on the use of paroxetine in 10:36:50
children? 10:36:52
A Okay. 10:36:54
Q I'm just trying to use -- 10:36:55
A Okay. 10:36:57
Q That's exactly what you did yesterday. I'm 10:36:57
not trying to -- all I'm asking is for some 10:36:59
clarity. It's unbelievable. 10:37:01
All I want to do is make sure that 10:37:03
you and I understand what 329 is when I ask 10:37:04
you did you meet with Neal Ryan to discuss 10:37:08
329. 10:37:11
Do you understand what I'm asking you 10:37:13
there? 10:37:14
A Yes. I'm just trying to make a -- draw a 10:37:16
firewall and a distinction between when it 10:37:19
was colleagues brainstorming the broadest 10:37:22
range of ideas until something formed into 10:37:26
an idea. 10:37:29
And the reason that's important is 10:37:30
because at various points along the way, we 10:37:32
had all sorts of other study designs. 10:37:35

So, you know, if you -- if you had a 10:37:39
tape recorder at those meetings, Chris, all 10:37:43
the meetings we talked about, some of the 10:37:45
designs we were going to do looked radically 10:37:49
different. Didn't look anything like what 10:37:52
is now 329. 10:37:54
So I just want you to appreciate and 10:37:56
understand that. It wasn't as though -- it 10:37:58
wasn't as though we had this design that you 10:38:04
call 329 and that's what we were talking 10:38:06
about. 10:38:08
Eventually something evolved into 10:38:09
that. There were many other ideas on the 10:38:10
table. 10:38:12
Is that clear? 10:38:15
Q I understand your distinction. 10:38:20
A So it would be fair -- what I'm saying, it 10:38:23
would be fair to say that we didn't 10:38:25
necessarily -- when we -- when we had for 10:38:26
many -- for quite a number of the meetings 10:38:28
that we had, we weren't necessarily 10:38:30
discussing anything which looked at all like 10:38:34
the design of 329. That's all. 10:38:37
Q Okay. 10:38:38

Which exhibit is the initial protocol 10:38:39
that you submitted for -- let me ask you 10:38:44
this: 10:38:47
You submitted a protocol or a plan 10:38:48
for a study to GSK, correct? 10:38:51
A Yes. 10:38:56
Q Okay. 10:38:57
And we admitted that as an exhibit in 10:38:57
your deposition yesterday, correct? 10:39:00
A Yes. 10:39:02
Q We marked it, I should say, as an exhibit. 10:39:02
And I believe it's Exhibit 10. Here 10:39:05
it is. Okay. Take a look at Exhibit 10. 10:39:25
Do you recognize that document? 10:39:27
(Witness read document.) 10:39:31
A I recognize it, yes. 10:39:42
Q Okay. 10:39:44
And was that document prepared after 10:39:46
you met with multiple of your peers about a 10:39:51
study to submit to GSK? 10:39:59
A Yes. 10:40:10
Q Okay. 10:40:11
And eventually that study was named 10:40:11
329 by GSK, correct? 10:40:15

distinction, or to do pubertal staging. 10:45:33
Q At the time that you met with your 10:45:42
colleagues who helped you prepare 10:45:46
Exhibit 10, were you personally aware at 10:45:49
that time that SSRIs were being prescribed 10:45:52
to children and adolescents? 10:45:55
A I was aware that SSRIs were being prescribed 10:46:07
to adolescents. I don't recall whether I 10:46:11
had awareness that they were being 10:46:15
prescribed for children, since the focus of 10:46:18
what we were dealing with had to do with 10:46:21
adolescents. 10:46:23
Q Okay. 10:46:25
And in that response you just gave, 10:46:25
how do you define children and how do you 10:46:27
define adolescents? 10:46:29
A One of two ways: Either by using an age 10:46:34
cutoff of 13, if you -- if you're younger 10:46:38
than 13, you would be a child. If you're 10:46:42
older -- 13 or above, you would be an 10:46:45
adolescent. Or you can do pubertal staging 10:46:47
to see what stage of puberty you're in. 10:46:51
Q No, that's not -- what I'm asking you is you 10:46:54
just gave me a response, and your terms were 10:46:56

that you -- 10:46:58
You said you were aware that SSRIs 10:46:59
were being prescribed to adolescents, but 10:47:01
you don't recall whether you were aware that 10:47:04
they were being prescribed to children. 10:47:07
Is that correct? 10:47:09
A Yes. 10:47:12
Q Okay. 10:47:12
My question is, in your response, how 10:47:13
do you distinguish between children and 10:47:16
adolescents? 10:47:18
A I thought -- I thought I answered it 10:47:23
perfectly fine. I said one of two ways. 10:47:24
Q All right. Let me ask you this: 10:47:27
When -- when you were preparing 10:47:29
Exhibit 10 with your colleagues, were you 10:47:31
aware that SSRIs were being prescribed to 10:47:35
individuals the age of 13 and older? 10:47:41
A Yes. 10:47:45
Q Were you aware at the time that you prepared 10:47:46
Exhibit 10 that you submitted to GSK that 10:47:49
SSRIs were being prescribed to individuals 10:47:54
12 and younger? 10:47:58
A I don't recall. 10:48:01

Q Okay. 10:48:04
A I do have a -- a clarification here. 10:48:04
When we talk about the preparation of 10:48:06
Exhibit 10, what I just noticed was that at 10:48:08
the bottom of Exhibit 10, there's all sorts 10:48:13
of -- there's this whole thing about 10:48:17
confidential, subject to protective order, 10:48:20
produced by GSK, so on and so forth. 10:48:24
We didn't -- I didn't prepare 10:48:27
anything that had that on it. 10:48:28
Q Right. 10:48:29
That's -- that's something that 10:48:30
GlaxoSmithKline stamps for the 10:48:31
confidentiality of the documents in this 10:48:34
case. 10:48:36
A Okay. I'm just trying to be precise. 10:48:36
Q I got you. I -- I appreciate that. 10:48:38
Going back to my questions about your 10:48:41
awareness of prescriptions to children and 10:48:43
adolescents, were you aware that at the time 10:48:48
you -- you prepared this with your 10:48:55
colleagues, were you aware that adolescents 10:48:57
were being prescribed Paxil for the 10:48:59
treatment of depression? 10:49:03

A I don't recall, because -- I'm going to 10:49:13
answer it. I'm not just going to say I 10:49:19
don't recall and then waste your time by 10:49:21
having to fumble in giving an answer. 10:49:23
The reason I don't recall is because 10:49:27
when I look at 1992 here and we started 10:49:29
meeting earlier than that, this may have 10:49:33
preceded when Paxil was approved by the FDA 10:49:35
as an antidepressant. 10:49:39
So I don't -- and I -- I have some -- 10:49:41
I have a vague memory that in the 10:49:45
discussions we had about whether or not -- 10:49:48
about which medications to use in the study, 10:49:50
there was an issue of which medications were 10:49:55
approved, at what time and not at what time. 10:49:57
So it's im -- it's possible that the 10:50:01
FDA -- I just don't -- I don't remember 10:50:06
that, when that date occurred. 10:50:08
Q Okay. 10:50:10
A So if, in fact, you know, whatever -- 10:50:10
whatever discussions took place regarding 10:50:14
this, if that preceded the FDA's approving 10:50:17
the use of paroxetine as a treatment for 10:50:20
depression in adults, if it preceded that, 10:50:24

A Yes. 10:40:17
Q Okay. 10:40:18
And you had meetings with 10:40:20
investigators, your peers, to discuss this 10:40:21
study that's described in Exhibit 10? 10:40:27
You had meetings with your peers, 10:40:33
investigators, about that, correct? 10:40:35
A Yes. 10:40:37
Q Okay. 10:40:37
And you had meetings with your peers 10:40:38
and investigators and with representatives 10:40:40
from GlaxoSmithKline after you submitted 10:40:41
that to GlaxoSmithKline, correct? 10:40:45
A I don't -- I don't recall if we had meetings 10:40:53
with peers and representatives of SmithKline 10:41:00
prior to the meeting that was -- that took 10:41:14
place after the study was finished, after -- 10:41:18
after 329 was completed, so... 10:41:23
Q You don't recall meeting with Jim McCafferty 10:41:27
and the other investigators on the study at 10:41:30
any time between the time you submitted 10:41:35
Exhibit 10 to GSK and the time that the -- 10:41:37
that the results were revealed? 10:41:40
Is that what you're saying? 10:41:41

A I recall meeting with the other 10:41:44
investigators. I do not recall whether Jim 10:41:46
McCafferty attended any meetings with myself 10:41:50
and the investigators to discuss 329 prior 10:41:56
to the meeting that was held after 329 was 10:42:01
completed that was discussed yesterday and 10:42:07
memorialized in one of the exhibits that's 10:42:10
marked and could probably be found on this 10:42:13
table. 10:42:18
Q What about telephone conferences, do you 10:42:20
recall having telephone conferences that 10:42:23
addressed the issues in the child and 10:42:25
adolescent study that -- that we're 10:42:30
referring to in this case? 10:42:33
MR. DAVIS: Just for reference, the 10:42:35
adolescent study didn't involve any 10:42:37
children, but -- so I object to the form. 10:42:38
A I would make that correction. There was no 10:42:41
children -- no children involved, only 10:42:44
adolescents. 10:42:45
But the answer is -- so the answer is 10:42:46
no to the question you asked. 10:42:49
Q Okay. 10:42:52
A If -- 10:42:53

Q Can you and I agree that when we talk about 10:42:54
the -- 10:42:56
The study that you published an 10:42:59
article on, that was -- ultimately was 329 10:43:01
at one point, correct? 10:43:07
A Yes. 10:43:08
Q Can we agree to when I ask you about 10:43:09
conversations regarding Study 329 that we're 10:43:12
talking about the meetings including prior 10:43:14
to your submission of the protocol to GSK, 10:43:17
meetings that occurred -- strike that. 10:43:23
In your meetings regarding Study 329, 10:43:30
do you recall -- and whether it was before 10:43:34
you submitted Exhibit 10 or after, do you 10:43:37
recall discussing the use of SSRIs for 10:43:41
treatment of psychiatric illness in children 10:43:47
and adolescents with your -- with your 10:43:49
coinvestigators? 10:43:51
MR. DAVIS: Object to the form. 10:43:54
A In the spirit of moving this along and being 10:44:01
helpful, I think it -- it's important that 10:44:04
don't include children, that you just say 10:44:07
adolescents, because no children were 10:44:10
included in the design and the 10:44:14

implementation of this study and for a lot 10:44:16
of reasons. There are differences between 10:44:21
children and adolescents. 10:44:23
So if you would restate it and 10:44:25
restrict it to adolescents, then it would be 10:44:26
easier for me to answer. 10:44:30
Q Okay. Well, let's just clear that up. 10:44:31
What was the age group of the 10:44:33
individuals included in the study? 10:44:34
A I think it was 13. I'm not exactly sure 10:44:38
whether we did -- how we staged it, but I 10:44:43
believe 13. 10:44:45
Q How do you define the difference between a 10:44:46
child and an adolescent? 10:44:48
A It's -- it's a distinction that is not 10:44:50
codified and universally accepted, you know, 10:44:55
with criteria that everybody would agree to. 10:44:58
As a convention, it's typically 10:45:03
approached in one of two ways: One is to 10:45:04
just pick an age, typically 13, and the 10:45:07
other is to do pubertal staging. And 10:45:10
it's -- if you -- 10:45:15
So I find either acceptable, either 10:45:21
picking an age, such as 13, to make that 10:45:29

then I would have no reason to think that 10:50:28
the drug was being prescribed for 10:50:32
adolescents or children or adults, for that 10:50:36
matter, other than for investigational 10:50:39
purposes. 10:50:41
Q Okay. 10:50:42
In light of your answer there, at 10:50:45
what point do you recall gaining an 10:50:47
awareness that Paxil was being prescribed to 10:50:55
children and adolescents? 10:50:59
A I don't remember. 10:51:00
Q Well, certainly you're aware of that today, 10:51:02
correct? 10:51:03
A Yes. 10:51:06
Q Okay. 10:51:07
And do you know whether you knew it 10:51:07
prior to GSK accepting for submission 10:51:14
Exhibit 10? 10:51:21
A I don't remember. 10:51:22
Q Okay. 10:51:26
A Because the -- the distinction -- at some 10:51:26
point it occurred. It just -- it just looks 10:51:29
to me -- 10:51:32
1992 looks to me in a very vague 10:51:34

memory somewhere around the time that 10:51:37
paroxetine was approved; but I also have a 10:51:42
memory that it may have been approved after. 10:51:46
I just simply don't remember. 10:51:49
Q Right. 10:51:51
A It's in that ballpark. 10:51:51
Q Right. 10:51:53
A And so if it had been approved in 1988, I 10:51:54
would remember. If it was -- wasn't 10:51:57
approved until 2000, I would remember. This 10:51:58
was -- 10:52:01
Q I'll represent it was approved at the very 10:52:01
end of 1992, end of December 1992. 10:52:03
All right? 10:52:06
A After this. 10:52:07
Q That's correct. 10:52:08
So -- but I'm -- and that's fine. 10:52:09
I'm trying to get clear -- 10:52:11
So after Paxil was approved by the 10:52:14
Food and Drug Administration for use in 10:52:19
adults, did you then become aware that it 10:52:20
was also being used for treatment of 10:52:26
depression in children and adolescents? 10:52:30
A At some time, yes, is the answer. 10:52:34

Q Okay. 10:52:38
And do you know when that was in 10:52:38
relation to its approval in -- at the end of 10:52:39
1992? 10:52:42
A When it was that I became aware? 10:52:43
Q Correct. 10:52:45
A No. 10:52:46
Q Okay. 10:52:46
Do you recall discussing the -- the 10:53:04
issue of Paxil being used in the treatment 10:53:09
of adolescent depression with the other 10:53:12
investigators that you were working on 10:53:17
Exhibit 10 with, either prior to or after 10:53:20
submission to GSK? 10:53:23
A Could you -- 10:53:27
Q Sure. 10:53:28
A -- clarify? 10:53:29
Q Do you ever -- do you ever -- do you ever 10:53:31
recall discussing with the other 10:53:33
investigators the trends in prescriptions of 10:53:34
Paxil to children and adolescents? 10:53:40
A No. 10:53:42
Q Okay. 10:53:43
What's your understanding of -- let 10:53:51

me ask you this: 10:53:55
What's your understanding of the 10:53:56
current state of prescriptions that are 10:54:01
provided to child -- children and 10:54:05
adolescents for the treatment of -- excuse 10:54:07
me. 10:54:11
What's your current understanding of 10:54:12
the prescriptions for Paxil that are 10:54:14
provided to children and adolescents for the 10:54:15
treatment of depression? 10:54:19
A I don't understand your question. 10:54:24
Q Do you know today that -- you said you have 10:54:27
a -- you at some time gained knowledge that 10:54:29
Paxil was being prescribed to children and 10:54:32
adolescents, correct? 10:54:34
A Correct. 10:54:36
Q Okay. 10:54:36
And you don't know when that was? 10:54:36
A Correct. 10:54:38
Q Was it more than ten years ago that you 10:54:38
gained that knowledge? 10:54:40
A I can't recall specifically. I think it's 10:55:00
likely that it was. 10:55:02
Q Okay. 10:55:03

Your -- your article that -- that 10:55:04
appeared in the Journal of the American 10:55:07
Academy of Child and Adolescent Psychiatry 10:55:11
was published in July of 2001, correct? 10:55:14
Do you want to see the exhibit? 10:55:20
A Yes. 10:55:25
Q Okay. 10:55:26
Prior to the publication of this 10:55:26
article that's marked as which exhibit? 10:55:28
MR. GREEN: 13. 10:55:33
A 13. 10:55:33
Q That's marked as Exhibit 13, did you have 10:55:34
knowledge that Paxil was being prescribed 10:55:36
for the treatment of depression in children 10:55:39
and adolescents? 10:55:40
A I can't recall specifically now. I assume 10:55:46
so, but I just can't recall. 10:55:50
Q And you can't recall any discussions about 10:55:53
whether or not Paxil was being prescribed to 10:55:58
children and adolescents for the treatment 10:56:02
of depression prior to the publication of 10:56:04
this article; is that correct? 10:56:06
A I don't recall, which doesn't mean I didn't 10:56:09
have a conversation, doesn't mean I did. 10:56:11

It means I don't remember such 10:56:14
conversations. 10:56:18
Q Okay. 10:56:29
Yesterday Mr. Murgatroyd asked you 10:56:44
about the analysis of the data that was 10:56:47
obtained from Study 329; do you recall that? 10:56:52
A Yes. 10:56:55
Q Do you know what I'm referring to when I say 10:56:56
"the data obtained from Study 329"? 10:56:57
A Yes. 10:57:01
Q Okay. 10:57:01
And you -- you testified that the 10:57:05
variables -- that you believe that the 10:57:09
variables used in Study 329 to analyze the 10:57:12
data were decided prior to the breaking of 10:57:21
the blind, correct? 10:57:24
A Yes. 10:57:25
Q Okay. 10:57:26
Do you know when the data was 10:57:27
analyzed? 10:57:28
A Actually, if I could -- can I -- 10:57:29
Q Sure. 10:57:31
A -- qualify that statement? 10:57:31
Q Sure. 10:57:34

A Any variable which was stated to be an a 10:57:41
priori variable in any writeups that we had, 10:57:44
any such designation, meant that the 10:57:49
variables were identified prior to doing 10:57:51
the -- the breaking of the blind. 10:57:54
It's possible, though I can't tell 10:57:59
you whether, in fact, happened -- or if it 10:58:02
happened which variables, it's possible that 10:58:05
certain variables which were not part of the 10:58:07
data analytic plan and not subsequently 10:58:09
labeled as, you know, a priori, were -- 10:58:14
someone decided to analyze these after the 10:58:19
blind -- 10:58:22
Q Okay. 10:58:22
A -- was broken. 10:58:23
These things happen in what's called 10:58:24
exploratory analyses in all sorts of 10:58:26
research. 10:58:29
Q Okay. 10:58:29
Do you recall any specific variables 10:58:30
that you or any of the other investigators 10:58:33
decided on after the data had been initially 10:58:38
obtained and the blind was broken? 10:58:42
A No. It -- no, to that question. 10:58:43

Q Okay. 10:58:47
How about the CGI of 1 or 2, do you 10:58:49
remember if that was decided before or after 10:58:53
the blind was broken? 10:58:57
MR. DAVIS: Objection. 10:59:00
Asked and answered. 10:59:00
A That was decided before the blind was 10:59:01
broken. 10:59:03
Q Okay. 10:59:03
And how about the K-SADS nine-item 10:59:03
depression scale, do you know whether that 10:59:07
was determined prior to or after the blind 10:59:09
was broken? 10:59:12
MR. DAVIS: Objection. 10:59:13
Asked and answered. 10:59:15
A Yes. 10:59:15
Q And when was it? 10:59:16
A Before the blind was broken. 10:59:17
Q And you don't recall any that were decided 10:59:20
after the blind was broken? 10:59:22
A No. 10:59:23
What I do know, though I cannot be 10:59:24
specific, is that at some point in the past 10:59:26
several years when the FDA asked for -- set 10:59:29

up a process whereby there was a reanalysis 10:59:38
of data from most, if not all, pediatric 10:59:41
studies, you know, a reanalyses occurred. 10:59:44
I was not part of that process per 10:59:49
se, but I have some general awareness that 10:59:50
analyses were done with all the datasets. 10:59:56
I'm assuming that also occurred with 11:00:00
329, but I don't know the specifics. 11:00:03
Q Do you know when the initial analyses of the 11:00:06
data obtained from Study 329 was conducted? 11:00:12
A No. 11:00:16
Q Were you involved in the initial analyses of 11:00:18
the data from Study 329? 11:00:21
A I don't know what you mean by involved in 11:00:25
the analyses of the data. 11:00:26
Q Did you ever review the data that was 11:00:32
obtained from Study 329 at all? 11:00:34
A Yes. 11:00:40
Q Okay. 11:00:40
And at what point did you first 11:00:41
review that information? 11:00:42
A I don't remember. But I was also -- 11:00:44
Q And what -- 11:00:46
A I was also involved in thinking and 11:00:48

discussing what the data analytic plan would 11:00:51
be and the process -- and, you know, how the 11:00:54
data would be analyzed. 11:00:58
And there's a distinction between 11:01:01
that and my actually analyzing the data. 11:01:03
The data analyst would do that, you know, 11:01:07
programmer, someone like that. 11:01:11
So -- so that you understand the 11:01:15
distinction, it's one thing to conceptualize 11:01:16
what analyses one will do. It's another 11:01:19
thing to actually write the program and the 11:01:22
code that you would have for a computer to 11:01:27
actually perform the analysis. 11:01:29
I'm not a code writer. I'm a 11:01:31
conceptualizer. 11:01:34
Q Did you contribute to decisions about which 11:01:37
variables would be used to test the data 11:01:40
and -- that was obtained from Study 329? 11:01:46
A Yes. 11:01:49
Q Okay. 11:01:50
You're aware that Mr. Jim McCafferty 11:01:52
was deposed in -- in these cases? 11:01:54
A It may have been mentioned yesterday. His 11:02:09
name was mentioned yesterday in relation to 11:02:11

a deposition. 11:02:13
Q Okay. 11:02:14
Well -- 11:02:14
A Which is the first time I knew that. 11:02:15
Q Okay. 11:02:18
He was deposed in these cases. And 11:02:19
in Mr. McCafferty's deposition, one of the 11:02:22
things he mentioned multiple times was that 11:02:25
there were multiple discussions amongst 11:02:30
himself and the investigators, including 11:02:31
you, with regard to which endpoints to use, 11:02:37
which variables to use for the analysis of 11:02:42
the data obtained in 329. 11:02:44
Do you recall that there were 11:02:47
multiple discussions regarding which 11:02:48
variables to use to analyze the data? 11:02:51
A I don't have specific recall of those 11:03:04
conversations; however, as I mentioned 11:03:06
earlier in describing the process, I assume 11:03:11
that we had many conversations about how 11:03:17
to -- you know, how to plan the analyses and 11:03:23
how to do them. 11:03:27
It's just that I can't remember 11:03:28
the -- any of the actual conversations. 11:03:29

We -- we wrote the plan, we wrote the grant, 11:03:32
and, indeed -- so -- 11:03:36
But, again, you understand the 11:03:39
distinction I'm making. 11:03:40
Q Is there anything that sticks out in your 11:03:42
mind with regard to the decisions made by 11:03:43
you and the other investigators to 11:03:49
include -- of which variables to include? 11:03:51
Is there anything that sticks out in 11:03:58
your mind about your conversations about 11:03:59
those variables? 11:04:01
A Only that we always tried to do the right 11:04:02
thing, to do it properly, to figure out 11:04:05
what's the -- what's the proper way to 11:04:08
analyze the data to achieve the goal of 11:04:10
testing the hypotheses and aims of the 11:04:15
study. 11:04:19
That's the abiding, you know, ethos 11:04:19
that drives our decision-making, and -- and 11:04:24
that's -- it's -- it's often not easy. 11:04:28
It's often complicated to figure out 11:04:32
what's the most parsimonious, efficient and 11:04:35
best way to analyze it. 11:04:38
Q Okay. 11:04:41

A So, you know, with those parameters in mind, those are the parameters that we always bat around. 11:04:41 11:04:46 11:04:50

What's the best way to do it? What's the best way to get there? What's the proper way to do it? 11:04:51 11:04:53 11:04:55

Other than that, the guiding principles, I can't recall the specifics of any of the discussions. 11:04:56 11:04:57 11:04:59

The goal is to complete the science -- complete the scientific project using the integrity of the scientific design. 11:05:08 11:05:09 11:05:14 11:05:16

Q Right. 11:05:16

And you mentioned that you had wanted to test the hypothesis to determine whether or not it was successful, correct? 11:05:17 11:05:18 11:05:21

A Yes. 11:05:25

Q And what was the hypothesis with regard to Study 329? 11:05:26 11:05:29

A If you let me -- 11:05:32

(Witness read document.) 11:05:33

A There were four hypotheses listed in the agreement. If you would like, I can read 11:05:51 11:05:55

those to you. 11:06:00

Q Sure. 11:06:01

A Number one, we hypothesized the following: 11:06:02

Number one: Paroxetine will be significantly superior to placebo at the end of the eight-week treatment trial. 11:06:06 11:06:08 11:06:11

Number two: IMI, capital I-M-I, which is an abbreviation for imipramine, those are my -- that's -- IMI will be significantly superior to placebo at the end of the eight-week treatment trial. 11:06:13 11:06:19 11:06:24 11:06:29 11:06:30

Number three: There will be fewer dropouts and adverse events among patients on paroxetine compared to patients on imipramine. 11:06:32 11:06:34 11:06:37 11:06:40

Number four: Responders to the eight-week experimental phase who are maintained on their study treatment for six months will experience significantly fewer MDD, which is an abbreviation for Major Depressive Disorder, relapses on IMI, I-M-I, and paroxetine than on placebo. 11:06:41 11:06:43 11:06:47 11:06:49 11:06:52 11:06:57 11:07:02

There are also two secondary aims. would you care for those to be read? 11:07:08 11:07:12

Q No, that's okay. 11:07:14

The first one you read there, first hypothesis, was that paroxetine, Paxil, would be shown to be significantly superior to placebo with regard to effectiveness, correct? 11:07:18 11:07:19 11:07:23 11:07:27 11:07:33

A It says -- what was said was, Paroxetine will be significantly superior to placebo at the end of the eight-week treatment trial. 11:07:34 11:07:36 11:07:38

Q Okay. 11:07:41

A We didn't have the phrase "with regard to effectiveness" in there. 11:07:41 11:07:44

Q Okay. 11:07:45

That -- that particular hypothesis failed, correct? 11:07:49 11:07:51

MR. DAVIS: Object to the form. 11:07:52

A No. 11:07:54

Q It didn't? Well, let me ask you this: 11:07:54

Was paroxetine -- was Paxil shown to be statistically superior to placebo on either of the primary endpoints? 11:07:58 11:08:00 11:08:07

Do you know? 11:08:12

A No. 11:08:15

It was significantly superior to 11:08:15

placebo on the HAM-D total score of less than or equal to 8, the HAM-D depressed mood item, the Kiddie K-SADS-L depressed mood item and the CGI score of 1 or 2. 11:08:20 11:08:23 11:08:26 11:08:31

And on the basis of those, variables being positive, the conclusion of the investigators, as well as the reviewers who reviewed the paper, as well as people who have seen it, all agreed that paroxetine was significantly superior than placebo at the end of Week 8. 11:08:42 11:08:45 11:08:47 11:08:51 11:08:53 11:08:58 11:09:02

Q None of those variables that you read are primary endpoints, correct? 11:09:04 11:09:06

A My -- none of the four that I just read are among the two primary endpoints listed in the protocol, the exhibits that you showed me. 11:09:15 11:09:19 11:09:26 11:09:27

Q Right. 11:09:28

So the question was, neither of or none of the endpoints that you just listed were primary endpoints in Study 329, correct? 11:09:28 11:09:32 11:09:35 11:09:41

A They weren't primary endpoints listed in the protocol, but they were judged by the 11:09:43 11:09:45

investigators to be important endpoints in the determination of the subject's response to paroxetine. 11:09:50 11:10:00 11:10:05

And I believe most experts knowledgeable would also agree that these are clinically and research-relevant endpoints to use in determining efficacy of treating depression. 11:10:16 11:10:19 11:10:22 11:10:30 11:10:33

Q All right. 11:10:35

Well, Mr. Murgatroyd will get into that a little bit later, and we'll see what the experts actually do think. 11:10:35 11:10:37 11:10:39

Let me ask you to turn to -- let me ask you this first: 11:10:41 11:10:43

Yesterday with regard to question about your expectations for Study 329, do you recall that you testified that you didn't have any expectations, you and the other investigators didn't have any expectations with regard to the outcome of 329 when you began the study? 11:10:45 11:10:47 11:10:55 11:10:57 11:10:59 11:11:02 11:11:03

Do you recall that? 11:11:05

A I don't recall exactly what I said, so I'd appreciate having what I said about 11:11:07 11:11:10

expectations being read back to me so I can make sense -- 11:11:12 11:11:14

Q How about this: 11:11:15

Why don't you tell us, what were your expectations when you began Study 329? 11:11:16 11:11:18

What were your expectations of the outcome? 11:11:24 11:11:28

A Well, as I stated to you very shortly ago, our expectations were the following hypotheses: 11:11:33 11:11:42 11:11:45

Number one: Paroxetine will be significantly superior to placebo at the end of the eight-week treatment trial. 11:11:48 11:11:49 11:11:50

Number two: Imipramine will be significantly superior to placebo at the end of the eight-week treatment trial. 11:11:52 11:11:58 11:11:59

Number three: There will be fewer dropouts and adverse events among patients on paroxetine compared to patients on imipramine. 11:12:01 11:12:04 11:12:06 11:12:09

Number four: Responders to the eight-week experimental phase who are maintained on the study treatment for six months will experience significantly fewer 11:12:10 11:12:12 11:12:14 11:12:16

MDD relapses on imipramine and paroxetine than on placebo. 11:12:18 11:12:22

Those were the expectations. 11:12:24

Q Okay. 11:12:37

Can you tell me, do you know what a reprint is? 11:12:37 11:12:39

A Yes. 11:12:45

Q Okay. 11:12:45

What is a reprint? 11:12:45

A Well, my understanding of a reprint is when a -- an article appears in a journal, and I'm most familiar with scientific journals, but I believe -- I assume this is the case with the broad range of journals, the journal makes available for a fee the production or the -- the whatever, the publisher of the journal makes available for a fee copies of the article. 11:12:49 11:12:56 11:13:04 11:13:06 11:13:08 11:13:11 11:13:18 11:13:22 11:13:24

I'm trying to think of the right word. Will produce for you a -- the article without Xeroxing it, so it's some type of freestanding independent copy that's been printed -- that's been specifically printed by the publisher. 11:13:33 11:13:34 11:13:43 11:13:48 11:13:50 11:13:53

Q Okay. 11:13:55

A And typically it's bound with a staple, and that's what we generally refer to as reprints. 11:13:55 11:14:00 11:14:03

That's my understanding. 11:14:03

Q Okay. 11:14:05

A From journals. 11:14:05

Q Okay. 11:14:06

And what -- do you know what -- what's your understanding -- 11:14:06 11:14:09

A As opposed to this, which I wouldn't call a reprint. I would say that someone took -- made a Xerox copy of something. 11:14:11 11:14:13 11:14:17

Q Okay. 11:14:19

What is your understanding of the purpose of reprints? 11:14:20 11:14:21

A Currently, I see -- I think there's minimal to no purpose for reprints, because most journals have mechanisms whereby things can be obtained through the Internet. 11:14:35 11:14:37 11:14:44 11:14:46

In the good old days, back in the early '90s when I was still in high school and people didn't have that ability to transmit, you know, manuscripts and 11:14:50 11:14:53 11:15:00 11:15:03

articles, the re -- what would happen -- it 11:15:07
was a way of communicating information. 11:15:12
Typically, the author -- first author 11:15:16
of an article would be asked at the time an 11:15:18
article was I guess accepted at some point 11:15:20
or about to -- about to be published, they 11:15:25
would -- you would get a form from the 11:15:27
journal asking you if, and if so, how many 11:15:29
reprints you would like, which you had to 11:15:34
pay for. 11:15:36
And I certainly did, and mostly all 11:15:37
my peers did, to the extent that we could 11:15:40
afford it. 11:15:42
We would order a certain number of 11:15:42
copies, and then what would usually happen 11:15:45
is peers would send us a postcard or 11:15:47
sometimes a letter asking if we would send 11:15:49
them a reprint of our article. 11:15:52
Or if I went to a scientific meeting, 11:15:55
people would ask for reprints, because it's 11:15:57
my understanding, though I don't -- I'm not 11:15:59
a copyright attorney, that you're not 11:16:01
allowed to -- you're not allowed to take a 11:16:03
bound journal and make a Xerox of it 11:16:08

So that -- I understood that was the 11:16:10
only legitimate way to give someone a 11:16:13
hardcopy of it. 11:16:17
Q Okay. 11:16:19
And your understanding, from what I 11:16:20
understand you've just said, is that the 11:16:25
purpose of a reprint was basically to 11:16:26
disseminate information that was contained 11:16:28
in the article, correct? 11:16:30
A Yes. 11:16:33
Q And did you do that when you had reprints 11:16:34
that were provided to you? 11:16:36
A Rarely. And after a while, I just stopped, 11:16:42
because it just -- it was expensive and 11:16:44
time-consuming and -- 11:16:51
Q Expensive? In what sense? 11:16:53
A As the first author, I had to buy the 11:16:56
reprints myself. The journal sold me the 11:16:58
reprints, so I had to spend money to do it 11:17:04
and with -- so that was expensive. 11:17:10
And if someone sent me a postcard and 11:17:14
asked me for it, I had to mail them a copy 11:17:18
of it, and that was both costly for the 11:17:21
stamp and time-consuming. 11:17:26

So after a while, I stopped and at 11:17:28
some point stopped ordering reprints and 11:17:32
just said I don't have reprints. Here's the 11:17:35
reference. Read the article. 11:17:38
Q So what -- tell me this: 11:17:40
What was the -- when you did in your 11:17:43
past -- when you did receive reprints, what 11:17:46
was the usual ballpark figure, number of 11:17:51
reprints you would -- you would request? 11:17:55
A Well, it -- it varied enormously, and I 11:17:59
can't remember the exact amount. 11:18:08
The principle when I was first 11:18:09
starting out as a researcher and I was 11:18:11
extremely excited, thrilled and proud that 11:18:13
one of my papers was in a journal, I assumed 11:18:16
that thousands of people would ask me for 11:18:18
copies. 11:18:21
And if it was -- and if I thought it 11:18:22
was a really seminal article, I might order 11:18:25
couple of hundred. I think at one point I 11:18:28
might have even ordered a thousand. 11:18:31
After I noticed that the requests 11:18:32
were far fewer, I started ordering the 11:18:36
minimal amount, and my thinking was at least 11:18:39

we'd have some copies that we could keep on 11:18:44
file locally for -- in memoriam. 11:18:46
But the process of -- the process 11:18:49
that I described to us of people 11:18:51
requesting -- requesting them was for me, 11:18:52
even with my finest of research, was always 11:18:57
a -- was always very minimal. 11:19:01
So I just kind of stopped, you know? 11:19:03
Q Okay. 11:19:05
Let me -- do you -- 11:19:09
A But I cannot remember the last time I 11:19:10
requested -- I ordered reprints, and I 11:19:12
frankly don't remember -- I don't. I don't 11:19:15
actually recall. 11:19:19
I don't know the extent the journals 11:19:21
still send that offer to you anymore, so... 11:19:23
Q Okay. 11:19:37
A But we also didn't have BlackBerrys then. 11:19:37
Q Do you recall requesting any reprints of 11:19:40
your article -- 11:19:43
A No. 11:19:43
Q -- that was published in July of 2001 -- 11:19:43
A No. 11:19:46
Q -- regarding -- 11:19:46

A No. 11:19:49
Q -- Study 329? 11:19:49
A Sorry. No. 11:19:51
Q Okay. 11:19:52
(Exhibit No. 26 marked for 11:19:52
identification.) 11:19:52
BY MR. COFFIN: 11:19:52
Q Let me show you what's been marked as 11:19:52
Exhibit 26. 11:19:54
MR. DAVIS: Can I see that? 11:19:55
(Counsel read document.) 11:19:56
MR. COFFIN: And, Todd, while you're 11:20:08
at it, can you dedesignate the 11:20:09
confidentiality -- 11:20:11
MR. DAVIS: Yes, I can. 11:20:12
This is not subject -- Exhibit 26 is 11:20:13
not subject to the protective order. 11:20:14
BY MR. COFFIN: 11:20:16
Q Can you just take a look at that document? 11:20:16
(Witness read document.) 11:20:18
Q Actually, it's a series of emails, so the 11:20:19
first one starts at the end, but read it how 11:20:22
you -- how you like. 11:20:25
(Witness read document.) 11:20:26

Q Okay. 11:21:17
Can you identify that document? 11:21:17
A I'm not sure -- 11:21:24
Q What is the document? 11:21:25
A It's a series of, I guess, emails between 11:21:27
individuals talking about the request that I 11:21:34
am said to have made, it doesn't specify 11:21:42
whether it was verbal or in writing, to 11:21:47
have -- 11:21:51
(Witness read document.) 11:22:00
A I'm trying to see here. 11:22:00
Ask if -- it says, Dr. Keller was 11:22:07
wondering if GSK will fund the purchase of 11:22:11
these -- of reprints of 329. 11:22:15
Q Okay. 11:22:18
And what's the date of that email? 11:22:19
A Well, there are many dates. One is -- one 11:22:24
date is 4/27/2001. One date is 4/25/2001. 11:22:28
I guess there are two dates. 11:22:35
Q Okay. 11:22:38
Does that appear to be a true and 11:22:42
correct copy of the email? 11:22:44
A I have no idea. 11:22:46
Q Do you have any reason to doubt that it's 11:22:46

not what it purports to be? 11:22:48
MR. DAVIS: Objection. 11:22:54
I don't think this witness can 11:22:54
authenticate another document that's not 11:22:56
involved in. 11:22:58
A I'm not a documentation -- I'm not a 11:22:58
document authenticator, so I have no reason 11:23:01
to either believe it or not believe it. 11:23:04
I have no idea. 11:23:06
Q Okay. 11:23:06
Can you turn to -- actually, it's the 11:23:13
bottom of the first page and the concluding 11:23:15
on the second page, does that appear to be 11:23:17
an email from Sally Laden? 11:23:20
A Yes. 11:23:32
Q Okay. 11:23:33
And can you please read that middle 11:23:33
paragraph there that Ms. Laden writes that's 11:23:36
referring to you specifically so we don't 11:23:41
get confused on which paragraph? 11:23:45
A Well, there are six paragraphs. 11:23:48
Q Okay. 11:23:49
Do you see any referring to you? 11:23:50
A I do. 11:23:51

Q Okay. 11:23:52
Could you read the one that refers to 11:23:52
you, please? 11:23:54
A "Marty Keller is a corresponding author and 11:23:55
will need a supply of reprints. I 11:23:58
anticipate that he will need a sizable 11:24:00
quantity because of the importance of this 11:24:02
paper. Probably in the vicinity of 500 11:24:04
reprints. Dr. Keller is wondering if GSK 11:24:06
will fund the purchase of these reprints." 11:24:09
Q Okay. 11:24:11
Do you recall asking either Sally 11:24:12
Laden or someone at GSK whether they'd fund 11:24:16
the purchase of reprints of your article? 11:24:20
A I don't recall asking them, which isn't to 11:24:26
say that I didn't or did. I just don't 11:24:28
recall. 11:24:29
Q Do you know one way or another whether they 11:24:31
actually paid for the reprints for you? 11:24:33
A No. 11:24:36
Q Well, according to your testimony before, 11:24:37
you always paid for your own, correct? 11:24:38
MR. DAVIS: Object to form. 11:24:40
A No. 11:24:41

Q That's not what you said? 11:24:41
That's okay. 11:24:43
A I -- I think that's a mis -- what you did is 11:24:44
a mischaracterization of what I said. I 11:24:46
said it was expensive. 11:24:49
Q Okay. 11:24:50
Well, what did you -- 11:24:51
A I said it was expensive to pay for them. 11:24:52
Q Okay. 11:24:55
A And actually had I extended it, I would have 11:24:55
said the sources of revenue that are used to 11:24:59
pay for them, you know, vary. 11:25:01
So sometimes if it's a grant, you pay 11:25:02
for them off a grant or by departmental 11:25:05
funds. 11:25:07
I didn't -- I didn't -- I never -- I 11:25:08
didn't pay for them out of my own. I've 11:25:10
always been in a position where I've either 11:25:14
had grants or discretionary research funds 11:25:18
that would be used to pay for them. 11:25:21
So I never took money out of a bank 11:25:24
account that was a Martin Keller's personal 11:25:26
money; however, in terms of my stewardship 11:25:29
of resources, I've tried to be efficient in 11:25:35

stewarding resources and to be careful not 11:25:39
to spend dollars of grants or discretionary 11:25:43
funds unless it was absolutely necessary. 11:25:46
And in that context, it would have 11:25:49
been perfectly reasonable for me to try to 11:25:53
identify a source of money to pay for the 11:25:57
reprints so that I could save other 11:26:01
resources. 11:26:06
Q Okay. 11:26:07
So your prior testimony, you didn't 11:26:08
mean to imply that the ordering of reprints 11:26:09
was a financial burden for you personally; 11:26:13
is that right? 11:26:14
A Not from my -- from my own personal dollars, 11:26:15
but I am the steward of dollars, and 11:26:20
stewardship of those dollars is something -- 11:26:25
of dollars, of money, is something I take 11:26:27
very seriously. 11:26:29
Q Okay. 11:26:30
Take a look at what's been marked as 11:26:31
Exhibit 27, if you would, please. 11:26:33
(Exhibit No. 27 marked for 11:26:34
identification.) 11:26:34
(Witness read document.) 11:26:41

A I've looked at it. 11:26:55
Q Okay. 11:26:57
And what's that document that you 11:26:58
have in your hand? 11:26:59
A It's a letter in Sally Laden to Jim 11:27:01
McCafferty. 11:27:03
Q Okay. 11:27:04
And are you referenced in that 11:27:05
letter? 11:27:06
A Yes. 11:27:06
Q Okay. 11:27:07
Could you please read the letter? 11:27:07
A "Dear Jim: 11:27:08
"I am pleased to enclose a small 11:27:09
supply of reprints of the 11:27:12
paroxetine-imipramine adolescent depression 11:27:13
paper that was recently published in the 11:27:13
Journal of the American Academy of Child and 11:27:15
Adolescent Psychiatry. GSK funded the 11:27:18
purchase of reprints. A total of 300 went 11:27:20
to Marty Keller, who is corresponding author 11:27:22
on the paper, and the balance being sent to 11:27:25
Zach Hawkins for distribution to the 11:27:27
Neuroscience sales force. Samples are also 11:27:29

being sent to Rocco and Neal." 11:27:33
Next paragraph, "The paper looks 11:27:35
excellent and demonstrates the commitment of 11:27:37
GSK to the field of psychiatry. Thank you 11:27:40
for your support. 11:27:42
"Sincerely, Sally Laden -- Sally K. 11:27:43
Laden, MS, Associate Editorial Director." 11:27:45
Q Okay. 11:27:48
Does that refresh your recollection 11:27:49
that you received 300 reprints of the 11:27:50
article you published? 11:27:53
A No. 11:27:55
Q Okay. 11:27:56
Does it -- okay. 11:27:56
Do you know whether or not you 11:27:59
received 300 reprints? 11:28:00
A No. I -- 11:28:01
Q You don't have any reason to disagree with 11:28:06
that? 11:28:08
A I don't have any reason to disagree, but -- 11:28:08
Q Okay. 11:28:09
A -- if you're asking me if I remember 11:28:09
receiving a package that contained 300 11:28:15
reprints, I have absolutely no recall of 11:28:18

that. 11:28:20
Q Okay. 11:28:20
And does that refresh your 11:28:21
recollection that you did not pay for out of 11:28:22
your funds or your stewardship funds the 11:28:24
copies of the reprints that you requested? 11:28:28
A No. 11:28:31
Q Okay. 11:28:32
You just don't recall that, correct? 11:28:32
A Correct. 11:28:34
Q Okay. 11:28:34
Do you know that your article was 11:28:35
used by GSK to send out to doctors who made 11:28:39
inquiries about Paxil's use for the 11:28:44
treatment of children and adolescents? 11:28:46
MR. DAVIS: Object to the form. 11:28:49
A No. 11:28:50
Q You don't know whether that was done or not? 11:28:50
A No. I have no recall that it was done. 11:28:52
Q Okay. 11:28:59
A It was -- as a matter of fact -- 11:28:59
No awareness that it was done. No 11:29:01
recall. 11:29:02
Q Okay. 11:29:04

Did you ever receive any inquiries 11:29:04
about your article on Study 329? 11:29:07
A Could you be more specific about what you 11:29:15
mean by inquiries? 11:29:16
Q Do you know what an inquiry is? 11:29:19
A Not -- 11:29:22
Q You don't? 11:29:23
A Most words have a lot of meaning, so why 11:29:24
don't you just tell me what you mean and 11:29:26
don't ask me -- 11:29:28
Q Do you know what a question is? 11:29:29
A Yes. 11:29:30
Q Okay. 11:29:31
Did you ever receive any questions 11:29:31
with regard to the article you published on 11:29:34
Study 329? 11:29:38
MR. DAVIS: Object to the form. 11:29:39
A I don't remember. 11:29:45
Q Did any doctors ever call or write to you 11:29:45
and ask you to provide them with a reprint 11:29:52
of your study on article -- on Study 329? 11:29:54
A No memory of that. 11:30:00
Q Okay. 11:30:01
A I'm not saying they didn't, but I just don't 11:30:02

remember it. 11:30:04
Q Okay. 11:30:05
Do you ever recall any physicians 11:30:05
asking you either verbally or in writing 11:30:07
about the results that were obtained from 11:30:12
Study 329 that you had published? 11:30:16
A I don't recall. 11:30:26
Q So you don't recall anyone -- any physicians 11:30:27
ever asking you about the results of Study 11:30:31
329 that you published in your article; is 11:30:35
that correct? 11:30:39
A That's correct. 11:30:40
Q Okay. 11:30:40
A I have -- I certainly have had -- 11:30:41
I can't recall any of the recall any 11:30:49
of the specifics, but I know that I have 11:30:54
discussed, which maybe isn't and answer to 11:30:58
your question, but I know I've discussed the 11:31:00
results of 329 of fairly extensively with my 11:31:03
colleagues. 11:31:13
And one of the specific reasons that 11:31:13
I can recall that is that a group of 11:31:18
colleagues and I submitted a grant to the 11:31:22
National Institute of Mental Health for 11:31:25

funding, which is currently ongoing, called 11:31:28
the Treatment of Depression-resistant 11:31:30
Adolescent -- something to that effect. 11:31:36
And as part of the background, a 11:31:39
significant section of that grant, as we 11:31:43
described the choice of treatments that we 11:31:45
would use in that NIMH protocol, we included 11:31:49
the findings from 329. 11:31:56
Now, I believe that preceded the 11:32:01
publication. In other words, I believe that 11:32:06
the submission of that grant preceded the 11:32:08
publication of the article referred to in 11:32:12
Exhibit 13, though we had the results. 11:32:18
And that required a lot of discussion 11:32:23
as to what is the most proper way to, you 11:32:25
know, include material in an application for 11:32:27
another grant to the NIMH of results, you 11:32:33
know, which are known perhaps in a draft of 11:32:36
an article but not yet citeable -- but not 11:32:39
yet -- but where the material is not yet in 11:32:46
print. 11:32:49
If it's in print, the rules are that 11:32:50
you're allowed to include a copy the -- of a 11:32:51
reprint of the article as part of the NIMH 11:32:56

grant submission. 11:33:01
If it's not in print, you're allowed 11:33:02
to discuss it in your preliminary study 11:33:03
section. 11:33:08
So there was a lot of discussions 11:33:10
about that. 11:33:13
Q Outside of that particular study from NIMH 11:33:14
that you're talking about, you don't recall 11:33:18
discussing -- you might not want to break 11:33:22
that -- 11:33:28
(Laughter.) 11:33:28
Q You don't recall any -- any other 11:33:28
discussions with physicians about the 11:33:32
prescribing of Paxil to children or 11:33:33
adolescents in the context of the article 11:33:35
you published? 11:33:39
A No, I don't recall the conversation -- I 11:33:41
guess the short answer is no. I mean, 11:33:43
again, a lot of discussion -- lots of 11:33:45
discussion with regard to the grant, you 11:33:47
know, the grant was submitted. I don't 11:33:49
think it was funded. I don't think it was 11:33:53
approved for funding on the first 11:33:54
submission. 11:33:56

You know, we then get comments back 11:33:57
from the reviewers of grant. We have to 11:33:59
modify the grant, so on and so forth. 11:34:01
So that was a -- a rather extensive 11:34:03
and lengthy process about that. 11:34:06
And there also came to be a time 11:34:07
following the publicity surrounding, which 11:34:09
started in Great Britain with the British 11:34:15
Medical Council which led to this grant 11:34:19
which -- that I'm referring to, which is 11:34:23
under a cooperative agreement with the NIMH 11:34:25
which led to a halting of the grant and a 11:34:28
lot of deliberation as to whether or not we 11:34:32
would continue with the -- you know, with 11:34:36
the design that included Paxil and so on and 11:34:40
so forth. 11:34:43
So there's an enormous -- there's 11:34:45
been an enormous amount of discussion about 11:34:46
the issues, but as the only -- those that I 11:34:48
remember are all in the context of the 11:34:53
research. 11:34:56
(Exhibit No. 28 marked for 11:34:56
identification.) 11:34:56
BY MR. COFFIN: 11:34:56

Q Okay. 11:34:58
Let me show you one other exhibit. 11:35:01
We're going to have to change the tape in 11:35:03
just a second. 11:35:04
So let me just close up on the 11:35:05
reprint issue. That's Exhibit 28. 11:35:07
Could you identify that? 11:35:10
A That's a letter from Sally Laden to me. 11:35:11
Q Okay. 11:35:14
And do you -- can you read the date, 11:35:17
please? 11:35:19
A August 7, 2001. 11:35:20
Q Do you recall receiving that letter? 11:35:22
A No. 11:35:25
Q Does that appear to be a true and correct 11:35:25
copy of a letter from Sally Laden to you? 11:35:27
A You know, to be fair, I can't authenticate 11:35:33
the letter. 11:35:35
Q Actually, you can. 11:35:36
Is it -- 11:35:37
A How? 11:35:37
Q Does it appear to be a letter? 11:35:37
Have you ever seen a letter before? 11:35:39
A Have I ever seen a letter before? 11:35:41

Q Yes. 11:35:44
A Is that what some people would call a 11:35:45
facetious or smart-ass comment? 11:35:47
Q Well, I mean, if -- you give me a facetious 11:35:48
response, Doctor. 11:35:49
I'm just trying to ask you to 11:35:50
identify a document. It's very simple. 11:35:51
A But you're an attorney. I ask you to keep 11:35:52
your composure and not be a smart-alec. 11:35:54
Q It's very simple. 11:35:57
A I can't authenticate the letter. People 11:35:57
make up letters. My signature isn't on 11:35:59
here. 11:36:01
If my signature were on here, I could 11:36:01
recognize my signature. I can't recognize 11:36:03
this person's signature, and I can't tell 11:36:05
you that this was an authentic letter or not 11:36:07
an authentic letter. 11:36:09
That's a simple, straightforward 11:36:12
answer, which I think is valid. 11:36:13
Q I have a question to ask you about this, 11:36:17
Doc. 11:36:19
Could you please read the letter? 11:36:19
(Witness read document.) 11:36:21

A "Dear Marty: 11:36:22
"Enclosed please find a supply of 11:36:23
reprints of the adolescent depression study 11:36:25
that was recently published in the Journal 11:36:27
of the American Academy of Child and 11:36:30
Adolescent Psychiatry. Purchase of the 11:36:31
reprints was funded by the Paxil Product 11:36:32
Management group at GSK. 11:36:34
"Thank you very much for your 11:36:36
patience and support as this difficult 11:36:36
project was finally completed. 11:36:38
"Sincerely, Sally K. Laden." 11:36:40
Q Does that refresh your recollection of who 11:36:44
paid for the reprints received? 11:36:45
A No. 11:36:47
MR. COFFIN: All right. Let's go off 11:36:50
the record. 11:36:51
THE VIDEOGRAPHER: The time is 11:38. 11:36:52
We're off the record. 11:36:54
(Recess.) 11:36:56
THE VIDEOGRAPHER: We're back on the 11:54:42
record. This is Tape No. 2. The time is 11:54:43
11:56. 11:54:45
BY MR. COFFIN: 11:54:48

Q Dr. Keller, do you recall receiving any 11:54:50
comments from practitioners regarding your 11:54:58
publication of the results of Study 329? 11:55:03
A Only those individuals who I engaged in 11:55:12
research with, some of whom I believe, but I 11:55:20
don't know, also have clinical practices, 11:55:26
presumably, small to modest ones. 11:55:31
So they would consider themselves 11:55:36
perhaps clinicians, whatever you called 11:55:38
them, practitioner scientists, scientist 11:55:42
practitioners. 11:55:46
Q Okay. 11:55:47
Do you recall that you and the other 11:55:47
investigators submitted a copy of the 11:55:52
manuscript for what became the article for 11:55:58
329 to JAMA? 11:56:02
A No. 11:56:04
Q Can you tell the jury what JAMA is? 11:56:05
A It's the Journal of the American Medical 11:56:08
Association. 11:56:09
Q And you just don't recall one way or another 11:56:12
whether the abstract -- or, excuse me, the 11:56:15
manuscript was submitted to JAMA; is that 11:56:19
correct? 11:56:21

A Yes. 11:56:22
Q Okay. 11:56:22
What -- what's your understanding of 11:56:23
the reputation of JAMA in the medical 11:56:27
community? 11:56:31
A I think it's well regarded as a journal 11:56:34
which goes out to a broad range of 11:56:41
practitioners, not -- not typically read -- 11:56:48
it's -- it's -- 11:57:00
It's rarely subscribed to or read by 11:57:03
specialists such as psychiatrists -- by 11:57:06
psychiatrists, and I believe by many other 11:57:09
specialists. 11:57:12
Tend -- it would tend to be most 11:57:14
widely subscribed to and read by people in 11:57:16
internal medicine. 11:57:19
Q And do you know why the manuscript for 329 11:57:27
was submitted to JAMA? 11:57:35
A I don't recall, but the logic that I go 11:57:38
through and that of my peers at times when 11:57:46
we think of submitting an article which has 11:57:49
to do with psychiatry or psychiatric illness 11:57:52
to JAMA is -- 11:57:57
Excuse me. 11:57:59

(Telephone interruption.) 11:57:59
MR. DAVIS: Want to go off the 11:58:01
record? 11:58:02
THE WITNESS: No, it's all right. 11:58:02
During the next break. 11:58:05
A But sometimes we wonder -- we think that 11:58:08
perhaps this would be of -- even though it's 11:58:12
specifically about psychiatry, we think 11:58:16
maybe it would be an interest to the general 11:58:21
medical community. 11:58:26
Very often, the editor of JAMA will 11:58:27
send things back to us and to peers of mine 11:58:31
in other specialty areas of medicine, such 11:58:33
as OB, rheumatology or whatever, and say 11:58:37
thanks for sending us your article, but I 11:58:41
think it would be more appropriate to a 11:58:45
specialty journal. 11:58:46
Oftentimes the reviews that come back 11:58:48
deal with what they consider to be the fit 11:58:51
of the material for JAMA and not -- if it's 11:58:57
a specialty article and not just the 11:59:01
substance, you know, of what's in the 11:59:03
article. It's a suitability/fit issue. 11:59:06
Q Okay. 11:59:10

You do know that the article that you 11:59:13
prepared for publication and that your 11:59:18
colleagues helped you prepare was not 11:59:20
accepted by JAMA, correct? 11:59:22
A I don't remember that. If you have a 11:59:23
document that says it wasn't and you show it 11:59:27
to me -- 11:59:29
Q Let me ask you this: 11:59:30
You know that your article was not 11:59:31
published in JAMA, correct? 11:59:33
A Yes. 11:59:34
Q Okay. 11:59:35
Do you recall ever seeing any of the 11:59:36
reviews by reviewers who -- at JAMA who 11:59:39
looked at your article submission? 11:59:42
A I believe that Skip asked me this question 11:59:47
yesterday, and what I said was I don't 11:59:51
recall seeing any of the reviews, and then 11:59:53
went on to explain how if, indeed, we had 11:59:55
submitted it, I am sure I would have either 12:00:01
gotten a letter -- 12:00:02
You know, it would be unheard of to 12:00:05
not receive a letter back from the editor 12:00:07
either saying that, you know, thanks a lot, 12:00:09

but we've decided not to review it or we've 12:00:12
sent it out to review. 12:00:14
And if it's sent out to review, it 12:00:16
would be unheard of not to get letters back 12:00:18
from reviewers, and if I got them I 12:00:20
certainly read them, but I don't recall 12:00:22
that. 12:00:24
So it was quite an extensive amount 12:00:25
of discussion, which is on the record from 12:00:27
yesterday. 12:00:29
Q Okay. 12:00:57
Do you recall -- do you recall 12:00:57
submitting the manuscript -- manuscript for 12:00:58
publication to the American Journal of 12:01:01
Psychiatry? 12:01:01
A No. 12:01:03
MR. COFFIN: Can we go off the record 12:01:09
for just a few minutes? I need to sort some 12:01:10
things out. 12:01:12
THE VIDEOGRAPHER: The time is three 12:01:13
minutes after 12:00. We are off the record. 12:01:14
(Recess.) 12:01:16
THE VIDEOGRAPHER: We're back on the 12:08:18
record. The time is ten minutes after 12:08:19

12:00. 12:08:21
BY MR. COFFIN. 12:08:22
Q Okay. 12:08:23
Dr. Keller, we were talking about 12:08:23
whether you recalled receiving reviews from 12:08:25
publications you had submitted a manuscript 12:08:32
to. 12:08:36
Do you recall that questioning? 12:08:36
A Yes. 12:08:37
Q Okay. 12:08:37
Do you recall reviewing any reviews 12:08:38
from individuals at JAMA? I believe you 12:08:43
already answered that, actually. 12:08:46
A Yes. 12:08:49
Q And do you recall reviewing those? 12:08:49
A No. 12:08:53
Q Okay. All right. 12:08:54
(Exhibit No. 29 marked for 12:08:54
identification.) 12:08:54
BY MR. COFFIN: 12:08:54
Q Let's look at what's been marked as 12:08:55
Exhibit 29. 12:08:56
MR. DAVIS: Okay. We'll dedesignate 12:09:03
this as subject to the protective order. 12:09:06

That's Exhibit 29. 12:09:08
MR. MURGATROYD: So the record's 12:09:11
clear, all of them have been dedesignated 12:09:11
with the sole exception of 24 thus far, 12:09:14
correct? 12:09:17
MR. DAVIS: I believe that's true. 12:09:18
MR. COFFIN: That is correct. 12:09:20
MR. MURGATROYD: Okay. 12:09:21
MR. GREEN: And we would like to make 12:09:23
sure of that at the end since we both signed 12:09:25
affidavits we wouldn't disclose anything. 12:09:27
I want to know exactly what I'm not 12:09:29
disclosing 12:09:31
MR. MURGATROYD: Yes, so far it's 12:09:32
only one page. 12:09:33
MR. GREEN: Okay. 12:09:34
MR. COFFIN: Makes it easy. 12:09:36
MR. GREEN: Yes. Don't want to be 12:09:37
going down to Pennsylvania and get in 12:09:38
trouble with the judge. 12:09:39
(Witness read document.) 12:09:57
A Do you want me to read the whole thing? 12:10:17
Q No, I just wanted you to familiarize 12:10:19
yourself with it. 12:10:22

I'll ask you some specific questions, but, you know, you don't have to read every word, unless you'd like to. 12:10:23 12:10:25 12:10:28

A Pretty interesting. 12:10:31

(Witness read document.) 12:11:25

A Okay. 12:11:34

Q Have you ever -- do you recall ever seeing that document? 12:11:36 12:11:37

A No. 12:11:39

Q Okay. 12:11:40

Do you know one way or another whether you received that document? 12:11:42 12:11:44

A My -- my assumption is that it was sent to me since it's reviewing -- it's a review by JAMA of the article, I'm a corresponding author, I'm assuming it was sent to me; and I'm assuming I read it carefully at the time I received it. 12:11:52 12:11:56 12:12:03 12:12:09 12:12:12 12:12:14

I just can't remember. 12:12:16

Q Considering -- considering you're the primary author on the article, would it be the normal course and practice for you to receive comments on the article from reviewers of a journal such as JAMA? 12:12:18 12:12:20 12:12:24 12:12:28 12:12:29

A Yes. 12:12:33

Q Okay. 12:12:33

And you don't have any reason to doubt that that happened in this case, I assume? 12:12:35 12:12:37 12:12:39

A No reason to doubt. 12:12:39

Q Okay. 12:12:42

I want to ask you some questions outside of this before I get to the specifics of this document that's been marked as 29. 12:12:43 12:12:46 12:12:48 12:12:50

Study 329 included a supportive therapy component for each participant in the study, correct? 12:12:55 12:13:00 12:13:03

A Yes. 12:13:04

Q Do you recall that? 12:13:04

A Yes. 12:13:06

Q Okay. 12:13:06

And can you explain what the supportive therapy component entailed? 12:13:07 12:13:10

A I can give you a general explanation and rationale, but there's a specific -- 12:13:17 12:13:20

I believe that we used a specific manual that set up the -- codified the -- 12:13:26 12:13:30

how the supportive therapy was to be performed. I seem to recall that we had that. 12:13:38 12:13:40 12:13:41

And so in order to give you the specifics that should be part of the, you know, the grant, the procedure materials for the grant -- so if you want specificity, if you gave that to me, I could go through it with you. 12:13:42 12:13:46 12:13:48 12:13:53 12:13:57 12:13:59

Q Well, it would be in the protocol for the study? 12:14:00 12:14:01

A It should either be in -- it wouldn't be in -- in one of the -- 12:14:05 12:14:08

The exhibits that I received were relatively short, you know, descriptions of the study. 12:14:10 12:14:13 12:14:20

It would be an appendix to -- it's typically in -- it's typically what we call an appendix, and it's a manual. 12:14:21 12:14:23 12:14:26

And I'm not sure that we used the manual, but there is a manual for supportive treatment that's commonly used in placebo-controlled pharmacologic studies, which we may have adopted at that particular 12:14:31 12:14:32 12:14:35 12:14:40 12:14:43

study. 12:14:45

I seem to recall that. I just don't remember for sure. 12:14:46 12:14:47

Q Okay. 12:14:48

Well, without going back through all those documents, the point is that there was supportive psychotherapy, if you will, provided to patients in the study, correct? 12:14:49 12:14:51 12:14:55 12:14:57

A Just -- I just don't remember for sure exactly what we did. 12:15:00 12:15:03

Q Okay. 12:15:05

A I mean, that's clearly a matter of -- you know, a fact that we could easily determine, so... 12:15:06 12:15:10 12:15:12

Q Okay. 12:15:15

A Depends whether you want to spend the time digging through the stuff. 12:15:18 12:15:20

Q Well, actually, I can -- let me see if I can refresh your recollection just by using a document that we already have marked as Exhibit 13, which is the article that you published. 12:15:23 12:15:26 12:15:27 12:15:29 12:15:35

Maybe this will help us without going specifically back into all the protocol and 12:15:35 12:15:37

so on. 12:15:39
A Sure. 12:15:40
Q If you read the first -- excuse me, the 12:15:42
second full paragraph under Limitations on 12:15:45
page 770 of Exhibit 13. 12:15:48
You don't have to read it out loud. 12:15:52
I just want to see if that refreshes your 12:15:54
recollection. 12:15:56
(Witness read document.) 12:15:59
A It's the second sentence which is germane, 12:16:05
so I've read that. 12:16:08
Q Okay. 12:16:09
So based on that, can you give an 12:16:09
explanation of the -- of the type of therapy 12:16:12
that was provided? 12:16:16
A Again, what this says is that we had weekly 12:16:18
supportive case management sessions, so -- 12:16:21
and as I was saying earlier, which I guess 12:16:27
is on the record, I believe, but I'm not 12:16:30
sure, that we had a manual which specified 12:16:32
what would be done. 12:16:35
But in general, the principal is that 12:16:36
you're -- you're being empathetic, you're 12:16:46
being warm in your interaction, you're 12:16:53

listening to their problems. 12:16:56
So in that case you're being 12:17:02
supportive of them, listening in a -- in a 12:17:04
caring way. 12:17:06
But what you're not doing is you're 12:17:08
not doing what's traditionally known as 12:17:11
psychotherapy, whereby you are, you know, 12:17:15
making an effort to understand the causes or 12:17:20
contributing factors to their depression or 12:17:28
other psychiatric troubles. 12:17:32
You're not trying to get to 12:17:35
understand why those have occurred from a 12:17:36
psychological perspective, nor are you then 12:17:39
making suggestions as to how using 12:17:42
psychological processes they could improve 12:17:48
themselves. 12:17:51
It's much more than as I described to 12:17:52
you. 12:17:54
Q It's much more supportive? 12:17:55
A Supportive -- 12:17:58
Q Hence supportive therapy? 12:17:59
A Without being prescriptive. 12:18:00
Q Okay. 12:18:02
Understandable. 12:18:03

A And the efforts made to standardize it so 12:18:06
that all the patients would be, you know, in 12:18:09
clinical trials. 12:18:12
That's what I'm saying, the effort is 12:18:13
to have that be very standardized. So 12:18:15
obviously you can't, you know, from 12:18:18
individual to individual, you can't be 12:18:20
exact, but there are certain things you can 12:18:24
say and cannot say. 12:18:28
Q Okay. 12:18:30
You recognize that the use of 12:18:31
supportive therapy can contribute to 12:18:32
positive outcomes for individuals who have 12:18:37
depression. 12:18:39
Do you recognize that? 12:18:42
A Yes. 12:18:44
But what I'm -- what this says here, 12:18:44
and. again, Chris, to the extent that it's 12:18:46
important, you might well want to go back to 12:18:49
the manual. This says "supportive case 12:18:52
management sessions" as opposed to saying 12:18:54
"supportive psychotherapy." 12:18:57
Q Okay. 12:19:01
A There is such a -- just so you know, I'm not 12:19:02

trying to be overtechnical. 12:19:04
Q I understand. 12:19:06
A When you talk about types of 12:19:07
psychotherapy -- 12:19:09
Someone asked me yesterday if I did 12:19:11
psychoanalysis, or maybe today, that was 12:19:12
you, there is something called supportive 12:19:15
psychotherapy -- 12:19:18
Q Right. 12:19:20
A -- in which you're there primarily to 12:19:20
support the person and so on and so forth. 12:19:21
But this isn't supportive 12:19:26
psychotherapy. This is helping to manage 12:19:28
the situation. 12:19:33
Q Okay. 12:19:34
How would you term what you're 12:19:35
referring to? You're pointing to in the 12:19:37
article. 12:19:39
A In order to be more specific, I would really 12:19:40
have to get the manual, because there are 12:19:42
different -- there are different support -- 12:19:44
there are different supportive therapies -- 12:19:47
There are different supportive 12:19:50
different ways of providing support in 12:19:55

different psycho -- in different 12:19:59
psychopharmacologic designs. I don't 12:20:00
remember which ones we used. 12:20:03
Just to give you an example of the 12:20:05
differences, there's a manual for a 12:20:08
nonspecific supportive therapy that's used 12:20:10
to test whether cognitive behavioral therapy 12:20:13
is effective. So that's -- that's one type. 12:20:16
And then there's a nonspecific 12:20:19
supportive management procedure in 12:20:22
pharmacologic trials. 12:20:25
There are many of them, but there are 12:20:27
at least -- those would be the two 12:20:29
distinctions. I'm not -- I just don't 12:20:30
remember which of those were used. 12:20:32
Among the different ones, some are 12:20:36
much more active than others in their 12:20:39
approach. 12:20:41
Q Okay. 12:20:42
Well, let me ask you this: You 12:20:46
recognize that case management therapy, as 12:20:47
we've been discussing, can also improve a 12:20:49
person's -- person's depression? 12:20:54
A It may. 12:21:01

Q And, in fact, yesterday, actually, you 12:21:02
testified that sometimes when you visit with 12:21:05
patients and you're seeing them, you're not 12:21:11
actually performing psychotherapy, that you 12:21:13
see an improvement with them; is that 12:21:15
correct? 12:21:17
A Yes. 12:21:19
But to clarify, I don't believe what 12:21:19
I'm seeing is something which is reversing a 12:21:22
major depression. 12:21:25
I believe that when -- at least my 12:21:29
understanding of what happens, sometimes 12:21:33
when people come to see me, because they'll 12:21:34
tell me that themselves, that they'll think 12:21:36
that I've understood their problems. 12:21:39
They'll think that I have some -- 12:21:41
have covered some material that wasn't 12:21:43
covered, you know, by the -- by the treating 12:21:46
therapist, that I have some ideas, perhaps, 12:21:48
of things that they should explore. And 12:21:52
they end up -- 12:21:55
It's not universal. It doesn't 12:21:57
always happen, but sometimes they end up 12:21:59
saying they're feeling more optimistic and 12:22:01

positive that -- that on the basis of this, 12:22:03
they might move forward, and things might 12:22:07
work out better with their therapist. 12:22:10
So they feel better. They feel 12:22:12
better. It's been helpful. 12:22:14
Rarely -- I mean, I can't recall 12:22:16
seeing that I've reversed someone who was in 12:22:18
a very, very bad state and they're all 12:22:21
better. 12:22:25
Q Right. 12:22:26
And you're saying that you've seen 12:22:27
this improvement without actual 12:22:30
psychotherapy? 12:22:34
Is that what you're saying? 12:22:34
A Yes. 12:22:36
Q Okay. 12:22:37
And you've seen it without actual 12:22:37
pharmacotherapy? 12:22:39
A Yes. 12:22:41
Now, it's also true that what makes 12:22:42
it very hard to interpret what that means, 12:22:45
which is why you need to go double-blind and 12:22:48
not just rely on your what your impression 12:22:53
is, is that the natural course of depression 12:22:56

is -- in children and adolescents as well as 12:22:58
in adults, though we now are studying 12:23:03
bipolar disorder in children, is to be one 12:23:07
that's fluctuating so that there's a 12:23:10
confounding, which is why you need to 12:23:14
double-blind and why what the clinician 12:23:16
believes happens with the patient isn't 12:23:18
always -- you know, isn't accepted by a 12:23:22
regulatory body as evidence, because the 12:23:26
onus can fluctuate, can wax and wane. 12:23:31
And you -- given a person that I've 12:23:37
seen -- or yesterday you might have been 12:23:39
feeling really pretty depressed, and today 12:23:41
you may feel better without having seen me 12:23:45
or seen anyone just without there being a 12:23:47
reason that we can understand why. 12:23:50
And that can last for a week or a few 12:23:51
weeks or whatever, and that's known as a 12:23:54
natural course of depression. 12:23:55
Indeed, a high proportion of people 12:23:57
change. You know, their state fluctuates 12:24:00
even without treatment, gets worse, gets 12:24:06
better, so on. 12:24:10
So it just -- that's what confound 12:24:10

being able to -- to interpret with 12:24:11
confidence the meaning of the change agent. 12:24:13
Q Okay. 12:24:18
Just so I'm clear, I understand your 12:24:22
lengthy explanation that you gave. 12:24:24
My question was, you have seen 12:24:31
improvement in individuals who come to visit 12:24:33
you but who you do not treat with 12:24:36
pharmacotherapy, correct? 12:24:39
A I've seen improvement in how they're 12:24:41
feeling. 12:24:43
Q Right. 12:24:45
A I -- I make a distinction between that and 12:24:45
saying -- I don't necessarily mean that 12:24:48
they've recovered -- 12:24:50
Q Right. 12:24:51
A -- from their depression. 12:24:51
Q I'm not suggesting that you've cured them. 12:24:53
A I just wanted to make sure we understand -- 12:24:55
Q Right, okay. 12:24:57
A People mean different things when they say 12:24:58
"improvement." 12:24:59
Q Okay. 12:25:00
The point is, you've seen improvement 12:25:00

with people who visit you who you haven't 12:25:02
provided pharmacotherapy to? 12:25:04
A Yes. 12:25:06
Q And you've also seen improvement with people 12:25:06
who have visited you who you have not 12:25:08
provided psychotherapy? 12:25:11
A Yes. 12:25:13
Q Okay. 12:25:13
Let's look at the article -- 12:25:14
what's -- Exhibit No. 20 -- 12:25:15
MR. GREEN: 29. 12:25:18
Q 29, okay. 12:25:19
And this appears to be -- actually, 12:25:20
can you just read the heading of that? 12:25:24
A "Comments from three JAMA reviewers and 12:25:26
suggested revisions to be made before 12:25:28
submitting to American Journal of 12:25:30
Psychiatry." 12:25:30
Q Okay. 12:25:32
And these comments appear from this 12:25:33
document to be comments on the manuscript 12:25:37
that was submitted to JAMA, correct? 12:25:39
A Yes. 12:25:42
Q Okay. 12:25:42

Now -- 12:25:42
MR. DAVIS: Excuse me, did you mean 12:25:45
JAMA or the other journal? 12:25:46
MR. COFFIN: Well, actually, these 12:25:48
are comments from three JAMA reviewers, as 12:25:49
he just read; but it appears -- 12:25:53
MR. GREEN: Oh. 12:25:56
MR. COFFIN: -- that the comments 12:25:57
from the JAMA reviewers were used to then 12:25:58
create a submission to the American Journal 12:26:02
of Psychiatry. 12:26:04
BY MR. COFFIN: 12:26:05
Q Is that correct? 12:26:05
A I'm not sure if that's true. 12:26:08
Because, see, what happened is -- I 12:26:11
don't know if it was submitted to the 12:26:13
American Journal. If you know, you can tell 12:26:15
me. 12:26:17
But what -- what JAMA often does is 12:26:17
they often -- they often, actually, offer to 12:26:22
sent it along to another journal for you. 12:26:29
There's a -- there's a consortium of 12:26:33
journals under the aegis of the American 12:26:36
Medical Association. So oftentimes JAMA 12:26:38

will say we think this is appropriate for 12:26:42
this journal. And, indeed, it -- here's 12:26:44
the -- these are the suggestions made by our 12:26:47
reviewers, and you might want to go ahead 12:26:49
and take those and send it to that journal. 12:26:51
I don't know that we went ahead and 12:26:53
did that next. We might have decided 12:26:56
instead to just not take their suggestion 12:26:59
and just submit it to the JA -- journal that 12:27:03
it was published in. 12:27:10
I just don't remember. 12:27:11
(Exhibit No. 30 marked for 12:27:12
identification.) 12:27:12
BY MR. COFFIN: 12:27:12
Q Okay. 12:27:12
Let me ask you to take a look at 12:27:13
Exhibit 30, and maybe we can clear this up. 12:27:15
And take a read over that. 12:27:19
(Witness read document.) 12:27:21
MR. DAVIS: Chris, is that the letter 12:27:40
from JAMA to Dr. Keller? 12:27:41
MR. COFFIN: That's the letter -- no, 12:27:44
actually, I don't believe that's correct. 12:27:45
He'll show it to you when he's done. 12:27:47

A Should I hand it -- 12:27:57
Q Sure. 12:28:00
MR. DAVIS: Thank you, Doctor. 12:28:01
(Counsel read document.) 12:28:07
MR. DAVIS: Thank you. 12:28:08
MR. COFFIN: Okay. 12:28:09
MR. MURGATROYD: Did you dedesignate 12:28:11
that one? 12:28:13
MR. DAVIS: It's been accidentally 12:28:13
designated subject to the confidentiality 12:28:14
order. We withdraw it. 12:28:17
MR. COFFIN: Okay. 12:28:18
BY MR. COFFIN: 12:28:18
Q Dr. Keller, that's letter, correct? Appears 12:28:19
to be? 12:28:22
A Yes. 12:28:23
Q Okay. 12:28:23
And who is the letter to and from? 12:28:23
A It's to Jim McCafferty from Sally Laden. 12:28:26
Q Okay. 12:28:31
And are you referenced in that 12:28:31
letter? 12:28:33
A Yes. 12:28:34
Q Okay. 12:28:34

Does this refresh -- refersh your 12:28:37
recollection as to submissions that were 12:28:38
made to JAMA? 12:28:43
A No. 12:28:44
Q Okay. 12:28:45
Well, just -- how about this. Just 12:28:45
read the first paragraph. 12:28:47
A Okay. 12:28:49
"Enclosed is the draft rebuttal to 12:28:49
the JAMA reviewer comments for PAR329. As 12:28:52
was agreed in the conference call with Drs. 12:28:57
Keller, Ryan and Strober on November 15, we 12:28:59
will seek -- we will, one, seek approval 12:29:02
from the authors on the plan revisions to be 12:29:04
made. Two, we will make the revisions. And 12:29:07
three, we will submit the manuscript to 12:29:10
the -- to American Journal of Psychiatry." 12:29:13
Q Okay. All right. 12:29:15
So now let's look back and -- at the 12:29:16
document that was marked prior to that which 12:29:21
is comments from the three JAMA reviewers. 12:29:23
A Yes. 12:29:26
Q Now, if you read that in conjunction with 12:29:26
the letter that I just put in front of you, 12:29:28

it appears, does it not, that these -- there 12:29:33
are suggested revisions to the article based 12:29:38
on comments from JAMA reviewers, correct? 12:29:43
A Yes. 12:29:45
Q Okay. 12:29:46
Let's look at Reviewer No. 1, if you 12:29:47
could turn to that page. I believe it's 12:29:53
page 2. 12:29:57
Are you on -- 12:29:58
A So done. 12:30:01
Q Okay. 12:30:01
Could you please read -- have you 12:30:02
read over this paragraph? Look at No. 1 12:30:04
under Reviewer No. 1 12:30:06
A Okay. 12:30:11
Q Look at the sixth line down, begins with 12:30:20
"readers of this paper." 12:30:22
Could you please read that into the 12:30:24
record? 12:30:26
A "Readers of this paper might receive the 12:30:26
wrong impression and believe that a 65 to 70 12:30:29
percent response rate could be achieved with 12:30:33
paroxetine without the education and support 12:30:36
of psychotherapy that the placebo-treated 12:30:37

patients in the study received." 12:30:41
Q Go ahead and continue. 12:30:44
A "That outcome is particularly worrisome in 12:30:44
this area of health cost containment. Thus, 12:30:47
this study could do more harm than good 12:30:50
unless the authors devote much more 12:30:53
attention in their discussion to the fact 12:30:55
that the bulk of the effect of the study was 12:30:56
the result of good clinical management and 12:30:58
not the medication." 12:31:00
Q Okay. 12:31:01
Now, do you agree that -- with this 12:31:04
reviewer from JAMA that -- with the 12:31:08
statement that he makes or she makes that 12:31:12
this study could do more harm than good 12:31:13
unless the authors devote more attention in 12:31:18
their discussion to the fact that the bulk 12:31:20
of the effect of the study was the result of 12:31:22
good clinical management and not the 12:31:25
medication? 12:31:27
A I disagree strongly. 12:31:28
Q Okay. 12:31:30
And I assume you disagree with the 12:31:31
JAMA reviewer's comment that the bulk of the 12:31:33

effect of the study was the result of good 12:31:36
clinical management and not the medication? 12:31:39
A Right. The reviewer has no -- there's no 12:31:42
scientific basis to support what this 12:31:44
reviewer said. 12:31:46
The only way that he could 12:31:47
possibly -- that that could be supportive is 12:31:48
if you did a controlled -- if you had two -- 12:31:50
if you had two different types of 12:31:52
nonpharmacologic activities going on so that 12:31:56
if you -- if you had a multicell design and 12:31:59
some people received the -- what's described 12:32:04
as the -- you know, whatever type of 12:32:07
management we gave and another group, you 12:32:11
know, received nothing, that's the only way 12:32:13
you could parse out and determine whether it 12:32:15
had an effect. 12:32:18
So this is an ill-informed statement 12:32:19
scientifically. 12:32:21
Q Well, wouldn't it also be true that you 12:32:26
can't make a statement as to whether or not 12:32:28
the psychotherapy or the supportive case 12:32:30
management contributed significantly or did 12:32:33
not contribute significantly to the effect 12:32:35

of the stuff that's shown in the study? 12:32:38
MR. DAVIS: Object to the form. 12:32:42
A What you're saying is partially correct. 12:32:52
Q Okay. 12:32:56
The distinction is -- which is -- 12:32:57
First of all, we did say in the 12:32:59
manuscript that a probable contributing 12:33:01
factor was a -- weekly supportive case 12:33:03
management sessions which may have 12:33:05
contributed to the clinical improvement of 12:33:07
patients in the placebo and active treatment 12:33:08
group. 12:33:12
So the pertinent thing, Chris, which 12:33:13
I believe is responsive to your question to 12:33:18
me, is that -- that subjects in both the 12:33:20
placebo group and the active medication 12:33:27
group received, you know, what we're 12:33:30
assuming was a similar -- the same type of 12:33:34
supportive case management treatment. 12:33:37
Despite that, there was still a 12:33:40
difference between the two groups. So that 12:33:42
on whole, there was an effect of the 12:33:46
medication relative to placebo that was 12:33:51
statistically significant on the -- in the 12:33:54

four depressive measures that we've talked 12:33:58
about. 12:34:00
Now -- so that -- so that's where -- 12:34:02
that's where the value of the medication is 12:34:08
shown. 12:34:10
Now, it is correct that the both -- 12:34:11
the placebo both -- the subjects on either 12:34:14
placebo or medication may well have received 12:34:17
meaningful benefit from the psycho -- from 12:34:22
the case management, but even with that 12:34:25
benefit, they were -- they were 12:34:32
significantly better off to have received 12:34:34
the medication and the management compared 12:34:36
to placebo and the management. 12:34:39
Q But you don't actually know that -- 12:34:42
A Yes, you do. 12:34:44
Q -- as you just testified, because -- 12:34:44
A No. Of course you do. Of course you do. 12:34:46
What I'm saying is -- 12:34:48
Q Well, you don't know the effect that the -- 12:34:49
that the psychotherapy or case management 12:34:51
had on each individual patient? 12:34:52
A But that's not -- that's not relevant here. 12:34:54
The relevant thing is in measure -- in 12:34:56

making a judgment as to whether medication, 12:35:00
in this case, paroxetine, was beneficial 12:35:05
relative to placebo. 12:35:12
The fact that the subjects on placebo 12:35:13
and -- I should talk to the jury. I'm 12:35:17
sorry. I shouldn't be looking at you guys. 12:35:20
I don't mean to be rude 12:35:22
But the fact that the -- that the 12:35:24
subjects in the study on the placebo and 12:35:26
paroxetine both -- all received the same 12:35:30
type of supportive treatment and yet there 12:35:35
was still a difference between the 12:35:39
medication and placebo that was 12:35:40
statistically significant is an indication 12:35:41
of the efficacy of the treatment for 12:35:45
depression in adolescents in this trial. 12:35:49
It doesn't matter -- you know, to 12:35:54
whatever extent the -- the supportive 12:35:59
treatment contributed -- I can't tell -- we 12:36:01
can't -- we can't say -- 12:36:04
A goal of this study was not to say 12:36:06
how much of the effect was a result of the 12:36:09
case management sessions. But taking 12:36:16
into -- that into consideration, we still 12:36:22

saw a statistically significant difference. 12:36:24
Is that clear? 12:36:27
Q I understand what you're -- I understand 12:36:28
your response. I understand your response. 12:36:30
So you -- you disagree with the 12:36:33
statement that the bulk of the effect of the 12:36:37
study was the result of good clinical 12:36:39
management and not medication? 12:36:41
A Absolutely. There's no basis to say this. 12:36:42
Q Well, when the reviewer -- in the normal 12:36:45
course and practice, is it your 12:36:49
understanding that a reviewer for a journal 12:36:51
article like JAMA reviews the manuscript and 12:36:54
the data that you provide in the manuscript? 12:37:00
A I sure hope so. 12:37:04
Q You would think so, right? 12:37:07
That's why they're called a reviewer, 12:37:08
correct? 12:37:09
A Right. 12:37:10
On the other hand, sir, as an editor 12:37:11
of several journals and as someone who has 12:37:14
published probably 400 articles, I see 12:37:20
reviews as an editor that are absolutely 12:37:23
totally off base. 12:37:25

Moreover, just -- perhaps not to -- 12:37:29
not to -- if you were to say to me how do 12:37:31
you know they're off base, I often get 12:37:33
totally contradictory reviewers. 12:37:35
So as an editor when I send a 12:37:37
manuscript out to anywhere between three and 12:37:40
seven people, depending upon the manuscript, 12:37:42
I'll get one reviewer whichd that says, 12:37:44
Accept as-is. You know, the greatest thing 12:37:46
since sliced bread. And I'll get another 12:37:49
reviewer which is highly critical, rips it 12:37:52
to shreds and says, Don't accept. I don't 12:37:55
want to see it again. 12:37:58
And you can get those opinions on the 12:37:59
same article. 12:38:00
Q Do you discount either of those opinions? 12:38:01
A Sometimes. 12:38:03
Q Okay. 12:38:05
And on what basis? 12:38:06
A Well, as the editor, I have to move forward 12:38:09
with life and make a judgment, and I then -- 12:38:11
and the reason -- 12:38:17
You know, I just have to weigh it 12:38:18
out. 12:38:19

Q You consider both of them, correct? 12:38:19
A I certainly consider them. I don't always 12:38:21
agree with them. 12:38:25
But -- but what I want to make clear 12:38:26
is, the fact that any given reviewer has a 12:38:28
criticism of an article or a grant, for that 12:38:30
matter, which is -- which is very consistent 12:38:34
with the same line of thinking, and that a 12:38:38
grant -- 12:38:42
You know, an article can be turned 12:38:42
down by three journals and end up being, you 12:38:43
know, a prize-winning article, if you will. 12:38:47
It can go down as having a major positive 12:38:49
impact in the field. 12:38:52
A grant can be turned down three 12:38:53
times before it's funded on then go on and 12:38:54
produce science which is fantastic. 12:39:00
So the fact that something is 12:39:03
criticized, A, doesn't mean the criticism is 12:39:05
valid; and, B, doesn't mean that with some 12:39:08
modification after in response to the 12:39:10
criticism, either partial or complete, you 12:39:13
don't have something which is the better 12:39:16
product for it. 12:39:17

So I just hope that's -- you 12:39:20
understand it. 12:39:22
Q You recognize that in clinical practice, 12:39:23
individuals who are receiving antidepressant 12:39:27
therapy don't usually have weekly supportive 12:39:32
therapy that goes along with that? 12:39:35
A I don't know that that's true. 12:39:36
In -- in my own practice, however 12:39:41
currently limited, but at one point in my 12:39:46
career after I was done with my training, I 12:39:51
saw as many as 20 hours of patients a week. 12:39:54
I saw people -- I pretty much -- I 12:39:57
pretty much saw everybody on as close to a 12:40:01
weekly basis as possible, even if they were 12:40:04
also on medication. 12:40:06
I happen to think that's the ideal 12:40:09
way for patients to be treated. 12:40:12
Q Are you familiar with the prescribing 12:40:13
practices of general practitioners with 12:40:16
regard to antidepressant therapy? 12:40:20
A I don't know what you mean by am I familiar. 12:40:29
Q Have you read literature or have you heard 12:40:31
presentations regarding the prescribing 12:40:37
habits of general practitioners in -- with 12:40:39

using antidepressants? 12:40:43
A I haven't read literature or heard 12:40:45
presentations about the prescribing, 12:40:52
whatever word you used, practices of general 12:40:57
practitioners. 12:40:58
Q Okay. Okay. 12:40:59
What's your -- what's your general 12:41:00
understanding of the prescribing practices 12:41:04
of general practitioners with regard to 12:41:06
antidepressant therapy, if you have an 12:41:09
understanding? 12:41:14
A I know that a meaningful proportion -- and I 12:41:19
can't tell you what, but a meaningful 12:41:21
proportion of antidepression medication is 12:41:23
prescribed by general medical physicians, be 12:41:33
it an internist, a family practice doctor or 12:41:40
a primary care doctor. 12:41:43
Q Does that include prescriptions to children 12:41:45
and adolescents? 12:41:48
A I don't know that. 12:41:49
It's my impression -- actually, based 12:41:54
on an experience of one, when I once gave a 12:41:56
talk to the American Academy of Family 12:42:01
Practitioners, that just during the question 12:42:05

and answer -- and I can't tell you how long 12:42:10
ago it was, when it was. It was warm in the 12:42:13
winter. 12:42:17
And it was their academy meeting and 12:42:17
they asked me to talk about depression and I 12:42:20
was talking generally, and I do know that I 12:42:22
just remember -- it just made an impression 12:42:30
on me that they were -- felt far more 12:42:32
comfortable seeing and treating adults than 12:42:36
they did adolescents. 12:42:38
Now, of course, I do know that within 12:42:40
family -- within general medicine, there is 12:42:42
a specialty called adolescent medicine so 12:42:44
that certainly, you know, primary care 12:42:46
doctors do -- can choose to get training in 12:42:49
adolescent medicine, so I don't think it was 12:42:52
that group. 12:42:55
But I think those that don't have -- 12:42:55
you know, those general medical 12:42:57
practitioners who don't have specialty 12:42:59
training I think are less comfortable, it's 12:43:02
my impression, in treating adolescents and 12:43:04
children with mental illness than they are 12:43:10
in treating adults. 12:43:12

Q How about with regard to individuals 12:43:17
practicing psychiatry, what is your 12:43:19
impression of the prescribing habits they 12:43:21
have they have with regard to prescribing 12:43:25
antidepressants to children and adolescents? 12:43:30
A Please be more specific, Chris, in asking 12:43:32
the thing about prescribing habits. 12:43:35
Q Yes. 12:43:44
Have you ever read any literature or 12:43:44
heard any presentations discussing the -- 12:43:46
discussing the prescribing practices of 12:43:59
psychiatrists with regard to antidepressants 12:44:01
to children and adolescents? 12:44:08
A A long time ago in the 1980s I wrote an 12:44:19
article myself on the use -- this isn't the 12:44:24
exact title, but it's something to the 12:44:31
effect of the use of anti -- the treatment 12:44:33
of antidepressants, and it might have said 12:44:35
adolescents or children, or something to 12:44:40
that effect. It might have actually been 12:44:41
published in this very same journal. 12:44:43
And at the time I reviewed the 12:44:46
literature, and what stands out in my 12:44:53
mind -- because it's consistent with a body 12:44:56

of work that I've published over the 12:45:01
years -- was what I call to be the 12:45:03
undertreatment of depression for everybody 12:45:07
who's depressed. 12:45:08
But in this case, and I can't quote 12:45:09
you the amount, I was stunned that I had -- 12:45:11
in my study, because I -- I mentioned to you 12:45:15
all yesterday that I was the coprincipal 12:45:18
investigator on the cohort of offspring of 12:45:21
parents who had mood disorders, and we were 12:45:24
studying the offspring, some of whom were 12:45:28
children; and we looked at those who were 12:45:32
depressed and simply recorded, you know, 12:45:36
what treatments they received. 12:45:38
And I was stunned that something like 12:45:39
less than ten percent of some combination in 12:45:41
this study, of children and adolescents who 12:45:46
were depressed -- this is back in the 12:45:48
1980s -- were receiving any type of 12:45:50
treatment for their depression, let alone an 12:45:53
antidepressant. 12:45:56
And I do remember at the time 12:45:57
reviewing whatever literature there was, 12:45:59
and -- it was extremely sparse -- and being 12:46:03

stunned at how much undertreatment there was. 12:46:07 12:46:10

In response to your question about prescribing practices, you know, in general I've published several articles which have had wide -- have been read widespread and translated into many languages on, quotes, the undertreatment of depression. 12:46:11 12:46:13 12:46:16 12:46:19 12:46:22 12:46:26

And circa, you know, the last major piece of work I did in the late 1990s, my conclusion which was published, so I don't know if the reviewers agreed in that case, was that less than ten percent of people suffering from major depression in the United States and worldwide received even one course of an antidepressant in an adequate dose for a sufficient duration. 12:46:27 12:46:30 12:46:34 12:46:38 12:46:41 12:46:43 12:46:45 12:46:47 12:46:51

And now as part of that, because it comes back to me, we looked -- we also reviewed what was done in general medical practice and not just psychiatry, the lion's share, if not all, had to do with adults, because that was in the literature. 12:46:53 12:46:57 12:47:00 12:47:02 12:47:05 12:47:09

But underprescription is a major problem, in my judgment. 12:47:11 12:47:13

Q Right. 12:47:14

And since the 1980s when you were discussing about it and the advent of SSRIs and new therapies -- 12:47:14 12:47:19 12:47:23

A Hasn't changed. 12:47:24

I'm sorry, you didn't finish your question. 12:47:25 12:47:28

Q And do you believe that there's an increased amount of prescribing of antidepressants than there was in the '80s? 12:47:28 12:47:30 12:47:34

A A lot of -- so a number of things point to that; but when we did our most recent study, which was an NIH consensus conference at which I chaired in the late 1990s, we found no -- we did not find a difference. 12:47:37 12:47:42 12:47:44 12:47:47 12:47:51

And this was published in JAMA, in fact, in 19 -- I think it was published in JAMA -- you could look it up. It was in the late 1990s. 12:47:53 12:47:56 12:47:59 12:48:01

It was a lead article in JAMA on the -- it was called the treatment of the depression that was from a consensus conference, and the conclusion then was -- 12:48:02 12:48:04 12:48:06 12:48:09

So the SSRIs have been available since December of 1987. So approximately ten years later, we still found that approximately ten percent of people with major depression had only received one course of adequate dose of sufficient duration. 12:48:13 12:48:17 12:48:20 12:48:23 12:48:25 12:48:28 12:48:31

Q Let me turn you to -- 12:48:32

A It's a major problem in society. 12:48:34

Q Let me turn you to page 3 of this document that's in front of you. It's the JAMA reviewers' comments. 12:48:37 12:48:40 12:48:47

Do you see No. 6? 12:48:49

Could you please read that into the record? 12:48:54 12:48:56

A "The high dose of imipramine employed in this study likely also comprised the blind." 12:48:57 12:48:59

I'm not familiar with the word comprised, the definition. 12:49:04 12:49:07

Q Do you believe that might be an error? 12:49:08

A I don't know, frankly. I just don't know. 12:49:09

Q Would it make sense that maybe that sentence should be read -- should read, "This study also likely compromised the blind"? 12:49:12 12:49:14 12:49:17

A Could be. Just don't know. 12:49:20

"The authors do not address this issue. However, the anticholinergic adverse events cited in Table 5 are such that one would expect the authors should have been able to determine who was on imipramine with reasonable certainty." 12:49:22 12:49:24 12:49:29 12:49:32 12:49:33 12:49:35

Q Do you disagree with that statement? 12:49:37

A Absolutely. 12:49:39

Q Okay. 12:49:40

A There is evidence and studies have been done -- I can't tell you exactly where in the literature -- that have actually made an effort to have both the -- both subjects in research studies as well as the investigators guess what treatments that they're on based on the presumptive adverse events. 12:49:40 12:49:42 12:49:48 12:49:51 12:49:54 12:49:55 12:49:59 12:50:03

And the results have been stunning, that typically people guess no better than -- much better than 50 percent as to whether they're on placebo or active treatment or whether they can differentiate treatments. 12:50:03 12:50:09 12:50:12 12:50:14 12:50:16 12:50:19

So there is a literature which shows that despite what you would believe to be sufficient enough differences in package inserts that people can guess, that they're not accurate in guessing what treatment condition they're under. 12:50:19 12:50:23 12:50:27 12:50:28 12:50:32 12:50:34

Otherwise, the blind would be so highly compromised, because, as you may be aware, when the FDA makes a judgment as to whether a treatment should be approved for any disease in medicine, but here let's just stick to depression, the comparisons are between an active drug and placebo. 12:50:36 12:50:38 12:50:41 12:50:44 12:50:48 12:50:51 12:50:53

And since that -- so -- so this is a very -- this -- 12:50:55 12:51:04

Q Let's look at Reviewer No. 2. Starts on page 5. 12:51:07 12:51:17

I'd like to look at the second comment, which I believe starts at the beginning, top of page 6. 12:51:25 12:51:28 12:51:32

A "The strength of the study is that it is a first replication of the efficacy of antidepressant in treatment" -- 12:51:35 12:51:37 12:51:40

Q Top of page 6, "The study"? 12:51:41

A Oh, the second -- hold on. 12:51:47

Q I just want you to -- you can read that to yourself. 12:51:56 12:51:58

A No, no. I had two pages stuck together, so -- 12:51:59 12:52:01

MR. DAVIS: How is everyone holding up in terms of lunch break? 12:52:01 12:52:02

MR. MURGATROYD: I think we've got -- as soon as we finish this document, we should take a break. 12:52:04 12:52:05 12:52:07

MR. COFFIN: Yes. We can do that. 12:52:08

MR. DAVIS: Sure. 12:52:10

If that's okay with Dr. Keller and his counsel, it's fine with us. 12:52:10 12:52:12

THE WITNESS: Getting weak. Depends how much time we need. 12:52:15 12:52:16

MR. COFFIN: No, that's -- there's only a few more pages, so... 12:52:16 12:52:16

THE WITNESS: Either that or we just go straight through without eating. 12:52:16 12:52:17

MR. MURGATROYD: No, no. 12:52:20

(Laughter.) 12:52:20

BY MR. COFFIN: 12:52:20

Q Okay. 12:52:20

Just read to yourself that first paragraph on the top of page 6. I'll ask you a few questions about it. 12:52:20 12:52:21 12:52:24

(Witness read document.) 12:52:32

A I read it quickly, so... 12:53:25

Q Okay. 12:53:27

Look at the sentence that starts about the middle of the paragraph. It says, "In fact"? 12:53:27 12:53:28 12:53:31

A Okay. 12:53:34

Q Can you read that, please? 12:53:35

A "In fact, it is troubling that the authors do not note a significant increase in SAEs" -- 12:53:36 12:53:39 12:53:43

Q Which means -- Which means what? Do you know what SAEs means? 12:53:46 12:53:49

A Adverse events. I'm blocking on the S. 12:53:51

Q Serious adverse events. 12:53:54

A Serious adverse events. "After paroxetine but not imipramine." 12:53:56 12:53:59

Wait. And, "In fact, it is troubling that the authors do not note a significant increase in serious -- in SAEs after paroxetine (but not imipramine) relative to 12:54:00 12:54:03 12:54:05 12:54:07

placebo (P less than .05) by Fisher's exact test." 12:54:10 12:54:17

Q Okay. 12:54:18

So this reviewer finds it obviously -- "troubling" the word he or she uses that you as the authors didn't note the significant increase in serious adverse events after paroxetine use, correct? 12:54:19 12:54:23 12:54:26 12:54:28 12:54:30

MR. DAVIS: Objection to form. 12:54:32

Q Is that how you read it? 12:54:35

A Say that again, please? 12:54:38

Q Do you read that this reviewer's concern is that you as the authors did not note the signature increase in serious adverse events that individuals in the study experienced after taking Paxil? 12:54:39 12:54:44 12:54:48 12:54:51 12:54:54

A Relative to the placebo. 12:54:57

Q Right. 12:54:58

A Yes. That's what the person said. 12:54:59

Q Okay. 12:55:00

And -- and did you find in your read of the data obtained from Study 329 that there was a significant increase in serious adverse events after individuals used Paxil? 12:55:01 12:55:06 12:55:10 12:55:12

A I'd have to go back to the article, but -- 12:55:18
but my gestalt memory is that, as we 12:55:20
concluded in the manuscript which was 12:55:26
published in the Journal of the America 12:55:30
Academy of Child and Adolescents Psychiatry, 12:55:35
that paroxetine is generally well tolerated 12:55:37
and effective for major depression in 12:55:40
adolescents. So generally well tolerated. 12:55:44
And if I go back to the adverse 12:55:46
events section, I don't think we were 12:55:48
concerned based on our findings about 12:55:50
serious adverse events. 12:55:55
And I would point out to you again 12:55:56
that each reviewer is a reviewer. They're 12:55:59
not necessarily, you know, a qualified, you 12:56:03
know, expert anymore so than anyone else. 12:56:05
Indeed, one of the biggest problems 12:56:09
journals have today is finding people to 12:56:12
review articles. 12:56:15
I typically have to send an article 12:56:15
out to 15 people before I can get three 12:56:18
people to agree to review them. 12:56:21
It's very tough. 12:56:22
Q I understand. 12:56:23

A So that the quality of the people of the 12:56:24
reviews are mixed. 12:56:26
Q Okay. 12:56:27
A So if I get to the -- let me look at the 12:56:28
adverse events. 12:56:31
Q Let me ask you this question: 12:56:32
A One second, please. 12:56:34
Q Well, there's no question pending. You've 12:56:36
already answered my other question. 12:56:38
A Well, yes, my answer is I disagree. And as 12:56:40
we state here, most -- most adverse events 12:56:44
were not serious. 12:56:46
Q Most adverse events were not serious, okay. 12:56:47
Do you believe that a fivefold 12:56:49
increase in serious adverse events over a 12:56:50
placebo is considered a significant increase 12:56:53
in serious adverse events over placebo? 12:56:58
MR. DAVIS: Object to the form. 12:57:01
A It depends on the sample size. 12:57:05
Q Well, let's take the sample size in Study 12:57:07
329. 12:57:09
There was 275, correct, total in the 12:57:10
study? 12:57:17
A If you could please be more specific about 12:57:17

which adverse events you're referring to? 12:57:20
Q Well, let me ask you this: 12:57:26
Do you know what a serious adverse 12:57:28
event is? 12:57:30
(Witness read document.) 12:57:33
A Yes. 12:57:35
Q Okay. 12:57:35
I'm referring to serious adverse 12:57:38
events, and that's a term of art that's used 12:57:40
commonly in clinical studies, correct? 12:57:42
A Yes. 12:57:45
The problem with the term of art is 12:57:46
that it's art and not science, so that the 12:57:47
meaning is very variable. 12:57:53
Q All right. 12:57:54
Well, let's -- 12:57:54
A That's why I asked you to get specific. 12:57:55
Q All right. 12:57:58
Well, I want your definition of a 12:57:58
serious adverse event. Don't you use 12:58:01
that -- 12:58:03
A I consider it to be a catch phrase category 12:58:05
that has -- doesn't have -- that is -- that 12:58:08
is very -- it's a very -- 12:58:15

I consider it to be a very poor 12:58:17
descriptive category. It's a -- it's a -- 12:58:21
you know, it's a bucket that things -- it's 12:58:23
a bucket category, and that in order for 12:58:26
it -- 12:58:28
In order to be meaningful, you need 12:58:29
to look at the individual event and to see 12:58:32
what, in fact, the event is. 12:58:34
Q Okay. 12:58:38
A You can take, for example, a digestive 12:58:39
system here and take diarrhea, and diarrhea 12:58:41
can be not a big deal, but diarrhea can be 12:58:43
the entire day. It can be totally disabling 12:58:46
as somebody, you know, with, you know, 12:58:49
Crohn's Disease would have. 12:58:53
So it can totally -- it can keep 12:58:55
you house -- diarrhea can keep you 12:58:58
housebound, or it can just be annoying. 12:58:59
So it -- 12:59:02
Q Okay. I understand what you're saying. 12:59:03
On page 769 of the article that you 12:59:04
published, do you see the top left paragraph 12:59:07
says, "Serious adverse events occurred." 12:59:11
Do you see that sentence? 12:59:14

A Yes. 12:59:15
(Telephone interruption.) 12:59:17
THE WITNESS: Can we take a break for 12:59:23
a second? 12:59:24
Q You need to answer that call? 12:59:25
A It's my daughter. Can I take break for a 12:59:27
second? 12:59:29
MR. COFFIN: Okay. 12:59:30
Why don't we go off the record? 12:59:30
THE VIDEOGRAPHER: The time is 2:00. 12:59:33
We're off the record. 12:59:36
(Luncheon recess.) 12:59:40
THE VIDEOGRAPHER: We are back on the 02:05:22
record. The time is seven minutes after 02:05:31
2:00. This is Tape 3. 02:05:34
BY MR. COFFIN: 02:05:36
Q Okay, Dr. Keller, when we left for our lunch 02:05:37
break, we were talking about serious adverse 02:05:41
events, and I had referred you to page 769 02:05:44
of the article that you published. 02:05:47
You see there where it says -- refers 02:05:49
to "Serious adverse events occurred in 11 02:05:51
patients in the paroxetine group, five in 02:05:54
the imipramine group and two in the placebo 02:05:56

group." 02:05:59
Do you see that? 02:06:00
A Yes. 02:06:01
Q Okay. 02:06:01
And so when you authored this 02:06:02
article, you clearly had a definition of 02:06:06
serious adverse events in mind, correct? 02:06:08
A As I -- as I said earlier, it's a -- -- 02:06:14
the -- it's a -- it's just a bucket. It's 02:06:17
just a -- it's a rough category, and I don't 02:06:20
think there is -- 02:06:26
You know, I don't think there's a 02:06:29
scale. I don't think there's a serious 02:06:30
scale that enables you to make a cutoff and 02:06:35
distinguish. 02:06:37
I think it's much more of an 02:06:38
impressionistic thing. And the reason why 02:06:39
that's I think so relevant is like when you 02:06:41
say summarizing in grouping, like the 02:06:44
sentence that you just read, serious adverse 02:06:47
events, 11 patients, and if I look at it, 02:06:51
they're spread over a wide variety of 02:06:55
categories of different organ systems. 02:06:58
So that what might be a serious 02:07:01

event, you know, in one organ in the system 02:07:03
may not be very relevant -- 02:07:08
I don't need to answer this unless 02:07:11
it's a -- 02:07:13
(Telephone interruption.) 02:07:13
A What may not be so relevant, you know -- 02:07:14
This -- you know, how you would 02:07:17
define it would be different. I gave you an 02:07:18
example of diarrhea, and so it's -- and 02:07:20
so -- 02:07:22
Q Well, certainly it would be defined in the 02:07:23
protocol for the study that you did, 02:07:25
correct? 02:07:27
A Even that, it's -- if we -- if we got the 02:07:29
protocol, if you -- if you would get it, I 02:07:31
would be happy to read it and then go 02:07:36
through individual events with you -- 02:07:37
individual types of events, because what I'm 02:07:39
trying to say, it's so different -- 02:07:44
Q All right. 02:07:46
A In other words, a serious cardiovascular 02:07:47
adverse event, you know, would be different 02:07:50
than a serious case of diarrhea. 02:07:52
Q Okay. 02:07:56

Let me -- let me just ask you this. 02:07:56
A I'm not saying necessarily -- not just worse 02:07:59
or better, but just so different. 02:08:01
Q Okay. 02:08:03
You see Exhibit 14 which has been 02:08:03
marked in this case, and it is the -- it's 02:08:05
actually the protocol, final protocol for 02:08:09
Study 329. 02:08:11
A Okay. 02:08:15
Q If you refer to 7.5.1, do you see where that 02:08:15
defines a serious adverse event? 02:08:20
A I can read it to myself or -- 02:08:27
Q Sure. 02:08:28
(Witness read document.) 02:08:29
A Yes. 02:08:46
Q Okay. 02:08:46
A See, this definition in here is so variable 02:08:46
that it's extraordinary. That's why I think 02:08:51
of it as a bucket that doesn't mean much 02:08:53
until you go after the individual. 02:08:57
So if you take the first sentence, "A 02:08:58
serious adverse event is any event which is 02:09:01
fatal, life-threatening, disabling, 02:09:03
incapacitating or results in 02:09:06

hospitalization." 02:09:08
Okay, those sound really bad, right? 02:09:09
"In addition, any experience which 02:09:12
the investigator regards as serious or which 02:09:16
would suggest a significant hazard, 02:09:18
contraindication, side effect or precaution 02:09:21
with reuse of the drug may be reported as 02:09:24
serious." 02:09:27
So if I said something, you know, is 02:09:27
a, you know, a side effect, meaning, you 02:09:33
know, meaning that I'm developing a tremor 02:09:36
when I take the drug, that's so different 02:09:40
than a fatality or something which is 02:09:45
life-threatening but with something which is 02:09:47
disabling, that the category I don't -- is 02:09:51
not -- 02:09:54
It's too general to be meaningful, in 02:09:55
my opinion. 02:10:00
Q Well, this is -- 02:10:01
A There should be -- there should be -- the 02:10:02
distinctions should be much finer. 02:10:04
Q Okay. 02:10:06
And the protocol you're looking at in 02:10:07
that exhibit is a protocol for 329, correct? 02:10:08

A Yes. 02:10:12
Q And that's a scientific study, correct? 02:10:12
A Yes. 02:10:16
Q Okay. 02:10:16
And so it's your goal in the 02:10:17
scientific study to have the investigators 02:10:21
all be on the same pages with regard to what 02:10:24
variables are being measured, correct? 02:10:29
A Yes. 02:10:31
Q And you want all the scientists to also 02:10:32
understand and have the same definition of a 02:10:34
serious adverse event, correct? 02:10:37
A Yes. 02:10:41
Q Okay. 02:10:43
A But the category here and the convention -- 02:10:43
and the convention that's used, in my 02:10:44
opinion, is not useful at all. 02:10:50
Q Okay. 02:10:53
A It's useful -- I don't want to be 02:10:53
misinterpreted to say it's -- it's 02:10:55
essential. It's essential to know if 02:10:58
something is fatal. It's essential to know 02:11:02
if it's life-threatening. It's essential to 02:11:04
know if it's disabling; and, yes, it's 02:11:07

essential to know whether it's a side effect 02:11:09
or precaution. 02:11:12
But those are so different that I 02:11:12
don't think it's -- I don't -- it's the 02:11:14
interpretation of it. 02:11:17
In other words, I can understand why 02:11:18
you want to pick up and grab everything that 02:11:20
looks like it might be important and dump it 02:11:22
in a pot; but when you then go to interpret 02:11:24
it and analyze it, you have to separate out 02:11:27
the individual events, as we did in the 02:11:30
manuscript on page 769, where I believe you 02:11:34
either asked me to read the first sentence 02:11:40
or you read it for me, in which you said 02:11:41
there were serious adverse events in 11 02:11:44
patients in paroxetine, five in imipramine 02:11:46
and two in placebo, and then we go on to 02:11:49
give, you know, with a number -- we describe 02:11:52
the event and give the number of patients 02:11:56
with that event. 02:11:59
That's where I believe it becomes 02:12:01
meaningful. And if you look at those, 02:12:04
you'll see how varied they are. 02:12:06
So five serious events in the 02:12:09

imipramine group consisted of a 02:12:11
maculopapular rash -- 02:12:12
Q All right. 02:12:15
I don't need you to go through each 02:12:15
and every one. 02:12:17
A I'm just trying to -- I think this is -- you 02:12:18
know, to the extent that this is such a -- 02:12:19
an important matter with regard to the issue 02:12:23
at hand and a matter with regard to 02:12:29
interpreting and understanding what you're 02:12:32
asking me, I just -- I just want -- I just 02:12:34
want to be clear. 02:12:37
Q You want to explain. I just don't want to 02:12:37
go through every specific -- 02:12:39
A All right. 02:12:40
Q We'll be here for five more days if we have 02:12:41
to go through all the specific things on 02:12:43
every question. 02:12:45
A I didn't know you could stay. 02:12:45
Q I might. I might have to. 02:12:49
(Laughter.) 02:12:50
A Cancel his flight. 02:12:51
Q Let me ask you this: 02:12:55
Were you aware -- first of all, do 02:12:56

you -- are you familiar with the term 02:12:58
"suicidality"? 02:13:00
A Yes. 02:13:01
Q Okay. 02:13:01
And were you aware that the results 02:13:02
from Study 329 found a fivefold increase in 02:13:06
suicidality in adolescents involved in the 02:13:10
study? 02:13:14
MR. DAVIS: Object to the form. 02:13:14
It's vague and ambiguous. 02:13:17
A Yes. You know, there again, maybe you can 02:13:19
tell me where I could find it in the paper. 02:13:30
Q I'm asking you if you're aware -- 02:13:32
A I don't remember the specifics. 02:13:34
Q Okay. 02:13:35
Well, have you at any time been 02:13:35
informed through literature, presentations, 02:13:37
speaking with colleagues that the results of 02:13:39
Study 329 indicated that those adolescents 02:13:42
who use Paxil are at a five-times greater 02:13:47
risk at experiencing suicidality than those 02:13:52
on placebo? 02:13:55
MR. DAVIS: Object to the form. 02:13:56
There's no foundation that that's 02:13:56

reflected in the article or the data you're 02:13:58
talking about. 02:14:00
A I don't understand your question. 02:14:00
You're saying in this -- in these 02:14:01
data? 02:14:03
Q No, I'm asking -- let me ask you this: 02:14:04
The question is, in the data that was 02:14:06
obtained from Study 329, have you ever 02:14:08
learned through publication, through 02:14:11
presentation or through speaking with 02:14:14
colleagues that the data indicated that 02:14:16
there is a fivefold increase in suicidality 02:14:20
for those adolescents who took Paxil as 02:14:24
opposed to placebo? 02:14:27
MR. DAVIS: Same objection. 02:14:29
A Are you saying -- are you saying that we 02:14:30
reported that in the paper? 02:14:31
Q I'm asking you have you ever heard ever that 02:14:33
there is a fivefold increase -- this data 02:14:36
shows -- the data from 329 shows there's a 02:14:39
fivefold increase in suicidality in those 02:14:42
adolescents who take Paxil compared to 02:14:45
placebo? 02:14:48
MR. DAVIS: Same objection. 02:14:49

Q Have you ever heard that? 02:14:49
A I'm not aware -- I don't believe that that's 02:14:50
reported in this paper. 02:14:55
Q No. 02:14:56
I'm asking you if you've ever heard 02:14:56
it. 02:14:59
A No. 02:14:59
Q I'm not asking about the paper. 02:14:59
A No. 02:15:01
Q You've never heard of that? 02:15:01
A No. 02:15:02
Q Has -- 02:15:03
A I do know -- I do know that data was -- data 02:15:03
from -- at some point it came to my 02:15:09
attention that almost every -- or that every 02:15:14
pharmaceutical company that had an SSRI, and 02:15:17
eventually including the companies that had 02:15:23
SNRIs as well, the dual reuptake inhibitors, 02:15:26
had to turn over all of -- either had to 02:15:31
analyze themselves or turn over their data 02:15:33
for someone else to analyze. I don't know 02:15:36
which of the two. 02:15:37
And I do know that there were 02:15:40
extensive FDA meetings and hearings to -- in 02:15:41

which people were called in -- and this is 02:15:47
within the past -- I don't know when, two 02:15:51
years ago, somewhere around two to four 02:15:52
years ago, and that definite -- 02:15:55
There was enormous debate and 02:15:59
discussion about the definition of 02:16:00
suicidality. 02:16:02
And eventually -- because I saw some 02:16:05
reports from hearings. And eventually, 02:16:07
excuse me, the data was -- 02:16:09
I don't know exactly how it worked, 02:16:12
but eventually a group at Columbia 02:16:13
Presbyterian or led by people there were 02:16:16
asked to take charge of reanalyzing the data 02:16:19
from the -- from all of the SSR studies, I 02:16:22
believe. 02:16:26
I don't know the outcomes of that, 02:16:27
but I do know that the definitions that were 02:16:29
arrived at at that period varied from the 02:16:35
definitions that were reported in any number 02:16:40
of the studies that were done. 02:16:44
In other words, they tried to create 02:16:46
a consensus, you know, a consensus 02:16:48
definition. 02:16:50

So I know that there was activity in that regard, but I never -- I did not learn anything specific about this study. 02:16:51 02:16:53 02:17:00

Q Okay. 02:17:05

So you aren't aware whether -- 02:17:06

A Except, except that there's an article which was produced -- not an article. There was a draft -- 02:17:07 02:17:09 02:17:15

There was an article or a draft of an article that I -- I don't remember if I produced it. 02:17:16 02:17:18 02:17:20

MR. GREEN: You produced it. 02:17:22

A The documents that I produced that I assume you're probably going to ask about at some point that was -- that combined the results from several studies of -- that were conducted that included Paxil. 02:17:23 02:17:26 02:17:27 02:17:33 02:17:37

And I did see that article, and I do remember -- though I can't remember now, I'd have to get into it, I do remember having concerns that the way things were being reported represented a difference from what we found, because different definitions were used, and that was not made explicit in that 02:17:39 02:17:42 02:17:44 02:17:47 02:17:52 02:17:56 02:17:58

report. 02:18:00

So, you know, as we're talking now, I do have a memory of that. With regard to the specifics of what it was and what's in that article, I don't remember. 02:18:01 02:18:06 02:18:07 02:18:09

So if you were to show me that article and if that article were to show rates of suicidality, you know, differences in suicidality rates between Paxil and placebo that are different than what we reported, what I would say to you, yes, I read that material. I don't remember what the findings are so -- 02:18:11 02:18:13 02:18:17 02:18:19 02:18:25 02:18:27 02:18:31 02:18:32

MR. DAVIS: I'm sorry. 02:18:37

A Is that -- so I'm trying to be responsive by saying I do know something about it. 02:18:37 02:18:39

I don't remember the details. I don't remember the specifics. And the number fivefold doesn't -- is not something I remember at all. 02:18:41 02:18:42 02:18:45 02:18:47

Q Okay. 02:18:48

MR. DAVIS: We designate discussions about the draft manuscript as confidential pursuant to the protective order. 02:18:49 02:18:50 02:18:53

MR. COFFIN: Okay. 02:18:55

Q Let's look at this Reviewer No. 2's -- continuing the same paragraph we were looking at, Reviewer No. 2 of the JAMA reviewers. 02:18:59 02:19:02 02:19:03 02:19:06

MR. GREEN: Exhibit 29. 02:19:07

A Which page, Chris? 02:19:09

Q I'm sorry, it's Exhibit -- yes, I think it's 29, page 6. 02:19:11 02:19:12

A Okay. 02:19:14

Q Do you see where it -- where it reads, "However"? 02:19:37 02:19:39

It's in the middle of the paragraph on the left side. 02:19:40 02:19:40

A The first -- top paragraph? 02:19:45

Q Yes, top paragraph, left side, about halfway down. 02:19:48 02:19:50

A Okay, I see "however." 02:19:50

Q It says, "However, given the high rate of primary care prescription of antidepressants and the readership of JAMA, it is important to emphasize the behavioral side effects in the minority of patients treated with paroxetine may be more serious than with 02:19:51 02:19:53 02:19:54 02:20:02 02:20:02 02:20:03

TCAs." 02:20:06

Do you agree with that? 02:20:08

A I don't think it's accurate, no. 02:20:13

Q Okay. 02:20:16

And do you agree that there's a high rate of primary care providers who prescribe antidepressants to adolescent population? 02:20:17 02:20:19 02:20:22

A I don't know if it's true with regard to adolescents. 02:20:27 02:20:30

I do know with regard to adults, I think we covered this -- 02:20:31 02:20:38

Q We did. 02:20:39

A -- that a high proportion of antidepressant prescriptions are done by primary care physicians. 02:20:39 02:20:44 02:20:47

I don't know if it's -- where -- I can't tell you how the percentages compare to psychiatrists, but it is -- it is a meaningfully high proportion of the antidepressant prescriptions in a primary care setting in adults. 02:20:50 02:20:53 02:20:57 02:20:59 02:21:01 02:21:04

I don't know about children. And, actually, we did talk about -- 02:21:06 02:21:07

Q Right. 02:21:09

You just don't know one way or the other how the numbers fall out for prescriptions of -- with children -- 02:21:10 02:21:11 02:21:13

A All right, yes, we did talk about it. I said I think the primary care doctors who specialize in adolescent medicine are probably much more likely to prescribe than those who are general. 02:21:15 02:21:18 02:21:20 02:21:23 02:21:25

And I do believe there's a reluctance on the part of primary care docs to treat adolescents and children with depression. 02:21:26 02:21:28 02:21:30

Q Right. 02:21:33

A But that's all. 02:21:33

Q Okay. 02:21:46

You see there's also another paragraph after the suggested revisions? 02:21:47 02:21:49

A Uh-huh, I do. 02:21:53

Q Do you see the second line there? 02:21:55

A "It is also easier to assume"? 02:21:56

Q Yes, but see the second line on that paragraph? 02:21:58 02:22:00

You could please read that? 02:22:00

A "Visits with experts in the treatment of adolescent depression"?. 02:22:02 02:22:05

Q No, "The authors." 02:22:07

A Oh. 02:22:09

"The authors do not sufficiently highlight that the level of psychological treatment provided in this study is much more intense than that covered by almost every healthcare insurance plan and far exceeds the usual time spent between a primary care physician and a depressed patient given continuing pressure from third-party payers and ongoing discrimination against psychiatric patients and psychiatric treatment (provided by generalists or psychiatrists)." 02:22:09 02:22:11 02:22:14 02:22:16 02:22:18 02:22:21 02:22:24 02:22:27 02:22:30 02:22:32 02:22:35 02:22:38

Q Do you agree with that statement? 02:22:40

A No. 02:22:46

Q And that's by a different reviewer than the reviewer we went through before who also commented on the effect in the study being related to good clinical management and not the medication, correct? 02:22:46 02:22:50 02:22:54 02:23:01 02:23:04

A But the part of this -- 02:23:06

Q Is that correct? 02:23:07

A Excuse me? 02:23:08

Q Is that correct? It's a different reviewer? 02:23:09

A I don't remember. You'd have to -- I mean -- 02:23:11 02:23:12

Q You don't remember? 02:23:14

A No. 02:23:15

Q Well, this is Reviewer No. 2. 02:23:17

A Okay. 02:23:19

Q Right? 02:23:19

A Right. 02:23:20

Q And it was Reviewer No. 1, if you flip back to page 2, who also commented on the bulk of the effect in the study was the result of good clinical management and not medication, correct? 02:23:20 02:23:22 02:23:27 02:23:29 02:23:32

A Yes, two different reviewers. 02:23:32

Now, the part of this that I think is just -- for which there's absolutely no evidence for the reviewer to state this is the -- what you asked me to read: 02:23:34 02:23:36 02:23:39 02:23:42

"The level of psychological treatment provided in this study is much more intense than that covered by almost every healthcare insurance plan and far exceeds"... 02:23:43 02:23:44 02:23:49 02:23:52

Now, I -- I can't imagine what the 02:23:54

factual basis is for that statement. I mean, I just can't imagine it. 02:23:59 02:24:01

I mean, I would like to see the evidence that this reviewer draws on. I'd like to see the source of data and evidence that this reviewer draws on in a scientific way to support the premise that -- that the amount of psychological treatment provided in this study is both more intense as well as -- than that covered by almost every insurance -- you know, than every insurance plan. 02:24:03 02:24:05 02:24:09 02:24:11 02:24:14 02:24:18 02:24:21 02:24:25 02:24:28 02:24:30

Because, in fact -- and I'd also like to see insurance plan records that prescribe the intensity of the psychological treatment you can give. 02:24:31 02:24:33 02:24:36 02:24:39

I mean, I am not aware -- I have never seen an insurance plan that prescribes -- that tells a primary, whatever he calls it, that tells a doctor the intensity with which they're allowed to give psychological treatment. 02:24:40 02:24:42 02:24:45 02:24:47 02:24:51 02:24:54

Q Do you understand that the point of this reviewer's comment and the other reviewer's 02:24:57 02:24:58

comment is that the therapy or clinical 02:25:00
management that was performed in Study 329 02:25:03
is far different than that that you actually 02:25:07
see in the clinical setting outside of a -- 02:25:10
of a clinical study? 02:25:12
A I read -- I -- the statement that you made 02:25:15
appears to be accurate that that's their 02:25:19
point. 02:25:22
Q But you disagree with this? 02:25:22
A But when you ask me if I agree, I am telling 02:25:24
you that I disagree, and I'm giving you my 02:25:26
reason. And I would challenge you or anyone 02:25:28
else to show me the data that supports this 02:25:33
statement. 02:25:36
I just -- I just -- to me, I would be 02:25:36
stunned if anybody could produce any data 02:25:39
that -- in an insurance plan which says -- 02:25:44
which prescribes the level of intensity of 02:25:47
treatment that a primary care physician is 02:25:51
allowed to give. 02:25:54
Q Yes. 02:25:55
But the point -- the point is -- 02:25:55
A This is just plain wrong. 02:25:56
Q Well, that's your opinion; but there's two 02:25:58

reviewers who are basically -- 02:25:59
A Well, no, no, no, it's not -- 02:26:01
Q There are two reviewers who are making the 02:26:02
same point about -- about data that was 02:26:04
published by you and other authors showing 02:26:07
that -- their point is that the clinical 02:26:09
trial setting cannot be carried over into 02:26:11
clinical practice. 02:26:14
A But that's not what they'd they said, Chris, 02:26:15
and we should live in a world of evidence; 02:26:18
and I assume that the jury in this case 02:26:19
want -- would want to see the evidence. 02:26:22
Q Absolutely. And they will. 02:26:24
A And I would encourage you to present the 02:26:26
evidence by showing a healthcare insurance 02:26:30
plan -- and I would appreciate it if you 02:26:34
send me a copy of a healthcare insurance 02:26:35
plan that says what the level of intensity 02:26:38
is of psychological treatment that primary 02:26:41
care doctors should use. 02:26:44
I've never seen it. 02:26:45
Q But you're -- that's -- that's not the point 02:26:46
of what either reviewer is saying. 02:26:48
A That is the point. 02:26:49

Q No. 02:26:50
A That is exactly the point. 02:26:51
Q The point -- 02:26:52
A I'm quoting. Chris, I'm giving a quote. 02:26:52
Q I hear what you're saying. I hear what 02:26:55
you're saying. 02:26:57
A Well, if a quote isn't the point -- 02:26:58
Q Let me ask you this -- 02:26:59
A -- then was it was maladroitly stated and it 02:26:59
wasn't -- it was -- it's wrong. It's just 02:27:04
wrong. 02:27:06
Q You didn't agree with the point that either 02:27:08
reviewer made about the use of case 02:27:10
management therapy actually being different 02:27:13
than that that is in the primary care 02:27:17
setting; is that correct? 02:27:19
A What I said earlier is a matter of record. 02:27:20
Q You didn't agree with that? 02:27:22
A I don't -- I'm not going to go back and give 02:27:23
a generalization. I'm dealing with a 02:27:25
specific point -- 02:27:28
Q I'm asking you a question. 02:27:28
A What's the question? 02:27:29
Q The deposition is I ask you the question and 02:27:30

you provide a response. 02:27:32
A Oh, I didn't realize that. 02:27:33
Q So all I'm asking is, you disagree with the 02:27:34
two reviewers who stated that the therapy -- 02:27:36
the clinical management therapy that was 02:27:40
provided for in Study 329 is different than 02:27:44
or not the same as what would be applied in 02:27:49
clinical -- in clinical practice. 02:27:53
You disagree with that, correct? 02:27:55
A I don't think you are accurately 02:27:57
characterizing what each of the two 02:28:00
reviewers said; so that if you were to go 02:28:04
back, Chris, and -- to each of the two 02:28:06
reviewers that you want to ask me about and 02:28:11
read me the sentence or the line or the 02:28:16
paragraph that you believe is germane to the 02:28:18
point you're asking me about, then I can 02:28:20
answer your question. 02:28:23
But I don't believe you're accurately 02:28:24
characterizing what's written. 02:28:25
Q Okay. 02:28:27
A I think it's just wrong. 02:28:27
Q I hear what you're saying. We'll let the 02:28:28
jury decide when they get to review it and 02:28:31

they get to hear testimony. All right. 02:28:33
MR. COFFIN: In the interest of time, 02:28:34
of which we have very little, Mr. Murgatroyd 02:28:36
is going to take over questioning. 02:28:40
I need to catch a flight, but we'll 02:28:42
obviously reserve our right, as we've 02:28:44
discussed earlier, to come back and talk to 02:28:46
you about this same subject material at a 02:28:48
later date. 02:28:52
So let's go off the record, and 02:28:53
Mr. Murgatroyd will take over. 02:28:54
THE VIDEOGRAPHER: Okay. The time is 02:28:56
2:30. We are off the record. 02:28:57
(Recess.) 02:28:59
THE VIDEOGRAPHER: Stand by. We're 02:31:47
back on the record. The time is 2:33. 02:31:48
CONTINUED EXAMINATION 02:31:49
BY MR. MURGATROYD: 02:31:51
Q Okay. 02:31:52
Doctor, before I go into some 02:31:52
questions that I've laid out, I want to pick 02:31:54
up on the question Mr. Coffin asked you 02:31:56
about the fivefold increase of the Paxil 02:31:59
kids experiencing suicidality over the 02:32:01

placebo kids. 02:32:05
Do you recall those questions? 02:32:06
A I do. 02:32:07
[redacted]
Q That actually is not correct, though. 02:32:15
I mean, you actually -- this was an 02:32:16
issue that had been presented to you by a 02:32:18
number of different reporters that you 02:32:20
personally responded to; is that correct? 02:32:22
MR. DAVIS: Object to the form. 02:32:24
A I don't remember. 02:32:25
Q Well -- 02:32:26
A If -- let me -- I'm saying I don't remember 02:32:27
if, in fact, there is -- 02:32:28
When you say "reporters," if it's in 02:32:37
the materials that I produced, then -- 02:32:38
Q It is, indeed. Let's take a look at it. 02:32:42
A I'm happy to go over it. 02:32:44
(Exhibit No. 31 marked for 02:32:45
identification.) 02:32:45

BY MR. MURGATROYD: 02:32:45
Q Great. I'm handing you Exhibit 31. 02:32:46
Take your time, look at that; and 02:32:49
then after you've read it, we'll identify it 02:32:51
for the record. 02:32:54
(Witness read document.) 02:32:55
MR. DAVIS: I'd like to look at that, 02:32:58
too, before you question him. It won't take 02:32:59
very long for me to look at it. 02:33:02
I would also designate the portion of 02:33:03
the transcript dealing with the draft 02:33:06
manuscript that he just referenced as 02:33:07
confidential pursuant to the protective 02:33:10
order. 02:33:12
MR. MURGATROYD: Okay by me. 02:33:15
MR. GREEN: I'll add that to the list 02:33:17
of things I won't talk about. 02:33:18
A I'm a little confused by the different 02:34:57
emails buried in here. This is all one -- 02:34:59
Q I got it from you, so -- 02:35:03
A No, no, no. 02:35:04
I'm trying to reorient myself. I 02:35:04
assume this is all one string? 02:35:06
Q I'm giving it to you the way it was produced 02:35:09

to me by your lawyer. 02:35:11
A I know. 02:35:13
Q Normally that's the case. 02:35:14
A Normally. I'm trying to line up the dates. 02:35:18
(Witness read document.) 02:35:32
A Okay. 02:36:33
Q Have you had a chance to review that 02:36:34
document? 02:36:36
A Yes. 02:36:37
Q Does that refresh your recollection that, in 02:36:37
fact, you were familiar with the fivefold 02:36:38
increase of Paxil patients over placebo 02:36:40
patients in their study? 02:36:42
MR. DAVIS: May I review it, pursuant 02:36:44
to my request? 02:36:45
Thanks, Doctor, before you answer 02:36:47
that... 02:36:49
(Counsel read document.) 02:36:50
A Do you have one of those in bigger print? 02:37:04
Q It's all I've got. It's only what you gave 02:37:07
me. 02:37:10
MR. GREEN: Blame me. 02:37:10
Q Doctor, do you recall the question that was 02:38:18
pending? 02:38:19

A One second. 02:38:23
(Witness read document.) 02:38:27
A I would appreciate it if you repeat it. 02:38:37
MR. MURGATROYD: I'll have the court 02:38:40
reporter read it back to you. 02:38:40
(Record read as requested.) 02:38:41
A Well, at the time -- no. 02:39:05
At the time Mr. -- Chris asked me the 02:39:12
question, I didn't recall this. So now that 02:39:17
I'm reading it, I -- I know that this is me 02:39:21
and I wrote it and I know I interacted with 02:39:29
it. 02:39:33
I mean, this is obviously something 02:39:33
that I was -- read carefully and -- 02:39:35
My understanding of what's written 02:39:53
here is that it was in the context of I 02:39:55
guess this report is -- questions, which is 02:40:03
sometime in 2005, that the issue of rates of 02:40:09
suicidality was examined. 02:40:12
It's -- from reading this, I believe 02:40:16
my initial response was that the rate of 6.5 02:40:18
to I had to do with emotional lability, 02:40:24
which was in the table. 02:40:29
What I believe to be the case, 02:40:32

because I've cross-referenced the article 02:40:33
since we -- we give examples of emotional 02:40:35
lability. 02:40:39
What I believe is the case is that 02:40:41
sometime -- at some point during the period 02:40:43
of time when there's various bodies, 02:40:45
external bodies, FDA and others, were 02:40:49
looking at this data, and I don't know the 02:40:52
process, but I believe GSK or someone else 02:40:59
went -- went -- reviewed the data and in 02:41:02
this instance examined -- from my 02:41:07
understanding, examined the narrative 02:41:15
reports that were written down and then had 02:41:17
those reviewed by -- by, you know, some 02:41:19
consensus group of individuals to define 02:41:26
what was considered suicidality. 02:41:32
So I don't -- I'm not sure that I 02:41:33
fully understand your question, Skip; but 02:41:36
what I think is going on here is that this 02:41:39
issue and discussion of it occurred 02:41:41
around -- around these dates. 02:41:45
Q Okay. Well, let's authenticate the document 02:41:47
first. 02:41:49
I think you agree that that is a 02:41:50

document that you produced in this 02:41:51
litigation? 02:41:53
A Yes. 02:41:53
Q Okay. 02:41:54
And you wrote that document? 02:41:54
A It's an email that I wrote. 02:41:57
Q Okay. 02:41:59
And you received that in the ordinary 02:42:00
course of your business? 02:42:01
A Yes. 02:42:03
Q Or wrote that? 02:42:03
A Yes. 02:42:05
Q Okay. 02:42:05
And does it discuss a fivefold 02:42:05
increase in suicidality in paroxetine 02:42:08
patients over kids who took placebo? 02:42:10
MR. DAVIS: Object to the form. 02:42:14
(Witness read document.) 02:42:17
A What -- I'm sorry, repeat the question. 02:42:36
MR. MURGATROYD: Can you read the 02:42:40
question back, please? 02:42:40
(Record read as requested.) 02:42:41
A Yes, it discusses it. 02:42:53
Q Okay. 02:42:54

Now, you agree that your study, 329, 02:42:55
did show a fivefold increase of suicidality 02:43:01
of kids taking Paxil over placebo? 02:43:04
That's not in dispute, is it? 02:43:08
MR. DAVIS: Object to the form. 02:43:10
A What I believe to be the case is that -- I'm 02:43:11
having trouble fighting through the language 02:43:17
here. 02:43:18
What I believe to be the case is that 02:43:18
what -- what we found and reported was a 02:43:25
fivefold increase in emotional lability. 02:43:31
And within the category of emotional 02:43:36
lability, it included suicidal ideation, 02:43:40
suicide attempts. I believe it included 02:43:44
worsening of depression. I believe it 02:43:47
included changes of mood. And that was the 02:43:48
information that we had at that time. 02:43:50
So I -- unless I'm really missing 02:43:58
something here... 02:44:00
Q I'm asking as of you sit here today, not as 02:44:03
of that time. 02:44:05
Do you agree that now that the data 02:44:06
is available, that Study 329 showed at least 02:44:09
a fivefold increase of suicidality in kids 02:44:14

taking Paxil over those kids who were taking placebo? 02:44:17 02:44:20

MR. DAVIS: Object to the form. 02:44:21

A I -- I -- it's my understanding that based on the redefinition of suicidality through this process that occurred sometime -- sometime around two to three years ago, that -- and reanalysis of this data somewhere around this time, that using those definitions and that reanalysis, that the rates of suicidality on paroxetine compared to placebo are in the fivefold range. 02:44:47 02:44:57 02:45:04 02:45:06 02:45:09 02:45:14 02:45:18 02:45:20 02:45:25

Q Okay. 02:45:31

And when you were doing the clinical trial, during the course of the clinical trial, you -- your site -- you had a site, correct? 02:45:32 02:45:34 02:45:36 02:45:39

A Yes. 02:45:40

Q Okay. 02:45:40

And you were were responsible for that site, correct? 02:45:41 02:45:43

A Yes. 02:45:44

Q And you had suicidality events occur among the kids at your site, right? 02:45:44 02:45:47

MR. DAVIS: Object to the form. 02:45:50

A I don't recall what was specific to our site. I believe in the end run, there were 15 sites in the study. 02:45:52 02:45:57 02:46:00

Q Right. 02:46:02

I'm asking about your site. 02:46:03

A And I -- 02:46:04

Q Do you recall the suicide events that occurred in your site? 02:46:05 02:46:07

MR. DAVIS: Object to the form. 02:46:08

A I do not recall it. If there were any suicide events at our site, we would have filled out incident reports and submitted those to the institutional review boards that, you know, had -- what's the word, you know, had governed the study. 02:46:09 02:46:12 02:46:14 02:46:17 02:46:20 02:46:26

And we had at least three institutional review boards that got -- that got each event. 02:46:28 02:46:30 02:46:33

So we would have to go back through the study records from the site at Brown, which was also conducted at two other hospitals, Butler and Rhode Island -- and Lifespan Hospitals, and see which ones. 02:46:34 02:46:36 02:46:40 02:46:43 02:46:45

I don't remember what -- 02:46:47

Q Okay. 02:46:50

A What happened at our site. 02:46:51

Q Okay. 02:46:52

A I'm not saying there werent. 02:46:52

Q Okay. That's all. 02:46:54

A But I'm sure if there are, we reported -- we did a full-blown incident report. 02:46:55 02:46:58

Q That's fine. 02:47:00

And we'll get into that at our next session, because I will show you documents that show there were such incidents at your site. 02:47:00 02:47:03 02:47:05 02:47:07

But my question is, when you reported those suicide events, did you code them personally as emotional lability? 02:47:07 02:47:09 02:47:11

Is that something you were told to do? 02:47:15 02:47:16

A No, I didn't -- I did not do any coding. 02:47:16

(Exhibit No. 32 marked for identification.) 02:47:16 02:47:18

BY MR. MURGATROYD: 02:47:18

Q Okay. 02:47:18

Now, let me show you what I've marked 02:47:19

as Exhibit 32. 02:47:21

MR. DAVIS: Can I see that before you hand it to -- 02:47:22 02:47:23

May I see that, Doctor, before you look at it? Thanks. 02:47:24 02:47:27

(Counsel read document.) 02:47:29

MR. DAVIS: This document has already been dedesignated as not being subject to the protective order, but it still bears the legend on it. 02:47:33 02:47:34 02:47:36 02:47:39

MR. MURGATROYD: You've got to send me a new one. 02:47:42 02:47:43

MR. DAVIS: I think I did. 02:47:43

MR. MURGATROYD: Did you? My -- my fault. 02:47:45 02:47:47

(Witness read document.) 02:47:47

A I've read it quickly to get the gist. 02:48:08

Q That's fine. 02:48:10

You see that it is an email from the FDA to GSK. 02:48:11 02:48:12

Do you recognize that as being so? 02:48:14

A I'm just trying to find the "from" and "to." From David Paul? 02:48:21 02:48:24

Q Yes. 02:48:25

You see where it says cedr.fda.gov at the top? 02:48:25

Right here, right here. 02:48:32

A Oh, David Paul -- 02:48:36

Q Right. 02:48:38

A -- at cderf [sic] -- yes, yes, yes, yes, yes. 02:48:40

Q Okay. 02:48:42

And it's addressed to Jim Murray, correct, at GSK? 02:48:43

A Yes. 02:48:45

Q Okay. 02:48:46

And you see that it references Paxil 329 at the bottom? 02:48:46

A Yes. 02:48:48

Q And it has in quotes "possibly suicide-related." 02:48:51

Do you see that? 02:48:52

A Yes. 02:48:56

Q And do you see that it has a risk ratio? 02:48:58

A Yes. 02:48:58

Q And what is that risk ratio? 02:48:59

A 5.9. 02:49:01

Q So that's actually a six -- almost sixfold 02:49:01

increase of suicidality in kids taking Paxil over placebo? 02:49:03

A Well, no, but -- 02:49:07

Skip, with -- what this says is possibly -- possibly suicide-related. It doesn't say suicide event. 02:49:11

Q Okay. 02:49:12

It says possible suicide-related? 02:49:14

A It says possible. There's a big difference between possible and suicide. 02:49:18

Q Okay. 02:49:21

And it's an increased rate now. Now we're seeing a sixfold rate instead of a fivefold rate? 02:49:23

A But -- no, Skip, please. It says possible. Possible isn't a suicide attempt. It is possibly suicide-related. 02:49:29

So there's a big difference. To qualify "possibly" is enormous. It's an adjective which qualifies it, so it doesn't say "suicide-related." It says "possibly." 02:49:33

Q Okay. 02:49:43

And it's a sixfold increase? 02:49:45

A It says it's possibly -- it -- 02:49:50

Q It's sixfold -- 02:49:55

02:49:57

A There's a -- there's a 5.9 risk ratio or, you know, approximately a sixfold increase. 02:49:57

Q Of paroxetine kids over placebo kids taking drugs, right? 02:50:01

MR. DAVIS: Objection to form. 02:50:01

Mischaracterizes the document. 02:50:02

A Not -- who -- with possible suicide-related events. 02:50:06

Q Okay. 02:50:09

So a child taking Paxil had a six-time increased risk of experiencing a possible suicide-related event as opposed to a child taking placebo, correct? 02:50:13

MR. DAVIS: Objection. 02:50:14

Mischaracterizes the study in terms of the participants. 02:50:15

Q Is that correct, Doctor? 02:50:17

A I'm sorry, just say it once more and I'll let you know. 02:50:20

MR. MURGATROYD: We'll have it read back to you. 02:50:21

(Record read as requested.) 02:50:22

A Yes. 02:50:34

Q Okay. 02:50:34

Now, let's drop down to suicide attempts. 02:50:35

Do you see that right below that? 02:50:37

A Yes. 02:50:37

Q And how many suicide attempts were on the drug? 02:50:38

MR. DAVIS: Object to the form of the question. 02:50:39

Mischaracterizes the document. 02:50:39

MR. GREEN: You can answer. 02:50:39

THE WITNESS: What? 02:50:40

MR. GREEN: You can answer. 02:50:40

A This says 5.4 percent. 02:50:41

Q Okay. 02:50:43

So that's -- so 5.4 percent of the kids who were in your study, 329, tried to kill themselves, correct? 02:50:43

MR. DAVIS: Object to the form. 02:50:45

Mischaracterizes the document and the data. 02:50:45

A I don't think that's correct. 02:50:46

Q Do you think the FDA has wrong numbers here? 02:50:46

A No. I think the way you stated it is -- is not precise enough. 02:51:48 02:51:53

Suicide attempts are then typically rated in terms of what's considered to be the intent of the attempt. So there are suicide attempts. 02:51:56 02:52:01 02:52:04 02:52:09

There are people that char -- some attempts are characterized as something and it's not thought to be an effort to kill oneself. 02:52:11 02:52:13 02:52:15 02:52:20

It's often perceived to be, you know, something between a -- they use the word gesture, which I don't particularly like, but itself-harm, self-harm. 02:52:21 02:52:25 02:52:32 02:52:35

And, in fact, I do know -- I -- I did read a quote from Tom Laughren of the FDA in which he made the statement that he thought that -- because it struck all of us, that -- that cutting one's wrist, you know, wrist slashing with a little bit of blood, he didn't see that as necessarily a suicide attempt. 02:52:38 02:52:41 02:52:46 02:52:48 02:52:52 02:52:55 02:52:58 02:53:01

Q Right. 02:53:02

A It was an attempt at self-harm. 02:53:03

So when you said -- when you -- what I'm objecting to, Skip, because this is such a serious matter, I mean, I know people, I know parents whose children have killed themselves, so I take this very seriously. 02:53:05 02:53:06 02:53:08 02:53:11 02:53:14

That the children were trying to kill themselves, I think that's an improper way to state it. 02:53:16 02:53:18 02:53:21

I think to go with the suicide attempt is different; and in many of these cases, I believe it was an attempt at self-harm or a gesture but definitely not an attempt to kill oneself. 02:53:23 02:53:26 02:53:29 02:53:32 02:53:37

Q Well, there were kids in Study 329 who did try to kill themselves, weren't there? 02:53:39 02:53:43

MR. DAVIS: Object to the form. 02:53:45

A I don't know that that's true. 02:53:46

Indeed, there have been no suicides reported on any of the -- by adolescents in any of the suicide databases, no actual suicides. 02:53:47 02:53:54 02:53:57 02:54:00

Therefore -- 02:54:02

Q Wait, let me stop you right there. 02:54:03

Are you talking about in clinical 02:54:05

trials or in -- 02:54:06

A Clinical trials. 02:54:07

Q Because there are suicide deaths by lots of kids who are given antidepressants and then not monitored and left alone that are registered in the FDA database, correct? 02:54:08 02:54:11 02:54:14 02:54:16

MR. DAVIS: Object to the form. 02:54:18

There's no data to support that. 02:54:20

A Yes, I don't -- I don't -- I'm not aware of any data to support that. 02:54:22 02:54:24

Q But -- 02:54:26

A But I can say -- 02:54:26

Q Well, let me just explore that for a second. 02:54:27

You're not -- you have -- 02:54:31

GSK has not shown you the documents that show the number of kids who kill themselves on Paxil? 02:54:32 02:54:33 02:54:34

A That is correct. 02:54:37

MR. DAVIS: Excuse me. Let me going to object to the form. 02:54:38 02:54:38

Let's stop with the grandstanding. 02:54:40

If you've got a serious, legitimate question, ask the witness; but don't make up data, don't make up facts, don't make up 02:54:42 02:54:44 02:54:45

what you call as evidence. 02:54:48

Ask him a serious, legitimate question. 02:54:49 02:54:52

MR. MURGATROYD: You can object and that's fine. 02:54:52 02:54:53

I asked him a question that I think is very important, because GSK knows that kids were killing themselves on Paxil -- 02:54:54 02:54:55 02:54:56

MR. DAVIS: You have got -- 02:54:59

MR. MURGATROYD: -- and they have documented them, and I will show him the documents. 02:54:59 02:54:59 02:55:01

MR. DAVIS: You have got no data -- 02:55:01

MR. MURGATROYD: I want to know whether or not -- 02:55:03 02:55:03

MR. DAVIS: You have no data to support that statement. 02:55:03 02:55:04

MR. MURGATROYD: Well, that's incorrect. You can lay your objection, and that's it. 02:55:05 02:55:05 02:55:07

MR. DAVIS: No, no. 02:55:08

BY MR. MURGATROYD: 02:55:08

Q My question to you, Doctor, has GSK ever showed you the data, the FDA data that shows 02:55:09 02:55:11

that kids were killing themselves on Paxil prior to the date of that email?

MR. DAVIS: Same objection.

No foundation for that question.

A I'm not sure whether the -- whether the yes and nos -- I don't know if there's a double-negative in your question, so if you just --

Q I want to know whether or not --

A Yes.

Q -- GSK has shared with you the data from the FDA database that showed kids were killing themselves on Paxil.

MR. DAVIS: Objection.

Q That's the only question.

MR. DAVIS: Object to the form.

A The answer is that GSK has never showed me any database that showed that kids were killing themselves, nor am I aware from any source that such a database exists.

Q Well, that would be --

A I have no knowledge of that.

Q Well, that would be very important to you, wouldn't it, for you to know that kids were

actually killing themselves on Paxil?

Wouldn't that be important to you?

MR. DAVIS: Object to the form.

It's argumentative.

A If it were an established scientific fact that kids -- but I believe we're talking about adolescents here in terms of 329; but if it were an established fact that kids or specifically adolescents were killing themselves, that would be something that would be -- that I would want to know about.

Q Okay. That's good.

A I don't know that that's true.

Q I will gladly show you the documents at the next session.

Now, going back to --

MR. DAVIS: Move to strike comments --

Q -- Exhibit 31.

MR. DAVIS: Comments of counsel.

Q Well, let me ask you this:

I showed you a document yesterday where GSK acknowledges that there was a definite risk of suicidality in kids,

correct?

MR. DAVIS: Objection.

MR. GREEN: You were going to show it to him, but you never did.

Q Oh, you never -- you never had a chance to read it?

MR. GREEN: No.

Q Okay. Let's look at Exhibit 24.

MR. MURGATROYD: Jim, can you dig that out for me, please?

MR. GREEN: That's the one we signed the notice about, but then you didn't --

MR. MURGATROYD: Yes, correct.

A Are we off the record?

Q No. We're going to stay on the record.

We need to move things along, or we're going to run out of daylight.

THE WITNESS: I think it's cortical function that's a higher, more immediate risk than daylight.

MR. GREEN: It wasn't 23 --

MR. MURGATROYD: It was 24 at the bottom.

MR. GREEN: Here it is. You want to

see it?

MR. DAVIS: Thank you.

(Counsel read document.)

MR. DAVIS: GSK designates discussions concerning these documents as confidential.

There's also been no foundation laid whatsoever that this witness has any knowledge of the document, has any familiarity with what issues are being discussed, the context of the discussions, or what data is being discussed and analyzed in the document.

MR. GREEN: And you'd like him to read it?

MR. MURGATROYD: Yes, please.

[redacted]

Now, do you contend that the results of Study 329 as written up in your article demonstrate efficacy in pediatric depression? 03:01:53 03:01:59 03:02:04 03:02:08

Efficacy of paroxetine in treating pediatric depression, to be exact. 03:02:13 03:02:14

A Yes. I believe as stated in the conclusion, that paroxetine -- that -- let me put it this way: 03:02:20 03:02:24 03:02:27

That this study, this -- the only thing I'm counting upon is this experiment. 03:02:28 03:02:33

Q Mm-hmm. 03:02:35

A That this study showed evidence that paroxetine is effective for major depression in adolescents. 03:02:36 03:02:40 03:02:44

And as a way -- a partial support for that would -- I believe that this is supported more broadly, that in some of the FDA materials that I did look at -- and I only saw parts of it -- there was a special notation made in one of the tables that 03:02:46 03:02:49 03:02:52 03:02:57 03:03:03 03:03:05

pointed out specifically that on several of the depression improvement outcome variables, Study 329 -- I don't know if they called it 329, but they were referring to this study -- did show evidence of efficacy. 03:03:10 03:03:14 03:03:16 03:03:21 03:03:23

So in that -- in the whole sea of studies that were reviewed and so on and so forth, specific mention was made in the table about this study showing evidence. 03:03:25 03:03:28 03:03:30 03:03:33

And the same, I believe -- I don't know whether it was someone that the FDA asked to review the materials or whether it was a member of the FDA, but I know I've read that. 03:03:37 03:03:39 03:03:42 03:03:48 03:03:51

Q Right. 03:03:52

And that was the table that stated that 329 was a negative or failed study? 03:03:52 03:03:54

Do you remember that part of the table? 03:03:57 03:03:58

MR. DAVIS: Objection. 03:03:58

A No. 03:03:59

Q Well, let me show it to you. 03:03:59

I believe what you're referring to is Thomas Laughren's memo. And I'm going to 03:04:16 03:04:17

mark as it Exhibit 33. 03:04:23
(Exhibit No. 33 marked for 03:04:27
identification.) 03:04:27
BY MR. MURGATROYD: 03:04:27
Q And there is a table -- 03:04:28
A Can I ask my counsel a question? 03:04:29
Q Sure, you can. You can go out -- you can go 03:04:31
off the record. 03:04:33
THE VIDEOGRAPHER: Don't forget your 03:04:34
microphone. It's four minutes after 3:00. 03:04:35
We're off the record. 03:04:40
(Recess.) 03:04:41
THE VIDEOGRAPHER: We are back on the 03:10:16
record. The time is 12 minutes after 3:00. 03:10:17
BY MR. MURGATROYD: 03:10:20
Q Before we took the break, Doctor, you said 03:10:20
you had reviewed or seen an FDA document 03:10:22
that had a table that referenced the -- some 03:10:25
efficacy coming out of 329; is that correct? 03:10:29
A Referening what? 03:10:32
Q Some efficacy coming out of 329? 03:10:33
A Yes, yes. 03:10:35
Q And I've presented you with an exhibit which 03:10:36
we've marked as Exhibit 33, correct? 03:10:38

A Yes. 03:10:41
Q Okay. 03:10:42
And I've shown you a table that's 03:10:42
attached -- that's part of that exhibit, 03:10:44
correct? 03:10:45
A Yes. 03:10:46
Q And is that the table you were referring to? 03:10:46
A There's something in addition to this that I 03:10:51
am pretty sure we produced. There's 03:10:56
something in addition to this, and I believe 03:10:59
it was -- 03:11:01
I don't see the name on here. Either 03:11:02
someone named Mosbach or -- there were two 03:11:04
people, Mosbach and someone else. 03:11:08
Q Mosholder. 03:11:11
A Something like that. 03:11:13
Q Yes. Okay. 03:11:14
A And another one, there was another 03:11:14
individual. 03:11:16
So in addition to this material, 03:11:16
which I think I've seen before -- 03:11:20
Q Okay. 03:11:22
A -- and I may even have produced this, I 03:11:22
believe there's something else. 03:11:24

Q Yes, I think we'll get to that in a minute. 03:11:26
Let's go to that table in the back. 03:11:27
A Okay. 03:11:29
Q Do you see the table in the back? 03:11:31
MR. DAVIS: Can I go off the record 03:11:34
and take this for a second? 03:11:35
THE VIDEOGRAPHER: The time is 3:13. 03:11:37
We're off the record. 03:11:38
(Exhibit No. 34 marked for 03:12:23
identification.) 03:12:23
THE VIDEOGRAPHER: We're back on the 03:12:32
record. The time is 3:14. 03:12:32
BY MR. MURGATROYD: 03:12:34
Q Okay. 03:12:35
And, Doctor, we were talking about 03:12:35
the chart that's attached or part of that 03:12:36
Exhibit 33, correct? 03:12:38
A Yes. 03:12:41
Q And does it reference Study 329? 03:12:41
A Yes. 03:12:43
Q And does it say that it was a negative 03:12:44
study? 03:12:46
A It says that it was -- it says the summary 03:12:47
is outcome negative, and the footnote is 03:12:51

Keller, et al. 2001; positive on most 03:12:56
secondary endpoints. 03:12:59
Q Okay. 03:13:01
So the -- 03:13:01
A And the description in here says one paper 03:13:02
describes one of the Paxil studies as a 03:13:04
positive on those secondary endpoints while 03:13:06
acknowledging that it failed on the primary 03:13:09
endpoint. 03:13:11
Q Okay. 03:13:12
A So I guess -- 03:13:13
Q And it's listed as a negative study, 03:13:14
correct? 03:13:16
MR. DAVIS: Object to the form. 03:13:17
A The interpretation in here is that it's a 03:13:18
negative study. 03:13:20
Q And that's consistent -- that's consistent 03:13:22
with the Mosholder statement that you were 03:13:24
talking about earlier, that you saw another 03:13:26
document by a man by the name of Mosholder 03:13:28
from the FDA? 03:13:31
Do you recall that? 03:13:32
A You'd have to show me. 03:13:33
Q All right. 03:13:34

I'm going to show you what I've marked as Exhibit 34, which is clinical review by a reviewer by the name of Andrew D. Mosholder, MD, MPH, dated 10/7/02. 03:13:36 03:13:36 03:13:40 03:13:42

And I will show you that he analyzed -- you can take a look through the document. I think you're familiar with it, the efficacy -- 03:13:49 03:13:54 03:13:56 03:13:57

A Yes. I have to see it again -- 03:13:58

Q Okay. Great. We'll let you take a look at that. 03:13:59 03:14:02

(Witness read document.) 03:14:03

MR. DAVIS: Can we go off the record again? 03:14:20 03:14:21

THE VIDEOGRAPHER: The time is 3:16. We're off the record. 03:14:22 03:14:24

(Recess.) 03:14:37

THE VIDEOGRAPHER: We're back on the record. The time is 3:17. 03:15:20 03:15:21

A Okay. 03:15:37

Q Okay. 03:15:38

And is that the document you were referring to a few minutes ago? 03:15:38 03:15:39

A I think so. 03:15:41

Q Okay. 03:15:41

And it is by Andrew Mosholder, you see that on the front cover? 03:15:42 03:15:45

A Yes. 03:15:46

Q And it does talk about three Paxil studies, and they refer to the treatment of MDD or Major Depressive Disorder. 03:15:47 03:15:49 03:15:52

Do you see that? 03:15:54

A Yes. 03:15:55

Q Okay. 03:15:55

And the three are 377, 701 and then your study, 329; is that correct? 03:15:56 03:16:01

A Yes. 03:16:04

Q Okay. 03:16:04

And with regard with 329, does Mr. Mosholder refer to it as a failed study? 03:16:04 03:16:08

MR. DAVIS: Object to the form. 03:16:12

A What he says is interesting. He says, "On balance, this trial should be considered as a failed trial." 03:16:17 03:16:20 03:16:24

Q Okay. 03:16:26

And why is -- 03:16:26

A And that neither -- 03:16:27

Q Okay. Go ahead. 03:16:29

A -- active treatment group shows superiority over placebo by a statistically significant margin. 03:16:30 03:16:33 03:16:35

So he's saying that on balance, he does -- he did enumerate at least four outcome measures which were positive. 03:16:38 03:16:40 03:16:46

Q But concluded that the trial was a failed study, right? 03:16:51 03:16:52

MR. DAVIS: Object to the form. 03:16:53

Q That's his words? 03:16:56

A Failed trial. 03:16:57

Q Okay. 03:16:57

And are you aware that GSK has disavowed your assertion that Study 329 showed efficacy of paroxetine in treating kids for depression? 03:16:58 03:17:03 03:17:07 03:17:09

MR. DAVIS: Objection to the form. Mischaracterizes the testimony. 03:17:09 03:17:11

A No. 03:17:16

Q Let's take a look at a whole slew of documents. 03:17:16 03:17:18

MR. DAVIS: Move to strike counsel's colloquy. 03:17:18 03:17:20

MR. MURGATROYD: We're at 35? 03:17:20

THE WITNESS: Well, actually, in terms of -- if I can elaborate in my response to your question, just because I -- 03:17:22 03:17:23 03:17:26

Though I don't remember the details, and I assume that we're going to go through the article, as I said to you earlier, because when I jumped and said no, there is this manu -- draft of the manuscript that GSK did send me that was produced which both aggregated the results three studies as well as had a reanalysis of the data in Study 329, and I don't remember the details of that, of what was in there right now. 03:17:33 03:17:33 03:17:37 03:17:41 03:17:45 03:17:50 03:17:55 03:17:57 03:18:01 03:18:05

When I look at it, I'm sure it will refresh me, but I do remember disagreeing strongly with the way the manuscript was constructed and the conclusions reached by the authors of the manuscript at GSK. 03:18:09 03:18:10 03:18:13 03:18:17 03:18:20

BY MR. MURGATROYD: 03:18:22

Q Okay. 03:18:22

A And there was quite a bit of exchange about that, so... 03:18:23 03:18:25

Q Yes, we'll get into that. 03:18:26

A So -- no, so what I'm saying, Skip, I'm 03:18:28

trying to make sure I don't misrepresent. 03:18:29
When I quickly answered no, it's 03:18:32
possible that what I was disagreeing with 03:18:35
was the -- the conclusion that they reached 03:18:39
through the process I described, which was 03:18:41
different than -- which I thought was not 03:18:43
accurate. 03:18:45
Q That's all right. 03:18:47
Well, let's take a look at the 03:18:47
conclusion they arrived at just by looking 03:18:49
at your study with the next document that 03:18:51
I'll show you, which is -- I've marked as 03:18:53
Exhibit 35. 03:18:55
(Exhibit No. 35 marked for 03:18:56
identification.) 03:18:56
(Witness read document.) 03:18:57
MR. DAVIS: And I'd like to see that 03:19:10
before the witness is questioned about the 03:19:11
document. 03:19:12
(Witness read document.) 03:19:12
A Okay, I've read that. 03:19:27
Q Okay. 03:19:28
MR. DAVIS: May I see that, please? 03:19:29
MR. MURGATROYD: Let's show it to 03:19:30

Mr. Davis. 03:19:31
(Counsel read document.) 03:19:32
MR. DAVIS: Okay. 03:19:39
MR. MURGATROYD: Okay. 03:19:40
Can I have that for a second? 03:19:42
MR. DAVIS: Okay. 03:19:43
BY MR. MURGATROYD: 03:19:45
Q And, Doctor, you see that that is an email, 03:19:50
correct? 03:19:54
A Yes. 03:19:56
Q Okay. 03:19:56
It's not addressed to you, though, is 03:19:57
it? 03:19:58
A No. 03:19:58
Q Okay. 03:19:59
And it's talking about Study 329; is 03:19:59
that correct? 03:20:02
Do you see that in the referenced 03:20:03
section of the email? 03:20:04
A Yes. 03:20:05
Q Okay. 03:20:06
And what -- do you see the sentence 03:20:06
that begins with the word "essentially" in 03:20:08
the first big paragraph? 03:20:10

A Yes. 03:20:13
Q Can you read that into the record, please? 03:20:14
A "Essentially the study did not really show 03:20:16
Paxil was effective in treating adolescent 03:20:19
depression, which is not something we want 03:20:21
to publicize. However, we should prepare a 03:20:24
Q&A and key messages in case reporters do 03:20:27
cover this study. The proofs would come in 03:20:31
handy." 03:20:34
Q Now, would you agree, sir, that that 03:20:37
statement is inconsistent with your 03:20:40
conclusion in your article that paroxetine 03:20:43
or Paxil is efficacious for kids who have 03:20:45
depression? 03:20:50
MR. DAVIS: Objection. 03:20:50
No foundation as to the circumstances 03:20:50
surrounding the document that the witness is 03:20:52
being presented with. 03:20:54
MR. GREEN: You can answer it. 03:20:56
A Yes, again, Skip, I'm not trying to be -- 03:20:57
well, I am trying to be precise. I'm not 03:21:00
trying to be picky unnecessarily. 03:21:03
You said kids and -- 03:21:05
Q Children and adolescents. 03:21:07

A No, I would say adolescents. 03:21:10
Q Okay. Fine. 03:21:12
A That -- so if you -- if you wouldn't mind 03:21:13
restating your question to me. 03:21:16
Q Well, I just want to know whether or not the 03:21:19
statement that you just read into the record 03:21:21
is inconsistent with the conclusion that you 03:21:23
drew or you state in your article. 03:21:26
MR. DAVIS: Same objections. 03:21:30
A It's -- it's inconsistent to an extent, but 03:21:42
not completely. It's a matter of emphasis, 03:21:45
because the sentence, as I read it, says, 03:21:48
"Essentially, the study did not really show 03:21:51
Paxil was effective." 03:21:58
And I think that we concluded, as was 03:22:01
characterized by Laughren or someone else, 03:22:06
that though our study wasn't positive on the 03:22:08
primary outcome measures, it was positive on 03:22:12
four other outcome measures. 03:22:17
So I don't think this is a -- you 03:22:19
know, I think it's a partial -- you know, 03:22:21
it's a disagreement in -- in emphasis. 03:22:27
But I -- and I don't really -- I 03:22:34
don't know specifically what was meant by 03:22:36

the phrase "did not really show." 03:22:38
Q Okay. 03:22:41
A But that may well have been the part which 03:22:41
was in agreement that we had for 03:22:44
statistically significant differences. 03:22:48
Q All right. Well, let's take a look at the 03:22:50
next document. 03:22:52
(Exhibit No. 36 marked for 03:22:53
identification.) 03:22:53
BY MR. MURGATROYD: 03:22:53
Q I think it's a little clearer, and I'll mark 03:22:53
this Exhibit 36. 03:22:56
It's a GSK sales connection memo that 03:22:57
has attached to it use of Paxil CR or Paxil 03:22:59
in pediatric patients. 03:23:02
And I've put a red sticky -- you're 03:23:04
free to read the document. I've put a red 03:23:07
sticky by the part that I'm going to 03:23:10
question you about. 03:23:13
MR. MURGATROYD: Todd, you need -- I 03:23:15
think you stuck a confidential stamp on that 03:23:16
as well as almost every other document 03:23:17
you've produced in this case, and I want to 03:23:21
know if you're willing to remove that from 03:23:23

under seal, as well as the previous 03:23:24
document. 03:23:26
Actually, this one isn't under seal. 03:23:27
MR. DAVIS: Well, if you're going 03:23:30
question him about the attachment -- 03:23:31
MR. MURGATROYD: Yes. 03:23:33
MR. DAVIS: That the attachment is a 03:23:33
medical information letter that gets sent to 03:23:34
healthcare providers upon an unsolicited 03:23:37
request, then that would not be subject to 03:23:39
the protective order. 03:23:41
MR. MURGATROYD: Okay. 03:23:43
How about the whole document? 03:23:43
MR. DAVIS: Certainly can -- yes, 03:23:54
we'll dedesignate that. That's fine. 03:23:57
BY MR. MURGATROYD: 03:23:59
Q All right. Doctor, if you would, take a 03:24:00
look at that exhibit. 03:24:02
The red tagged -- feel free to look 03:24:03
at the whole document, but I'm talking about 03:24:05
the paragraph that has the red sticky on it. 03:24:08
(Witness read document.) 03:24:25
A Okay. 03:24:47
Q Have you had a chance to review that? 03:24:48

A Yes. 03:24:49
Q Okay. 03:24:50
Can I see that for a second, please? 03:24:50
Can you read into the record, please, 03:24:59
the third bullet point that starts with the 03:25:00
word "from"? 03:25:02
A "From an efficacy standpoint, trials in 03:25:03
pediatric patients have shown Paxil to be 03:25:05
statistically superior to placebo in the 03:25:07
treatment of OCD and social anxiety 03:25:09
disorder. The studies did not show a 03:25:13
benefit for the treatment of MDD in children 03:25:15
or adolescents under the -- under 18 years 03:25:20
of age. Conclusions regarding efficacy and 03:25:22
safety of Paxil and Paxil CR in children and 03:25:25
adolescents for the treatment of panic 03:25:29
disorders, GAD and PTSD await further 03:25:31
study." 03:25:35
Q Okay. 03:25:36
We're just talking about Major 03:25:36
Depressive Disorder, correct? 03:25:38
And what does it say again regarding 03:25:39
just Major Depressive Disorder? 03:25:41
A The studies did not show a benefit for the 03:25:42

treatment of Major -- of MDD in children or 03:25:45
adolescents under 18 years of age. 03:25:48
Q And would you agree, Doctor, that that 03:25:51
statement is inconsistent with your 03:25:52
conclusion in your article? 03:25:54
A Yes. 03:25:55
Q Okay. 03:25:56
Let me show you the next document. 03:25:57
(Exhibit No. 37 marked for 03:25:59
identification.) 03:25:59
MR. DAVIS: Can I see that? 03:25:59
MR. MURGATROYD: 37 or 38? 03:26:09
Todd, what's the number on the front 03:26:12
of that? 03:26:14
MR. DAVIS: 37 -- excuse me, 36. 03:26:15
MR. MURGATROYD: 36? 03:26:19
MR. DAVIS: Yes, you're up to 37. 03:26:20
May I look at that, please, before 03:26:21
you show it to the witness? 03:26:23
MR. MURGATROYD: Yes. 03:26:25
(Counsel read document.) 03:26:26
MR. DAVIS: Okay. 03:26:37
(Witness read document.) 03:27:34
A Okay. 03:27:48

BY MR. MURGATROYD: 03:27:48
Q Have you had a chance to review that 03:27:48
document? 03:27:50
A Yes. 03:27:50
Q And can you identify for the record what 03:27:50
that document is? 03:27:52
It's a Dear Healthcare Provider 03:28:02
document? 03:28:04
A Yes, yes. 03:28:04
Q Okay. 03:28:05
And is it from -- look like -- does 03:28:05
it appear to be sent out from GSK? 03:28:06
A Yes. 03:28:08
Q Okay. 03:28:08
And can I see it for a second, 03:28:09
please? 03:28:11
MR. MURGATROYD: So the record's 03:28:15
clear, it's dated June 2003, which is in the 03:28:16
bottom right-hand corner. 03:28:18
Q And, Doctor, can you read the paragraph into 03:28:20
the record that starts with "A recently"? 03:28:23
A "A recently completed program of clinical 03:28:28
trials in children and adolescents under 18 03:28:32
years of age failed to demonstrate efficacy 03:28:33

in Major Depressive Disorder and there was a 03:28:36
doubling of the rate of reporting of adverse 03:28:40
events in the paroxetine group compared with 03:28:42
the placebo, including: Concluding 03:28:44
decreased appetite, tremor, sweating, 03:28:46
hyperkinesia, hostility, agitation, 03:28:49
emotional lability (including crying, mood 03:28:52
fluctuations, self-harm, suicidal thoughts 03:28:55
and attempted suicide)." 03:28:58
Q Now, would you agree, Doctor, that that 03:29:01
statement is inconsistent with the 03:29:02
conclusion that you drew or you stated in 03:29:03
your article in 329? 03:29:06
MR. DAVIS: Object to the form. 03:29:09
A Well, this Exhibit 37 does not specifically 03:29:26
refer to Study 329. It refers to a program 03:29:31
of completed clinical trials, so this does 03:29:38
not specifically contradict 329. 03:29:42
Q Well, 329 says the drug is safe and 03:29:50
effective, right? 03:29:53
I mean, your -- your article 03:29:54
basically says that Paxil was safe and 03:29:55
effective for kids, right? 03:29:57
A It says it's well-tolerated, and I -- I 03:29:59

don't think this agrees -- disagrees about 03:30:01
its being well tolerated, and -- 03:30:05
Q Does it disagree about it being effective? 03:30:08
A What I'm saying is that this says that the 03:30:10
recent -- the completed program of 03:30:12
studies -- 03:30:15
Q Right. 03:30:16
A -- whatever the word is, failed to 03:30:18
demonstrate. 03:30:21
Q Okay. 03:30:22
A I'm making a distinction between that. And 03:30:23
it doesn't comment specifically on this. 03:30:25
Q Okay. 03:30:27
Will you agree that 329 is included 03:30:27
in that program; will you not? 03:30:29
A Yes. 03:30:31
Q Okay. 03:30:31
Now -- 03:30:31
MR. DAVIS: Just to give you a 03:30:36
heads-up, it's almost 3:45. 03:30:36
MR. MURGATROYD: Okay. Thank you. 03:30:39
BY MR. MURGATROYD: 03:30:42
Q Doctor, would you consider a drug that 03:30:43
causes -- that has a sixfold increase of 03:30:45

possible suicide events of kids or children 03:30:47
and adolescents who take Paxil over those 03:30:53
who take placebo to be a safe drug? 03:30:54
MR. DAVIS: Object to the form. 03:30:59
A I think the issue is one of tolerability and 03:31:21
degree and safety to an extent. 03:31:31
The concern I have about this whole 03:31:48
issue is that the distinction's been blurred 03:31:49
between possible suicide events, some of 03:31:57
which were rather minor efforts of -- of 03:32:04
self-mutilation or self-harm and between a 03:32:13
child -- an adolescent or a child; but I'm 03:32:17
more talking about the adolescents 03:32:23
attempting to kill themselves. 03:32:26
Now, killing oneself certainly -- and 03:32:28
an effort to kill oneself, to the extent 03:32:32
that that's the case, I would certainly 03:32:35
think that any medication that did that is 03:32:37
not safe. 03:32:42
Q Okay. 03:32:43
A But I'm just -- I'm just wanting to be 03:32:43
careful. 03:32:46
Q I understand. 03:32:47
A Because of the -- how important the issue 03:32:48

is. 03:32:50
Q I agree, and I appreciate your candor. 03:32:50
A To not, you know, blur the -- to not lump 03:32:52
everything. 03:32:55
Q Okay. That's fine. 03:32:56
Now, we have a lot more documents. I 03:33:02
think we've agreed to one more day. I think 03:33:04
Mr. Davis needs to leave to catch his plane. 03:33:06
I think you asked to stop at this 03:33:08
time. Is that correct, Todd? 03:33:10
MR. DAVIS: We all agreed that we 03:33:12
were going to stop at 4:00, and I've just 03:33:13
asked for an additional -- or 3:45, I guess, 03:33:15
is when we talked about stopping. 03:33:18
I just asked for an additional couple 03:33:19
of minutes so I could get on a plane. 03:33:21
MR. MURGATROYD: Okay. 03:33:24
I'm obviously not going to requite 03:33:24
you a couple of minutes, so we will stop for 03:33:27
now. 03:33:29
THE WITNESS: Okay. 03:33:30
BY MR. MURGATROYD: 03:33:30
Q And we'll pick this up at a date that's 03:33:30
convenient to you. 03:33:32

A Okay. 03:33:32
Q And if it's okay with you, we'd like to 03:33:32
communicate with your counsel, Mr. Green -- 03:33:34
A Sure. 03:33:36
Q -- to get an appropriate date and time. 03:33:36
A Yes. 03:33:38
MR. MURGATROYD: Okay? 03:33:38
MR. GREEN: Mm-hmm. 03:33:38
MR. MURGATROYD: Thank you. 03:33:40
MR. DAVIS: I reserve the right to -- 03:33:40
well, I think until the deposition is 03:33:44
complete, I think it's appropriate that -- 03:33:46
that the deposition not be utilized until 03:33:48
the questioning that I have is done, and 03:33:52
that's what's -- what the next session is 03:33:54
designed to do. 03:33:56
MR. MURGATROYD: Okay. 03:34:00
THE WITNESS: I have a question. Am 03:34:00
I -- am I free to go when you guys discuss 03:34:01
this? 03:34:03
MR. MURGATROYD: Yes, you're done. 03:34:03
THE VIDEOGRAPHER: The time is 3:35. 03:34:04
We're off the record. 03:34:06
(Discussion off the record.) 03:34:20

MR. MURGATROYD: By stipulation of 03:34:42
counsel, provided Mr. Davis agrees, that 03:34:45
under California law, you're supposed to 03:34:48
maintain the original, but we're going to 03:34:49
relieve you of that duty, and you're going 03:34:51
to send the original to me at Baum Hedlund. 03:34:54
You're going to send a copy to 03:34:59
Mr. Green at our expense, who will forward 03:35:01
it to Mr. -- Dr. Keller for his review and 03:35:04
signature and with a note that any changes 03:35:08
need to be forwarded on to me. Okay? 03:35:13
Todd, you agree to that? 03:35:17
MR. DAVIS: I agree. 03:35:18
MR. MURGATROYD: Thank you very much. 03:35:18
(Proceedings adjourned at 3:35 p.m.) 03:35:19

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EXHIBITS

CERTIFICATE

I, Jill K. Ruggieri, Registered Merit Reporter and Certified Realtime Reporter, do certify that the deposition of MARTIN B. KELLER, M.D., in the above-captioned matters, on September 7, 2006, was stenographically recorded by me, having been duly sworn by me, a Commissioner of Deeds for the State of Rhode Island and Providence Plantations; that the transcript produced by me is a true record and accurate record of the proceedings to the best of my ability; that I am neither counsel for, related to, nor employed by any of the parties to the above action; and further that I am not a relative or employee of any attorney or counsel employed by the parties thereto, nor financially or otherwise interested in the outcome of the action.

_____

Jill K. Ruggieri, RMR/CRR

My commission expires: April 7, 2007