1 IN THE UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS 2 _____ IN RE: CELEXA AND LEXAPRO :MDL NO. 2067 3 MARKETING AND SALES PRACTICES : Master Docket No. LITIGATION :09-MD-2067-(NMG) 4 PAINTERS AND ALLIED TRADES :Case No. 13-CV-13113 5 DISTRICT COUNCIL 82 HEALTH : (NMG) CARE FUND, A THIRD-PARTY : HEALTHCARE PAYOR FUND, on 6 : behalf of itself and all : 7 others similarly situated, : Plaintiffs, 8 v. 9 FOREST PHARMACEUTICALS, INC. : and FOREST LABORATORIES, INC.,: 10 Defendants. 11 IN RE: CELEXA AND LEXAPRO :MDL NO. 2067 MARKETING AND SALES PRACTICES : Master Docket No. 12 :09-MD-2067-(NMG) LITIGATION DELANA S. KIOSSOVSKI and :Judge Nathaniel M Gorton 13 RENEE RAMIREZ, on behalf of : themselves and all others :Case No. similarly situated, :14-CV-13848 (NMG) 14 15 Plaintiffs, : v. 16 FOREST PHARMACEUTICALS, INC. : and FOREST LABORATORIES, INC.,: 17 18 Defendants. ______ 19 20 NOVEMBER 4, 2016 21 CHARLES FLICKER, Ph.D. _ _ _ 22 GOLKOW TECHNOLOGIES, INC. 23 877.370.3377 ph /917.591.5672 fax deps@golkow.com 24

1	Videotaped sworn deposition of CHARLES
2	FLICKER, Ph.D., held at The Wilshire Grand
3	Hotel, 350 Pleasant Valley Way, West Orange,
4	New Jersey, commencing at 7:48 a.m., before
5	Margaret M. Reihl, a Registered Professional
6	Reporter, Certified Court Reporter, Certified
7	Realtime Reporter, and Notary Public.
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1	THE VIDEOGRAPHER: We are going on the
2	record at 7:48 a.m. on Friday, November 4th,
3	2016. Please note that recording will continue
4	with any objection to going off the record. My
5	name is Bob Jorissen, your certified legal
6	videographer associated with Golkow. This
7	deposition is being held at the Wilshire Grand
8	Hotel located at 350 Pleasant Avenue Way, West
9	Orange, New Jersey. The caption of this case
10	is re: Celexa and Lexapro marketing and sales
11	practice litigation, Kiossovski and Ramirez on
12	behalf of themselves and all others similarly
13	situated versus Forest Pharmaceuticals, Inc.,
14	et al. in the United States District Court for
15	the District of Massachusetts.
16	The name of the witness is Charles
17	Flicker. Appearances will be noted on the
18	stenographic record. At this time our court
19	reporter, Peg Reihl, of Golkow will swear in
20	the witness and we can proceed.
21	Go ahead, Peg.
22	CHARLES FLICKER, Ph.D., having been
23	duly sworn as a witness, was examined and
24	testified as follows

1 BY MR. BAUM: 2 Ο. Good morning, Dr. Flicker. 3 Can you please state and spell your full name for the record. 4 5 Α. C-h-a-r-l-e-s F-l-i-c-k-e-r, Charles Flicker. 6 7 Do you have a middle name? Ο. 8 Edward, E-d-w-a-r-d. Α. 9 What is your current address? 0. 10 Α. 1155 North Courtney Avenue, Merritt 11 Island, Florida 32953. 12 0. What are you doing up here? 13 It's where my daughter lives. Α. 14 Okay. Mine lives up here too. Q. 15 You're represented by counsel today? 16 Α. Yes. 17 How did you come about having counsel Q. 18 here today? 19 They contacted me by telephone. Α. 20 Is your attorney -- are your attorneys Ο. 21 paid by Forest? 22 Α. Not sure. 23 Ο. You don't know who's paying them? 24 I'd say that's a reasonable conjecture. Α.

1	Q.	You're not paying them yourself?
2	Α.	No.
3	Q.	You've been deposed before, right?
4	Α.	Yes.
5	Q.	How many times?
6	Α.	I think twice.
7	Q.	One was in connection with securities
8	litigation; is	that correct?
9	Α.	Securities? I don't know if it was
10	securities.	
11	Q.	What do you think the depos the
12	depositions th	at you already underwent were about?
13	Α.	There was a it was a Department of
14	Justice invest	igation.
15	Q.	Regarding Celexa or Lexapro?
16	Α.	It must have been Celexa. I'm not sure.
17	Q.	Do you know what the what they were
18	trying to find	out about?
19	Α.	I believe there were a number of issues,
20	but I was aske	d about Celexa marketing.
21	Q.	Do you recall what you said?
22	Α.	Not really. I mean fragments.
23	Q.	Did you get a copy of the transcript of
24	those depositi	ons?

1	Α.	No.
2	Q.	So there were two depositions?
3	Α.	Perhaps one.
4	Q.	One deposition?
5	Α.	Perhaps one, perhaps two.
6	Q.	One with a court reporter?
7	Α.	It was definitely a court reporter at
8	one.	
9	Q.	Okay. And the other was maybe being
10	interviewed by	a couple of US attorneys?
11	Α.	Yeah, I don't really remember.
12	Q.	Do you remember when they were?
13	Α.	About ten years ago.
14	Q.	Well, you understand that you're under
15	oath today, co	prrect?
16	Α.	Mm-hmm.
17	Q.	That's the same oath as if you were
18	sitting in a c	courtroom in the witness stand in front of
19	the jury and a	judge.
20		Do you understand that?
21	Α.	Yes.
22	Q.	Okay. So we have a court reporter here,
23	and her job is	to take down each question and each
24	answer and get	every word we say, and so it's important

1	for us to try to make a clean record for her and so
2	that your answers need to be oral. Shaking your head
3	or saying uh-huh or uh-uh are hard for her to
4	transcribe.
5	Did you get that?
6	A. I'll try not to mumble.
7	Q. Good, and I'll try not to as well. It's
8	also important that if possible only one of us talk at
9	a time. So I sometimes ask long questions, and at the
10	very end stick a word on the end and it makes the
11	difference of what the question means and changes what
12	your answer might be, and it also gives your attorneys
13	an opportunity to object.
14	When they object, it means that they are
15	making a comment or a query or a placeholder so that
16	they can talk to the judge and say my question wasn't
17	any good and may want to strike the answer, but unless
18	they tell you not to answer, even if they object, you
19	should go ahead and answer.
20	Does that make sense?
21	A. Yes.
22	Q. At the end of the deposition, after it's
23	done the court reporter will make a transcription of
24	it, and you'll have an opportunity to take a look at it
<u> </u>	Tachnologiag Ing Dago 11

1	and make corre	ections. If you do make corrections, if
2	this gets pres	sented at trial or you appear at trial,
3	I'll be able t	to comment on the fact that you made
4	corrections.	So try to give your best answers if you
5	can today, oka	ay?
6	Α.	Okay.
7	Q.	Are there any medical reasons for your
8	not being able	e to give your best testimony today?
9	Α.	No.
10	Q.	Okay. Are you under any medications
11	that would int	erfere with your memory or being able to
12	give your best	answers?
13	Α.	No.
14	Q.	Have you had any contact with Forest
15	attorneys abou	at today's deposition?
16	Α.	Yes.
17	Q.	What contact did you have?
18	Α.	I met with them yesterday.
19	Q.	For how long?
20	Α.	A couple of hours.
21	Q.	You understand that you're here today in
22	connection wit	ch lawsuits involving the drugs Celexa and
23	Lexapro?	
24	Α.	I understood Celexa, I guess Lexapro
L		

also. 1 2 Ο. Okay. And Celexa is the brand name of 3 citalopram? 4 Α. Yes. 5 Q. And Lexapro is the brand name for escitalopram? 6 7 Α. Yes. 8 And do you understand that they're both Q. 9 SSRIs? 10 Α. Yes. 11 Ο. Are you familiar with any of the allegations in the complaint that's the subject of this 12 13 litigation? 14 MR. ROBERTS: I just want to object and 15 say to the extent that we had any conversations yesterday, you're not to discuss that, that's 16 17 privileged, but anything -- any independent 18 recollection that you have of the allegations, 19 you can answer. 20 THE WITNESS: Then the answer would be 21 no. 22 BY MR. BAUM: 23 Ο. You didn't read the complaint? 24 Α. No.

1 Q. And so your only understanding wh	nat the
2 allegations are based on information that your 1	awyers
3 discussed with you yesterday?	
4 A. Yes.	
5 Q. Did you have any contact with For	rest
6 lawyers before yesterday?	
7 A. Ten years ago.	
8 Q. But since then you've not had any	7
9 meetings with them?	
10 A. No.	
11 Q. No telephone calls?	
12 A. No. Well, they called regarding	this
13 case.	
14 Q. To set up the	
15 A. Yes.	
16 Q. The place and date, okay.	
17 Are you aware that there have bee	en legal
18 actions concerning Forest's off-label marketing	of
19 Celexa to children and adolescents?	
20 MR. ROBERTS: Objection. You can	1
21 answer, to the extent you have any indep	endent
22 knowledge.	
23 THE WITNESS: Could you repeat th	le

1	BY MR. BAUM:
2	Q. Yeah, are you aware that there have been
3	legal actions against Forest for off-label marketing of
4	Celexa to children and adolescents?
5	MR. ROBERTS: Objection.
6	THE WITNESS: That's what I thought the
7	DOJ thing included.
8	BY MR. BAUM:
9	Q. I think you're right about that.
10	And according to your 2007 deposition,
11	you testified that you were interviewed by the
12	Department of Justice lawyers regarding the off-label
13	promotion of Celexa in the pediatric population, right?
14	A. I think we're agreed on that, yeah.
15	Q. Do you recall if the attorneys were Jim
16	Arnold and Greg Shapiro?
17	A. For the Department of Justice?
18	Q. Yes.
19	A. No.
20	Q. You don't recall their names?
21	A. No.
22	Q. And are you aware that Forest pled
23	guilty to misbranding in that case?
24	A. No.

Have you followed any of the outcomes of 1 0. that litigation, seen it in the press, anything like 2 that? 3 4 Α. Yes. 5 Q. What was your understanding of what happened? 6 7 Α. I don't remember. Forest paid a fine is 8 my recollection. 9 Ο. Do you know what the fine was for? 10 I don't remember what the fine was for. Α. It didn't seem to me that it had anything to do with 11 the marketing of even citalopram, as I recollect, but I 12 don't really remember. 13 14 Okay. Well, I'm going to show you some Ο. 15 documents, and that might, you know, refresh your recollection. 16 17 Now, are you aware that Forest employees such as William Heydorn and James Jin have been deposed 18 19 in this present case? 20 Α. No. 21 Have you had any contact with any Forest 0. 22 employees over the last ten years? 23 Α. Yes. 24 Who have you had contact with? Q.

1	Α.	I spoke to Anjana Bose not that long
2	ago.	
3	Q.	When was that?
4	Α.	Several years ago, actually.
5	Q.	Have you spoken to any Forest employees
6	about this par	ticular deposition?
7	Α.	No.
8	Q.	Are you aware that Karen Wagner has been
9	named as a co-	conspirator in this case?
10	Α.	No.
11	Q.	Have you had any communications with any
12	of the vendors	s for Forest, that were working with
13	Forest at the	time you were there?
14	Α.	No.
15	Q.	Natasha Mitchner?
16	Α.	No.
17	Q.	Mary Prescott?
18	Α.	No.
19	Q.	Christina Goetjen?
20	Α.	No.
21	Q.	Do you recall those people?
22	Α.	I recall Mary Prescott.
23	Q.	Did you review any documents in
24	preparation fo	or your deposition today?

1	A. I looked at some documents, yeah.
2	Q. And what documents did you look at?
3	MR. ROBERTS: Objection. To the extent
4	that you can answer any documents that
5	reflects reflected your
6	MR. BAUM: Refreshed.
7	MR. ROBERTS: refreshed your
8	recollection that we sort of talked about
9	yesterday, so to the extent that you remember
10	any documents that specifically refreshed your
11	recollection, you can answer.
12	So if there's any documents that we
13	showed you that refreshed your recollection,
14	you can answer.
15	THE WITNESS: What was the question
16	again?
17	BY MR. BAUM:
18	Q. Did you review any documents in
19	preparation for your deposition?
20	A. Yes.
21	Q. And what documents did you review?
22	MR. ROBERTS: To the extent they
23	refreshed your recollection, you can answer.
24	THE WITNESS: That refreshed my

1	recollection or that I had seen before or?
2	MR. ROBERTS: Refreshed your
3	recollection.
4	THE WITNESS: What does that mean?
5	MR. ROBERTS: That you saw.
6	THE WITNESS: When I saw them I
7	remembered them or when I
8	BY MR. BAUM:
9	Q. Saw them they reminded you of things
10	related to this action
11	MR. ROBERTS: Yes.
12	BY MR. BAUM:
13	Q and related to things that you
14	experienced back when you were working for Forest?
15	A. Well, they included the citalopram child
16	and adolescent depression protocol and the related
17	study report and a variety of communications related to
18	the drug packaging error.
19	Q. These were e-mails or memos?
20	A. E-mails, fax, memos, yeah.
21	Q. Some of them had your name on them?
22	A. Yes.
23	Q. Some from Dr. Tiseo?
24	A. Tiseo, yes.

1	Q.	Tracey Varner?
2	Α.	Tracey? I don't know.
3	Q.	Now, we have a transcript of your 2007
4	deposition. Ha	ave you reviewed that recently?
5	Α.	No.
6	Q.	Did you ever look at it?
7	А.	I don't think so.
8	Q.	Based on your recollection of what
9	happened, to th	ne limited extent you do recall, do you
10	have any feelin	ng that you need to change any of the
11	answers you gav	ve in the 2007 deposition?
12	А.	I told the truth then.
13		MR. BAUM: Okay. Let's mark as Exhibit
14	1 the 1	notice for the deposition.
15		(Document marked for identification as
16	Flicker	r Deposition Exhibit No. 1.)
17	BY MR. BAUM:	
18	Q.	And I'm just going to just show this to
19	you. So this :	is the notice that you're appearing
20	under.	
21		Do you recall receiving a subpoena?
22	Α.	Yes.
23	Q.	And so you're under subpoena to appear
24	for a depositio	on, and you've appeared and I appreciate
	ow Tochnologiog	

that. 1 2 How did you come to be involved in the Celexa pediatric trials? 3 4 I was working --Α. 5 MR. ROBERTS: Objection. 6 You may answer. 7 BY MR. BAUM: 8 You're going to have to get used to Q. 9 that. He's going to say that a lot, and unless he says don't answer that question, just pretend he didn't say 10 11 anything. 12 Α. All right. 13 Q. You want me to start again? 14 How did I get involved? Α. 15 Ο. Yes. 16 Α. I was working at Forest Laboratories, and the project was under my purview. 17 18 This is around 1999 or so? Q. 19 MR. ROBERTS: Objection. 20 THE WITNESS: I don't recall. Based on 21 the documents I saw yesterday, I know it was 22 probably around 1999. 23 BY MR. BAUM: 24 And one of the Celexa pediatric trials 0.

was CIT-MD-18? 1 2 MR. ROBERTS: Objection. 3 THE WITNESS: Yes. 4 BY MR. BAUM: 5 Q. And you had some responsibilities in the medical department for Forest? б 7 MR. ROBERTS: Objection. 8 THE WITNESS: It was the -- yeah, I don't know if it's called medical or clinical 9 research. It was the medical area. 10 11 BY MR. BAUM: 12 0. Did you participate in the process of gaining regulatory approval of Celexa? 13 14 Α. Yes. 15 In your 2007 deposition you said that 0. 16 you were a medical director of CNS research. 17 Does that ring a bell? Medical director? Yeah. Well, at one 18 Α. point I was senior director. At one point I was the 19 20 executive director. I don't know if I was ever medical 21 director, but it might have been my title. 22 Q. Okay. You were director of something in 23 the CNS department? 24 Yes. Well, no, it wasn't the CNS Α.

1	department. It was the clinical research department.
2	Q. Okay. Were you involved in the
3	application of the FDA to gain an indication for the
4	pediatric use of Celexa in major depression?
5	A. I was surprised I believe so. There
6	was definitely a filing.
7	Q. What were you surprised about?
8	A. Well, I was
9	MS. KIEHN: Hold on, just to the extent
10	that you're about to reveal communications
11	you've had with us, you shouldn't testify about
12	those.
13	MR. ROBERTS: Any conversation we had
14	yesterday, anything about that, you can't talk
15	about.
16	BY MR. BAUM:
17	Q. But to your own recollection?
18	A. Can you repeat the question.
19	Q. Yes. Were you involved in the
20	application to the FDA to gain an indication for the
21	pediatric use of Celexa in major depression?
22	A. Yeah, I believe I was.
23	Q. And what were you surprised about?
24	MS. KIEHN: Objection. He's not going

1	to answer that question.
2	MR. BAUM: You're directing him to not
3	answer that question?
4	MS. KIEHN: It would require revealing
5	privileged information.
6	MR. BAUM: How do you know that?
7	MS. KIEHN: Because I know what he's
8	going to say.
9	BY MR. BAUM:
10	Q. All right. Do you have any independent
11	recollection of why you were surprised about something?
12	A. No.
13	Q. So your only basis of surprise was
14	something that your attorneys told you?
15	A. Yes.
16	Q. Was it something that the attorneys were
17	surprised about or something that you, yourself were
18	surprised about?
19	MR. ROBERTS: Objection.
20	THE WITNESS: I was surprised.
21	BY MR. BAUM:
22	Q. Okay. Well, we'll circle back around to
23	that later at some point, maybe something that I show
24	you will refresh your recollection.

1	Were you also involved in the
2	application to the FDA to obtain the pediatric to
3	extend the pediatric exclusivity let me say it
4	again to obtain a pediatric exclusivity extension
5	for Celexa in the US?
6	MR. ROBERTS: Objection.
7	THE WITNESS: Isn't that the same thing?
8	BY MR. BAUM:
9	Q. One is to get an indication to market
10	the drug for prescription to children, the other is to
11	extend the patent in general.
12	A. In my mind, the two are intermixed.
13	Q. Okay. But you recall working on
14	something to get the patent extended for Celexa?
15	A. Yes.
16	Q. Okay. And that had something to do with
17	a couple pediatric trials?
18	MR. ROBERTS: Objection.
19	THE WITNESS: Yes.
20	BY MR. BAUM:
21	Q. And those two trials were MD-18 and
22	94404, Lundbeck 94404?
23	MR. ROBERTS: Objection.
24	THE WITNESS: No. Forest didn't

undertake 94404. 1 2 BY MR. BAUM: 3 0. Lundbeck did, correct? 4 Α. Yeah. 5 Q. But the Lundbeck 94404 trial was 6 submitted as part of the package to get the exclusivity 7 extension? 8 MR. ROBERTS: Objection. 9 THE WITNESS: I'm a little confused 10 about the distinction in my recollection about a distinction -- in my recollection about a 11 12 distinction between the exclusivity filing, the 13 patent extension filing and the application for 14 the indication. 15 So what was your question again? 16 BY MR. BAUM: 17 Q. I guess what I was trying to get across is -- find out is that you were involved with the 18 process of having those applications submitted to the 19 FDA and that 94404 and Celexa MD-18 were part of that 20 21 process? 22 MR. ROBERTS: Objection. 23 THE WITNESS: Yeah, I don't know that 94404 was the part -- my recollection is that 24

1	the exclusivity entailed the company conducting
2	a study. 94404 had already been run, so I
3	basically as my recollection was is that
4	18 was conducted for the purpose of
5	exclusivity, but I don't so I don't know
6	what part of the package 94404 was.
7	BY MR. BAUM:
8	Q. Do you recall working on the study
9	report generated for 94404?
10	MR. ROBERTS: Objection.
11	THE WITNESS: No.
12	BY MR. BAUM:
13	Q. Okay. Now, when you worked at Forest,
14	how did you convey written communications to and from
15	Forest personnel and non-Forest contractors?
16	MR. ROBERTS: Objection.
17	THE WITNESS: How did I communicate with
18	non-Forest contractors?
19	BY MR. BAUM:
20	Q. How did you communicate in writing with
21	Forest employees and non-Forest employees that were
22	like contractors to Forest?
23	MR. ROBERTS: Objection.
24	THE WITNESS: So Forest employees, how

1	did I communicate in writing to Forest
2	employees?
3	BY MR. BAUM:
4	Q. Right.
5	MR. ROBERTS: Objection.
6	THE WITNESS: Well, I mean, there were
7	e-mails. Usually like I didn't write my own
8	e-mails. I would draft an e-mail and give it
9	to my secretary.
10	BY MR. BAUM:
11	Q. And then she'd send it?
12	MR. ROBERTS: Objection.
13	THE WITNESS: Yeah.
14	BY MR. BAUM:
15	Q. What was your secretary's name?
16	A. Clara Iorio.
17	Q. How do you spell Iorio?
18	A. As it sounds, I-o-r-i-o, I-o-r-i-o.
19	Q. And would the e-mails go out under your
20	name or under her name?
21	A. Under my name.
22	Q. One of the things that we noticed we
23	asked for all of the e-mails that you sent or received.
24	There weren't very many.

Charles Flicker, Ph.D.

1	I was wondering if you could explain why
2	there aren't very many.
3	MR. ROBERTS: Objection.
4	THE WITNESS: I don't know that there
5	weren't very many. It seemed like there were
6	many to me, but I suppose that my practice of
7	not writing them myself might have limited the
8	volume.
9	BY MR. BAUM:
10	Q. You would do something in handwriting,
11	deliver it to your secretary, and she would transcribe
12	it into an e-mail?
13	MR. ROBERTS: Objection.
14	THE WITNESS: Yes.
15	BY MR. BAUM:
16	Q. Would you also do things written on a
17	hard copy of a document and have the hard copy
18	circulated?
19	MR. ROBERTS: Objection.
20	THE WITNESS: Circulated, probably not,
21	but I mean, if there were a draft of a
22	document, I would put notes on it in
23	handwriting and give it back to the author.
24	BY MR. BAUM:

Would you hand deliver it to the author? 1 Q. 2 Α. No. 3 Ο. How would you get it to the author? 4 Put it in my outbox, I guess. Α. So that's kind of what I was asking is 5 Q. how did it get from like your desk when you were -б 7 see, I'm writing on this, just like you probably wrote 8 on documents, right? 9 Α. I always use pencil. 10 Q. Yeah, I use pencil a lot too. See, 11 right there. 12 So you would handwrite in pencil on a document and then either give it to your secretary or 13 14 put it in an outbox for it to be delivered to the 15 person you wanted it to go to? 16 MR. ROBERTS: Objection. 17 BY MR. BAUM: 18 0. Is that right? 19 Yes, that was not uncommon. Α. 20 Okay. And then you received e-mails and Ο. 21 read those, correct? 22 MR. ROBERTS: Objection. 23 THE WITNESS: Often. 24 BY MR. BAUM:

1	Q.	Did you ever just respond back by
2	e-mail?	
3		MR. ROBERTS: Objection.
4		THE WITNESS: Rarely.
5	BY MR. BAUM:	
6	Q.	Why was that?
7	Α.	Stylistic choice. I thought it was more
8	efficient to h	nave my secretary as a buffer.
9	Q.	And Clara was a good buffer?
10	Α.	I would often correct what she had
11	generated, so	it wasn't 100% accurate.
12	Q.	Was she your secretary the entire time
13	you worked the	ere?
14	Α.	No.
15	Q.	Did you have another secretary?
16	Α.	Did I have another secretary?
17	Q.	Yeah.
18	Α.	Yes.
19	Q.	Who was that?
20	Α.	Joan Singh.
21	Q.	How do you spell that?
22	Α.	J-o-a-n S-i-n-g-h.
23	Q.	What time period did Joan Singh work for
24	you?	

The latter part of my years. 1 Α. And was it the same drill, you would 2 0. 3 handwrite things and hand them to her, and she'd transcribe them into e-mails? 4 5 MR. ROBERTS: Objection. 6 THE WITNESS: Yeah. 7 BY MR. BAUM: 8 0. And then she would send the e-mails out 9 under your name, but not her name; is that correct? 10 MR. ROBERTS: Objection. 11 THE WITNESS: Right. BY MR. BAUM: 12 13 If I wanted to find -- would it be 0. 14 possible that some of the e-mails that were sent out 15 for you might have actually gone out under their names? 16 MR. ROBERTS: Objection. 17 THE WITNESS: No. 18 BY MR. BAUM: 19 Do you recall communicating with vendors Ο. or contractors like medical communication companies 20 21 that worked with Forest? 22 MR. ROBERTS: Objection. 23 THE WITNESS: That would usually be in 24 meetings.

1 BY MR. BAUM: In in-person meetings? 2 0. Yeah. 3 Α. 4 Q. Did you ever have e-mail contact with 5 people like Mary Prescott or PharmaNet? 6 MR. ROBERTS: Objection. 7 THE WITNESS: PharmaNet I'm not sure I 8 recall, but I'm sure at some point there 9 were -- there was an e-mail communication that 10 I would have received -- well, an e-mail? 11 Yeah, I might have gotten e-mails from Mary 12 Prescott. I mean --BY MR. BAUM: 13 14 Ο. Natasha Mitchner? 15 I remember the name, but I don't recall Α. 16 communicating with Natasha Mitchner. 17 How would you get writings to and from Q. people like Mary Prescott or Natasha Mitchner or 18 19 Christina Goetjen? 20 MR. ROBERTS: Objection. 21 THE WITNESS: Writings about what? 22 BY MR. BAUM: 23 0. Any of the marketing issues that --24 writings, like posters, CMEs, drafts of the manuscript

1	for CIT-MD-18?
2	MR. ROBERTS: Objection.
3	THE WITNESS: Yeah, well, I I mean,
4	if there was a draft of some manuscript, I
5	might but, I mean, I wouldn't usually
6	communicate with I don't recall
7	communicating that much directly with Mary
8	Prescott. A manuscript or would probably be
9	in the medical writing department.
10	BY MR. BAUM:
11	Q. Would you communicate through somebody
12	with them?
13	MR. ROBERTS: Objection.
14	THE WITNESS: I don't know. What I
14 15	
	THE WITNESS: I don't know. What I
15	THE WITNESS: I don't know. What I recall is, you know, being in various meetings
15 16	THE WITNESS: I don't know. What I recall is, you know, being in various meetings with Mary Prescott, but not really a lot of
15 16 17	THE WITNESS: I don't know. What I recall is, you know, being in various meetings with Mary Prescott, but not really a lot of written communication. I mean, I imagine there
15 16 17 18	THE WITNESS: I don't know. What I recall is, you know, being in various meetings with Mary Prescott, but not really a lot of written communication. I mean, I imagine there was some.
15 16 17 18 19	THE WITNESS: I don't know. What I recall is, you know, being in various meetings with Mary Prescott, but not really a lot of written communication. I mean, I imagine there was some. BY MR. BAUM:
15 16 17 18 19 20	THE WITNESS: I don't know. What I recall is, you know, being in various meetings with Mary Prescott, but not really a lot of written communication. I mean, I imagine there was some. BY MR. BAUM: Q. So that would have been through e-mails
15 16 17 18 19 20 21	THE WITNESS: I don't know. What I recall is, you know, being in various meetings with Mary Prescott, but not really a lot of written communication. I mean, I imagine there was some. BY MR. BAUM: Q. So that would have been through e-mails or the U.S. Mail or Fed Ex?

```
items by mail from Mary Prescott.
 1
 2
    BY MR. BAUM:
 3
             0.
                    Do you recall when you actually stopped
 4
    working at Forest?
 5
             Α.
                    I think it was 2002.
 б
                    Which part of 2002, like the latter
             0.
 7
    part?
 8
             Α.
                    I would say the latter part.
                    November, December?
 9
             0.
10
             Α.
                    I would be guessing.
11
             Q.
                    Do you have a general recollection of
     like approximately when?
12
13
             Α.
                    No.
14
                    So it would not have been as early as
             Q.
15
     August?
16
             Α.
                    It could have been.
17
                    Do you recall what the last project was
             Q.
    you worked on?
18
19
                    The memantine NDA was going in.
             Α.
20
                    Do you recall what the last project on
             Ο.
21
     Celexa or Lexapro was that you worked on?
22
             Α.
                    No.
23
             Ο.
                    Why did you leave?
24
                    Partly because they were moving.
             Α.
```

1	Q.	What else?
2	Α.	I was going to have a kid, and I wanted
3	to spend some time with her.	
4	Q.	When you left Forest, did you go work
5	someplace else?	
6	Α.	No.
7	Q.	You have not worked since then?
8	Α.	I've worked as a consultant.
9	Q.	Who did you work as a consultant for?
10	Α.	Most recently Actelion.
11	Q.	What sort of consulting work did you do?
12	Α.	That was a licensing candidate review.
13	Q.	When you so since the time you left
14	Forest and the	e present day, you've just done consulting
15	work?	
16	Α.	Yes.
17	Q.	For how many companies do you think?
18	Α.	Maybe five.
19	Q.	Which companies are those?
20	Α.	Pfizer, Alkermes.
21	Q.	When you say you did consulting, is that
22	2 are there like can you describe what type of	
23	B projects you did?	
24	Α.	It was mostly medical writing type work.
L		

On pharmaceuticals? 1 Q. 2 Α. Yes. When you left Forest, did you sign any 3 Ο. Confidentiality Agreement that prevents you from 4 5 discussing in this deposition the work that you did while at Forest? 6 7 Α. I don't remember. 8 Are you subject to any agreement or 0. 9 requirement not to say anything negative about Forest or your work at Forest? 10 11 Α. No. 12 If you were to say anything disparaging Ο. or negative about Forest today in this deposition, 13 14 would you be subject to any penalty from Forest? 15 Α. No. 16 Do you have any allegiance to Forest Ο. that would prevent you from telling the truth today? 17 18 Objection. MR. ROBERTS: 19 THE WITNESS: No. 20 BY MR. BAUM: 21 So you mentioned that -- well, when did 0. 22 you first become aware that the Department of Justice was conducting an investigation of Forest in connection 23 24 with off-label marketing of Celexa or Lexapro?

1 MR. ROBERTS: Objection. 2 THE WITNESS: I don't remember. BY MR. BAUM: 3 4 Do you remember approximately? Was it a 0. year or two after you left Forest? 5 6 MR. ROBERTS: Objection. 7 THE WITNESS: No, I don't remember. Ιt 8 might have been before I left Forest. 9 BY MR. BAUM: 10 Oh, you might have been contacted by the Q. DOJ before you left Forest? 11 12 MR. ROBERTS: Objection. 13 THE WITNESS: I don't know. I don't 14 remember. Well, I'm not talking about when I 15 was contacted, when I became aware that there 16 was a case. BY MR. BAUM: 17 18 There's a distinction. All right. 0. 19 So let's -- how did you become aware of an investigation by the DOJ of Forest regarding Celexa 20 21 or Lexapro? 22 MR. ROBERTS: Objection. 23 THE WITNESS: I think I was aware that 24 some individuals had been subpoenaed.

1	BY MR. BAUM:	
2	Q.	And that was before you got subpoenaed?
3		MR. ROBERTS: Objection.
4		THE WITNESS: Yes.
5	BY MR. BAUM:	
6	Q.	Who got subpoenaed before you?
7	Α.	I thought that some of the executives.
8	Q.	Which executives?
9		MR. ROBERTS: Objection.
10		THE WITNESS: I'm not sure.
11	BY MR. BAUM:	
12	Q.	Ivan Gergel?
13	Α.	Possibly Howard Solomon.
14	Q.	Howard Solomon. I was going to go there
15	next.	
16		Lawrence Olanoff?
17	Α.	Possibly.
18	Q.	Anybody else?
19	Α.	No.
20	Q.	Julie Kilbane?
21	Α.	I wasn't aware any subpoena that she
22	got. I wasn't	aware that she testified.
23	Q.	Amy Rubin?
24	Α.	No.

1 0. So you became aware that other people got subpoenaed. Do you know what they were subpoenaed 2 about? 3 4 MR. ROBERTS: Objection. 5 THE WITNESS: I was aware that there was a Department of Justice investigation. 6 7 BY MR. BAUM: 8 And did you have any discussions with 0. any of the people who were subpoenaed about that 9 10 investigation? 11 MR. ROBERTS: Objection. 12 No. THE WITNESS: BY MR. BAUM: 13 14 Q. You didn't talk to Lawrence Olanoff or 15 Ivan Gergel or Howard Solomon about the investigation? 16 MR. ROBERTS: Objection. 17 THE WITNESS: No. 18 BY MR. BAUM: 19 Ο. You weren't worried about it? 20 MR. ROBERTS: Objection. 21 THE WITNESS: No. 22 BY MR. BAUM: 23 0. And is it your recollection that those 24 subpoenas occurred while you still worked for Forest?

I'm not sure. 1 Α. 2 Ο. When you were interviewed by the Department of Justice lawyers, were you still working 3 at Forest? 4 5 Α. I don't think so. б Are you aware that Forest pled guilty 0. 7 and agreed to pay \$313 million as a result of the 8 investigation of Forest? 9 MR. ROBERTS: Objection. 10 THE WITNESS: No. 11 (Document marked for identification as 12 Flicker Deposition Exhibit No. 2.) BY MR. BAUM: 13 14 I'm going to hand you what we're marking Q. 15 as Exhibit 2, which is the plea agreement between Forest and --16 17 MR. BAUM: Oh, that's his. 18 MS. KIEHN: Sorry. 19 BY MR. BAUM: 20 0. Have you seen that before? 21 Α. No. 22 Q. This is a plea agreement dated 23 September 15, 2010. It's from the Department of 24 Justice to Mary Jo White, Christopher Tahbaz, Andrew

Ceresney, Kristin Kiehn at Debevoise Plimpton. 1 2 Do you see that? 3 Α. Okay. Yes, I see that. 4 Q. Do you recognize those names? 5 Α. I recognize Kristin's name. I recognize Debevoise. б 7 Those are the people representing you Ο. today, right? 8 9 MR. ROBERTS: Objection. THE WITNESS: Well, Debevoise is, yes. 10 11 BY MR. BAUM: 12 0. Do you recall working with Andrew Ceresney back then? 13 14 Α. No. 15 You didn't have any contact with him? 0. 16 Α. Might have. 17 Q. Were Forest attorneys present when you were interviewed by the Department of Justice? 18 19 I think so. Α. 20 Who was there? 0. 21 I don't think it was Debevoise. I think Α. 22 it was another firm. 23 0. So none of these people, Mary Jo White 24 or Andrew Ceresney or Christopher Tahbaz or Kristin

1	were there?	
2		MR. ROBERTS: Objection.
3		THE WITNESS: They might have been, but
4	I don'	t recall.
5	BY MR. BAUM:	
6	Q.	Were you represented by somebody at
7	that at tha	it meeting?
8	Α.	Yes.
9	Q.	Who represented you?
10	Α.	A different firm, I believe.
11	Q.	Was it a firm hired by Forest?
12	Α.	I think so.
13	Q.	It wasn't someone you paid?
14	Α.	No.
15	Q.	Did you sign any agreements with the
16	Department of	Justice in exchange for your testimony?
17	Α.	I don't remember.
18	Q.	Did you have any agreements for
19	immunity?	
20		MR. ROBERTS: Objection.
21		THE WITNESS: No.
22	BY MR. BAUM:	
23	Q.	Do you recall having a queen for a day
24	immunity?	

1 Α. No. You don't recall that phrase? 2 Ο. 3 MR. ROBERTS: Objection. 4 I do recall the phrase. THE WITNESS: 5 BY MR. BAUM: 6 You mentioned it in your last Ο. 7 deposition. 8 MR. ROBERTS: Objection. 9 BY MR. BAUM: 10 Q. It doesn't ring a bell? 11 Α. No. 12 Okay. So are you aware that Forest pled 0. guilty to charges of illegal off-label promotion? 13 14 MR. ROBERTS: Objection. 15 THE WITNESS: No. 16 BY MR. BAUM: 17 Let's go to Page 8 of this document, and Q. if you go to the last paragraph there on that page. 18 19 I'm just going to read that into the record. "Forest expressly and unequivocally further admits that it 20 21 committed the offenses charged in the Information and 22 is in fact guilty of those offenses. Forest agrees that it will not make any statements inconsistent with 23 24 its explicit admission of guilt to these offenses."

1	Do you see that?
2	A. Yes, I do.
3	Q. Then if you go further up the page under
4	the heading "8. Cooperation," the first sentence there
5	says, "Forest shall cooperate completely and truthfully
6	in any trial or other proceeding arising out of any
7	ongoing civil, criminal or administrative investigation
8	of its current and former officers, agents, employees,
9	and customers in connection with the matters described
10	in the Information."
11	Do you see that?
12	A. Yeah.
13	Q. Have you been shown this before?
14	A. No.
15	Q. Do you think it applies to you?
16	MR. ROBERTS: Objection.
17	THE WITNESS: What applies to me?
18	BY MR. BAUM:
19	Q. The obligation to be truthful in any
20	proceeding in connection with.
21	MR. ROBERTS: Objection.
22	THE WITNESS: Are you referring to this
23	proceeding?
24	BY MR. BAUM:

1 Q. Yes. 2 Α. I was sworn in. 3 0. Okay. You think it applies to Forest, for sure, right? 4 5 MR. ROBERTS: Objection. 6 THE WITNESS: Forest shall cooperate 7 completely and truthfully in any trial or other 8 proceeding arising out of any -- sorry. What 9 are you asking me? 10 BY MR. BAUM: Do you think this applies to Forest? 11 0. 12 MR. ROBERTS: Objection. THE WITNESS: This certainly applies to 13 14 Forest. This whole document apparently applies 15 to Forest. MR. BAUM: Let's move on to Exhibit 3. 16 17 You can set that down. (Document marked for identification as 18 19 Flicker Deposition Exhibit No. 3.) 20 BY MR. BAUM: 21 This is the Information which was 0. 22 referenced in what we just looked at, which is sort of 23 a summary of the allegations that the government had 24 against Forest.

1	MR. ROBERTS: Objection.
2	BY MR. BAUM:
3	Q. And have you seen that before?
4	A. I don't know.
5	Q. You didn't see it yesterday?
6	MR. ROBERTS: Objection, to the extent
7	you have to the extent that it refreshes
8	your recollection, you may answer.
9	THE WITNESS: To the extent what
10	refreshes my recollection?
11	MS. KIEHN: Go ahead and answer.
12	MR. ROBERTS: Just answer the question.
13	MS. KIEHN: Do you remember seeing it?
14	THE WITNESS: Did I see this yesterday?
15	I don't think so, no.
16	BY MR. BAUM:
17	Q. So I'm going to turn to Pages 21 and 22,
18	and at Paragraph 59 it says you found it there?
19	A. Yeah.
20	Q. From the outset, Forest Pharmaceuticals
21	was well aware that the FDA had not approved Celexa for
22	treatment of any conditions other than adult
23	depression. Moreover, in or about April 2002, Forest
24	Labs, in an attempt to obtain, inter alia, a pediatric

1	indication for Celexa, submitted data to the FDA from
2	two double-blinded, placebo-controlled studies
3	involving the use of Celexa in children. One of these
4	studies (hereafter referred to as the "Forest study"),
5	which has been sponsored which had been sponsored by
6	Forest Labs, had been conducted in the United States.
7	The Forest study had positive results, that is, the
8	study indicated that Celexa was more effective than
9	placebo in treating pediatric patients suffering from
10	depression. The other study (hereinafter referred to
11	as the "European study"), had been conducted in Europe
12	and sponsored by the Danish company that developed and
13	owned the rights to Celexa. The European study had
14	negative results, that is, the study did not show
15	Celexa to be any more effective than placebo in
16	treating pediatric depression. On or about
17	September 23rd, 2002, the FDA denied Forest Labs'
18	request for a pediatric indication for Celexa, stating
19	in part that the European study "is a clearly negative
20	study that provides no support for the efficacy of
21	citalopram in pediatric patients with [major depressive
22	disorder]."
23	Did I read that correctly?
24	A. That's what I see here.

1 0. Okay. So the Forest study that's referenced there involving the use of Celexa in 2 children referred to in this Information was the 3 4 CIT-MD-18, right? MR. ROBERTS: Objection. 5 6 THE WITNESS: I would assume so. 7 BY MR. BAUM: 8 Did you convey to any government lawyers 0. 9 or investigators that CIT-MD-18 was a positive trial? 10 I don't know. Α. 11 Q. You don't recall talking to them about 12 it? 13 Yeah, that was definitely a subject of Α. 14 discussion. 15 0. What was discussed? 16 Α. I don't know. 17 Well, you just said it was a subject of Q. discussion? 18 19 Α. Yeah. 20 So what was talked about? 0. 21 Α. I don't know. There were questions 22 about the study. 23 What kind of questions? 0. 24 I don't really remember the drift. Α.

1	Q. Was there a drift that one of the trials
2	was positive and one of the trials was negative?
3	MR. ROBERTS: Objection.
4	THE WITNESS: I don't recall that being
5	particularly the subject of discussion.
6	BY MR. BAUM:
7	Q. What was the subject of discussion?
8	A. I'm not sure. I'd have to look at the
9	transcript and maybe I would remember.
10	Q. Do you recall a discussion that there
11	were publications regarding regarding Celexa's use
12	in children without disclosing Lundbeck's 94404 having
13	failed?
14	MR. ROBERTS: Objection.
15	THE WITNESS: I don't recall that being
16	the subject of a discussion with with the
17	Department of Justice?
18	BY MR. BAUM:
19	Q. Yes.
20	A. I don't recall that being part of the
21	discussion. It may well have been.
22	Q. Okay. So let's go to Page 23, Paragraph
23	61.
24	MR. ROBERTS: Flip the page.

Γ

BY MR. BAUM: 1 Well, before we do that, this Paragraph 2 Ο. 59 that we just read, do you recall any of that 3 4 occurring during the time frame that you were there? 5 MR. ROBERTS: Objection. 6 THE WITNESS: Do I recall what 7 occurring? 8 BY MR. BAUM: 9 Ο. That Forest Labs around April 2002 attempted to obtain a pediatric indication for Celexa 10 for use in children? 11 12 Α. I'm surprised at that date, but that seems quite possible. 13 14 And you recall that the European study, Q. the Lundbeck study had a negative result? 15 16 Α. Study 94404? 17 Q. Yes. 18 I wouldn't call it negative. Α. 19 What would you call it? Ο. 20 I would call it a failed study. Α. 21 Do you recall that 94404 was a failed 0. 22 study? 23 Α. Yes. 24 So now let's go on to Paragraph 61 on Q.

1	Page 23, "Beginning in 1998 and continuing thereafter
2	through at least September 2002, Forest Pharmaceuticals
3	promoted Celexa for use in treating children and
4	adolescents suffering from depression, even though
5	Celexa was not FDA-approved for pediatric use. Forest
б	Pharmaceuticals' off-label promotion consisted of
7	various sales techniques including: (1) directing
8	Forest Pharmaceuticals sales representatives who
9	promoted Celexa to make sales calls to physicians who
10	treated children and adolescents; (2) promoting Celexa
11	by various Forest Pharmaceuticals sales representatives
12	for use in children and adolescents; (3) hiring outside
13	speakers to talk to pediatricians, child psychiatrists,
14	and other medical practitioners who specialized in
15	treating children and adolescents about the benefits of
16	prescribing Celexa to that patient population; and (4)
17	publicizing and circulating the positive results of the
18	double-blind, placebo-controlled Forest study on the
19	use of Celexa in adolescents while, at the same time,
20	failing to discuss the negative results of the second
21	double-blind, placebo-controlled European study on the
22	use of Celexa in adolescents."
23	Did I read that correctly?
24	A. Yes.

 Number 1, directing pharmaceuticals, do you see th A. The one in parentheses. Q. Yes. Were you aware that Forest 	omoted
4 Q. Yes. Were you aware that Forest	
5 directed its sales reps representatives who pro	ed
6 Celexa to make sales calls to physicians who treat	
7 children and adolescents?	
8 MR. ROBERTS: Objection.	
9 THE WITNESS: No.	
10 BY MR. BAUM:	
11 Q. Referring to 2, were you aware that	-
12 Forest while you worked there, were you aware t	hat
13 Forest sales reps promoted Celexa for use in child	lren
14 and adolescents?	
15 MR. ROBERTS: Objection.	
16 THE WITNESS: No.	
17 BY MR. BAUM:	
18 Q. Did you ever become aware of it?	
19 MR. ROBERTS: Objection.	
20 THE WITNESS: No.	
21 BY MR. BAUM:	
22 Q. As far as you know, that never happ	ened?
23 MR. ROBERTS: Objection.	
24 THE WITNESS: Promoting Celexa for	use

1	in children and adolescents, I have a
2	recollection of some sales reps getting in
3	trouble in Florida for attending some event,
4	but that might have been in the course of these
5	proceedings.
6	BY MR. BAUM:
7	Q. What did they do that caused them to be
8	in trouble?
9	A. I thought they gave out T-shirts or
10	something.
11	Q. And you're not aware that Forest sales
12	representatives went to pediatric physicians to suggest
13	prescribing Celexa to children?
14	MR. ROBERTS: Objection.
15	THE WITNESS: I wouldn't be surprised if
16	some of the physicians they went to were
16 17	some of the physicians they went to were pediatric had pediatric patients.
17	pediatric had pediatric patients.
17 18	pediatric had pediatric patients. BY MR. BAUM:
17 18 19	pediatric had pediatric patients. BY MR. BAUM: Q. Did you understand that sales reps going
17 18 19 20	<pre>pediatric had pediatric patients. BY MR. BAUM: Q. Did you understand that sales reps going to pediatric physicians or physicians and recommending</pre>
17 18 19 20 21	<pre>pediatric had pediatric patients. BY MR. BAUM: Q. Did you understand that sales reps going to pediatric physicians or physicians and recommending the use of Celexa for children was an off-label use?</pre>

1 BY MR. BAUM: 2 0. Was it your understanding that sales 3 reps going to physicians and recommending the use of Celexa in children would have been an off-label 4 5 promotion? 6 MR. ROBERTS: Objection. 7 THE WITNESS: I do understand that if 8 the drug was not approved for the indication 9 and a sales representative went to a pediatric 10 clinician and recommended its use, then that 11 would be an off-label promotion. BY MR. BAUM: 12 13 0. And you were aware that was illegal? 14 Objection. Not a lawyer. MR. ROBERTS: 15 THE WITNESS: I am aware that to do such 16 a thing is illegal. BY MR. BAUM: 17 18 0. Were you aware at the time? 19 I don't think I was particularly Α. thinking about that issue at the time. 20 21 Okay. Did it ever come to your 0. 22 attention through the marketing department, like 23 through John MacPhee or through Nefertiti Greene or 24 your work with Mary Prescott that there was a plan to

have some form of promotion done of the MD-18 results 1 to physicians? 2 3 MR. ROBERTS: Objection. 4 THE WITNESS: A promotion? 5 BY MR. BAUM: 6 Ο. Yes. 7 Α. No. 8 Conveying the results of MD-18 to Q. 9 physicians? 10 MR. ROBERTS: Objection. 11 THE WITNESS: Well, we were seeking the 12 indication. BY MR. BAUM: 13 14 Q. And you were making posters? 15 MR. ROBERTS: Objection. 16 THE WITNESS: Well, seeking indication 17 is not the same as making posters. Were there 18 any posters; is that what you're asking? 19 BY MR. BAUM: 20 Yes. Before there was even an 0. 21 indication request, were there posters made? 22 Α. I don't know the exact timing, but there 23 definitely -- definitely posters were made presenting 24 the results of the 18 study.

1	Q. And that was the purpose of those
2	posters?
3	MR. ROBERTS: Objection.
4	THE WITNESS: Scientific communication.
5	BY MR. BAUM:
6	Q. They were conveyed to physicians?
7	MR. ROBERTS: Objection.
8	THE WITNESS: Whoever, whatever
9	scientists or clinicians would be attending the
10	meetings.
11	BY MR. BAUM:
12	Q. Like the ACNP?
13	A. Yes.
14	Q. Was the ACNP considered an authoritative
15	group of physicians and scientists?
16	MR. ROBERTS: Objection.
17	THE WITNESS: Authoritative? I don't
18	know if you call it authoritative.
19	BY MR. BAUM:
20	Q. What would you call it?
21	MR. ROBERTS: Objection.
22	THE WITNESS: Prominent maybe.
23	BY MR. BAUM:
24	Q. Influential?

1	MR. ROBERTS: Objection.
2	THE WITNESS: I'd say prominent. I'd
3	say if they're prominent, it's likely that
4	they're influential.
5	BY MR. BAUM:
6	Q. Looking at Number 3 on that Paragraph 61
7	says, were you aware that Forest hired outside speakers
8	to talk to pediatricians, child psychiatrists and other
9	medical practitioners who specialized in treating
10	children and adolescents about the benefits of
11	prescribing Celexa to that patient population?
12	MR. ROBERTS: Objection.
13	THE WITNESS: No.
14	BY MR. BAUM:
15	Q. Did you work with any outside speakers
16	who did do that?
17	MR. ROBERTS: Objection.
18	BY MR. BAUM:
19	Q. Like Karen Wagner?
20	A. I worked with Karen Wagner.
21	Q. Were you aware that she was giving talks
22	to physicians and recommending the use of Celexa?
23	MR. ROBERTS: Objection.
24	THE WITNESS: I believe she was the I

remember she had a poster. 1 2 BY MR. BAUM: 3 0. Do you recall that she actually did like speeches and presentations to physicians at CME type --4 continuing medical education type seminars? 5 6 MR. ROBERTS: Objection. No foundation. 7 THE WITNESS: That sounds possible. 8 BY MR. BAUM: 9 0. Did you ever help prepare her for any of those? 10 11 MR. ROBERTS: Objection. 12 I was in communication THE WITNESS: with her. Did I prepare speeches for her? 13 14 BY MR. BAUM: 15 Ο. Yeah, like PowerPoint presentations --16 MR. ROBERTS: Objection. 17 BY MR. BAUM: -- for her to lecture on at CMEs? 18 Q. 19 I don't recall. Α. 20 Or dinners? 0. 21 MR. ROBERTS: Objection. 22 THE WITNESS: Yeah, I don't recall. 23 BY MR. BAUM: 24 Do you recall what you were working with 0.

1	her on?
2	A. Well, she was an investigator in the 18
3	study, and, well, some of this material I learned
4	yesterday.
5	MR. ROBERTS: So you can't talk about
6	it. If you have any independent recollection
7	of the question, you can talk about it. If
8	it's something you learned through
9	communication with Kristin and I.
10	MR. WISNER: Unless, of course, it
11	refreshed your recollection yesterday when you
12	saw it.
13	THE WITNESS: Yeah, I didn't
14	independently recollect.
15	BY MR. BAUM:
16	Q. Okay. And then on Number 4 it says were
17	you aware that Forest publicized and circulated the
18	positive results of a double-blind, placebo-controlled
19	Forest study on the use of Celexa in adolescents while
20	at the same time failed to discuss the negative results
21	of the second double-blind, placebo-controlled European
22	study on the use of Celexa in adolescents?
23	MR. ROBERTS: Objection.
24	THE WITNESS: I'm aware that Forest

1	publishe	ed the results of the 18 study.
2	BY MR. BAUM:	
3	Q. <i>P</i>	And are you aware that they failed to
4	convey informati	ion regarding the European study?
5	Ν	MR. ROBERTS: Objection.
6	C	THE WITNESS: Well, Lundbeck
7	publishe	ed I believe Lundbeck published the
8	other st	tudy.
9	BY MR. BAUM:	
10	Q. E	But Forest had the results, correct?
11	Ν	MR. ROBERTS: Objection.
12	r	THE WITNESS: They had access to the
13	results,	, yes.
13 14	results, BY MR. BAUM:	, yes.
	BY MR. BAUM:	, yes. You had access to the results, right?
14	BY MR. BAUM: Q. Y	
14 15	BY MR. BAUM: Q. Y	You had access to the results, right?
14 15 16	BY MR. BAUM: Q. Y	You had access to the results, right? MR. ROBERTS: Objection.
14 15 16 17	BY MR. BAUM: Q. Y N BY MR. BAUM:	You had access to the results, right? MR. ROBERTS: Objection.
14 15 16 17 18	BY MR. BAUM: Q. Y M BY MR. BAUM: Q. Y	You had access to the results, right? MR. ROBERTS: Objection. THE WITNESS: 94404?
14 15 16 17 18 19	BY MR. BAUM: Q. Y M BY MR. BAUM: Q. Y	You had access to the results, right? MR. ROBERTS: Objection. THE WITNESS: 94404? Yeah.
14 15 16 17 18 19 20	BY MR. BAUM: Q. N BY MR. BAUM: Q. A. Lhe results.	You had access to the results, right? MR. ROBERTS: Objection. THE WITNESS: 94404? Yeah.
14 15 16 17 18 19 20 21	BY MR. BAUM: Q. N BY MR. BAUM: Q. A. the results. Q.	You had access to the results, right? MR. ROBERTS: Objection. THE WITNESS: 94404? Yeah. In some form I would have had access to

1 THE WITNESS: Well, as I said, it's a 2 failed study. BY MR. BAUM: 3 4 Q. Did you have any concerns about its 5 being a failed study? 6 MR. ROBERTS: Objection. 7 THE WITNESS: Yes. 8 BY MR. BAUM: 9 Ο. What were your concerns? 10 MR. ROBERTS: Objection. THE WITNESS: The concern was that it 11 12 wouldn't provide adequate support for the -for the indication. 13 14 BY MR. BAUM: 15 What about adequate support for the 0. 16 exclusivity extension? 17 MR. ROBERTS: Objection. 18 THE WITNESS: My recollection of the 19 exclusivity filing is that the submission --20 that the conduct -- it was the conduct of the 21 study by a company, regardless of the results, 22 was sufficient for the exclusivity. 23 BY MR. BAUM: 24 Q. You recall it being necessary that the

Charles Flicker, Ph.D. results were interpretable? 1 2 MR. ROBERTS: Objection. 3 THE WITNESS: No. 4 BY MR. BAUM: 5 Q. Do you consider a failed study interpretable? 6 7 MR. ROBERTS: Objection. 8 THE WITNESS: I'd say that's a pretty 9 fuzzy semantic question. BY MR. BAUM: 10 Well, I was wondering if maybe you were 11 Ο. 12 concerned or anyone at Forest was concerned about 13 whether the 94404 results were interpretable 14 sufficiently to support the exclusivity submission? 15 MR. ROBERTS: Objection, calls for 16 speculation. 17 THE WITNESS: Yeah, I mean, I can't --18 it's pretty difficult to put a -- to clearly 19 define what interpretable means. 20 BY MR. BAUM: 21 Was there any concern that because of 0. 22 the outcome of 94404, Forest would not be able to get 23 the pediatric exclusivity extension for Celexa? 24 MR. ROBERTS: Objection.

THE WITNESS: As I said, I didn't --1 based on my current recollection, I didn't 2 think that it had much to do with it. 3 4 BY MR. BAUM: 5 Q. All they had to do was have a trial conducted, it didn't matter what the outcome was? 6 7 MR. ROBERTS: Objection. 8 THE WITNESS: I think they needed to 9 conduct the study in the US, but I could be 10 wrong. 11 BY MR. BAUM: 12 Q. And you don't recall whether 94404 was part of the application for the exclusivity extension? 13 14 MR. ROBERTS: Objection. 15 THE WITNESS: I don't specifically 16 recall. I would assume that all relevant data 17 were submitted. 18 BY MR. BAUM: 19 O. And 94404's results would have been relevant data? 20 21 MR. ROBERTS: Objection. 22 THE WITNESS: Relevant, yes. 23 BY MR. BAUM: 24 0. Did anyone at Forest ever instruct you

to conceal the Lundbeck 94404 study results? 1 2 MR. ROBERTS: Objection. 3 THE WITNESS: No. 4 BY MR. BAUM: 5 Q. Did you have any concerns about any of the adverse event outcomes in the 94404 study? 6 7 MR. ROBERTS: Objection. 8 THE WITNESS: The adverse event rates 9 were higher in the 94404 study than the 18 10 study. 11 BY MR. BAUM: 12 0. Do you recall any particular adverse events that were higher? 13 14 Α. No. 15 0. Suicidality? 16 MR. ROBERTS: Objection. 17 THE WITNESS: I vaguely recollect that, in general, there was a suicidality issue. 18 19 BY MR. BAUM: 20 With respect to 94404 or with pediatric Ο. 21 use of SSRIs in general? 22 MR. ROBERTS: Objection. 23 BY MR. BAUM: 24 0. Or both?

1	MR. ROBERTS: Objection.
2	THE WITNESS: There was an FDA concern
3	about it.
4	BY MR. BAUM:
5	Q. Did you have a concern about it?
6	MR. ROBERTS: Objection.
7	THE WITNESS: Did I have a concern about
8	what?
9	BY MR. BAUM:
10	Q. The adverse event of suicidality related
11	to pediatric use of an SSRI like Celexa or Lexapro?
12	MR. ROBERTS: Objection.
13	THE WITNESS: Yes.
14	BY MR. BAUM:
15	Q. Do you recall well, skip that.
16	Let's go to Page 26, take a look at
17	Paragraph 67. Here it says, At various times and in
18	New England, certain Forest Pharmaceuticals Regional
19	Directors and Division Managers provided their sales
20	representatives with copies of posters and journal
21	articles on studies of Celexa for use in children and
22	adolescents and directed the sales representatives to
23	read the studies and use them as sales aids in their
24	details to physicians. Various Forest Pharmaceutical

1	Division Managers also directed sales representatives	
2	to show off labels sorry to show off-label	
3	studies to physicians, but not leave copies of those	
4	studies with the physicians so as to avoid detection	
5	that would get the sales representative and Forest	
б	Pharmaceuticals in trouble.	
7	Do you see that?	
8	A. Yes.	
9	Q. Do you recall any physicians being	
10	well, do you recall any of this activity occurring?	
11	MR. ROBERTS: Objection.	
12	THE WITNESS: No.	
13	BY MR. BAUM:	
14	Q. Did you ever hear about any of that	
15	activity occurring?	
16	MR. ROBERTS: Objection.	
17	THE WITNESS: I knew that a physician	
18	could request a copy of a study or a study	
19	report.	
20	BY MR. BAUM:	
21	Q. Were you aware or did you hear that	
22	sales reps were actually trained to deliver pediatric	
23	submissions like posters and things of that to	
24	physicians in order to encourage them to prescribe	

Celexa to children? 1 2 MR. ROBERTS: Objection. 3 THE WITNESS: No, I wasn't aware of 4 that, but it seems possible that those materials could have been made available. 5 6 BY MR. BAUM: 7 With or without the physician asking for 0. 8 them? 9 MR. ROBERTS: Objection. 10 THE WITNESS: I thought the procedure 11 was that a physician needed to request such articles. 12 13 BY MR. BAUM: 14 Q. And if they didn't, it would have been 15 improper, right? 16 MR. ROBERTS: Objection, calls for 17 speculation. 18 THE WITNESS: Can you repeat the 19 question. 20 BY MR. BAUM: 21 Q. If the physician didn't ask for the 22 materials, giving it to them would have been improper, 23 correct? 24 MR. ROBERTS: Objection.

1 THE WITNESS: I think it would be 2 improper to provide material regarding an off-label use if not requested for a sales rep. 3 4 BY MR. BAUM: 5 Q. Okay. And were you aware that any of that activity was occurring at Forest while you were б there? 7 8 MR. ROBERTS: Objection. 9 THE WITNESS: No. BY MR. BAUM: 10 11 0. So you were not aware that Forest sales 12 reps used data from CIT-MD-18 in posters for off-label promotion of Celexa for use in children and 13 14 adolescents? 15 MR. ROBERTS: Objection. No foundation. 16 THE WITNESS: No. 17 BY MR. BAUM: 18 Q. Were you aware that any of the posters you actually participated in creating were used by 19 20 sales reps for physicians? 21 MR. ROBERTS: Objection. 22 THE WITNESS: I'm sure they had access 23 to that material. 24 BY MR. BAUM:

Q. Why are you sure that they had access to 1 2 that material? 3 I believe it was given to them or at Α. least made available to them. 4 5 Q. For what purpose? 6 A. Education. 7 Q. In order to get physicians to prescribe 8 Celexa for children? 9 MR. ROBERTS: Objection. 10 THE WITNESS: I wouldn't know. 11 BY MR. BAUM: 12 Q. Were you aware that Forest ordered reprints of journal articles and posters to be 13 14 presented by sales reps? 15 MR. ROBERTS: Objection. No foundation. 16 THE WITNESS: No. I believe sales reps 17 had access to that material. 18 BY MR. BAUM: 19 Q. You don't know whether or not they were given copies of it? 20 21 MR. ROBERTS: Objection. 22 THE WITNESS: No. 23 BY MR. BAUM: 24 Q. Do you believe they were?

1	MR. ROBERTS: Objection, calls for
2	speculation.
3	THE WITNESS: I believe it was part of
4	their training.
5	BY MR. BAUM:
6	Q. Look at that subheading B under
7	Paragraph 67 on Page 26. Do you see that? "Forest
8	Pharmaceuticals' Use of Outside Speakers to Promote
9	Celexa for Use in Children and Adolescents."
10	Do you see that?
11	A. Yes.
12	Q. Did you participate with any outside
13	speakers to promote Celexa for use in children and
14	adolescents?
15	MR. ROBERTS: Objection.
16	THE WITNESS: No.
17	BY MR. BAUM:
18	Q. You didn't do that with Karen Wagner?
19	MR. ROBERTS: Objection.
20	THE WITNESS: Did I give a talk?
21	BY MR. BAUM:
22	Q. No. Did you assist her to give speeches
23	to promote Celexa for use in children and adolescents?
24	MR. ROBERTS: Objection.

THE WITNESS: 1 No. 2 BY MR. BAUM: 3 0. Did you assist her with any posters or PowerPoint presentations for her to give to 4 5 physicians --6 MR. ROBERTS: Objection. 7 BY MR. BAUM: 8 -- regarding CIT-MD-18? Q. I think I discussed material and results 9 Α. from 18 with her. 10 11 Q. For what purpose? 12 Α. Well, again, this is partly based on material I was given yesterday. 13 14 MR. ROBERTS: Then don't answer. 15 BY MR. BAUM: 16 Q. Would it refresh your recollection of what you actually did do? 17 18 Well, I know Karen Wagner did a poster Α. presentation, I recollect that independently, and I 19 probably helped her with that. 20 21 Q. And that poster presentation was to 22 whom? 23 Α. Well, you mentioned ACNP, so I guess 24 ACNP.

1	MR. ROBERTS: Michael, when are you
2	thinking about a break?
3	MR. BAUM: In a little bit, but not
4	quite yet.
5	MS. KIEHN: We've been going over an
б	hour.
7	MR. ROBERTS: Are you okay, or do you
8	want to take a break?
9	THE WITNESS: I'm good.
10	MR. BAUM: We're trying to keep the
11	breaks to a minimum, I think, right?
12	MS. KIEHN: Yeah.
13	MR. ROBERTS: I just want to make sure
14	he's okay.
15	BY MR. BAUM:
16	Q. Yeah. By the way, if you ever need to
17	take a break, you know, just to get a drink of water or
18	go to the bathroom, please let us know, and if you're
19	in the middle of a question, though, I want you to
20	answer the question before you take the break. And
21	just let us know we're trying to get a full seven
22	hours of testimony in today, so I know you have
23	something you're scheduled to go do later, so we're
24	trying to cram in as much as we can with as few breaks

as possible, but it's not a torture event, more or 1 2 less. 3 MS. KIEHN: Matter of opinion. It's a matter of opinion. 4 THE WITNESS: 5 MR. BAUM: Yeah. 6 MS. KIEHN: Let's take a break in a few 7 minutes. 8 MR. BAUM: I'm almost done with this 9 section, I just wanted to wrap it up. 10 MR. ROBERTS: Okay. 11 BY MR. BAUM: (Document marked for identification as 12 Flicker Deposition Exhibit No. 4.) 13 14 BY MR. BAUM: 15 I'm going to hand you what we're marking 0. as Exhibit 4 which is the United States complaint 16 17 intervention against Forest Labs. 18 Have you seen that before? 19 Not that I recollect. Α. 20 At the bottom of this page it says, Ο. 21 "Over the course of more than half a decade, Forest 22 illegally marketed two related antidepressant drugs, Celexa and Lexapro, for off-label use in pediatric 23 24 patients when both drugs had been approved only for

adult use." 1 2 Do you see that? 3 Α. Yes. 4 Q. Were you aware of Forest illegally marketing for off-label use of Celexa in the pediatric 5 6 population? 7 MR. ROBERTS: Objection. 8 THE WITNESS: I was aware of those 9 T-shirts. 10 BY MR. BAUM: 11 0. And what was on the T-shirts? 12 I don't know. Α. 13 Something to do with pediatric use of Q. 14 Celexa or Lexapro? 15 MR. ROBERTS: Objection. 16 THE WITNESS: It was just -- it was a 17 pediatric event. BY MR. BAUM: 18 19 And at that event they were suggesting 0. the use of Celexa or Lexapro for kids? 20 21 MR. ROBERTS: Objection. 22 THE WITNESS: They were giving out 23 T-shirts or something, and it must have said 24 Celexa on it.

1	BY MR. BAUM:	
2	Q. Okay. Let's take a look at Page 17,	
3	Paragraph 60. It says, "Forest paid a medical writing	
4	firm to ghost-write an academic article on the Wagner	
5	study, and Forest arranged to have the article	
6	published in the June 2004 issue of The American	
7	Journal of Psychiatry, with Dr. Wagner listed as the	
8	lead author. The article did not mention that the only	
9	other double-blind, placebo-controlled trial on	
10	pediatric use of Celexa had shown no efficacy and had	
11	an incidence of suicide attempts and suicidal ideation	
12	among those taking Celexa that was almost three times	
13	higher than in the group taking the placebo."	
14	Did I read that correctly?	
15	A. Yes.	
16	Q. This article mentioned here is referring	
17	to the published report of CIT-MD-18 with Dr. Wagner as	
18	an author?	
19	MR. ROBERTS: Objection.	
20	THE WITNESS: Is that a question?	
21	BY MR. BAUM:	
22	Q. Yes.	
23	A. What's the question? Is that the	
24	Q. Is this paragraph referring to the	

1	article in whi	ch Dr. Wagner was the lead author
2	regarding CIT-	-MD-18's results?
3		MR. ROBERTS: Objection.
4		THE WITNESS: I assume so.
5	BY MR. BAUM:	
6	Q.	Do you know why Dr. Wagner was viewed as
7	a principal ir	nvestigator?
8		MR. ROBERTS: Objection.
9		THE WITNESS: I wasn't aware that she
10	was th	ne principal investigator.
11	BY MR. BAUM:	
12	Q.	Did you think she wasn't?
13	Α.	No.
14	Q.	What was her relationship to the
15	CIT-MD-18 proj	ject?
16	Α.	She was an investigator on it.
17	Q.	Was she an author?
18	Α.	Yeah, well, I mean, I knew she did the
19	poster. I dic	n't know she was first author on the
20	on this articl	le.
21	Q.	Do you recall Natasha Mitchner being
22	involved	
23	Α.	No.
24	Q.	with writing the first draft of the

manuscript for CIT-MD-18? 1 2 MR. ROBERTS: Objection. THE WITNESS: I don't know who Natasha 3 4 Mitchner is. 5 BY MR. BAUM: 6 0. Do you recall that there was a medical writing company that Forest worked with to get the 7 8 manuscript drafted? 9 MR. ROBERTS: Objection, lack of foundation. 10 11 THE WITNESS: No. 12 BY MR. BAUM: 13 Q. Who do you think wrote it? 14 MR. ROBERTS: Objection, calls for 15 speculation. 16 THE WITNESS: I think it was a collaborative effort. 17 18 BY MR. BAUM: 19 Q. Did it involve a medical writing company that was hired by Forest? 20 21 Not that I knew of. I would think they Α. 22 would be more involved in production, but sometimes 23 they were used to facilitate. 24 Q. What do you mean by that?

1	A. You know, if there was if there were
2	a bunch of authors on the study, the manuscript has to
3	be circulated and comments have to be incorporated, and
4	there's also other a lot of logistics with a
5	submission and so forth.
6	Q. You don't recall the medical writing
7	company actually drafting the manuscript?
8	MR. ROBERTS: Objection.
9	THE WITNESS: No.
10	BY MR. BAUM:
11	Q. You never saw a draft of a manuscript
12	that was prepared by Natasha Mitchner and Mary
13	Prescott?
14	MR. ROBERTS: Objection.
15	THE WITNESS: Oh, I don't know that. If
16	I was around, it would be very likely that I
17	commented on the manuscript.
18	BY MR. BAUM:
19	Q. Do you recall that a manuscript was
20	generated by companies that Mary Prescott or Natasha
21	Mitchner worked for?
22	MR. ROBERTS: Objection.
23	THE WITNESS: I don't recall Natasha
24	Mitchner. Did she work for Mary?

BY MR. BAUM: 1 2 0. Yeah. That's possible. 3 Α. 4 Okay. Do you recall that you provided Q. 5 information to Mary Prescott or an outside writing б agency for drafting the manuscript? 7 MR. ROBERTS: Objection. 8 THE WITNESS: If it was drafted by an 9 outside agency, then they would have to get it 10 from Forest. 11 BY MR. BAUM: Did you help provide that information to 12 0. 13 them? 14 MR. ROBERTS: Objection. 15 THE WITNESS: Oh, not that I recall. 16 BY MR. BAUM: Q. 17 Do you know whether or not the published article and the June 2004 issue of American Journal of 18 19 Psychiatry mentioned the 94404 results? 20 Objection. MR. ROBERTS: 21 THE WITNESS: Based on what I see here 22 you mean? 23 BY MR. BAUM: 24 At the time did you recall whether or 0.

Charles Flicker, Ph.D. not it mentioned 94404? 1 2 MR. ROBERTS: Objection. 3 THE WITNESS: No. 4 BY MR. BAUM: 5 Q. Are you aware now that it did not? 6 MS. KIEHN: Objection. 7 MR. ROBERTS: Objection. 8 THE WITNESS: If this allegation is 9 correct, then it did not. 10 BY MR. BAUM: Okay. Would you agree that it's 11 0. 12 scientifically unsound to promote positive results and conceal negative results of testing on a drug? 13 14 MR. ROBERTS: Objection, not an expert. THE WITNESS: Is it scientifically --15 16 scientifically unsound? BY MR. BAUM: 17 18 0. Yes. 19 My first thought wouldn't be that Α. scientific was primary issue but --20 21 What would you call it? 0. 22 Α. What are you suggesting, to promote 23 positive results, or do what with positive results, 24 communicate positive results?

To promote positive results and conceal 1 0. negative results of clinical trials. 2 3 MR. ROBERTS: Objection. 4 THE WITNESS: I'd say it's undesirable. 5 BY MR. BAUM: 6 Do you have any regrets of being part of Ο. any of this illegal activity of Forest? 7 8 MR. ROBERTS: Objection, calls for 9 speculation. 10 MS. KIEHN: Lack of foundation. THE WITNESS: What illegal activity did 11 12 I participate in? 13 BY MR. BAUM: 14 Q. You worked at Forest. 15 MR. ROBERTS: Objection. 16 BY MR. BAUM: 17 Q. We just went through the Information and this complaint and --18 19 This complaint is just an allegation Α. 20 from I don't know where. 21 Q. So the Information, the exhibit before, 22 is not just an allegation. Forest pled guilty to it 23 and pled guilty to having conducted activities --24 MR. ROBERTS: Objection.

	·
1	MS. KIEHN: Objection.
2	MR. ROBERTS: Mischaracterizes the
3	documents.
4	MS. KIEHN: Completely mischaracterizing
5	the documents, misleading.
6	MR. WISNER: Kristin, Kristin.
7	MS. KIEHN: Brent, Brent, Brent.
8	MR. WISNER: He's defending the
9	deposition, you're not.
10	MS. KIEHN: Fine.
11	MR. WISNER: So you have no right to
12	object. Only one witness deposes, that's it.
13	You're not sick. You don't get to object.
14	Josh can handle himself.
15	MS. KIEHN: Calm down.
16	BY MR. BAUM:
17	Q. And so they're just objecting and
18	disagreeing with it. They can't stop you from
19	answering that question.
20	A. Yeah, but what paragraph, what?
21	MR. ROBERTS: I am objecting to it, but
22	you can answer, to the extent that you remember
23	what the question is.
24	THE WITNESS: Are we going back to the

DOJ? 1 2 BY MR. BAUM: Q. This is the Information. This is the 3 4 plea agreement. MR. ROBERTS: Let the record reflect 5 what the exhibits are. 6 7 BY MR. BAUM: 8 Q. Exhibit 3 is the Information, and 9 Exhibit 2 is the plea agreement, and in Exhibit 2 they've pled guilty to the Informations contained in 10 the Information? 11 12 MR. ROBERTS: Objection to the extent that it mischaracterizes the document. 13 14 BY MR. BAUM: 15 So what I'm asking you is do you regret 0. 16 having been involved with any of the activity that's described in these documents? 17 18 MR. ROBERTS: Objection. 19 THE WITNESS: I regret anything I did 20 that got me here today. 21 BY MR. BAUM: 22 Q. Well, that's a slightly different answer 23 to a slightly different question, and I'd like the 24 answer to my question.

1	MR. ROBERTS: And I object to his
2	question, but you can answer.
3	THE WITNESS: Yeah, well, I mean, I'm a
4	little confused by your question because, I
5	mean, actually, my recollection was that when
6	the Department of Justice case was settled, I
7	didn't think Celexa was even mentioned, or at
8	least it was very secondary. Isn't that true?
9	BY MR. BAUM:
10	Q. Well, if you look here at what I just
11	showed you, Celexa was involved, wasn't it?
12	MR. ROBERTS: Objection.
13	THE WITNESS: Yes, it was involved in
14	the allegations, but then when it was settled,
15	I didn't I thought it was about other drugs,
16	wasn't it?
17	BY MR. BAUM:
18	Q. No, there are other drugs as well, but
19	they're also Celexa and Lexapro.
20	MS. KIEHN: You're not testifying,
21	Michael.
22	MR. ROBERTS: Objection.
23	BY MR. BAUM:
24	Q. So the documents I just showed you

1	involve Celexa and Lexapro, didn't they?
2	MR. ROBERTS: Objection, to the extent
3	that it mischaracterizes the document. If you
4	want to take your time and go through the
5	document, you can take your time and go through
6	the document. You don't have to accept his
7	characterization of the document.
8	BY MR. BAUM:
9	Q. Take a look at the bottom of Page 8.
10	MR. ROBERTS: Are we going back to 2?
11	BY MR. BAUM:
12	Q. In Exhibit 2. Do you see that?
13	MR. ROBERTS: See what? What are we
14	BY MR. BAUM:
15	Q. The bottom of
16	A. "Forest expressly and unequivocally
17	further admits that it committed the offenses charged
18	in the Information." So this is the Information?
19	Q. Yes. I showed you paragraphs in the
20	Information that related to Celexa and the off-label
21	promotion of Celexa.
22	MR. ROBERTS: Objection to your
23	characterization of it.
24	BY MR. BAUM:

1		Q.	If you take a look at Paragraphs 61 and
2	59.		
3		A.	So your question is, do I regret any
4			MR. ROBERTS: You don't have to ask him
5		his qu	estion. He can ask his own questions.
6			MR. BAUM: You're going to have to stop
7		guidin	ng him.
8			MR. ROBERTS: He's not asking you the
9		questi	ons. You get to ask the questions.
10			MR. BAUM: You do not get to guide him.
11			MR. ROBERTS: I'm not guiding him.
12			MR. BAUM: You have to stop guiding him.
13			MR. ROBERTS: I'm not guiding him.
14			MR. BAUM: Yes, you are.
15			MR. ROBERTS: I'm trying to get him to
16		the ri	ght place.
17			MR. BAUM: I already had him at that.
18			MR. ROBERTS: Okay. Well, I'm getting
19		to the	e right place now. What page are we on?
20			MR. BAUM: We're at Paragraphs 59 and
21		61?	
22			MR. ROBERTS: Okay, perfect. What's the
23		questi	.on?
24	BY MR.	BAUM:	

Do you see Paragraphs 59 and 61, do you 1 Ο. recall our having read those into the record? 2 3 MR. ROBERTS: Objection. 4 BY MR. BAUM: 5 Q. Do you see those? б I'm looking at 61. Α. 7 Okay. You see that those relate to 0. 8 Celexa and Lexapro? 9 MR. ROBERTS: Objection. 10 THE WITNESS: Yes. 11 BY MR. BAUM: 12 0. And do you see that Forest in the Information has pled guilty to the activities described 13 14 here in the information? 15 MR. ROBERTS: Objection. He's not a lawyer. 16 17 THE WITNESS: Assuming that these two 18 are linked, then I guess there was a guilty 19 plea. 20 BY MR. BAUM: 21 All right. Do you regret having been 0. 22 involved with any of the activity that's described in 23 the Information and that to which Forest pled guilty? 24 MR. ROBERTS: Objection, calls for

1		speculation.
2		THE WITNESS: I don't think I was
3		involved in the activity of these things.
4	BY MR.	BAUM:
5		Q. Well, you worked on MD-18, correct?
б		MR. ROBERTS: Objection.
7		THE WITNESS: But I didn't direct Forest
8		Pharmaceuticals sales reps to promote Celexa.
9		I didn't promote Celexa. I didn't hire outside
10		speakers. I didn't publicize and circulate
11		positive results.
12	BY MR.	BAUM:
13		Q. Your employer did, though, right?
14		A. Well, no, I did
15		MR. ROBERTS: Objection.
16		THE WITNESS: I did help to I don't
17		regret helping to publish 18. No, I don't
18		regret it.
19	BY MR.	BAUM:
20		Q. Okay.
21		MR. ROBERTS: Are we ready for a break?
22		MR. BAUM: Yeah.
23		THE VIDEOGRAPHER: We will be going off
24		the record at 9:16 a.m. This marks the end of

Media 1. 1 2 (Brief recess.) 3 THE VIDEOGRAPHER: We are back on the 4 record at 9:29 a.m. This marks the beginning of Media 2. Go ahead, counselor. 5 MR. BAUM: We're going to move on to 6 7 Exhibit 5. 8 (Document marked for identification as 9 Flicker Deposition Exhibit No. 5.) BY MR. BAUM: 10 11 Q. Which is an e-mail from Karoline Als at 12 Lundbeck to Ivan Gergel at Forest dated July 16, 2001. 13 Have you seen that document before? 14 MR. ROBERTS: You can answer to the 15 extent that it refreshed your recollection. 16 THE WITNESS: No, I don't recognize this 17 document. BY MR. BAUM: 18 19 Q. You see that it's addressed to you up at the top there? 20 21 Α. Yes. 22 Q. It's -- the subject is "94404: Headline 23 results." 24 Do you see that, right at the subject

line? 1 2 Α. Yeah. 3 Ο. Then the importance is high, do you see that further down? 4 5 Α. Mm-hmm. 6 And it says, Dear Ivan Gergel, 94404 0. 7 citalopram versus placebo in the treatment of 8 adolescent depression have been unblinded and 9 unfortunately with a negative result. It was not possible to detect a significant difference between the 10 11 two treatment groups. 12 Do you see that? 13 Α. Yes. 14 Do you recall having received this Q. 15 document? 16 Α. No. 17 Do you recall having being informed that Q. the 94404 results were negative? 18 19 Α. No. 20 Does this document refresh your Ο. 21 recollection at all that during this time frame you were advised that the outcome of 94404 was negative? 22 23 Α. Yes, I mean, that's new information. 24 You never knew at the time that 94404 Ο.

1	was negative?	
2	MR. ROBERTS: Objection.	
3	THE WITNESS: I thought 94404 was older	
4	than this. I didn't think I didn't think I	
5	learned in 2001 that 94404 had failed results.	
6	BY MR. BAUM:	
7	Q. You think you learned that earlier?	
8	A. Yeah.	
9	Q. When do you think you learned it?	
10	A. I don't know. I thought it had been	
11	I had the impression it had been completed a lot	
12	earlier than this.	
13	Q. Do you have any reason to dispute what	
14	is stated in this e-mail?	
15	A. No.	
16	Q. Do you have any reason to dispute that	
17	you received it?	
18	A. Well	
19	MR. ROBERTS: Objection.	
20	THE WITNESS: Dispute anything that it	
21	says in this e-mail? I haven't read the entire	
22	e-mail. I mean, I believe that this was is	
23	an actual e-mail that was sent.	
24	BY MR. BAUM:	

It was produced in the ordinary course 1 0. 2 of business of Forest? 3 Α. Yes. 4 MR. ROBERTS: Objection. 5 BY MR. BAUM: 6 That was yes? Ο. 7 Α. Yes. 8 Okay. Do you recall that it was of high Q. 9 importance for Forest employees to learn that a 10 contemporaneous study on Celexa treatment for 11 adolescent depression in Europe was unfortunately a 12 negative result? 13 MR. ROBERTS: Objection. 14 THE WITNESS: The results of the 94404 15 study were of strong interest to Forest. 16 BY MR. BAUM: 17 Was there a plan orchestrated around Q. this time between Forest and Lundbeck to make sure that 18 19 the positive results from CIT-MD-18 were published 20 before the negative results of 94404? 21 MR. ROBERTS: Objection. 22 THE WITNESS: No. 23 BY MR. BAUM: 24 You don't recall that? 0.

1 MR. ROBERTS: Objection. 2 THE WITNESS: No. BY MR. BAUM: 3 4 Q. Ever? 5 MR. ROBERTS: Objection. 6 THE WITNESS: No. 7 BY MR. BAUM: 8 Do you recall any urgency on behalf of Q. 9 Forest to get the so-called positive data published regarding CIT-MD-18? 10 MR. ROBERTS: Objection. 11 12 THE WITNESS: That sounds familiar. 13 BY MR. BAUM: 14 Q. Were you personally involved with 15 delaying publication of the study 94404 until after the 16 results of CIT-MD-18 were published? 17 MR. ROBERTS: Objection. 18 THE WITNESS: No. 19 MR. BAUM: Okay. We're going to move on 20 to Exhibit 6, it's MDL-FORP0018834. 21 (Document marked for identification as 22 Flicker Deposition Exhibit No. 6.) 23 BY MR. BAUM: 24 Q. This is an e-mail chain between you,

Bill Heydorn, Karoline Als between November 14 and 20 1 of 2001 regarding 94404, second draft. 2 3 You see your name there on the to line? 4 Α. Yeah. 5 Q. Do you have any doubt -- reason to doubt that you received this e-mail chain? 6 7 Α. No. 8 Was this produced in the ordinary course 0. 9 of Forest business? 10 MR. ROBERTS: Objection. 11 THE WITNESS: Say again. 12 BY MR. BAUM: Was this e-mail part of the ordinary 13 0. 14 course of Forest business? 15 MR. ROBERTS: Objection. 16 THE WITNESS: I assume so. 17 BY MR. BAUM: You see at the bottom of this page that 18 0. 19 Karoline Als of Lundbeck writes to you on November 14, 2001 and asks you to review the second draft of the 20 21 report for -- study report for 94404? It says, "Dear 22 Charles, by today you will receive the second draft 23 report of 94404. Your review should focus on the 24 following aspects."

Golkow Technologies, Inc.

1 You see that? Here, let me point it to 2 you. It's there. 3 Α. You want me to read this whole thing? 4 I'm actually just asking you do you Q. No. recall having worked on the second draft of the study 5 б report for 94404? 7 Α. No. 8 You don't recall ever having worked on Q. 9 94404 study report? 10 MR. ROBERTS: Objection. 11 THE WITNESS: I could speculate, yeah. BY MR. BAUM: 12 13 0. Do you have any reason to doubt that you 14 were sent the results of 94404 and a second draft of 15 the 94404 study report for you to review? 16 MR. ROBERTS: Objection. 17 THE WITNESS: No. 18 BY MR. BAUM: 19 Do you have any reason to dispute any of Ο. the information that's discussed in this e-mail chain? 20 21 MR. ROBERTS: Objection. THE WITNESS: I'd have to read it. 22 23 BY MR. BAUM: 24 Well, the part that I'm interested in, 0.

in particular, is that you were sent a second draft of 1 the report for 94404 and you were asked to review 2 3 aspects of it. 4 Do you have any doubt that you received 5 the second draft? 6 I have only a small amount of doubt. Α. 7 And what is that? 0. 8 Maybe I didn't. Since I don't have any Α. 9 specific recollection of getting it, then it's hard for 10 me to confirm that. 11 Did you -- do you recall receiving 0. e-mails from Karoline Als at Lundbeck regarding 94404? 12 13 MR. ROBERTS: Objection. 14 THE WITNESS: Only because I'm looking 15 at this, I do recollect the name Karoline Als, 16 and I do associate her certainly with Lundbeck 17 and possibly as a person who collected comments 18 on that -- on that study report. 19 BY MR. BAUM: 20 Ο. The next e-mail up, it says, "Dear 21 Charles, by now you should be able to access the 22 draft." 23 Do you see that? Just a little bit 24 higher up in the middle of the page.

Α. Yeah. 1 2 And then the next one up has an e-mail 0. from you to -- from Joan Singh, I guess that was on 3 4 behalf of Charles Flicker; that was your secretary, 5 correct? 6 Yes. Α. 7 And it's to Bill Heydorn and cc'd to Ο. 8 Paul Tiseo, Jane Wu and Julie Kilbane. 9 Do you see that? 10 Α. Yes. 11 Q. And then you ask who is the contact 12 person on this. 13 Do you see that? 14 Α. Uh-huh. 15 And then the next one up shows Bill 0. 16 Heydorn to you saying, "I can coordinate return of comments on 94404." 17 18 Do you see all that? 19 Α. Yes. 20 Does any of that refresh your Ο. 21 recollection that you were involved with making some 22 modifications and comments to the study report for 94404? 23 24 MR. ROBERTS: Objection.

Charles Flicker, Ph.D.

1	THE WITNESS: It doesn't refresh my	
2	recollection.	
3	BY MR. BAUM:	
4	Q. Do you have any reason to doubt that	t you
5	were involved with making comments and changes to t	the
6	study report for 94404?	
7	MR. ROBERTS: Objection.	
8	THE WITNESS: No.	
9	MR. BAUM: Okay. Let's go to the ne	ext
10	exhibit.	
11	(Document marked for identification	as
12	Flicker Deposition Exhibit No. 7.)	
13	BY MR. BAUM:	
14	Q. Marked as Exhibit 7, MDL-FORP0011	- no
15	19228. And this is some handwritten comments on 94	4404
16	study report, CF with an arrow to W. Heydorn.	
17	Do you recognize that handwriting?	
18	A. It looks like my handwriting.	
19	Q. And CF, that would be you?	
20	A. Yes.	
21	Q. To Bill Heydorn?	
22	A. Yes.	
23	Q. And it's comments on 94404 study rep	port?
24	A. Yes.	

Q. Okay. So was this produced by you while 1 you were working at Forest? 2 3 It must have been. Α. 4 Something you would have done in the Q. ordinary course of your work at Forest? 5 6 MR. ROBERTS: Objection. 7 THE WITNESS: I don't know how ordinary, 8 but it would be part of the job. 9 BY MR. BAUM: 10 Okay. And do you see here that you were Q. 11 making comments on the 94404 study report? 12 Α. Yes. 13 And you had some detailed comments here, Q. 14 correct? 15 MR. ROBERTS: Objection. 16 THE WITNESS: Yes. 17 BY MR. BAUM: 18 Q. And you sent those comments to Bill 19 Heydorn, right? 20 MR. ROBERTS: Objection. 21 THE WITNESS: That would appear to be 22 the case. 23 BY MR. BAUM: 24 Do you know how they ended up getting to 0.

1	Bill Heydorn?	Was it via e-mail or did you hand them
2	to him?	
3		MR. ROBERTS: Objection.
4		THE WITNESS: I would assume I don't
5	know r	eally.
6	BY MR. BAUM:	
7	Q.	And these comments here are your
8	suggested chan	ges to the study report of 94404?
9		MR. ROBERTS: Objection.
10		THE WITNESS: These are comments on the
11	study	report. I don't know if they're changes
12	or cla	rifications.
13	BY MR. BAUM:	
14	Q.	Well, under "Discussion" it says "delete
15	statement rega	rding faster metabolism."
16		Do you see that?
17	Α.	Yes.
18	Q.	And it says "delete reference 25."
19		Do you see that?
20	Α.	Yes.
21	Q.	So are those recommendations of
22	suggested chan	ges to the study report for 94404?
23		MR. ROBERTS: Objection.
24		THE WITNESS: Yes.

1	BY MR. BAUM:
2	Q. So you were participating in making
3	comments and changes to the study report for 94404,
4	correct?
5	MR. ROBERTS: Objection.
б	THE WITNESS: Certainly comments. I
7	don't know to what extent the comments or
8	turned into changes.
9	BY MR. BAUM:
10	Q. But you suggested changes, correct?
11	A. Yes.
12	MR. BAUM: Okay. Let's go to Exhibit 8.
13	(Document marked for identification as
14	Flicker Deposition Exhibit No. 8.)
15	BY MR. BAUM:
16	Q. This is an e-mail chain between Ivan
17	Gergel, Bill Heydorn, I don't know how you pronounce
18	this, Dorte or is it Dorte?
19	MS. KIEHN: Dorte.
20	BY MR. BAUM:
21	Q. Dorte Thudium and another unidentified
22	Lundbeck employee by the name probably Anders,
23	Agpe@Lundbeck.com dated March 2nd through March 8, 2002
24	regarding 94404 report comments.

1		Do you know who Dorte Thudium is?
2	Α.	I recall that there was a Lundbeck
3	employee by th	at name.
4	Q.	And if you look part way down the page,
5	you'll see tha	t Bill Heydorn sent to Dorte Thudium and
6	cc'd to you an	e-mail that he forwarded to Dorte
7	Thudium.	
8		Do you see that? Your name is right
9	there.	
10	Α.	To Dorte.
11	Q.	Just above Dear Dorte, do you see your
12	name?	
13	Α.	Yeah.
14	Q.	Okay. So who is Dorte Thudium?
15	Α.	She was an employee or at least
16	representative	e of Lundbeck.
17	Q.	Okay. Did you have any contact with
18	her?	
19	Α.	Not that I recall.
20	Q.	Only through these e-mail chains?
21	Α.	Not that I recall.
22	Q.	Do you have any reason to doubt that you
23	were involved	with and received or sent e-mails related
24	to this e-mail	chain?

1	MR. ROBERTS: Objection.
2	THE WITNESS: I think I think I must
3	have gotten this e-mail from Bill.
4	BY MR. BAUM:
5	Q. Do you think it was produced in the
6	ordinary course of Forest business?
7	MR. ROBERTS: Objection.
8	THE WITNESS: Basically.
9	BY MR. BAUM:
10	Q. All right. So in the top e-mail it
11	says, "Anders, I am forwarding a memo relating to the
12	report on your pediatric study which was sent to your
13	team yesterday by Charlie Flicker and Bill Heydorn."
14	Do you see that?
15	A. Yes.
16	Q. "As you are aware, this is an extremely
17	important report for Celexa as it is one of the two
18	clinical efficacy reports that we will be submitting to
19	satisfy our 6 month exclusivity requirement."
20	Do you see that?
21	A. Yes.
22	Q. Does that refresh your recollection at
23	all that both studies were involved with getting the
24	six-month exclusivity?

1	MR. ROBERTS: Objection.
2	THE WITNESS: Well, no, it doesn't
3	refresh my recollection. As I stated, I had
4	the impression that we only needed to do one
5	study, so I was confused on that.
6	BY MR. BAUM:
7	Q. Do you have any reason to doubt what
8	Mr. Gergel Dr. Gergel is saying here?
9	MR. ROBERTS: Objection.
10	THE WITNESS: No.
11	BY MR. BAUM:
12	Q. "We believe that the changes to the
13	report detailed in the attached memo are very important
14	and may have significant bearing on the acceptability
15	of the report as 'interpretable' by the FDA."
16	Do you see that?
17	A. Yes.
18	Q. Do you recall there being some concern
19	about 94404's results being interpretable?
20	MR. ROBERTS: Objection.
21	THE WITNESS: I don't know if
22	interpretable would be the word I would use.
23	BY MR. BAUM:
24	Q. Well, you see here that Dr. Gergel did?

1	A. Yes.
2	Q. Do you know that interpretable was a
3	technical word that had something to do with whether or
4	not the study was useful for getting the exclusivity
5	extension?
6	MR. ROBERTS: Objection.
7	THE WITNESS: You know, my recollection
8	is refreshed that that was the criterion for
9	the exclusivity, that apparently it was two
10	studies, not one and that the two studies
11	needed to be interpretable.
12	BY MR. BAUM:
13	Q. And that Dr. Gergel is saying here that
14	changes need to be made in order for the study to be
15	viewed as interpretable.
16	Do you see that?
17	MR. ROBERTS: Objection.
18	THE WITNESS: Well, he thinks they have
19	significant bearing.
20	BY MR. BAUM:
21	Q. And he thought that your suggestions
22	would have a significant bearing, correct?
23	MR. ROBERTS: Objection.
24	THE WITNESS: He does say that the

source of the input was from Flicker and 1 2 Heydorn, yeah. BY MR. BAUM: 3 4 Q. And then he says, "I should be very 5 grateful for your support in ensuring that the changes are made." б 7 Do you see that? 8 Α. Yes. 9 Ο. Do you know who Anders is or was? 10 Anders was a senior executive or a Α. 11 senior employee at Lundbeck. Do you know whether your changes were, 12 0. in fact, implemented? 13 14 MR. ROBERTS: Objection. 15 THE WITNESS: No. 16 BY MR. BAUM: 17 Q. Do you agree that the changes you recommended might have -- you and the Forest team 18 19 recommended would have had a significant bearing on the study 94404 results being interpretable? 20 21 MR. ROBERTS: Objection, calls for 22 speculation. 23 THE WITNESS: Could you repeat that. 24 BY MR. BAUM:

1 0. Do you agree that the changes recommended by you and the Forest team would have a 2 significant bearing on the study 94404 results being 3 4 interpretable? 5 MR. ROBERTS: Objection. 6 THE WITNESS: Again, interpretable is so 7 vague, I can't really answer that. 8 BY MR. BAUM: 9 Ο. Well, do you recall being involved in making sure that the 94404 results were interpretable? 10 11 MR. ROBERTS: Objection. 12 THE WITNESS: No. BY MR. BAUM: 13 14 0. Does this indicate that you were 15 involved with making sure that the 94404 results were 16 interpretable? 17 MR. ROBERTS: Objection. 18 THE WITNESS: This suggests to me 19 that -- and based on the other sheet of the 20 comments that I provided, suggests to me that I 21 was involved in an effort to improve the 22 quality of the 94404 report. 23 BY MR. BAUM: 24 And to make it interpretable? 0.

1		MR. ROBERTS:	Objection.
2		THE WITNESS:	It would appear that Ivan
3	at leas	t was concerne	ed about the
4	interpr	etability iss	ue.
5	BY MR. BAUM:		
6	Q.	And that your	suggested changes would
7	affect the inte	erpretability,	correct?
8		MR. ROBERTS:	Objection.
9		THE WITNESS:	That's what he thought.
10	BY MR. BAUM:		
11	Q.	Did you think	that too?
12		MR. ROBERTS:	Objection.
13		THE WITNESS:	I don't know.
14	BY MR. BAUM:		
15	Q.	You don't reca	all?
16	Α.	I recall that	94404's design had
17	problems.		
18	Q.	That might hav	ve interfered with its
19	being interpret	able?	
20		MR. ROBERTS:	Objection.
21		THE WITNESS:	That could have undermined
22	the val	idity of the s	study.
23	BY MR. BAUM:		
24	Q.	Okay. If you	look at a couple pages in

1	to this e-mail chain, there's an attachment. Do you
2	recall having reviewed any material like this when you
3	were working at Forest related to 94404?
4	MR. ROBERTS: Objection, and the
5	attachment you're saying starts at 19160; is
6	that what you're think
7	MR. BAUM: Yes.
8	THE WITNESS: No.
9	BY MR. BAUM:
10	Q. From these last three documents we just
11	went over, is it clear to you now that you knew of the
12	results from 94404 by at least July of 2001?
13	MR. ROBERTS: Objection.
14	THE WITNESS: How do you know that?
15	BY MR. BAUM:
16	Q. Well, the first one I showed you was
17	dated July 2001. If you go back to Exhibit, I think,
18	б.
19	A. Okay.
20	Q. No, no, it's actually 5, sorry. Go back
21	to 5.
22	Each of these cover a time period
23	between July 16, 2001 and March 8, 2002. Do you see at
24	the top of Exhibit 5 it says July 16, 2001.

Yes. 1 Α. 2 0. And this is when word conveyed that the results were negative, and then the next ones coming 3 4 up --5 MR. ROBERTS: Objection. BY MR. BAUM: б 7 -- were drafts of the study report for 0. 8 94404. 9 Do you see that, Exhibit 6? 10 Α. Yeah. 11 0. All right. So what I wanted to find --12 ask you is is that based on these documents, by this time frame between July 16, 2001 and March 8, 2002, you 13 14 were aware of the results of 94404, correct? 15 MR. ROBERTS: Objection. 16 THE WITNESS: As I said, my recollection 17 is that I thought that 944 had been completed 18 far earlier, but in seeing these doc -- I don't 19 doubt the authenticity of these documents. 20 BY MR. BAUM: 21 Q. Okay. Did you convey the results of 22 94404 to Dr. Wagner? 23 MR. ROBERTS: Objection. 24 THE WITNESS: I don't know.

1	BY MR. BAUM:
2	Q. Did you convey the results of 94404 to
3	Mary Prescott?
4	MR. ROBERTS: Objection.
5	THE WITNESS: I don't know.
6	BY MR. BAUM:
7	Q. Did you withhold them for any reason?
8	MR. ROBERTS: Objection.
9	THE WITNESS: No.
10	BY MR. BAUM:
11	Q. Was there any would there have been
12	any reason for you to have not conveyed those to them?
13	MR. ROBERTS: Objection, calls for
14	speculation.
15	THE WITNESS: Was there a reason for me
16	to not tell Mary Prescott about 94404?
17	BY MR. BAUM:
18	Q. Right.
19	A. If she asked me about it?
20	Q. Well, you were communicating to her
21	about the results of studies, CIT-MD-18, on an
22	adolescent and child population. Do you think it would
23	have been important to convey to her also the results
24	of 94404?

	-
1	MR. ROBERTS: Objection,
2	mischaracterizes testimony.
3	THE WITNESS: Yeah, I don't think that
4	would be the type of conversation I would have
5	with Mary Prescott.
6	BY MR. BAUM:
7	Q. What type of conversation would you have
8	with Mary Prescott?
9	MR. ROBERTS: Objection, calls for
10	speculation.
11	THE WITNESS: You know, if her company
12	were generating slides, then I would get them
13	data.
14	BY MR. BAUM:
15	Q. So included in that data, would you not
16	want to include both positive and the negative data?
17	MR. ROBERTS: Objection, calls for
18	speculation.
19	THE WITNESS: You know, I did not make
20	any determinations about what general projects
21	Mary Prescott worked on.
22	BY MR. BAUM:
23	Q. What about Dr. Wagner?
24	MR. ROBERTS: Objection.
L	

1 THE WITNESS: Dr. Wagner is a nice lady. 2 BY MR. BAUM: 3 0. Did you convey the negative results of 4 94404 to Dr. Wagner? 5 MR. ROBERTS: Objection. 6 THE WITNESS: I don't know. 7 BY MR. BAUM: 8 What's a study protocol? Q. What is a study protocol? 9 Α. 10 Q. Yeah. 11 Α. It's a document that details how a study 12 should be -- how a particular study is to be conducted. 13 Q. Is it necessary for the conduct of a 14 clinical trial? 15 For a study -- certainly for a study Α. 16 conducted under the auspices of the FDA to be submitted to the agency. 17 18 Q. Why is it necessary for the conduct of a clinical trial? 19 20 MR. ROBERTS: Objection. 21 THE WITNESS: That's a little deep, but 22 can you repeat the question? Why is a study 23 protocol necessary? 24 MR. BAUM: Right.

1	MR. ROBERTS: Objection.
2	THE WITNESS: I'd say that it's designed
3	to ensure consistent conduct of the study
4	and consistent documented conduct of the
5	study.
6	BY MR. BAUM:
7	Q. Was Forest expected to follow the study
8	protocol for study CIT-MD-18?
9	MR. ROBERTS: Objection.
10	THE WITNESS: Well, usually it's the
11	investigators who are supposed to follow the
12	study protocol. The study protocol is given to
13	the investigators, and they follow the study
14	protocol.
15	BY MR. BAUM:
16	Q. And what did Forest have to do with
17	seeing to it that the protocol was followed?
18	MR. ROBERTS: Objection, just like to
19	state the witness is not an expert.
20	THE WITNESS: The monitors monitored the
21	study to ensure that there are study
22	monitors who visit the site and ensure that
23	it's being conducted in accordance with the
24	protocol.

BY MR. BAUM: 1 Did you have anything to do with making 2 0. sure that the study protocol for Study 18 was followed? 3 4 MR. ROBERTS: Objection. 5 THE WITNESS: Well, not that I specifically recollect. 6 7 BY MR. BAUM: 8 Do you recall having been involved with 0. 9 drafting the protocol for CIT-MD-18? 10 Α. Based on documents I saw yesterday. I'm going to hand you what we're marking 11 0. as Exhibit 9. 12 13 (Document marked for identification as 14 Flicker Deposition Exhibit No. 9.) 15 BY MR. BAUM: 16 0. Which is some of the protocol for MD-18. If you flip over to the -- it's dated September 1, 17 18 1999. 19 Do you see that, right there? 20 Α. Okay. 21 MR. ROBERTS: And let the record reflect 22 that it's part of a larger production that's 23 dated April 2nd, 2002. It's an excerpt from 24 that.

BY MR. BAUM: 1 Yeah, this is an excerpt from the study 2 0. 3 report itself that was dated April 8, 2002. This is the protocol for CIT-MD-18, correct? 4 5 Α. I don't dispute that. 6 Ο. Okay. So let's go to the next page. It 7 says, "Final Protocol Authorization Sign-off Sheet." 8 Do you see that? 9 Α. Yes. 10 Q. And it was submitted by Paul Tiseo. 11 Do you see that? 12 Α. Yes. 13 He was the associate medical Q. 14 director-CNS, medical monitor. 15 Do you see that? 16 Α. Yes. 17 Q. Then the next one underneath that says authorized by Charles Flicker, that was you, correct? 18 19 Α. Yes. 20 And it said you were senior medical 0. 21 director-CNS. 22 Do you see that? 23 Α. Yes. 24 Does that refresh your recollection you Q.

1	were a senior medical director of the CNS department at
2	some point in Forest?
3	A. No, I told you that already.
4	Q. I thought you disputed that you were in
5	the CNS section?
6	A. Oh, no, it wasn't a CNS department.
7	Q. What does this mean senior medical
8	director-CNS?
9	A. I was in Ivan's department, clinical
10	research, and CNS that was my title, but CNS
11	wasn't was it a separate depart I don't even
12	know.
13	Q. All right. It doesn't matter.
14	A. I believe clinical research was a
15	department and CNS was a division within that
16	department.
17	Q. Okay. So you were maybe a senior
18	medical director within the CNS division?
19	MR. ROBERTS: Objection.
20	THE WITNESS: I would have been senior
21	medical director of the CNS group or division
22	within the clinical research department.
23	Q. Okay. And you see Lawrence Olanoff
24	there?

1	Α.	I see his name and signature, yeah.
2	Q.	Do you recall his being involved with
3	MD-18?	
4	Α.	Well, no, I mean no, I don't directly
5	remember his i	nvolvement.
6	Q.	Do you have any reason to dispute that
7	he was involve	d, based on his having signed off on the
8	protocol sheet	?
9	Α.	No.
10	Q.	And Ivan Gergel, do you recall his being
11	involved with	MD-18?
12	Α.	Again, not directly, but having seen
13	that last memo	, I mean, yeah, sure, he was.
14	Q.	And Dr. Lakatos, is that right, Edward
15	Lakatos, do yo	u recall him?
16	Α.	I recall him.
17	Q.	Do you know what his job was?
18	Α.	He was head head of the stats group.
19	Q.	Okay. And Keith Rotenberg, do you
20	recall working	with him on MD-18?
21	Α.	On MD-18, no, but I remember he was head
22	of regulatory.	
23	Q.	Okay. You had some interaction with
24	regulatory aff	airs?

1 Α. Yes. 2 Ο. What was your involvement? 3 Α. Whatever they had to do for our studies in terms of filings to the FDA or communications. 4 5 Q. Part of your job was to make sure there was accurate and truthful information conveyed to the 6 7 FDA? 8 MR. ROBERTS: Objection. I don't know that it was 9 THE WITNESS: in a written job description, but I would say 10 11 yes. 12 BY MR. BAUM: If the protocol weren't followed, would 13 0. 14 that invalidate the results of the study, or could it 15 invalidate the results of the study? 16 Objection. MR. ROBERTS: 17 If the protocol is not THE WITNESS: 18 followed, could it invalidate the results of 19 the study? Yes, it possibly could. 20 BY MR. BAUM: 21 And the placebo effect and observer bias 0. 22 require an experiment to use a double-blind protocol 23 and a control group, correct? 24 MR. ROBERTS: Objection.

1 THE WITNESS: Why are you saying you need a double-blind control group? 2 BY MR. BAUM: 3 4 To avoid placebo effect, rule out 0. placebo effect and observer bias? 5 6 MR. ROBERTS: Objection. 7 THE WITNESS: I mean, yes, you're saying 8 to the extent that you need to demonstrate, 9 that you wish to demonstrate the drug effect is above and beyond the placebo effect, yes. 10 11 BY MR. BAUM: 12 Q. Was the protocol for Study 18 double-blind procedure? 13 14 A. Was the protocol --15 0. Yes. 16 Α. -- was the design of the study? It was 17 a double-blind study, yes. Q. Do you know who was responsible for the 18 19 overall conduct of study MD-18? 20 MR. ROBERTS: Objection. 21 THE WITNESS: Well, Paul Tiseo was the 22 lead clinician. 23 BY MR. BAUM: 24 Q. What was his role with respect to

1	CIT-MD-18 before he left Forest?
2	A. Well, I now see that he had a primary
3	role in generating the protocol, and what about
4	documents I've seen yesterday? He was obviously
5	involved in the in the oversight of the running of
6	the study.
7	MR. BAUM: Let's go to the next exhibit,
8	Exhibit 10.
9	(Document marked for identification as
10	Flicker Deposition Exhibit No. 10.)
11	BY MR. BAUM:
12	Q. Which is an e-mail with an attachment
13	from Irene Stockman dated April 10, 2002 and was sent
14	to Robert Ashworth, Im Abramowitz and Marcelo Gutierrez
15	and it's cc'd to you and Bill Heydorn.
16	Do you see that?
17	A. Yes.
18	Q. And it says, "Find attached the final
19	sign-off copy of citalopram pediatric study 18. The
20	sign-off sheet will be circulated to Harborshide
21	shortly; please sign and return to me shortly."
22	Do you see that?
23	A. Yes.
24	Q. Do you recall signing off on the study

report for MD-18? 1 2 Α. No. 3 0. Do you have any reason to doubt that you did sign off on it? 4 5 MR. ROBERTS: Objection. 6 THE WITNESS: Very little. 7 BY MR. BAUM: 8 Q. Does -- do you recall that CIT-MD-18 was a multisite clinical trial? 9 10 MR. ROBERTS: Objection. 11 THE WITNESS: Yes. 12 BY MR. BAUM: 13 Q. And was each site expected to follow the 14 study protocol? 15 MR. ROBERTS: Objection. 16 THE WITNESS: Yes. 17 BY MR. BAUM: 18 Q. When you signed off on the protocol, 19 were you affirming the accuracy of its contents? 20 MR. ROBERTS: Objection. 21 THE WITNESS: What do you mean by 22 "accuracy"? Oh, you mean the study report, you 23 mean the study report? 24 BY MR. BAUM:

Q. Well, there's the protocol and then the 1 2 study report. Let's back up. 3 When you signed off on the study report, did you -- were you affirming the accuracy of its 4 5 contents? 6 MR. ROBERTS: Objection, lacks 7 foundation. 8 THE WITNESS: Yeah. 9 BY MR. BAUM: 10 Q. Do you recall drafting any portions of 11 the protocol? 12 THE WITNESS: Objection. I'm losing 13 track of this refreshing recollection 14 reflecting. 15 MR. ROBERTS: If there's any documents 16 that you saw yesterday. So if you saw this 17 document yesterday and it refreshed your recollection, you can answer a question. 18 THE WITNESS: I could answer it 19 20 according to my refreshed recollection? 21 MR. ROBERTS: According to your 22 refreshed recollection, yes, but if it's 23 something that Kristin and I talked to you 24 about, that's different, then you can't answer.

1	THE WITNESS: Oh, okay. Yeah, I saw
2	documents yesterday that refresh my
3	recollection that I did work on the protocol
4	protocol?
5	BY MR. BAUM:
6	Q. Protocol and the study report, correct?
7	A. Both.
8	MR. ROBERTS: Objection.
9	BY MR. BAUM:
10	Q. And do you recall what your input was to
11	the protocol?
12	A. No.
13	Q. Let's go back to Exhibit 9 just for a
14	minute.
15	MR. ROBERTS: The protocol?
16	MR. BAUM: Yeah.
17	BY MR. BAUM:
18	Q. If you go to the synopsis, which is like
19	the third page in, see under evaluation?
20	MR. ROBERTS: You mean Page 1.
21	BY MR. BAUM:
22	Q. Yes, Page 1 of protocol, which is Page
23	313 of the study report, and it's about the third page
24	in, it's under Synopsis.

1 Do you see that? 2 Α. Mm-hmm. 3 Ο. And then under Synopsis there's evaluations. 4 5 Do you see that? 6 Α. Yes. 7 And it says there's a diagnosis for Ο. kiddie schedule for affective disorders and 8 9 schizophrenia - present and lifetime. 10 Do you see that? 11 Α. Yes. 12 Was that like a diagnosis was required Ο. to have a major depression disorder for a child in 13 14 order to be in this trial? 15 MR. ROBERTS: Objection. I have to look at the -- I 16 THE WITNESS: mean, there was a study in depressed children. 17 What the exact diagnosis required? I believe 18 19 it was major depressive disorder. BY MR. BAUM: 20 21 Yeah, if you look up at the objective on 0. 22 that same page, right up here, "The objective of this study is to evaluate the safety and efficacy of 23 24 citalopram in children and adolescent outpatients (7-11

and 12-17 years of age, respectively), diagnosed with 1 major depressive disorder." 2 3 Do you see that? 4 Α. Yes. 5 Q. All right. So does that refresh your recollection that this was addressing children with --6 7 and adolescents with major depressive disorder? 8 MR. ROBERTS: Objection. 9 THE WITNESS: Yes. 10 BY MR. BAUM: 11 Okay. And that the primary efficacy Ο. 12 measure was going to be the Children's Depression Rating Scale - Revised. 13 14 Do you see that? 15 Α. Yes. 16 0. And that there were some secondary efficacy measures, the Clinical Global Impression (CGI) 17 - Severity and Improvement subscales. 18 19 Do you see that? 20 Α. Yes. 21 And the K-SADS-P (depression module). 0. 22 Do you see that? 23 Α. Mm-hmm. 24 And the Children's Global Assessment 0.

Scale (CGAS). 1 2 Do you see that? 3 Α. Yes. 4 Q. Were those all secondary efficacy 5 measures for CIT-MD-18? 6 That appears to be the case. Α. 7 Did you have any involvement with Ο. choosing which ones were going to be used? 8 9 Α. Yes. 10 0. What was your involvement? 11 It was a very -- it was a very active Α. 12 area, and there were a lot of considerations that went 13 into selecting the efficacy measures. I don't recall 14 exactly, but there were the optimal efficacy measure --15 as I recollect, the optimal measure to use in these 16 studies had not been established. I think the CDRS was 17 relatively new, but it was -- it appeared to be 18 emerging as the optimal measure to use in such trials. 19 Ο. What was the purpose of having secondary 20 outcome measures? 21 Part of it was historical. Certainly in Α. 22 the case of the K-SADS, which had been -- the K-SADS and I believe also the CGAS had been -- I think they 23 24 might have been -- very likely were used in the

1	Lundbeck trial, maybe as the primaries. So since the
2	CDRS was relatively new, my impression is, as best I
3	recollect is that the K-SADS and the CGAS, even though
4	they were being had been deemed as to be less useful
5	measures, might have been kept in there for the sake of
6	continuity.
7	Q. Were the primary and secondary efficacy
8	evaluations the protocol specified outcome measures by
9	which the study drug citalopram was determined to be
10	successful or unsuccessful compared with placebo?
11	MR. ROBERTS: Objection.
12	THE WITNESS: What are you asking?
13	BY MR. BAUM:
14	Q. Were these primary and secondary
15	efficacy evaluations the protocol specified outcome
16	measures by which the study drug citalopram was
17	determined to be successful or unsuccessful compared
18	with placebo in CIT-MD-18?
19	MR. ROBERTS: Objection.
20	THE WITNESS: I would say yes.
21	BY MR. BAUM:
22	Q. Can you explain how efficacy of the
23	study drug versus placebo is demonstrated by an outcome
24	measure?

1	A. How is efficacy demonstrated relative to
2	placebo?
3	Q. Yes.
4	MR. ROBERTS: Objection. Are you asking
5	generally or specific to the study?
6	MR. BAUM: Okay. You're going to have
7	to stop coaching. I asked my question, and
8	he's thinking about answering.
9	MR. ROBERTS: I'm just trying to get a
10	clear record.
11	MR. WISNER: He didn't express any
12	confusion.
13	THE WITNESS: Could you repeat the
14	question.
15	BY MR. BAUM:
16	Q. Can you explain how efficacy of a study
17	drug versus placebo is demonstrated by an outcome
18	measure?
19	MR. ROBERTS: Objection.
20	THE WITNESS: Usually, basically, an
21	outcome assessment is made at baseline and at
22	the end of the study and to look and the
23	change from baseline in the active group is
24	compared to the change from baseline in the

placebo group. 1 BY MR. BAUM: 2 0. And what determines whether or not it 3 was successfully demonstrated? 4 5 MR. ROBERTS: Objection. THE WITNESS: Whether the difference was 6 7 successfully demonstrated is based on 8 statistical analysis. 9 BY MR. BAUM: 10 And the statistical analysis involves Q. whether or not the difference is statistically 11 significant? 12 13 MR. ROBERTS: Objection. 14 THE WITNESS: Yes. 15 BY MR. BAUM: 16 0. And that involves a P-value? 17 MR. ROBERTS: Objection. 18 THE WITNESS: Ultimately, yes. 19 BY MR. BAUM: 20 And is there a prespecified P-value that 0. 21 was arrived at with respect to MD-18? 22 MR. ROBERTS: Objection. 23 THE WITNESS: Not that I know of, but 24 that seems likely.

BY MR. BAUM: 1 Do you recall what the P-value normally 2 0. was used for determining significance? 3 4 MR. ROBERTS: Objection. 5 THE WITNESS: Well, classically, the 6 nominal P-value is .05. 7 BY MR. BAUM: 8 Q. And needs to -- the difference needs to be less than .05? 9 10 MR. ROBERTS: Objection. 11 THE WITNESS: Sometimes less than, 12 sometimes less than or equal. 13 BY MR. BAUM: 14 Q. Okay. If you take a look at Page 318 15 under subheading "6. Study Design and Duration," it says here, "A total of 160 patients will be randomized 16 to double-blind treatment." 17 18 Do you see that at the bottom -- the 19 last sentence under the first paragraph under 20 subheading 6? 21 Α. Yes. 22 Q. Was 160 the number needed to power the 23 study? 24 MR. ROBERTS: Objection.

1 THE WITNESS: It's likely that a power analysis was conducted. 2 BY MR. BAUM: 3 4 Q. Do you think that the 160 was the number 5 they arrived at? 6 MR. ROBERTS: Objection. 7 BY MR. BAUM: 8 In order to get a statistical 0. 9 significant number or outcome --10 Α. I would have to assume. 11 0. Okay. Do you recall whether MD-18 was powered to detect differences in the efficacy of 12 citalopram between children and adolescents? 13 14 MR. ROBERTS: Objection. 15 THE WITNESS: No, I assume so. 16 BY MR. BAUM: 17 Do you recall whether it was powered to Q. detect the efficacy of citalopram with children alone 18 19 or with children and adolescents as a group? 20 MR. ROBERTS: Objection. 21 THE WITNESS: I don't know. 22 BY MR. BAUM: 23 0. What is the difference between a primary 24 and a secondary efficacy measure?

1	A. I think there could be a lot of
2	differences depending upon the context. I would say
3	the primary efficacy measure is the one designated as
4	the as the measure that would be used to determine
5	whether the outcome of the study was positive. The
6	secondary efficacy measures provide supportive
7	information.
8	Q. Let's take a look at Page 326 under
9	Study Drug, Paragraph "9.1 Study Medication."
10	Do you see that?
11	A. Yes.
12	Q. It says citalopram (20 mg) and placebo
13	medication will be supplied by Forest Laboratories as
14	film-coated, white tablets of identical appearance.
15	For the single-blind lead-in period, patients will be
16	supplied with placebo tablets only. For the
17	double-blind treatment period, identically appearing
18	tablets will contain either 20 mg of citalopram or
19	placebo. Medication will be supplied in bottles
20	containing either 10 tablets for the lead for the
21	lead-in and for the excuse me. Medication will be
22	supplied in bottles containing either 10 tablets for
23	the lead-in and the first four weeks of double-blind
24	treatment or 40 tablets for remaining four weeks of the

treatment period. 1 2 Did I read that correctly? A. Yes. 3 4 Q. Was this the protocol specified procedure followed -- to be followed for CIT-MD-18? 5 б MR. ROBERTS: Objection. 7 THE WITNESS: Apparently. 8 BY MR. BAUM: Was it followed? 9 0. MR. ROBERTS: Objection. 10 THE WITNESS: I believe so. 11 12 BY MR. BAUM: 13 Q. Let's take a look at Page 328 under "9.7 14 Unblinding Procedures." 15 Do you see that? 16 Α. Yes. 17 What does it mean for a study to be Q. unblinded? 18 19 MR. ROBERTS: Objection. 20 THE WITNESS: A study is unblinded at 21 the end, when the code is broken and the 22 treatment groups that the patients belong to 23 are identified. BY MR. BAUM: 24

1	Q. What does it mean for a patient to be
2	unblinded?
3	MR. ROBERTS: Objection.
4	THE WITNESS: That's pretty difficult to
5	say. I can give an example. If a patient
6	were if a patient were receiving were
7	told that they were receiving active medication
8	or a patient were told that they were receiving
9	placebo medication, then that patient would be
10	unblinded.
11	BY MR. BAUM:
12	Q. What about with respect to the
13	investigators, if they were told what the patients were
14	getting, would they be unblinded?
15	MR. ROBERTS: Objection.
16	THE WITNESS: If the investigator knew
17	that what treatment the patient, an individual
18	patient was receiving, then I think it would be
19	appropriate to say that the investigator had
20	been unblinded.
21	BY MR. BAUM:
22	Q. Would you agree that a clinical trial is
23	blinded if the participants are unaware on whether they
24	are in the experimental or control arm of the study?
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1	MR. ROBERTS: Objection.
2	THE WITNESS: That is part and parcel,
3	that's part of unblinding of a study.
4 1	BY MR. BAUM:
5	Q. And then blinding would also be extended
6 t	to the investigator so that the patient observations
7 a	are less likely to be biased by their awareness of the
8 t	treatment the patient is receiving, correct?
9	MR. ROBERTS: Objection.
10	THE WITNESS: The investigator should
11	not know what treatment the patient is
12	receiving. That's part of the blinding.
13 I	BY MR. BAUM:
14	Q. So would you agree that if a study does
15 ı	not follow the unblinding procedures, as specified in
16 t	the study protocol, then the study cannot be considered
17 a	a randomized, placebo-controlled trial?
18	MR. ROBERTS: Objection,
19	mischaracterizes testimony.
20	THE WITNESS: Could you read that again.
21 1	BY MR. BAUM:
22	Q. Would you agree that if a study does not
23	follow the unblinding procedures, as specified in the
24	study protocol, then the study could not be considered
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1	a randomized, placebo-controlled trial?
2	MR. ROBERTS: Objection,
3	mischaracterizes testimony.
4	THE WITNESS: No, it would still be a
5	randomized, placebo-controlled trial. It might
6	undermine the validity of the study.
7	BY MR. BAUM:
8	Q. If you include data from patients who
9	were unblinded in an analysis of efficacy in a clinical
10	trial, does that not corrupt the integrity of the
11	clinical trial results?
12	MR. ROBERTS: Objection, calls for
13	speculation.
14	THE WITNESS: Inclusion of an unblinded
15	patient?
16	BY MR. BAUM:
17	Q. Right.
18	A. Could undermine the validity of the
19	study results.
20	Q. And that would corrupt the integrity of
21	the clinical trial results?
22	MR. ROBERTS: Objection.
23	THE WITNESS: I'd say that was a pretty
24	strong statement.

1	BY MR. BAUM:
2	Q. Is it true or not?
3	MR. ROBERTS: Objection.
4	THE WITNESS: No.
5	BY MR. BAUM:
6	Q. It doesn't corrupt it?
7	MR. ROBERTS: Objection.
8	THE WITNESS: It undermines the
9	validity.
10	BY MR. BAUM:
11	Q. Okay. So going down in that subsection,
12	there's some italicized words it says, "Any patient for
13	whom the blind has been broken will immediately be
14	discontinued from the study and no further efficacy
15	evaluations will be performed."
16	Do you see that?
17	A. Uh-huh.
18	Q. And that was the protocol unblinding
19	procedure, correct?
20	MR. ROBERTS: Objection,
21	mischaracterizes the document.
22	THE WITNESS: Yeah, it's a little
23	confusing. I mean, the language has been
24	ambiguous because the paragraph above describes

1	a particular situation, and it's not clear
2	whether it's referring whether the
3	subsequent statement is referring exclusively
4	to that particular situation or to any kind of
5	unblinding.
6	BY MR. BAUM:
7	Q. Do you think that any kind of unblinding
8	would invalidate the results if those results were
9	included in the efficacy analyses?
10	MR. ROBERTS: Objection.
11	THE WITNESS: It could undermine the
12	validity of the results.
13	BY MR. BAUM:
14	Q. So it's important to know whether or not
15	you've got some unblinded patients or investigators,
16	correct?
17	MR. ROBERTS: Objection.
18	THE WITNESS: Yes.
19	BY MR. BAUM:
20	Q. So if something were to happen that
21	would cause the blind to be broken for any reason,
22	Forest Laboratories would have to have been notified
23	immediately, correct?
24	MR. ROBERTS: Objection, calls for

1	speculation.
2	THE WITNESS: Well, that's what the
3	protocol says, and that would be appropriate.
4	BY MR. BAUM:
5	Q. And you think it would be appropriate
б	for any patient for whom the blind has been broken to
7	be immediately discontinued from the study and no
8	further efficacy evaluations performed on them?
9	MR. ROBERTS: Objection,
10	mischaracterizes the document.
11	THE WITNESS: As I said, I mean, that's
12	what the that's what the protocol reads.
13	BY MR. BAUM:
13 14	BY MR. BAUM: Q. Okay. If a patient were unblinded
14	Q. Okay. If a patient were unblinded
14 15	Q. Okay. If a patient were unblinded during the course of a clinical trial, would you
14 15 16	Q. Okay. If a patient were unblinded during the course of a clinical trial, would you consider that to be a minor or a major protocol
14 15 16 17	Q. Okay. If a patient were unblinded during the course of a clinical trial, would you consider that to be a minor or a major protocol violation?
14 15 16 17 18	Q. Okay. If a patient were unblinded during the course of a clinical trial, would you consider that to be a minor or a major protocol violation? MR. ROBERTS: Objection, calls for
14 15 16 17 18 19	Q. Okay. If a patient were unblinded during the course of a clinical trial, would you consider that to be a minor or a major protocol violation? MR. ROBERTS: Objection, calls for speculation.
14 15 16 17 18 19 20	Q. Okay. If a patient were unblinded during the course of a clinical trial, would you consider that to be a minor or a major protocol violation? MR. ROBERTS: Objection, calls for speculation. THE WITNESS: If one patient were
14 15 16 17 18 19 20 21	Q. Okay. If a patient were unblinded during the course of a clinical trial, would you consider that to be a minor or a major protocol violation? MR. ROBERTS: Objection, calls for speculation. THE WITNESS: If one patient were unblinded or I mean, is it a protocol

1	A. Yes, it's a protocol violation.
2	Q. If there was enough patients unblinded
3	to affect the P-value, would that be a major or a minor
4	protocol violation?
5	MR. ROBERTS: Objection, calls for
6	speculation.
7	THE WITNESS: Can you repeat the
8	question.
9	BY MR. BAUM:
10	Q. If there were enough patients unblinded
11	to affect whether or not the P-value was significant or
12	insignificant, would that be a major or a minor
13	protocol violation?
14	MR. ROBERTS: Objection, calls for
15	speculation.
16	THE WITNESS: Yeah, I don't know that
17	it sounds as if you're making a direct
18	connection between the P-value and the
19	unblinding. I don't know if I can answer that.
20	BY MR. BAUM:
21	Q. Well, if there are enough patients
22	unblinded to affect the P-value, would that be a major
23	or a minor protocol violation?
24	MR. ROBERTS: Objection, calls for

1	speculation.
2	THE WITNESS: Well, how do you know if
3	the unblinding of the patient affects the
4	P-value?
5	BY MR. BAUM:
6	Q. I'm asking you to answer my question.
7	Can you answer my question?
8	A. Okay. What's the question?
9	MR. ROBERTS: Objection.
10	BY MR. BAUM:
11	Q. If there were enough patients unblinded
12	to affect the P-value, would that be a major or a minor
13	protocol violation?
14	MR. ROBERTS: Objection, calls for
15	speculation.
16	THE WITNESS: The unblinding the
17	unblinding of a patient is a protocol
18	violation. Now, whether the in terms of the
19	number of patients who are unblinded and how
20	that relates to the magnitude of the protocol
21	violation, I can't really answer that.
22	BY MR. BAUM:
23	Q. If it affected the P-value?
24	A. If all the patients in the study

1 MR. ROBERTS: Objection. 2 THE WITNESS: -- were unblinded, it 3 would not be a double-blind study. 4 BY MR. BAUM: Okay. Would the patient --5 Q. б Or it would be an invalid double-blind Α. 7 study. 8 Q. Okay. Were any of the patients in study MD-18 unblinded? 9 10 MR. ROBERTS: Objection. 11 THE WITNESS: Well, based on material I 12 saw yesterday? 13 BY MR. BAUM: 14 Q. Yes. 15 I saw material yesterday indicating that Α. there was potentially unblinding information. 16 17 Q. Do you recall addressing CIT-MD-18 patients being unblinded at the time you were working 18 19 at Forest? 20 MR. ROBERTS: Objection. 21 THE WITNESS: No. 22 BY MR. BAUM: 23 You have no recollection of it? 0. 24 MR. ROBERTS: Objection.

1 THE WITNESS: No. 2 BY MR. BAUM: 3 0. So you don't have any recollection of any of the documents you were involved with authoring 4 5 regarding that? 6 MR. ROBERTS: Objection. 7 THE WITNESS: Based on documents I saw 8 yesterday? 9 BY MR. BAUM: 10 Q. Well, did those documents refresh your 11 recollection that you were involved with dealing with the unblinding problem --12 13 MR. ROBERTS: Objection. 14 BY MR. BAUM: 15 0. -- with CIT-MD-18 patients? 16 Α. I didn't recall that there was an unblinding issue with MD-18. 17 Did reviewing documents refresh your 18 0. 19 recollection there was one? 20 MR. ROBERTS: Objection. 21 THE WITNESS: I don't know. They were 22 -- they weren't inconsistent with my 23 recollection, but they didn't -- none of 24 those -- there was -- it was new to me. I

mean, it was believable with the documents I 1 saw, but did I recall the incident? No. 2 BY MR. BAUM: 3 4 Q. Okay. Do you recall that Forest Laboratories was notified of any unblinding in 5 6 CIT-MD-18? 7 MR. ROBERTS: Objection. 8 THE WITNESS: No. 9 BY MR. BAUM: 10 Q. Do you have any reason to doubt that 11 Forest was notified that there was some unblindings that occurred with respect to some of the patients in 12 13 the CIT-MD-18? 14 MR. ROBERTS: Objection, lacks 15 foundation. 16 THE WITNESS: There was a problem with 17 the packaging. 18 BY MR. BAUM: 19 Ο. When did you find out about it? 20 MR. ROBERTS: Objection. 21 THE WITNESS: Yesterday. 22 BY MR. BAUM: 23 That's the first time you found out 0. 24 about it?

1	MR. ROBERTS: Objection.
2	THE WITNESS: I would have to speculate
3	to tell you when I first found out about it.
4	BY MR. BAUM:
5	Q. Approximately when did you first find
6	out about it?
7	MR. ROBERTS: Objection, calls for
8	speculation.
9	THE WITNESS: As I said, I don't recall
10	ever finding out about it. I've seen documents
11	that indicate that I did.
12	BY MR. BAUM:
13	Q. All right. Let's go to Page 331. Under
14	heading "12.7 Sample Size Considerations."
15	Do you see that?
16	A. No. Okay.
17	Q. And there it says, "The primary efficacy
18	variable is the change from baseline in CDRS-R score at
19	Week 8."
20	Do you see that?
21	A. Yes.
22	Q. Is that and we discussed that a few
23	minutes ago, correct?
24	MR. ROBERTS: Objection.

BY MR. BAUM: 1 The CDRS is the primary efficacy 2 0. variable? 3 4 Α. Yes. 5 Q. And that it's the measure at the end at б Week 8, correct? 7 MR. ROBERTS: Objection. 8 THE WITNESS: Did we discuss that 9 previously? 10 BY MR. BAUM: 11 Ο. Well, you mentioned that it was --12 that -- yes, we did discuss that previously. 13 Do you recall discussing that? 14 MR. ROBERTS: Objection. 15 THE WITNESS: We talked about the change 16 from baseline. I don't recall talking about 17 Week 8. 18 BY MR. BAUM: 19 0. So Week 8 is the endpoint, correct? 20 MR. ROBERTS: Objection. 21 THE WITNESS: Week 8 is the last visit 22 of the study. 23 BY MR. BAUM: 24 So "the primary efficacy variable is the 0.

1	change from baseline CDRS-R score at Week 8," correct?
2	MR. ROBERTS: Objection.
3	THE WITNESS: According to the protocol,
4	according to this part of the protocol.
5	BY MR. BAUM:
6	Q. Okay. Is there something else you refer
7	to that would make it be a different point of the
8	study?
9	A. Just that it's that when they say at
10	Week 8, it's there are different the analyses
11	there are different types of analyses.
12	Q. But they would not be the primary
13	outcome measure, correct?
14	MR. ROBERTS: Objection.
15	THE WITNESS: Based on what I saw
16	yesterday, the primary outcome measure was the
17	last observation carried forward analysis, so
18	that's not necessarily at Week 8.
19	BY MR. BAUM:
20	Q. So some of the results might have been
21	from patients who dropped out of the study prior to
22	Week 8?
23	A. Yes.
24	Q. And their scores would be carried
Colke	w Technologies. Inc. Page 149

1	forward to Week 8?
2	A. Yes.
3	Q. And compiled with the other patients'
4	results that completed the trial at Week 8, correct?
5	A. Yes.
6	Q. And the primary efficacy measure would
7	be the results of all of the patients, including the
8	LOCF patients at Week 8, correct?
9	MR. ROBERTS: Objection.
10	THE WITNESS: If you're talking about an
11	LOCF analysis.
12	BY MR. BAUM:
13	Q. Okay. So let's go back to the prior
14	page under Section 12.5.1, just flip it back to Page
15	18. It says "Primary Efficacy Parameters."
16	Do you see that?
17	A. Yes.
18	Q. And it says, "Change from baseline
19	CDRS-R score at Week 8 will be used as the primary
20	efficacy parameter."
21	Do you see that?
22	A. Yes.
23	Q. And the it says, "descriptive statistics
24	will be calculated by visit."

1 Is that what you were referring to? No. Regarding last observation carried 2 Α. forward? 3 Regarding statistics for prior -- for 4 Q. 5 visits prior to Week 8. 6 MR. ROBERTS: Objection. THE WITNESS: No, that's not what I was 7 referring to. 8 9 BY MR. BAUM: 10 0. Oh, okay. All right. So but what I was 11 referring to is that the measure of the primary 12 efficacy parameter was the change from baseline on CDRS between the change from baseline to Week 8, correct? 13 14 MR. ROBERTS: Objection. 15 THE WITNESS: That's what it says here. 16 BY MR. BAUM: 17 Do you disagree with that? Q. 18 MR. ROBERTS: Objection. 19 THE WITNESS: Well, as I said, based on 20 what I saw yesterday, it would appear to be at 21 last observation carried forward analysis, 22 which is not every -- you know, it's a 23 shorthand, I would say. I would describe this as a shorthand for what I -- what apparently 24

1	was th	e primary efficacy analysis.
2	BY MR. BAUM:	
3	Q.	If you look up to the paragraph just
4	above under Ef	ficacy Analyses, it says, primary
5	analyses will	be performed using the Last Observation
6	Carried Forwar	d approach. In these analyses, the last
7	observed value	before the missing value will be carried
8	forward to imp	ute the missing value?
9	Α.	Yeah.
10	Q.	You see that?
11	Α.	Yeah.
12	Q.	And then, "If the missing value occurs
13	at Week 1, the	baseline value will be carried forward
14	to Week 1 prov	ided at least one subsequent post
15	baseline asses	sment is available."
16		Do you see that?
17	Α.	Yes.
18	Q.	And then the next line says, the
19	observed cases	approach will be used for supportive
20	analyses, wher	e only observed values will be used for
21	analyses.	
22		Do you see that?
23	Α.	Yes.
24	Q.	So that's going to be the observed

1	cases will be the group of patients who actually finish
2	the study, and it would be an analysis of their results
3	at Week 8 when they finish the study, correct?
4	MR. ROBERTS: Objection.
5	THE WITNESS: Or at least when they
6	appeared at Week 8, yes.
7	BY MR. BAUM:
8	Q. And the last observation carried forward
9	analysis would include both the observed cases results
10	at Week 8 and the patients' results that occurred prior
11	to that carried forward to Week 8 for an analysis at
12	Week 8, correct?
13	MR. ROBERTS: Objection.
14	THE WITNESS: Yes, that would be my
15	understanding of the LOCF approach.
16	BY MR. BAUM:
17	Q. Okay. So turning back to section 12.7
18	on Page 19 it says here, "The primary efficacy variable
19	is the change from baseline in CDRS-R score at Week 8."
20	Do you see that?
21	A. Yes.
22	Q. Do you agree with that?
23	MR. ROBERTS: Objection.
24	THE WITNESS: My understanding of the

protocol is that it's that variable using the 1 2 LOCF analysis, yes. BY MR. BAUM: 3 4 0. Okay. And then "Assuming an effect size 5 (treatment group difference relative to pooled standard deviation) of 0.5, a sample size of 80 patients in each 6 7 treatment group will provide at least 85% power at an 8 alpha level of 0.05 (two-sided)." 9 Do you see that? 10 Α. Yes. 11 Q. Do you know what that means? 12 MR. ROBERTS: Objection. 13 THE WITNESS: I don't have a clear 14 understanding of power analyses. 15 BY MR. BAUM: 16 Do you have a general concept of what 0. 17 that means? 18 MR. ROBERTS: Objection. 19 BY MR. BAUM: 20 Does it mean that it needed 160 patients 0. 21 essentially to power the study to arrive at .05 22 two-sided P-value? 23 MR. ROBERTS: Objection. 24 Yeah, I mean, my THE WITNESS:

1	understanding of how power analyses results get
2	presented is that this would mean that,
3	assuming that there is a significant difference
4	between the treatment groups, the analyses
5	expects that there would be an 85% chance that
6	that difference would be demonstrated at the
7	.05 level.
8	BY MR. BAUM:
9	Q. With 160 patients?
10	MR. ROBERTS: Objection.
11	THE WITNESS: Given that end, yeah.
12	BY MR. BAUM:
13	Q. Is that correct?
14	MR. ROBERTS: Objection.
15	BY MR. BAUM:
16	Q. So as long as MD-18 had 160 patients'
17	results in the equations, that was enough to power
18	statistically significant results?
19	MR. ROBERTS: Objection.
20	THE WITNESS: 160 patients were was
21	what was deemed needed to meet this level of
22	power.
23	BY MR. BAUM:
24	Q. And you didn't need more than 160 to
~ 11	

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power the study for statistical significant purposes,
 1
    right?
 2
 3
                    MR. ROBERTS: Objection, calls for
 4
             speculation.
 5
                    THE WITNESS: Yeah, I don't think -- you
 6
             know, I don't think the power analyses are that
             firm. I don't know to what extent 85% is the
 7
 8
             level that's -- that's accepted.
 9
    BY MR. BAUM:
10
             Q.
                    Well, here the protocol is specifying
11
     160 patients, correct?
12
                    MR. ROBERTS: Objection.
13
                    THE WITNESS:
                                  Yes.
14
    BY MR. BAUM:
15
             0.
                    And per this section of the protocol,
16
    Week 8 was the endpoint for efficacy, correct?
17
                    MR. ROBERTS: Objection.
18
                    THE WITNESS:
                                  Yes.
19
    BY MR. BAUM:
20
             Ο.
                    And measurements at Weeks 1, 2, 4 or 6
21
    would not be considered efficacy endpoints for study
22
    MD-18, right?
23
                                  Objection.
                    MR. ROBERTS:
24
                                  Endpoints is a word that's
                    THE WITNESS:
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used pretty loosely. 1 2 BY MR. BAUM: 3 0. What was the endpoint week for Study 18? 4 MR. ROBERTS: Objection. 5 THE WITNESS: Endpoint week was Week 8. BY MR. BAUM: б 7 Okay. And it would be inconsistent with 0. the protocol to suggest that positive results at weeks 8 9 earlier than Week 8 indicated a positive trial outcome for MD-18, right? 10 11 MR. ROBERTS: Objection. 12 THE WITNESS: No. BY MR. BAUM: 13 14 So you could measure the outcome Q. 15 differently than what the protocol says? 16 MR. ROBERTS: Objection, 17 mischaracterizes testimony. 18 THE WITNESS: Excuse me, no. You need 19 to abide by the protocol to measure your 20 outcome. 21 BY MR. BAUM: 22 Q. So attempting to measure the outcome by results at Weeks 1, 2, 4 or 6 would be inconsistent 23 24 with the protocol, correct?

1 MR. ROBERTS: Objection. 2 THE WITNESS: Not at all. I mean, if 3 you've got an effect at week 1, that's great. 4 BY MR. BAUM: 5 Q. All right. Well, is that the 6 prespecified endpoint? 7 MR. ROBERTS: Objection. 8 THE WITNESS: Primary endpoint. 9 BY MR. BAUM: 10 Q. Yeah, the primary endpoint? 11 Α. No, those --12 MR. ROBERTS: Objection. 13 THE WITNESS: Those visits are not 14 primary. 15 BY MR. BAUM: 16 Okay. That's what I'm trying to get at Ο. is that the outcome of the trial is measured by the 17 primary endpoint, correct? 18 19 MR. ROBERTS: Objection. 20 THE WITNESS: The trial has a primary 21 endpoint. 22 BY MR. BAUM: 23 0. And the outcome of whether it's positive 24 or negative is determined by the primary efficacy

measure, correct? 1 2 MR. ROBERTS: Objection. 3 THE WITNESS: Nominally. 4 BY MR. BAUM: 5 Q. What do you mean by "nominally"? I think in the assessment of the study, 6 Α. 7 all the results are considered. 8 So you look at all of the results? Q. 9 Α. Yeah. 10 Q. But the primary result is one that 11 determines whether or not the FDA will accept it as a 12 positive or a negative outcome, correct? 13 MR. ROBERTS: Objection, lack of 14 foundation. THE WITNESS: You know, I can't offhand 15 16 think of specific examples, but I don't know 17 that their thinking is guite that rigid. BY MR. BAUM: 18 19 So it doesn't matter what the primary 0. efficacy outcome was; is that what you're saying? 20 21 MR. ROBERTS: Objection, 22 mischaracterizes his testimony. 23 BY MR. BAUM: 24 0. You can go pick whatever outcome you

1 like? 2 No. The primary efficacy variable is Α. 3 important. 4 0. Why is it important? 5 Α. Because that's the predesignated main basis for reaching conclusions regarding the treatment 6 effect. 7 8 Q. And for MD-18 that was at Week 8, 9 correct? 10 MR. ROBERTS: Objection. THE WITNESS: That was at Week 8 with 11 12 last observation carried forward, yes. 13 BY MR. BAUM: 14 0. Thank you. Omitting the Week 8 result 15 while highlighting positive results from earlier weeks 16 would be inconsistent with the protocol and misleading, wouldn't it? 17 18 MR. ROBERTS: Objection, lacks foundation. 19 20 THE WITNESS: Omitting Week 8 from the 21 study? 22 BY MR. BAUM: 23 Omitting the Week 8 result while 0. 24 highlighting positive results from the earlier weeks

1	would be inconsistent with the protocol and misleading,
2	right?
3	MR. ROBERTS: Objection, lacks
4	foundation, calls for speculation.
5	THE WITNESS: Yeah, I'm not clear at all
6	what you're saying.
7	BY MR. BAUM:
8	Q. Well, if you highlighted the results
9	that occurred at Weeks 1, 2, 4 and 6, without
10	mentioning what happened at Week 8, you would be
11	discussing results that were different than what the
12	protocol called for as the primary endpoint for MD-18?
13	MR. ROBERTS: I renew my objection.
13 14	MR. ROBERTS: I renew my objection. THE WITNESS: So now you're talking
14	THE WITNESS: So now you're talking
14 15	THE WITNESS: So now you're talking about the study report?
14 15 16	THE WITNESS: So now you're talking about the study report? BY MR. BAUM:
14 15 16 17	THE WITNESS: So now you're talking about the study report? BY MR. BAUM: Q. Study report, the manuscript, posters,
14 15 16 17 18	THE WITNESS: So now you're talking about the study report? BY MR. BAUM: Q. Study report, the manuscript, posters, anything that's discussing and focusing on the Weeks 1,
14 15 16 17 18 19	THE WITNESS: So now you're talking about the study report? BY MR. BAUM: Q. Study report, the manuscript, posters, anything that's discussing and focusing on the Weeks 1, 2, 4 and 6 as if they're indicative of whether the
14 15 16 17 18 19 20	THE WITNESS: So now you're talking about the study report? BY MR. BAUM: Q. Study report, the manuscript, posters, anything that's discussing and focusing on the Weeks 1, 2, 4 and 6 as if they're indicative of whether the trial is positive or not would be inconsistent with the
14 15 16 17 18 19 20 21	THE WITNESS: So now you're talking about the study report? BY MR. BAUM: Q. Study report, the manuscript, posters, anything that's discussing and focusing on the Weeks 1, 2, 4 and 6 as if they're indicative of whether the trial is positive or not would be inconsistent with the protocol saying that Week 8 is the point of where you

1	THE WITNESS: Well, are you saying the
2	study report did not provide Week 8 results?
3	BY MR. BAUM:
4	Q. I'm not saying that.
5	I'm saying that if a writing were to
6	focus on the 1, 2 Weeks 1, 2, 4 and 6 results
7	without stating what the Week 8 results, that would be
8	misleading with respect to what the endpoint was of
9	Week 8?
10	MR. ROBERTS: Objection, calls for
11	speculation.
12	THE WITNESS: I would say it would be
13	important to also provide the Week 8 results.
14	MR. BAUM: Okay. We have a tape thing
15	we need to do?
16	THE VIDEOGRAPHER: We have another ten
17	minutes.
18	MR. BAUM: Oh, okay.
19	MR. ROBERTS: You want to keep going for
20	another ten minutes.
21	MR. BAUM: Yeah.
22	MR. ROBERTS: Are you good to go for
23	another ten minutes?
24	THE WITNESS: Yeah.

BY MR. BAUM: 1 Let's go to Page 329, Section "12.2 2 Ο. Patient Populations." 3 Do you see that? 4 5 Α. Yes. 6 0. And 12.2.1 is "Randomized population, 7 the randomized population will consist of all patients 8 randomized into this study." 9 Do you see that? 10 Α. Yes. 11 So that's a protocol defined Q. 12 randomization population, correct? 13 MR. ROBERTS: Objection. 14 THE WITNESS: Excuse me? 15 BY MR. BAUM: 16 It's a protocol defined definition for 0. the randomized population for MD-18, correct? 17 18 MR. ROBERTS: Objection. 19 THE WITNESS: That appears to be the 20 case, yeah. 21 BY MR. BAUM: 22 0. And then the next one down says "12.2.2 23 Safety population, the safety population will consist 24 of all randomized patients who receive at least one

dose of double-blind study medication." 1 2 Do you see that? 3 Α. Yes. 4 Q. And next one down, 12.2.3, 5 Intent-to-Treat population, the intent-to-treat population (ITT) -- the intent-to-treat (ITT) 6 7 population will consist of all patients in the safety 8 population who complete at least one post-baseline 9 efficacy evaluation of the primary efficacy variable. 10 Do you see that? 11 Α. Yes. 12 That's the intent-to-treat population, Ο. right? 13 14 MR. ROBERTS: Objection. 15 THE WITNESS: That's the intent-to-treat 16 population as defined here in the protocol, 17 yeah. 18 BY MR. BAUM: 19 Okay. And does the intent-to-treat Ο. 20 population apply to a randomized blinded population for 21 MD-18? 22 Α. Yeah. 23 And if the patients were unblinded at 0. 24 baseline before the first evaluation at Week 1, they

weren't valid members of the intent-to-treat 1 population? 2 3 MR. ROBERTS: Objection, calls for 4 speculation. 5 THE WITNESS: Wait. If they did not 6 receive a post-baseline efficacy assessment? 7 BY MR. BAUM: 8 If they were unblinded at baseline 0. 9 before the first evaluation at Week 1, they weren't 10 valid members of the intent-to-treat population, were 11 they? 12 MR. ROBERTS: Objection. 13 THE WITNESS: Well, this doesn't say 14 anything about blinding. 15 BY MR. BAUM: 16 Q. Okay. I'm asking you if patients were unblinded at baseline before their first evaluation, 17 would they be considered valid members of the 18 19 intent-to-treat population? 20 MR. ROBERTS: Objection, calls for 21 speculation. 22 THE WITNESS: If they were unblinded, 23 then their -- then their validity -- I would 24 say they're definitely members of the ITT

population. Their validity would be open to 1 question. 2 BY MR. BAUM: 3 4 Ο. What do you mean by that? 5 Α. Because they had a protocol violation. So the scientifically appropriate thing 6 Ο. 7 to do would be to exclude patients unblinded at 8 baseline from the efficacy outcome measure, right? 9 MR. ROBERTS: Objection. He's not an 10 expert. Calls for speculation. THE WITNESS: Patient unblinded at 11 12 baseline. BY MR. BAUM: 13 14 Ο. Should not be included in efficacy 15 measures for a double-blind, placebo-controlled trial? 16 MR. ROBERTS: Objection, calls for 17 speculation. 18 THE WITNESS: If -- I would say that if 19 you have patients who are unblinded, then it 20 would be -- you would probably do analyses of 21 both groups. 22 BY MR. BAUM: And the analyses of both groups ought to 23 Ο. 24 be conveyed to physicians and scientists who are

1	evaluating the merits of a drug like Celexa?
2	MR. ROBERTS: Objection, calls for
3	speculation.
4	THE WITNESS: I'd say if can you
5	repeat the question?
6	BY MR. BAUM:
7	Q. That you said that you should do both
8	evaluations, correct?
9	MR. ROBERTS: Objection.
10	THE WITNESS: I'd say that would be one
11	solution.
12	BY MR. BAUM:
13	Q. The fact that you did both evaluations
14	that you had an unblinding problem should be conveyed
15	to physicians?
16	MR. ROBERTS: Objection, assumes facts
17	not in evidence.
18	THE WITNESS: Well, you got a study and
19	there's an unblinding problem, that's what
20	your
21	BY MR. BAUM:
22	Q. Correct.
23	A. And so now the study is completed and
24	analyses are conducted, what are you asking me?

1	Q. Referring back to the answer you gave me
2	a minute ago where you said that you thought I
3	suggested that they should that the unblinded
4	patients at baseline ought not to be included in an
5	efficacy evaluation.
6	Do you remember that?
7	MR. ROBERTS: Objection,
8	mischaracterizes testimony. You can answer.
9	THE WITNESS: That's what you said.
10	BY MR. BAUM:
11	Q. Yeah, do you recall my having asked you
12	that?
13	MR. ROBERTS: Objection.
14	THE WITNESS: Yeah.
15	BY MR. BAUM:
16	Q. And you responded that I suggested
17	they should not be included at all, and you said, well,
18	maybe what we ought to do is have an analysis done with
19	the unblinded patients in and an analysis with the
20	unblinded patients out.
21	Do you recall that?
22	A. Yeah.
23	MR. ROBERTS: Objection,
24	mischaracterizes testimony.

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BY MR. BAUM: 1 2 And what I then was asking is so both 0. analyses ought to be conveyed to physicians and 3 4 academics evaluating the merits of a study like that, 5 correct? 6 MR. ROBERTS: Objection, calls for 7 speculation. 8 THE WITNESS: It would be hard for me to 9 speculate on that. 10 BY MR. BAUM: 11 Ο. Well, the conveying to physicians and academics only the result with the unblinded patients 12 included would be misleading, wouldn't it? 13 14 MR. ROBERTS: Objection, calls for 15 speculation. 16 THE WITNESS: Not necessarily. 17 BY MR. BAUM: 18 So it would be okay to do that? 0. 19 MR. ROBERTS: Objection, calls for 20 speculation, mischaracterizes testimony. 21 THE WITNESS: I mean, you're talking 22 about a pretty complex speculative situation. 23 You're talking about communications in some 24 unknown forum. I mean, it's pretty hard for me

1	to respond to what you're asking. And you're
2	talking about very detailed information about a
3	study.
4	BY MR. BAUM:
5	Q. Do you think it would be important for
б	physicians and academics who are receiving a manuscript
7	or a poster or a PowerPoint presentation regarding
8	CIT-MD-18 for them to know that there were patients who
9	had unblinding information at baseline?
10	MR. ROBERTS: Objection, calls for
11	speculation, lacks foundation.
12	THE WITNESS: Could you repeat the
13	question?
14	MR. BAUM: Can you read the question
15	back to him.
16	(The court reporter read back the record
17	as requested.)
18	THE WITNESS: I would say based on the
19	documents that I received that I looked at
20	yesterday, no.
21	BY MR. BAUM:
22	Q. No need to convey that information to
23	academics, physicians or parents who are considering
24	having their child take a drug?

1	MR. ROBERTS: Objection, calls for
2	speculation.
3	THE WITNESS: I think that to include
4	include in communications to physician some
5	information regarding every protocol violation
6	in the study would be impractical.
7	BY MR. BAUM:
8	Q. What about when it determines or affects
9	whether or not the P-value is significant or not?
10	MR. ROBERTS: Objection, calls for
11	speculation, lacks foundation.
12	THE WITNESS: Can you repeat the
13	question.
14	BY MR. BAUM:
15	Q. What if the violation results in the
16	P-value change going from insignificant to significant,
17	depending on whether you included the unblinded
18	patients?
19	MR. ROBERTS: Objection, calls for
20	speculation, lacks foundation.
21	THE WITNESS: Again, it would depend
22	upon the overall extent of information.
23	BY MR. BAUM:
24	Q. By your standards it would be okay to
	ou Technologica Ing

1	omit that information?
2	MR. ROBERTS: Objection,
3	mischaracterizes witness' testimony.
4	THE WITNESS: I mean, you're talking
5	about a speculative situation with a lot of
6	vague I mean, every study has many protocol
7	violations. There's no study that's done
8	without protocol violations. Those can't be
9	communicated in a top line presentation of a
10	study results.
11	MR. BAUM: We're going to come right
12	back to that, but we have to change the tape.
13	MR. ROBERTS: Do you want to take a
14	little break?
15	THE VIDEOGRAPHER: We'll be going off
16	the record at 10:55 a.m. This marks the end of
17	Media 2.
18	(Brief recess.)
19	THE VIDEOGRAPHER: We are back on the
20	record at 11:01 a.m. This marks the beginning
21	of Media 3.
22	Go ahead, counselor.
23	BY MR. BAUM:
24	Q. All right. So can you explain to the

jury what a study report is? 1 A study report is a writeup of the 2 Α. 3 results of a study. 4 Supposed to be presented to the FDA for Q. evaluating clinical trial's results? 5 6 MR. ROBERTS: Objection. 7 THE WITNESS: Study reports get 8 submitted to the FDA and the FDA evaluates 9 them, yes. 10 BY MR. BAUM: 11 Q. They should be accurate? 12 MR. ROBERTS: Objection. 13 THE WITNESS: Yes. 14 BY MR. BAUM: 15 Do you know who created the study report 0. 16 for MD-18? 17 Α. No. Did you participate in creation of the 18 Q. 19 study report for MD-18? 20 I've seen documents that indicate I did. Α. 21 Did you edit the study report for MD-18? 0. 22 Α. Did I? 23 Ο. Edit the study report for MD-18? 24 Α. Edit?

Yes. 1 Q. 2 Yeah, I provided comments. Α. So I think I've already handed you 3 0. Exhibit 10, can you pull that up again. 4 And Exhibit 10 has this e-mail that was 5 sent to you on April 10th of 2002, and it has "find 6 attached the final, sign-off copy of citalopram 7 8 pediatric study 18." 9 Do you see that? 10 Α. Yes. 11 Ο. Were you among the individuals who 12 signed off for the accuracy of study MD-18? 13 MR. ROBERTS: Objection. 14 BY MR. BAUM: 15 Ο. Study report? 16 Α. Signed off for the accuracy? I don't 17 know if I'd would put it that way. 18 How would you put it? 0. 19 Well, if I signed the study report, then Α. I approved it. 20 21 Did you review the tables for the 0. primary efficacy outcome data? 22 23 I have no recollection of doing so. Α. 24 Do you know whether or not you did? Q.

1	Α.	Do I know whether or not I did? I must
2	have.	
3	Q.	Was the CIT-MD-18 study report submitted
4	to the FDA?	
5	Α.	Yes.
6	Q.	Did you decide which tables would be the
7	main would	be in the main text of the study report
8	and which woul	d be in the appendix?
9		MR. ROBERTS: Objection.
10		THE WITNESS: I don't know.
11	BY MR. BAUM:	
12	Q.	Do you know who did?
13		MR. ROBERTS: Objection.
14		THE WITNESS: No.
15	BY MR. BAUM:	
16	Q.	Do you know whose responsibility it was?
17	Α.	No.
18	Q.	Did you review the appendices for Study
19	18's study rep	port?
20	Α.	I don't know.
21		MR. BAUM: Let's go to Exhibit 11.
22		(Document marked for identification as
23	Flicke	er Deposition Exhibit No. 11.)
24		MR. WISNER: Can we go off the record.

1 THE VIDEOGRAPHER: We will be going off 2 the record at 11:05 a.m. This marks the end of Media 3. 3 4 (Pause.) 5 THE VIDEOGRAPHER: We are going back on the record at 11:08 a.m. This marks the 6 beginning of Media 4. 7 8 Go ahead, counselor. 9 BY MR. BAUM: 10 Q. Okay. So I've handed you what we've 11 marked as Exhibit 11. Yes, no? 12 MR. ROBERTS: I don't think so. 13 MR. BAUM: Oh, here it is. 14 MR. ROBERTS: Now we have. 15 BY MR. BAUM: 16 0. Which is the study report for MD-18, and if you look at the middle of the page it says "Report 17 18 Date: April 8, 2002." 19 Do you see that? 20 Α. Yes. 21 MR. ROBERTS: Let the record reflect 22 that it's excerpted pages from the study 23 report. 24 BY MR. BAUM:

And since this document is actually 1 0. 2,135 pages long, only certain parts have been selected 2 here as the exhibit. 3 4 Have you seen sections of the 5 protocol -- I mean of the study report for MD-18 б before? 7 I'm sure I have. Α. 8 Have you seen it in the last few days to Q. 9 refresh your recollection? 10 Α. Yes. 11 0. Okay. So I want to take you through specific sections of it. 12 13 Do you see that the initiation date on 14 the cover page here says January 31, 2000. 15 Do you see that? 16 Α. Mm-hmm. 17 What is that date? Q. 18 MR. ROBERTS: Just so we have on the 19 record, what's the difference between Exhibits 20 10 and 11 that are both study reports? 21 MR. BAUM: They're the same. 22 MR. ROBERTS: Okay. Just different 23 excerpts? 24 MR. BAUM: Well, yeah, and one had an

1	e-mail attached to it. It was about the
2	sign-off sheet issue.
3	MR. ROBERTS: Okay.
4	MR. BAUM: All right. So this one is
5	focused in on the study report itself?
6	MR. ROBERTS: Okay.
7	BY MR. BAUM:
8	Q. So what is the initiation date,
9	January 31, 2000; what is that?
10	A. Probably first patient entered the
11	study. I don't know what the different definition is
12	of that, but basically first patient entered the study,
13	I believe.
14	Q. So prior to that, there was a protocol
15	and there was efficacy measures were determined and how
16	the pills are going to be delivered and what the
17	lead-in period how long it's going to be and what
18	patient is going to take during the lead-in period and
19	what tests are going to be done per the protocol,
20	that's all set up. And then at some point around
21	January 31, 2000, the patient shows up and does what's
22	in the protocol?
23	MR. ROBERTS: Objection.
24	BY MR. BAUM:
1	

Is that generally correct? 1 0. That would be very close to my overall 2 Α. understanding of what the initiation date means. 3 4 Q. Okay. And then the completion date is 5 10 April 2001. 6 Do you see that? 7 Α. Yes. 8 What is that? Q. 9 Α. That would approximately be the last day that a patient completed the study. 10 11 0. Okay. And relative to MD-18 with 12 respect to statistical significance, a P-value its used to determine the presence or absence of statistical 13 14 significance, correct? 15 MR. ROBERTS: Objection. 16 THE WITNESS: A P-value is derived from 17 the statistical analysis, yes. BY MR. BAUM: 18 19 And the P-value of less than .05 is the 0. threshold for statistical significance, correct? 20 21 MR. ROBERTS: Objection. 22 THE WITNESS: P of .05, that's the usual 23 nominal level for statistical significance. 24 BY MR. BAUM:

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1	Q.	Let's go to Page 69 under "Efficacy
2	Evaluations" a	nd go to the second paragraph under 10.1.
3		Do you see that?
4	Α.	Mm-hmm.
5		MR. ROBERTS: It's the one that starts
6	"At We	ek 8."
7	BY MR. BAUM:	
8	Q.	Yeah. So it says "At Week 8, the LOCF
9	analysis compa	ring the mean change from baseline and
10	CDRS-R in the	citalopram and placebo groups
11	demonstrated a	statistically significant treatment
12	effect in favo	r of citalopram (p=0.038; see Panel 11)."
13		Do you see that?
14	Α.	Yes.
15	Q.	So according to this, the CDRS-R was a
16	positive for e	fficacy, correct?
17	Α.	If by positive for efficacy you mean
18	demonstrated a	statistically significant treatment
19	effect, yes.	
20	Q.	Because it had a P-value of less than
21	.05, correct?	
22		MR. ROBERTS: Objection.
23		THE WITNESS: A P of .038.
24	BY MR. BAUM:	

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1 Q. And that's less than .05, correct? 2 Α. Yes. 3 Ο. And then if you go further down the page -- I want to go actually over to Page 70 and under 4 5 panel -- in Panel 11, at the top there, do you see that the P-value on the right is .038. 6 7 Do you see that? 8 Α. Yes. 9 And that's the change from baseline to 0. 10 Week 8 in the CDRS-R rating scale, correct? 11 MR. ROBERTS: Objection. 12 THE WITNESS: Yes. 13 BY MR. BAUM: 14 And if you go further down this page to Q. 15 the paragraph that starts "Appendix." 16 Do you see that? 17 Α. Yes. And it says, "Appendix Table 6 presents 18 Q. 19 the results from the LOCF analysis for the change from baseline to Week 8 excluding data from 9 patients for 20 21 whom the study blind was potentially compromised (see 22 Section 5.3.4)." 23 Do you see that? 24 Α. Yes.

Did you write that sentence? 1 Q. 2 I don't know. Α. 3 MR. ROBERTS: Objection. 4 BY MR. BAUM: 5 Q. Let's go to Page 244. б MS. KIEHN: I didn't hear the answer. 7 THE WITNESS: I don't know. 8 BY MR. BAUM: 9 Q. Do you have any reason to doubt that you 10 might have written it? I don't doubt that I might have written 11 Α. 12 it. 13 MR. ROBERTS: Objection. 14 BY MR. BAUM: 15 Well, we'll come up on that, so let's go 0. to Page 244 of this exhibit. 16 17 MR. ROBERTS: It's towards the back, almost all the way in the back. 18 19 BY MR. BAUM: 20 And this is Appendix Table 6, do you see 0. 21 that at the top? 22 Α. Mm-hmm, yes. 23 Ο. And it says, "Change from Baseline 24 CDRS-R after 8 weeks, ITT Sub-population - LOCF."

1 Do you see that? 2 Α. Yes. And then in a footnote at the bottom, it 3 Ο. says, "Note: Patients (105, 113, 114, 505, 506, 507, 4 5 509, 513, 514) with drug dispensing error are 6 excluded." 7 Do you see that? 8 Α. Yes. 9 0. Did you draft that line? 10 I don't know. Α. 11 Q. Do you think you might have? 12 MR. ROBERTS: Objection. 13 THE WITNESS: It's possible that I did. 14 BY MR. BAUM: 15 So these were the nine patients in Ο. 16 CIT-MD-18 who were subject to a dispensing error, 17 correct? 18 MR. ROBERTS: Objection. 19 THE WITNESS: I don't know that. I 20 learned yesterday that there were nine such 21 patients. 22 BY MR. BAUM: 23 Ο. Okay. And this table is saying there's 24 an analysis being done with those patients excluded,

1 correct? 2 Α. That's my understanding. 3 0. And if you look over to the next page. 4 MR. ROBERTS: Page 946? 5 MR. BAUM: Yes. BY MR. BAUM: б 7 Ο. And if you look at the -- over on the 8 right, see that P-value of .052? 9 Α. Yes. 10 Q. That's above .050, correct? That was on 11 both of them, sorry. 12 It's also on Page 244? Both of these 13 have that. 14 MR. ROBERTS: The two pages are exactly 15 the same? 16 MR. BAUM: Yeah, yeah, they are the 17 same. I don't know what -- I don't know how 18 that happened. All right, so sorry about that. 19 BY MR. BAUM: 20 0. So referring back to Page 244, just to 21 be clear, and relative to the -- this table that has, 22 according to the note, the patients subject to the 23 dispensing error excluded, the Week 8 result for the 24 change from baseline of CDRS after 8 weeks had a

P-value of .052, correct? 1 2 MR. ROBERTS: Objection. 3 THE WITNESS: Yes. 4 BY MR. BAUM: 5 Q. And that's greater than .050, correct? б .052 is greater than .050. Α. 7 And that's not a statistically 0. 8 significant outcome, is it? 9 MR. ROBERTS: Objection. 10 THE WITNESS: It depends upon what 11 criterion is being used. 12 BY MR. BAUM: 13 If the criterion prespecified in the 0. 14 study report was .050, less than .050 determines statistical significance, a result of .052 was not 15 16 statistically significant, correct? 17 MR. ROBERTS: Objection, calls for 18 speculation. 19 THE WITNESS: A P-value of .052 given a 20 specified nominal level of significance less 21 than .050 would not meet that criterion. 22 BY MR. BAUM: 23 So it was negative, not in favor of 0. 24 Celexa's efficacy, correct?

1 MR. ROBERTS: Objection, 2 mischaracterizes testimony. THE WITNESS: I wouldn't call that 3 4 negative, no. 5 BY MR. BAUM: б It's non-statistically significant 0. 7 P-value, correct? 8 MR. ROBERTS: Objection. THE WITNESS: It fails to meet the 9 10 criterion of statistical significance. 11 BY MR. BAUM: 12 Q. So by excluding these nine patients, the P-value went from a statistically significant .038 to a 13 14 statistically insignificant .052, right? 15 MR. ROBERTS: Objection, 16 mischaracterizes the document. 17 THE WITNESS: Yeah, I don't think the statistically insignificant is a word that I 18 19 would use. 20 BY MR. BAUM: 21 0. What would you use? 22 Α. I would say based on the data we're 23 looking at it, the P-value seems to have gone from .038 to .052. 24

1	Q. And that crossed the .050 requirement
2	for statistical significance for CIT-MD-18, correct?
3	MR. ROBERTS: Objection.
4	THE WITNESS: The .038 was below the
5	criterion for statistical significance, and the
6	.052 was slightly above.
7	BY MR. BAUM:
8	Q. Right. So by excluding the nine
9	patients, the P-value went from being below the .050
10	criterion to being above the .050 criterion, correct?
11	MR. ROBERTS: Objection.
12	THE WITNESS: Yeah.
13	BY MR. BAUM:
14	Q. And that would be the difference between
15	the CIT-MD-18 being considered a positive or a negative
16	trial under its primary efficacy measure, correct?
17	MR. ROBERTS: Objection.
18	THE WITNESS: No.
19	BY MR. BAUM:
20	Q. So the primary efficacy measure with
21	these nine patients excluded was statistically
22	significant; is that what you're saying?
23	MR. ROBERTS: Objection,
24	mischaracterizes testimony.

1 THE WITNESS: No. 2 BY MR. BAUM: So it was not statistically significant? 3 0. 4 MR. ROBERTS: Objection, 5 mischaracterizes testimony. 6 THE WITNESS: Can you repeat the 7 question. 8 BY MR. BAUM: The primary outcome measure for 9 0. CIT-MD-18 with the nine patients excluded was not 10 11 statistically significant? 12 MR. ROBERTS: Objection. THE WITNESS: The analysis with the nine 13 14 patients excluded appears to not be above the criterion of .05. 15 16 BY MR. BAUM: So that would be the difference between 17 Q. its being positive or negative under the primary 18 19 efficacy measure, correct? 20 MR. ROBERTS: Objection. 21 THE WITNESS: Between what being 22 positive or negative? 23 BY MR. BAUM: 24 Including or excluding those nine 0.

patients. 1 2 MR. ROBERTS: Objection. 3 THE WITNESS: Can you repeat the question? 4 5 BY MR. BAUM: 6 By excluding the nine patients who are Ο. 7 subject to the dispensing error, the P-value went from 8 .038 to .052, correct? 9 MR. ROBERTS: Objection. 10 THE WITNESS: Yes. 11 BY MR. BAUM: 12 0. And that's crossing the barrier of the .050 barrier between what would be considered a 13 14 positive result and a negative result per the protocol 15 for the primary efficacy measure, correct? 16 MR. ROBERTS: Objection. 17 THE WITNESS: I didn't see that in the 18 protocol. The protocol specified a statistical 19 significance level of .05. 20 BY MR. BAUM: 21 0. That's correct. So if the protocol specified .050 as the criterion for determining 22 23 statistical significance and a positive result for the 24 primary efficacy measure, going from .038 to .052

1	crossed that line from being positive outcome to
2	negative outcome, correct?
3	MR. ROBERTS: Objection,
4	mischaracterizes testimony, asked and answered.
5	THE WITNESS: I would regard that as a
6	pretty vague and incomplete assessment of the
7	study results.
8	BY MR. BAUM:
9	Q. So .052 was statistically significant;
10	is that what you're saying?
11	MR. ROBERTS: Objection,
12	mischaracterizes statement, asked and answered.
13	THE WITNESS: .052 is above the criteria
14	for statistical significance.
15	BY MR. BAUM:
16	Q. So it was not statistically significant?
17	MR. ROBERTS: Objection, asked and
18	answered.
19	THE WITNESS: It's above the criterion
20	for statistical significance.
21	MR. BAUM: I want my question answered,
22	and you have to quit guiding him.
23	MR. ROBERTS: I haven't been
24	MR. BAUM: You are guiding him.

1 MR. ROBERTS: I'm giving the
2 MR. BAUM: You need to knock it off.
3 MR. ROBERTS: reason for my
4 objection.
5 MR. BAUM: Just knock it off.
6 MR. ROBERTS: That is totally allowed
7 under the rules. You're not getting the answer
8 that you want. No reason to raise your voice.
9 MR. BAUM: I want my
10 MR. WISNER: Respectfully, he has not
11 answered the question.
12 MR. BAUM: I want my
13 MR. ROBERTS: Respectfully, if Kristin
14 can't talk, you can't talk.
15 MR. BAUM: I want my question answered
16 so
17 MR. ROBERTS: He has answered your
18 question twice now.
19 MR. BAUM: No, he's changed the question
20 and answered a different question.
21 MR. ROBERTS: You just don't like your
22 answer.
23 MR. BAUM: Okay. I'm going to be adding
24 extra time for your interfering. Every time

1	MR. ROBERTS: I talked like two minutes.
2	MR. BAUM: Yes, for every interference,
3	I am going to be adding time.
4	MR. ROBERTS: You're wasting time.
5	MR. BAUM: You are wasting time.
6	MR. ROBERTS: Okay.
7	BY MR. BAUM:
8	Q. So what I want is an answer to my
9	question.
10	MR. ROBERTS: For a third time.
11	MR. BAUM: Read the question.
12	(The court reporter read back the record
13	as requested.)
14	MR. ROBERTS: Objection.
15	THE WITNESS: That's not enough
16	information for me to
17	BY MR. BAUM:
18	Q. The .052 was not a statistically
19	significant P-value, correct?
20	MR. ROBERTS: Objection.
21	THE WITNESS: .052 is the above the
22	criterion for statistical significance.
23	BY MR. BAUM:
24	Q. So you're answering a different question

to what I'm asking you. 1 2 I want to know is .052 a not statistically significant P-value? 3 4 MR. ROBERTS: Objection, asked and 5 answered, calls for speculation. 6 THE WITNESS: I can't really answer that 7 question. 8 BY MR. BAUM: 9 Ο. Why not? 10 MR. ROBERTS: Objection. THE WITNESS: Because I think the 11 language is of questionable validity. 12 BY MR. BAUM: 13 14 Q. So the P-value determination, per the 15 protocol, is whether it's above or below .050, correct? 16 MR. ROBERTS: Objection. 17 That was the -- actually, THE WITNESS: 18 I don't even know that. Is that in the 19 protocol? In the power analysis it mentions 20 .05. 21 MR. BAUM: Okay. We're going to take a 22 break. 23 THE VIDEOGRAPHER: We will be going off 24 the record at 11:25 a.m. This marks the end of

Media 4. 1 2 (Pause.) 3 THE VIDEOGRAPHER: We are back on the 4 record at 11:27 a.m. This marks the beginning of Media 5. 5 6 Go ahead, counsel. 7 BY MR. BAUM: 8 So we're going back to Exhibit 9, which 0. 9 is the protocol. Take a look at Page 330. 10 MR. ROBERTS: Hold on, let me get there. 11 BY MR. BAUM: 12 Q. Under Section 12.5 Efficacy Analysis --Efficacy Analyses. 13 14 Α. Yes. 15 Okay. It says, "All efficacy analyses Ο. 16 will be based on the ITT population, i.e., patients who took at least one dose of study medication and had at 17 least one post-baseline efficacy assessment of CDRS-R 18 19 score. All tests will be two-sided with 5% significance level for main effects." 20 21 Do you see that? 22 Α. Yes. 23 Ο. Does that indicate to you that the 24 P-value needs to be above -- I mean below .05 for it to

be significant? 1 2 MR. ROBERTS: Objection. THE WITNESS: This indicates to me that 3 4 it would be less than or equal to .05. 5 BY MR. BAUM: 6 O. Okay. So a P-value of .038 would be less than the 5% significance level, correct? 7 8 MR. ROBERTS: Objection, asked and 9 answered. 10 THE WITNESS: Yes. 11 BY MR. BAUM: 12 Q. And .052 would be above the significance level for the specified outcome, correct? 13 14 MR. ROBERTS: Objection, asked and 15 answered. 16 THE WITNESS: Yes. 17 BY MR. BAUM: Q. So .052 would be a nonsignificant 18 19 P-value, correct? 20 MR. ROBERTS: Objection, 21 mischaracterizes testimony, asked and answered. 22 THE WITNESS: That's not what I would 23 say. 24 BY MR. BAUM:

What would you say? 1 0. I would say that it fails to achieve 2 Α. statistical significance, the statistical significance 3 criterion of .05. 4 5 Q. And that's the difference between whether or not CIT-MD-18 was a positive study or a б 7 negative study, correct? 8 MR. ROBERTS: Objection. 9 THE WITNESS: No. 10 BY MR. BAUM: 11 Ο. Why not? 12 Α. The overall positive or non-positive assessment of the study is based upon the overall 13 14 assessment of the results from the study. 15 So if all of the secondary outcome 0. 16 measures were negative and the observed cases was negative and the primary outcome measure is .05 --17 P-value is .052, it would be not a positive trial, 18 19 correct? 20 MR. ROBERTS: Objection, requires 21 speculation. 22 THE WITNESS: I mean, my understanding 23 of the interactions with the FDA is that they 24 are not so narrow minded. The results from a

1	clinical trial need to be evaluated in the
2	context of the study and in their overall
3	picture of the results obtained and
4	BY MR. BAUM:
5	Q. So a .0
6	MS. KIEHN: Let him finish his answer.
7	BY MR. BAUM:
8	Q. You have more to say?
9	A. No, that's good.
10	Q. So a P-value of .052 or a P-value above
11	.05 would not have a bearing on whether or not a study
12	was considered positive or negative?
13	MR. ROBERTS: Objection, asked and
14	answered, mischaracterizes the witness'
15	testimony.
16	THE WITNESS: The P-value criterion is a
17	important tool in the assessment of the study's
18	outcome.
19	BY MR. BAUM:
20	Q. And a P-value of above .050 would
21	indicate that it was a statistically insignificant
22	result and not positive for the drug, correct?
23	MR. ROBERTS: Objection, asked and
24	answered.

1 THE WITNESS: I wouldn't say that. 2 BY MR. BAUM: 3 Q. So it's your testimony that a P-value 4 above .050 suggests that the trial is positive for a 5 drug; is that what you're saying? 6 MR. ROBERTS: Objection, 7 mischaracterizes testimony, asked and answered. 8 THE WITNESS: I wouldn't say that. 9 MR. ROBERTS: Now you can go. 10 THE WITNESS: I wouldn't say that, no. 11 MR. BAUM: Okay. 12 MR. ROBERTS: Are we done with 9, or are 13 we still on Exhibit 9? 14 MR. WISNER: Why don't you just wait 15 until he asks the next question. 16 MR. ROBERTS: If Kristin can't talk, you 17 can't talk. 18 MR. BAUM: You're just adding time. 19 MR. ROBERTS: So are you. 20 BY MR. BAUM: 21 0. Okay. So the difference between a 22 P-value of .038 with the nine patients included and the .052 P-value with the patients subject to the 23 24 dispensing error not included would be a substantial

difference, correct? 1 2 MR. ROBERTS: Objection, calls for 3 speculation. 4 THE WITNESS: Incorrect. 5 BY MR. BAUM: 6 0. Why? 7 It's a trivial difference, .014. Α. 8 Q. And so the fact that it crosses the .05 barrier is insignificant to you? 9 10 MR. ROBERTS: Objection, 11 mischaracterizes the witness' testimony. 12 THE WITNESS: No. 13 BY MR. BAUM: 14 Q. It is significant? 15 MR. ROBERTS: Objection. 16 THE WITNESS: It has an impact upon how 17 the results are interpreted. 18 BY MR. BAUM: 0. So it's a substantial difference? 19 20 Α. No. 21 MR. ROBERTS: Objection. 22 BY MR. BAUM: 23 Q. So if it has an impact, but it's --24 never mind.

Charles Flicker, Ph.D.

1 This -- I'm going to refer you back to 2 this Appendix Table 6. 3 MR. ROBERTS: Is that Exhibit 10? 4 MR. BAUM: Yes. 5 MR. WISNER: No, it's Exhibit 11. 6 It's Exhibit 11, sorry. MR. BAUM: 7 MR. ROBERTS: Okay, thank you. 8 BY MR. BAUM: 9 Ο. You see that the subpopulation is 166 patients. It's 81 in the placebo group and 85 in the 10 11 citalopram group? 12 Α. Okay. 13 That's actually a difference of eight Q. 14 between the 174 that are included in the table used for 15 the study reports Panels 11 and 12. 16 Do you know why there was only a 17 difference of eight instead of nine? 18 Objection. MR. ROBERTS: THE WITNESS: 19 No. 20 BY MR. BAUM: 21 The 166 patients that were on this table 0. 22 are greater than the 160 patients needed to power CIT-MD-18, right? 23 24 MR. ROBERTS: Objection.

1	THE WITNESS: The study protocol called
2	for 160 patients.
3	BY MR. BAUM:
4	Q. And this is 166, so it's greater than
5	that, correct?
6	A. 166 is greater than 160.
7	Q. Okay. So let's go back to Page 70 of
8	the study report, and under Panel 12, it says, Appendix
9	Table 6 presents the results from the LOCF analysis for
10	the change from baseline to Week 8 excluding data from
11	the 9 patients for whom the study blind was potentially
12	compromised (see Section 5.3.4). The results from the
13	Week 8 LOCF analysis comparing the mean change from
14	baseline in CDRS-R in the citalopram and placebo groups
15	was not substantially affected by the exclusion of
16	those patients. The LSM difference decreased from .46
17	to .43 and the P-value increased from .038 to .052.
18	Do you see that?
19	A. Yes.
20	Q. Do you know who drafted that language?
21	A. I think I saw it yesterday.
22	Q. And who drafted that language?
23	MR. ROBERTS: Objection.
24	THE WITNESS: I think I did.
L	

BY MR. BAUM: 1 And here it says that "9 patients for 2 0. whom the study blind was potentially compromised." 3 4 Do you see that? 5 Α. Yes. Do you recall there being discussions at 6 Ο. 7 Forest about how to characterize the dispensing error 8 that occurred during the conduct of study MD-18? 9 MR. ROBERTS: Objection. 10 THE WITNESS: No. 11 BY MR. BAUM: 12 0. Are you aware that the discussions did occur including you regarding how to characterize the 13 14 dispensing error? 15 MR. ROBERTS: Objection. 16 THE WITNESS: How to characterize? I 17 mean, I saw documents regarding the dispensing 18 error. 19 BY MR. BAUM: 20 Ο. Well, do you think it's an accurate 21 characterization of CIT-MD-18 to say that the study 22 blind was potentially compromised? 23 Objection. MR. ROBERTS: 24 THE WITNESS: Yes.

1 BY MR. BAUM: You don't think it was actually 2 0. 3 compromised? 4 For certain patients. Α. 5 Q. Do you think -- you don't think it was actually compromised for those certain patients? 6 7 MR. ROBERTS: Objection. 8 THE WITNESS: Well, I don't know, but I 9 think it seems to me -- well, I'm speculating. What's the question again? 10 11 BY MR. BAUM: 12 0. You don't think that the blind was unmistakenly violated for these nine patients? 13 14 Α. No. 15 MR. ROBERTS: Objection. 16 BY MR. BAUM: 17 Ο. You don't think that the blind was compromised for these nine patients? 18 19 MR. ROBERTS: Objection. He testified 20 he doesn't recall the dispensing error. 21 THE WITNESS: I think it was potentially 22 compromised. Seems to me perfectly possible 23 that none of those nine patients had any hint 24 whatsoever of what their treatment group was.

1	BY MR. BAUM:
2	Q. But the investigators knew, right?
3	MR. ROBERTS: Objection,
4	mischaracterizes testimony. No foundation.
5	THE WITNESS: I don't know.
6	BY MR. BAUM:
7	Q. Were the investigators informed what
8	patients had received the dispensing error tablets?
9	MR. ROBERTS: Objection, lacks
10	foundation.
11	THE WITNESS: I did see a document that
12	communicated to the investigators that there
13	was a dispensing error.
13 14	was a dispensing error. BY MR. BAUM:
14	BY MR. BAUM:
14 15	BY MR. BAUM: Q. So they would have known which patients
14 15 16	BY MR. BAUM: Q. So they would have known which patients received the dispensing error tablets, correct?
14 15 16 17	BY MR. BAUM: Q. So they would have known which patients received the dispensing error tablets, correct? MR. ROBERTS: Objection,
14 15 16 17 18	BY MR. BAUM: Q. So they would have known which patients received the dispensing error tablets, correct? MR. ROBERTS: Objection, mischaracterizes testimony.
14 15 16 17 18 19	BY MR. BAUM: Q. So they would have known which patients received the dispensing error tablets, correct? MR. ROBERTS: Objection, mischaracterizes testimony. THE WITNESS: That would require
14 15 16 17 18 19 20	<pre>BY MR. BAUM: Q. So they would have known which patients received the dispensing error tablets, correct? MR. ROBERTS: Objection, mischaracterizes testimony. THE WITNESS: That would require speculation. The investigators would have to</pre>
14 15 16 17 18 19 20 21	<pre>BY MR. BAUM: Q. So they would have known which patients received the dispensing error tablets, correct? MR. ROBERTS: Objection, mischaracterizes testimony. THE WITNESS: That would require speculation. The investigators would have to take further steps.</pre>

1	error tablets, correct?
2	MR. ROBERTS: Objection,
3	mischaracterizes the witness' testimony,
4	requires speculation.
5	THE WITNESS: What's the question?
6	BY MR. BAUM:
7	Q. Forest communicated to the investigators
8	which patients had received dispensing error tablets,
9	correct?
10	MR. ROBERTS: Objection.
11	THE WITNESS: That I don't know. I
12	mean, any they identified which supplies.
13	Based on what I saw, they identified which
14	supplies were incorrectly packaged.
15	BY MR. BAUM:
16	Q. Did they also identify which patients
17	were provided the incorrect tablets?
18	MR. ROBERTS: Objection.
19	THE WITNESS: I don't know.
20	BY MR. BAUM:
21	Q. I just wanted to admonish you that I
22	want you to tell me the truth. I don't want you to
23	tell me things based on what he's objecting. I want
24	you to tell me what you recall.

1 MR. ROBERTS: Objection. He is telling 2 the truth. BY MR. BAUM: 3 4 Ο. And I want you to be able to tell me 5 what you actually know, not what you are tipped off by the objections, but by what you actually recall. 6 7 MR. ROBERTS: That's what your --8 MS. KIEHN: He testified he doesn't --9 MR. ROBERTS: The witness is 10 testifying --MS. KIEHN: -- recall the unblinding. 11 MR. ROBERTS: He testified he doesn't 12 13 recall the unblinding. The witness knows he's 14 under oath, and the witness is telling the 15 truth. THE WITNESS: I don't actually recall 16 17 anything with the unblinding that you're 18 talking about. I'm basing anything I say based 19 upon documents I saw yesterday. 20 BY MR. BAUM: 21 Okay. So do you know who the target 0. 22 audience was for the CIT-MD-18 study report? 23 MR. ROBERTS: Objection. 24 THE WITNESS: FDA.

1 BY MR. BAUM: Did the FDA decide whether to approve 2 0. 3 Forest's request for a Lexapro pediatric major depressive disorder indication partially on the basis 4 of the study report for CIT-MD-18? 5 6 MR. ROBERTS: Objection. 7 THE WITNESS: CIT-MD-18 was filed in 8 support of the Lexapro -- of the Lexapro child 9 and adolescent depression indication. 10 BY MR. BAUM: 11 Ο. If they accepted this characterization of the P-value shift from .038 to .052 not being 12 substantial, they would have been misled, right? 13 14 MR. ROBERTS: Objection. 15 THE WITNESS: No. 16 BY MR. BAUM: 17 Had an impact on the validity of the Q. 18 outcome, correct? 19 MR. ROBERTS: Objection. 20 THE WITNESS: What had an impact on the 21 validity? 22 BY MR. BAUM: 23 The shift from P-value of .038 to .052. 0. 24 Objection. MR. ROBERTS:

1 THE WITNESS: Does that shift have an 2 impact upon the validity of the outcome of the 3 study? 4 MR. BAUM: Yes. MR. ROBERTS: Objection. 5 6 THE WITNESS: No. 7 BY MR. BAUM: 8 Q. Why not? It's trivial. 9 Α. 10 So it's trivial because the difference Q. between .038 and .052 is .014; is that what you're 11 12 saying? 13 MR. ROBERTS: Objection. 14 THE WITNESS: I'd say that's part of the 15 reason. 16 BY MR. BAUM: 17 Q. And so it didn't matter whether it crossed the .050 barrier, correct? 18 19 MR. ROBERTS: Objection. 20 THE WITNESS: I would say that needs to 21 be taken into consideration. 22 BY MR. BAUM: 23 O. So it's a factor to take into 24 consideration?

1 MR. ROBERTS: Objection. 2 THE WITNESS: Yes. BY MR. BAUM: 3 4 Q. And it is an important factor, isn't it? 5 MR. ROBERTS: Objection. 6 THE WITNESS: It's a factor. 7 BY MR. BAUM: 8 Q. Let's go to Page 100, which is Table 9 3.1. 10 So if you look at Table 3.1 it says the Primary Efficacy, Change from Baseline in CDRS-R, do 11 12 you see that, after 8 Weeks. 13 Α. Yes. 14 If you add the patients up there, you'll Q. 15 see that there's 85 placebo and 89 citalopram patients, 16 correct? 17 Α. Yes. 18 And that added up to 174, correct? Q. 19 Α. I agree. 20 0. So this table included the patients who 21 had the dispensing error, right? 22 MR. ROBERTS: Objection. 23 THE WITNESS: I would assume so. 24 BY MR. BAUM:

1	Q. Do you know why this table was included
2	as a primary efficacy outcome and not Appendix Table 6?
3	MR. ROBERTS: Objection.
4	THE WITNESS: Because this is the ITT
5	population.
6	BY MR. BAUM:
7	Q. All right. So there was a validity
8	problem with some of those patients, though, correct?
9	MR. ROBERTS: Objection.
10	THE WITNESS: The validity of those
11	patients, those patients' blind was potentially
12	compromised, yes.
13	BY MR. BAUM:
14	Q. So why not just exclude those?
15	MR. ROBERTS: Objection.
16	THE WITNESS: Well, that was the purpose
17	of the other table.
18	BY MR. BAUM:
19	Q. Well, the purpose could also be that
20	that other table could have been the primary efficacy
21	outcome, and this could have this Table 3.1 could
22	have been in Appendix 6 as additional information,
23	correct?
24	MR. ROBERTS: Objection.

1	THE WITNESS: Well, the protocol
2	specifies an ITT population, so excluding the
3	patients, excluding those patients would not
4	have been consistent with the analysis, the
5	population group defined in the protocol, or
6	you would have had to amend the protocol.
7	BY MR. BAUM:
8	Q. Do amendments get done to correct
9	mistakes?
10	MR. ROBERTS: Objection.
11	THE WITNESS: It's possible to amend a
12	protocol, yes.
13	BY MR. BAUM:
14	Q. To correct mistakes, correct?
15	MR. ROBERTS: Objection.
16	THE WITNESS: For any reason, to add an
17	efficacy measure or something.
18	BY MR. BAUM:
19	Q. And do you think it should have been
20	noted that the primary efficacy measure included these
21	eight patients wherever this primary efficacy measure
22	was disseminated?
23	MR. ROBERTS: Objection.
24	THE WITNESS: No.

BY MR. BAUM: 1 2 Because it's not substantial --0. 3 MR. ROBERTS: Objection. 4 BY MR. BAUM: 5 Q. -- per you? 6 What's not substantial? Α. 7 To include eight patients whose outcomes 0. 8 were questionably valid? 9 MR. ROBERTS: Objection. 10 THE WITNESS: I would agree that the 11 difference in the results was not substantial, 12 yes. BY MR. BAUM: 13 14 Ο. Okay. So that's kind of answering a 15 different question than what I asked. Shouldn't there be an asterisk of some form on Table 3.1 to indicate 16 17 that it includes patients whose outcomes may have not 18 been valid because they were unblinded at baseline? 19 MR. ROBERTS: Objection, calls for 20 speculation. 21 THE WITNESS: Yeah, well, that's -- I 22 don't know. 23 BY MR. BAUM: 24 That would have been a more valid 0.

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1	presentation, wouldn't it?
2	MR. ROBERTS: Objection.
3	THE WITNESS: The presence of a
4	potential potentially unblinding protocol
5	violation should be should be presented in
6	the study report. That it should be presented
7	in this table seems pretty I don't know.
8	BY MR. BAUM:
9	Q. Well, you wouldn't know by looking at
10	this?
11	MR. ROBERTS: Hold on. He wasn't
12	were you done with your answer?
13	THE WITNESS: I said enough, I'd say.
14	No, I was saying that it should be attached to
15	this table? Not necessarily.
16	BY MR. BAUM:
17	Q. But it could be, right?
18	MR. ROBERTS: Objection.
19	THE WITNESS: I would think it would
20	be I would think it would be more important
21	to attach it to the table where you're
22	excluding the patients. This is a
23	comprehensive table, the entire ITT population.
24	BY MR. BAUM:

1	Q. Yeah, but by looking at this, you don't
2	know whether or not there's unblinded patients
3	included, do you?
4	MR. ROBERTS: Objection.
5	THE WITNESS: This is the entire ITT
6	population.
7	BY MR. BAUM:
8	Q. Yeah. So you don't know whether or not
9	the unblinded patients are included by looking at this
10	table, do you?
11	MR. ROBERTS: Objection.
12	THE WITNESS: By looking at this table,
13	do I well, I guess I do based on the
14	numbers. Me, yes.
15	BY MR. BAUM:
16	Q. Okay. So in the MD-18 publication in
17	the American Journal of Psychiatry where it reports
18	this information from Table 3.1, is there any way of
19	telling that eight or nine of those patients had been
20	subject to a dispensing error?
21	MR. ROBERTS: Objection.
22	THE WITNESS: I don't know. I haven't
23	seen that paper.
24	BY MR. BAUM:

		-
1	Q.	You've never seen it?
2		MR. ROBERTS: Objection.
3	Α.	I don't know.
4	BY MR. BAUM:	
5	Q.	You weren't shown it yesterday?
б		MR. ROBERTS: Objection.
7		MS. KIEHN: Don't answer.
8		MR. BAUM: You're instructing him not to
9	answer	whether or not he saw the MD-18
10	manusc	ript published in the American Journal of
11	Psychi	atry?
12		MS. KIEHN: Yesterday, yes.
13		MR. BAUM: Really?
14		MS. KIEHN: Mm-hmm, unless it refreshed
15	his re	collection about something.
16		MR. ROBERTS: If it refreshed your
17	recoll	ection about a particular thing, you
18	could	answer, unless, no.
19		THE WITNESS: What's the question?
20	BY MR. BAUM:	
21	Q.	In the MD-18 manuscript published in the
22	American Journ	al of Psychiatry, which reported the data
23	from Table 3.1	as the primary efficacy measure, you
24	weren't able t	o tell whether or not there were eight or
Colkey Technologies Ing Dage 215		

1	nine unblinded patients included in that data, correct?	
2	MR. ROBERTS: Objection.	
3	THE WITNESS: Oh, no, I don't know that.	
4	How do I know that?	
5	BY MR. BAUM:	
6	Q. By looking at the manuscript, did it	
7	have any reference to those eight or nine patients	
8	being excluded?	
9	MS. KIEHN: Show him the document.	
10	THE WITNESS: I don't know.	
11	BY MR. BAUM:	
12	Q. Okay. Do you think Table 3.1 is a valid	
13	representation of the intent-to-treat analysis, even	
14	though it included patients who had been subject to a	
15	dispensing error at baseline?	
16	MR. ROBERTS: Objection.	
17	THE WITNESS: Yes.	
18	BY MR. BAUM:	
19	Q. They were unblinded at baseline before	
20	their first evaluation, why should they be included in	
21	the patient population at that point?	
22	MR. ROBERTS: Objection, testifying.	
23	THE WITNESS: I don't know that the	
24	patients can be identified as unblinded. I'd	

1	say the blind was potentially compromised. The
2	validity of the blind for those patients was
3	open to question.
4	BY MR. BAUM:
5	Q. For both the patients and the
6	investigators, correct?
7	MR. ROBERTS: Objection.
8	THE WITNESS: At some point the
9	investigators received potentially unblinding
10	information.
11	BY MR. BAUM:
12	Q. All right. So from your perspective,
13	it's scientifically appropriate to count patients who
14	have been exposed to unblinding information prior to
15	their first evaluation at Week 1, even though that
16	exposure occurred at baseline prior to the evaluation?
17	MR. ROBERTS: Objection.
18	THE WITNESS: No, I don't think patients
19	should be exposed to unblinding information.
20	BY MR. BAUM:
21	Q. It compromises the validity of the
22	outcome?
23	MR. ROBERTS: Objection.
24	THE WITNESS: It can potentially

undermine the validity. 1 2 BY MR. BAUM: 3 0. Let's go to Page 63, Section "7.0 Changes in the Conduct of the Study and Planned 4 Analyses." 5 6 In the last paragraph there it says, "Nine patients (Patients 105, 113, 114, 505, 506, 507, 7 8 509, 513 and 514) were mistakenly dispensed 1 week of 9 medication with potentially unblinding information 10 (tablets had an incorrect color coating)." 11 Do you see that? 12 Α. Do I see that, yes. 13 Did you write that? Q. 14 I don't know. Α. 15 "Therefore, in addition to the analysis Ο. 16 specified in Section 6.4.1 for the primary efficacy parameter, a post-hoc analysis was performed on an ITT 17 subpopulation that excluded these 9 patients." 18 19 Do you see that? 20 Α. Yes. 21 Do you recall the origin of the language 0. "potentially unblinding information"? 22 23 MR. ROBERTS: Objection. 24 THE WITNESS: No.

1 BY MR. BAUM: The post-hoc analysis referred to in 2 Ο. 3 this paragraph was Table 6 in the appendix, correct? 4 MR. ROBERTS: Objection. 5 BY MR. BAUM: 6 It's at Page 244, if you want to take a Ο. 7 look at it. 8 Α. Here? 9 Ο. Yeah. 10 Α. The same one we were just looking at? 11 We were just looking at Table 3.1, but Q. 12 I'm asking you to take a look at Appendix Table 6, which is at 244, page 244. Appendix Table 6 is the one 13 14 that had the patients excluded. 15 ITT subpopulation, okay. Α. 16 Ο. Okay. So is that Appendix Table 6 the post-hoc analysis that is referred to here on Page 63? 17 18 MR. ROBERTS: Objection. THE WITNESS: 19 I'm not sure. As you 20 pointed out, I guess the numbers are off, but I 21 assume so. 22 BY MR. BAUM: 23 Ο. Do you think that Table 6 actually 24 represented a more correct efficacy analysis for the

valid intent-to-treat population? 1 2 MR. ROBERTS: Objection. 3 THE WITNESS: No. 4 BY MR. BAUM: 5 Q. Do you consider it more valid than the Table 3.1 with the unblinded patients included? 6 7 MR. ROBERTS: Objection. 8 THE WITNESS: No. 9 BY MR. BAUM: 10 You don't consider it more valid? Q. MR. ROBERTS: Objection. 11 12 THE WITNESS: No. 13 BY MR. BAUM: You consider them equally valid? 14 Q. 15 MR. ROBERTS: Objection. 16 THE WITNESS: I think this should be examined. 17 18 BY MR. BAUM: 19 Q. By whom? 20 By anyone reviewing this study. Α. 21 By this you're referring to Appendix 0. 22 Table 6, correct? 23 Α. Yes. 24 Let's go to Page 83 of the study report Q.

under "Validity." 1 2 You see that? 3 Α. Yes. 4 0. It says, "The study was designed to 5 provide a valid, prospectively randomized, double-blind comparison of the treatment effects of citalopram and 6 placebo." 7 8 Do you see that? 9 Α. Yes. 10 Q. And it says, "A medication packaging 11 error partially compromised the study blind for 9 of 12 the 174 patients. Post-hoc analysis excluding these patients supported the results from the intent-to-treat 13 14 analysis. It is concluded that the study results are 15 valid and interpretable." 16 Did I read that correctly? 17 Α. Yes. So the line the post-hoc analysis 18 Q. 19 excluding these patients supported the results from the intent-to-treat analysis is actually not true, right? 20 21 MR. ROBERTS: Objection. 22 THE WITNESS: It's actually not true, 23 right? How am I supposed to answer that 24 question?

BY MR. BAUM: 1 Okay. So it's not accurate for this 2 0. line to say "post-hoc analysis excluding these patients 3 4 supported the results from the intent-to-treat analysis"? 5 6 MR. ROBERTS: Objection. 7 THE WITNESS: That Table 6 was 8 supportive, the results were supportive of the 9 conclusion that study was showing treatment 10 effect. BY MR. BAUM: 11 12 A statistically significant treatment 0. 13 effect? 14 MR. ROBERTS: Objection. 15 THE WITNESS: No. It failed to achieve the nominal .05 criterion of statistical 16 17 significance. BY MR. BAUM: 18 19 Q. So that to some degree contradicts the assertion that the study results were statistically 20 21 significant, correct? 22 MR. ROBERTS: Objection. 23 I'd say it's supportive. THE WITNESS: 24 It might undermine the robustness.

1 BY MR. BAUM: And undermine robustness is something 2 0. 3 that ought to have been conveyed to physicians and academics evaluating the merits of Study 18, correct? 4 5 MR. ROBERTS: Objection. 6 THE WITNESS: It's -- I'd stay it's a matter of how much information is to be 7 8 conveyed. 9 BY MR. BAUM: 10 It's an important piece of information? Q. 11 MR. ROBERTS: Objection. 12 THE WITNESS: Important? To the extent 13 that everything in the study report is 14 important, yes. 15 BY MR. BAUM: 16 Well, the .052 P-value was a negative 0. result, not a positive one, correct? 17 18 MR. ROBERTS: Objection. 19 THE WITNESS: You know, negative is in 20 my vocabulary not a legitimate description of 21 the finding. 22 BY MR. BAUM: 23 0. It was not a positive one, correct? 24 Objection. MR. ROBERTS:

1 THE WITNESS: It failed to achieve statistical significance based on the criterion 2 of .05. 3 4 BY MR. BAUM: 5 Q. Is that why the results were put in Appendix 6, were relegated to appendix and were not 6 7 reported as the primary outcome results? 8 MR. ROBERTS: Objection. 9 THE WITNESS: The placement of the 10 table, are you suggesting that the placement --11 what are you suggesting? 12 BY MR. BAUM: Well, Appendix Table 6 was placed in the 13 0. 14 appendix because it had a P-value that was above .050 15 and was not supportive of a positive outcome? 16 MR. ROBERTS: Objection. 17 It looks to me that THE WITNESS: 18 Appendix 6, that it was placed in the appendix 19 because it was a subpopulation analysis. 20 Aren't all the tables in the appendix? 21 MR. BAUM: No. Table 3.1 is in the body 22 of the report. 23 MR. ROBERTS: Objection, it's a 24 statement.

BY MR. BAUM: 1 Appendix Table 6 was relegated to not 2 Ο. 3 being the primary outcome result because it had a 4 P-value above .050, correct? MR. ROBERTS: Objection. 5 6 THE WITNESS: No. 7 BY MR. BAUM: 8 Q. Was there some concern about the 9 reporting it as a primary outcome measure because of 10 its P-value? 11 MR. ROBERTS: Objection. 12 THE WITNESS: Not that I know of. BY MR. BAUM: 13 14 Same here in Page 83, that post-hoc Q. 15 analysis excluding these patients supported the results 16 from the intent-to-treat analysis; that was misleading, 17 wasn't it? 18 MR. ROBERTS: Objection. 19 THE WITNESS: I think that's accurate. 20 BY MR. BAUM: 21 It's accurate to say that the post-hoc 0. 22 analysis excluding these patients supported the results 23 from the intent-to-treat analysis? 24 Α. Yes.

1 MR. ROBERTS: Objection. 2 BY MR. BAUM: Because a P-value of .052 supports the 3 0. positive outcome for the trial, correct? 4 5 MR. ROBERTS: Objection. BY MR. BAUM: 6 7 Is that what you're are saying? 0. 8 Α. Because the difference between the two 9 analyses in outcome were minimal in magnitude. 10 But the one was statistically Q. 11 significant and the other wasn't, correct? 12 MR. ROBERTS: Objection. 13 THE WITNESS: One -- the secondary 14 analyses did not meet the criterion on the 15 .05 -- less than .05 criterion for statistical 16 significance. 17 BY MR. BAUM: So when it did not meet the criterion 18 0. 19 for statistical significance, it failed to support the positive outcome asserted by Table 3.1, correct? 20 21 MR. ROBERTS: Objection, asked and 22 answered multiple times. 23 It's supportive in terms THE WITNESS: 24 of the mean effect that was observed.

1	BY MR. BAUM:	
2	Q. But not supportive with respect to the	
3	P-value, correct?	
4	MR. ROBERTS: Objection.	
5	THE WITNESS: It's not identical in	
6	terms of the P-value. If one focuses	
7	exclusively on the .05 level as a yes or no	
8	criterion, then it's not then obviously it's	
9	not the same.	
10	BY MR. BAUM:	
11	Q. And so it's not supportive?	
12	MR. ROBERTS: Objection, asked and	
13	answered, requires speculation.	
14	THE WITNESS: To my mind, it's clearly	
15	supportive because it's the difference is	
16	numerically trivial.	
17	BY MR. BAUM:	
18	Q. Does including these eight unblinded	
19	patients affect whether or not the trial was	
20	interpretable?	
21	MR. ROBERTS: Objection.	
22	THE WITNESS: Well, interpretable, as we	
23	previously discussed, is an ill-defined term.	
24	BY MR. BAUM:	

Well, it was in -- right here it says, 1 0. it is concluded that the study results are valid and 2 3 interpretable. That's in the report that you approved and may have even written this line. 4 5 Α. Mm-hmm. 6 MR. ROBERTS: Objection. 7 BY MR. BAUM: 8 Does having eight unblinded patients 0. 9 included in the primary efficacy measure affect the validity or interpretability of the study? 10 11 MR. ROBERTS: Objection, asked and 12 answered. 13 THE WITNESS: I'd say it's relevant. 14 BY MR. BAUM: 15 0. In what way? 16 Α. In that their potential unblinding needs to be considered. 17 18 MR. BAUM: We're going to take a short 19 break. 20 THE VIDEOGRAPHER: We will be going off 21 the record at 12:07 p.m. This marks the end of 22 Media 5. 23 (Brief recess.) 24 THE VIDEOGRAPHER: We are back on the

record at 12:17 p.m. This marks the beginning 1 of Media 6. 2 Go ahead, counselor. 3 4 BY MR. BAUM: 5 Q. Okay. We're going to start going over some of the secondary outcome measures for MD-18. 6 7 Do you recall that the secondary outcome 8 measures were each negative for MD-18? 9 MR. ROBERTS: Objection. 10 THE WITNESS: No. 11 BY MR. BAUM: 12 Q. Do you dispute whether or not they were negative? 13 14 MR. ROBERTS: Objection. 15 THE WITNESS: Excuse me? 16 BY MR. BAUM: 17 Q. Do you dispute whether or not they were negative, or you just don't recall it? 18 19 MR. ROBERTS: Objection. 20 THE WITNESS: I don't recall. 21 BY MR. BAUM: 22 Q. I thought you were going to say more. 23 Α. I don't recall the secondary efficacy 24 outcome measure results.

Let's go to Page 101, Table 3.2. This 1 0. is the statistical table reflecting the secondary 2 endpoint of "CGI Improvement after 8 weeks," correct? 3 4 Α. Yes. 5 Q. And this chart is dated October 30th, б 2001. Do you see that, up at the top right? 7 Α. Yes. 8 And the P-value listed for the 0. 9 difference between Celexa and placebo at Week 8 is 10 .257, correct? 11 Α. Yeah. 12 Q. And that's not statistically significant, is it? 13 14 MR. ROBERTS: Objection. 15 THE WITNESS: It's above the criteria 16 for statistically significant difference. 17 BY MR. BAUM: So that's not statistically significant, 18 Q. is it? 19 20 MR. ROBERTS: Objection. 21 THE WITNESS: It fails to achieve 22 statistical significance. 23 BY MR. BAUM: 24 Yeah, that means it's not statistically 0.

1	significant, correct?
2	MR. ROBERTS: Objection.
3	THE WITNESS: I would not call it
4	insignificant or not statistically significant.
5	I would say it fails to achieve the criterion.
6	BY MR. BAUM:
7	Q. Okay. So the secondary endpoint of CGI
8	improvement was negative for efficacy, correct?
9	MR. ROBERTS: Objection.
10	THE WITNESS: No. I mean, you're
11	talking about one analysis and the ITT
12	population using the last observation carried
13	forward.
14	BY MR. BAUM:
15	Q. It's not a positive outcome?
16	MR. ROBERTS: Objection.
17	THE WITNESS: What is not a positive
18	outcome?
19	BY MR. BAUM:
20	Q257.
21	MR. ROBERTS: Objection.
22	THE WITNESS: The difference between the
23	placebo and citalopram groups in the ITT
24	population using the last observation carried

1	forward analysis of the CGI Improvement Scale
2	at the end of Week 8 fails to achieve the
3	criteria of .05 statistically significant
4	level.
5	BY MR. BAUM:
6	Q. Let's go to the next page 102, which is
7	Table 3.3, and this is the secondary efficacy measure
8	for "Change from Baseline in CGI Severity after 8
9	weeks."
10	Do you see that?
11	A. Yes.
12	Q. And do you see the P-value over on the
13	right there is .266?
14	A. Yes.
15	Q. And that's not statistically significant
16	either, is it?
17	MR. ROBERTS: Objection.
18	THE WITNESS: The P-value .266 does not
19	meet the criterion for statistical significance
20	of .05.
21	BY MR. BAUM:
22	Q. So the secondary endpoint of CGI
23	severity was not positive for efficacy, was it?
24	MR. ROBERTS: Objection.

1	THE WITNESS: In the analysis at Week 8
2	of the ITT population using last observation
3	carried forward approach, the P-value for the
4	difference between the placebo and citalopram
5	groups failed to achieve a statistically
6	significant level of .05.
7	BY MR. BAUM:
8	Q. Let's go to the next table, Table 3.4 on
9	Page 103, and you see this is the secondary outcome for
10	the CGAS secondary efficacy measure.
11	Do you see that?
12	A. Yes.
13	Q. And the P-value there is .309.
14	Do you see that?
15	A. Yes, I do.
16	Q. And that's not statistically
17	significant, correct?
18	MR. ROBERTS: Objection.
19	THE WITNESS: I would say that the
20	difference between the citalopram and placebo
21	treatment groups in the ITT population using
22	the last observation carried forward approach
23	at Week 8 on the CGAS scale fails to achieve
24	the criterion of .05 in this analysis.

1 BY MR. BAUM: 2 0. Okay. And let's go over to the next 3 page for the secondary efficacy measure of "Change from Baseline in K-SADS-P Depression Module after 8 weeks." 4 5 Do you see that? 6 Α. Yes. 7 Ο. And the P-value for that one is .105? 8 Α. Yes. 9 Ο. And that's not statistically 10 significant, is it? 11 MR. ROBERTS: Objection. 12 THE WITNESS: I would say that the 13 analysis of the K-SADS-P depression module in 14 the ITT population using the last observation 15 carried forward approach at Week 8 does not 16 achieve in its treatment effect comparing 17 citalopram versus placebo the statistically significant level of .05. 18 19 BY MR. BAUM: 20 And that was true for all of the Ο. 21 secondary outcomes, correct? 22 MR. ROBERTS: Objection. 23 THE WITNESS: That seemed to be the case 24 for the ones that we just looked at.

1	BY MR. BAUM:
2	Q. Okay. Let's take a look at Page 72
3	under "Efficacy Conclusions," the second paragraph, it
4	says, significant differences let me wait for you to
5	get there. So it says in the second paragraph under
6	Efficacy Conclusions, Section 10.5.
7	Do you see that? It's significant
8	differences, second paragraph.
9	A. Is it the wrong page?
10	MR. ROBERTS: Yeah, that's the page.
11	Michael is right here.
12	THE WITNESS: Okay.
13	BY MR. BAUM:
13 14	BY MR. BAUM: Q. So it says significant differences, P
14	Q. So it says significant differences, P
14 15	Q. So it says significant differences, P less than 0.05, indicative of greater improvement in
14 15 16	Q. So it says significant differences, P less than 0.05, indicative of greater improvement in citalopram patients than placebo patients were also
14 15 16 17	Q. So it says significant differences, P less than 0.05, indicative of greater improvement in citalopram patients than placebo patients were also observed on the CGI-I, CGI-S and CGAS.
14 15 16 17 18	Q. So it says significant differences, P less than 0.05, indicative of greater improvement in citalopram patients than placebo patients were also observed on the CGI-I, CGI-S and CGAS. Do you see that?
14 15 16 17 18 19	Q. So it says significant differences, P less than 0.05, indicative of greater improvement in citalopram patients than placebo patients were also observed on the CGI-I, CGI-S and CGAS. Do you see that? A. Yes.
14 15 16 17 18 19 20	 Q. So it says significant differences, P less than 0.05, indicative of greater improvement in citalopram patients than placebo patients were also observed on the CGI-I, CGI-S and CGAS. Do you see that? A. Yes. Q. That's contradictory to what we just
14 15 16 17 18 19 20 21	 Q. So it says significant differences, P less than 0.05, indicative of greater improvement in citalopram patients than placebo patients were also observed on the CGI-I, CGI-S and CGAS. Do you see that? A. Yes. Q. That's contradictory to what we just read as the eight-week outcomes for those secondary

1	less than .05 was not found on these measures
2	in the Week 8 analysis of these variables
3	comparing to the citalopram treatment groups in
4	the ITT population using the last observation
5	carried forward approach at Week 8.
6	BY MR. BAUM:
7	Q. Did you write this sentence?
8	MR. ROBERTS: Objection.
9	THE WITNESS: I don't know.
10	BY MR. BAUM:
11	Q. This sentence suggests that the
12	differences between Celexa and placebo for the
13	secondary endpoints of CGI-I, CGI-S and CGAS were
14	statistically significant, doesn't it?
15	MR. ROBERTS: Objection,
16	mischaracterizes the document.
17	THE WITNESS: Excuse me. Can you repeat
18	it?
19	BY MR. BAUM:
20	Q. This sentence suggests that the
21	differences between Celexa and placebo for the
22	secondary endpoints were statistically significant,
23	doesn't it?
24	MR. ROBERTS: Renew my objection.

1	THE WITNESS: This indicates to me that
2	significant differences on the secondary
3	treatment variables, secondary assessment
4	variable were observed in the study, yes.
5	BY MR. BAUM:
6	Q. That's contradicted by what we just
7	looked at in the tables we just went over, Tables 3.2
8	to 3.5 for the Week 8 P-values, correct?
9	MR. ROBERTS: Objection.
10	THE WITNESS: Yes. In those particular
11	analyses that we looked at, the significance of
12	it was not below .05.
13	BY MR. BAUM:
14	Q. So this sentence, as phrased, is
15	misleading because it suggests the secondary endpoints
16	were positive when they were actually negative, right?
17	MR. ROBERTS: Objection.
18	THE WITNESS: My assumption is that this
19	sentence reflects other analyses that were
20	conducted that did show significant
21	differences.
22	BY MR. BAUM:
23	Q. It doesn't reflect that at Week 8 it was
24	negative, though, does it?

1	MR. ROBERTS: Objection.
2	THE WITNESS: This sentence clearly is
3	not referring to that Week 8 endpoint LOCF ITT
4	analysis that we looked at.
5	BY MR. BAUM:
6	Q. So it's misleading if it's suggested
7	that the greater improvement was statistically
8	significant?
9	MR. ROBERTS: Objection.
10	THE WITNESS: If this sentence were to
11	suggest that the Week 8 endpoint, LOCF ITT
12	analysis using last observation carried forward
13	at Week 8 for these variables, if this then
14	that would be misleading, if it said that.
15	BY MR. BAUM:
16	Q. Okay. So let's go to Page 69. Under
17	Section 10.1, the second paragraph from the bottom
18	starting with "analyses."
19	A. Yes.
20	Q. It says, "Analyses using the OC approach
21	likewise demonstrated significantly greater improvement
22	in the citalopram group compared to the placebo group,
23	with significant citalopram-placebo differences (p0.05)
24	observed at Weeks 1, 4 and 6 (Table 4.1B)."

1 Do you see that? 2 Α. Yes. And that OC stands for the observed 3 0. cases analysis, correct? 4 5 Α. Yes. б MR. ROBERTS: Objection. 7 BY MR. BAUM: 8 Q. And that's the people who actually 9 finished the trial, correct? 10 MR. ROBERTS: Objection. 11 THE WITNESS: No. 12 BY MR. BAUM: 13 It's not the people who actually Q. 14 completed through eight weeks? MR. ROBERTS: Objection. 15 16 THE WITNESS: No. 17 BY MR. BAUM: 18 Q. What is it? 19 Observed cases is patients who were Α. actually assessed. 20 21 From Weeks 1 through Weeks 8, right? Q. 22 MR. ROBERTS: Objection. 23 THE WITNESS: No. My understanding of 24 the observed case analysis is that an observed

1	case analysis at Week 1 is every patient who
2	had a Week 1 assessment, and case analysis Week
3	4 is every patient who had a Week 4 assessment.
4	BY MR. BAUM:
5	Q. So the observed cases analysis at Week 8
6	would be the people who finished actually finished
7	the trial?
8	MR. ROBERTS: Objection.
9	THE WITNESS: Who actually had an
10	assessment at Week 8, whether or not they
11	finished the trial.
12	BY MR. BAUM:
13	Q. So there were some patients that maybe
14	dropped off at Week 2 or Week 3 or Week 4 for whom they
15	had scores and evaluations prior to their dropping out,
16	and their scores were carried forward to Week 8,
17	correct?
18	MR. ROBERTS: Objection.
19	BY MR. BAUM:
20	Q. Those were the last observation carried
21	forward?
22	THE WITNESS: For the LOCF, yes.
23	BY MR. BAUM:
24	Q. Right. And these patients, observed

cases are people who actually made it through all eight 1 2 analyses, correct? 3 MR. ROBERTS: Objection. 4 THE WITNESS: No, that's not my understanding of the observed cases. Observed 5 6 cases at Week 4 is any patient who was there 7 Week 4. 8 BY MR. BAUM: 9 Ο. Yeah, and so at Week 8, it would be any 10 patient who was there at Week 8, correct? 11 MR. ROBERTS: Objection. 12 THE WITNESS: Yes. 13 BY MR. BAUM: 14 So they would be the people who actually Q. 15 finished getting through to Week 8, correct? 16 MR. ROBERTS: Objection. 17 THE WITNESS: Who -- to my mind it would be people who appeared for an assessment at 18 19 Week 8, yes, or were assessed at Week 8. 20 BY MR. BAUM: 21 Q. Okay. So here it suggests that there 22 were statistically significant outcomes at Weeks 1, 4 23 and 6, correct? 24 MR. ROBERTS: Objection.

1 THE WITNESS: For OC on whatever. 2 BY MR. BAUM: 0. For the observed cases? 3 4 Α. Okay. 5 Q. Right there, that paragraph. "With significant citalopram-placebo differences (p0.05) 6 observed at Weeks 1, 4 and 6." 7 8 Do you see that? 9 Α. Yes. 10 Does it reference Week 8? 0. 11 Α. No, nor Week 2. 12 Q. So let's take a look at Page 110, which is Table 4.1B, and if you go over to the next page --13 14 well, first off, Table 4.1B is the Change from Baseline 15 by Visit for CDS -- CDRS-R ITT population - Observed 16 Cases. 17 Do you see that? 18 Α. Yes. 19 So this is the table that represents the Ο. outcomes discussed back here at what we were just 20 21 reading about observed cases, correct? 22 MR. ROBERTS: Objection. 23 THE WITNESS: I believe so. 24 BY MR. BAUM:

1 Q. And if you go to the next page to see what the Week 8 outcome is, you see the P-value there 2 0.167, correct? 3 4 Α. Yes. 5 Q. That's not statistically significant, is 6 it? 7 MR. ROBERTS: Objection. 8 THE WITNESS: That fails to achieve the 9 .05 criterion of statistical significance. 10 BY MR. BAUM: 11 Ο. And that's different than what was said 12 back here in the study report at Page 69, where it said there was a significant difference, correct? 13 14 MR. ROBERTS: Objection. 15 THE WITNESS: No. 16 BY MR. BAUM: 17 Q. You're at Page 69? 18 Α. Yes. 19 So there's no mention of the negative 0. result at Week 8 for the observed cases analysis, is 20 there? 21 22 MR. ROBERTS: Objection. 23 THE WITNESS: This paragraph does not --24 does not refer to the results at Week 2 or Week

8. 1 2 BY MR. BAUM: 3 O. So the Week 2 had a P-value of .6; that's above .05 as well, right? 4 MR. ROBERTS: Objection. 5 6 THE WITNESS: Yes. 7 BY MR. BAUM: 8 Q. And this is a bit misleading with 9 respect to the endpoint for observed cases, isn't it? 10 MR. ROBERTS: Objection. 11 THE WITNESS: Endpoint is a word that's 12 not so often used with observed cases. 13 Observed cases is whoever is there. I mean, 14 endpoint kind of links in, in my mind, with 15 LOCF analyses. 16 BY MR. BAUM: Q. 17 So you don't think it's misleading to have omitted that the Week 8 was negative? 18 MR. ROBERTS: 19 Objection. 20 THE WITNESS: No, I do not. 21 MR. BAUM: Let's go to the next 22 document, Exhibit 12. 23 MR. ROBERTS: Are we done with 11 or 24 should I keep it?

1		MR. BAUM: We're going to come back to
2	it.	
3		(Document marked for identification as
4	Flicke	er Deposition Exhibit No. 12.)
5	BY MR. BAUM:	
6	Q.	This is MDL-FOREM0009717, and this is an
7	e-mail string	dated August 10 to August 13 between Bill
8	Heydorn, Chris	stina Goetjen, Mary Prescott and says "RE:
9	stop the press	ses."
10		Do you see that?
11	Α.	Yes.
12	Q.	We've already do you recall who
13	Christina Goet	jen is?
14	Α.	She worked at Lundbeck.
15	Q.	At Lundbeck?
16	Α.	No?
17	Q.	No, I think she was you don't
18	Α.	I'm doing my best.
19	Q.	Yeah, okay, I know. That's fine.
20		If you come down a little further on the
21	page, you'll s	see Christina Goetjen, product manager,
22	Celexa.	
23		Do you see that?
24	Α.	Yes.

1	Q. Do you recall her actually working for
2	someone like Forest?
3	MR. ROBERTS: Objection.
4	THE WITNESS: No, I'm sorry. I assumed
5	possibly just based on her name, but the name
6	did sound familiar, so I assumed she was a
7	Lundbeck personnel, because I certainly don't
8	remember her as a Forest personnel.
9	BY MR. BAUM:
10	Q. Do you recall encountering someone named
11	Christina Goetjen while you were working at Forest?
12	A. No, I definitely don't recall that.
13	Q. And you see Mary Prescott there?
14	A. Cc'd or something.
15	Q. Yeah, she's and one of the e-mails a
16	little further down from Christina Goetjen to Mary
17	Prescott, Bill Heydorn.
18	A. Yes.
19	Q. Do you recall who Mary Prescott is?
20	A. Yes.
21	Q. Who is she?
22	A. She headed a medical communications
23	agency.
24	Q. That was contracted by Forest
L	

1 MR. ROBERTS: Objection. 2 BY MR. BAUM: 3 Ο. -- to do work on MD-18? I can't say I particularly remember her 4 Α. 5 working on MD-18, but, certainly, she -- certainly, she worked on Celexa. 6 Okay. So if you go over to the second 7 Ο. page of this, and we're going to follow the e-mail 8 9 string from the back forward, so the first one is sent 10 Friday, August 10, 2001 to Bill Heydorn, Mary Bunker --11 Mark Bunker, sorry, Jeff Lawrence and Christina 12 Goetjen, a CC to Natasha Mitchner, and the subject is 13 stop the presses, and it says here, Charlie Flicker 14 just faxed to me some data from the citalopram 15 pediatric efficacy study. While I can't tell if this 16 is intent to treat or observed cases, citalopram is significantly different from placebo, P less than .05, 17 at all time points on the CDRS-R, the primary efficacy 18 19 measure. 20 Do you see that? 21 Α. Yes. 22 So according to Ms. Prescott, you sent Q. 23 some data to her on the efficacy of citalopram's 24 CIT-MD-18, right?

1	MR. ROBERTS: Objection.
2	THE WITNESS: That's what she's stating
3	here.
4	BY MR. BAUM:
5	Q. And then she writes to Bill Heydorn to
6	stop the presses because she believes that there's
7	positive data to promote from CIT-MD-18, right?
8	MR. ROBERTS: Objection.
9	THE WITNESS: Yeah, I don't know what
10	she's referring to.
11	BY MR. BAUM:
12	Q. You recall that she was involved with
13	helping get marketing done for Forest?
14	MR. ROBERTS: Objection.
15	THE WITNESS: She was she was hired
16	by marketing, I believe.
17	BY MR. BAUM:
18	Q. Does the claim that citalopram is
19	significantly different from placebo, P less than .05,
20	at all time points in the CDRS-R, the primary efficacy
21	measure, depend on whether or not the unblinded
22	patients are included in the analysis?
23	MR. ROBERTS: Objection.
24	THE WITNESS: I'm not sure what she's
1	

referring to here. 1 2 BY MR. BAUM: 3 0. Does the date August 10, 2001 ring a bell for when the -- these tables were run for the 4 5 primary efficacy analyses for CIT-MD-18? 6 MR. ROBERTS: Objection. 7 THE WITNESS: No. 8 BY MR. BAUM: 9 0. You recall that we just went through the 10 study report and that with the unblinded patients 11 included, you had a P-value of .038 and with them excluded it was .052, correct? 12 13 MR. ROBERTS: Objection. 14 THE WITNESS: There were some patients 15 for whom the blind was potentially compromised. 16 BY MR. BAUM: 17 And with them included, the P-value was Q. .038 on the CDRS-R, and with them excluded the P-value 18 19 was .052, correct? 20 MR. ROBERTS: Objection. 21 THE WITNESS: For the LOCF analysis at 22 Week 8, that appears to be the case. 23 BY MR. BAUM: 0. So the comment that she received 24

1	statistically significant data from point from
2	placebo with a P-value less than .05 indicates that she
3	received the .038 numbers, not the .052 numbers,
4	correct?
5	MR. ROBERTS: Objection.
6	THE WITNESS: Well, I don't know what
7	she received. I mean, we saw a table in the
8	observed cases analysis where it was not
9	significant at Week 2 and she's talking about
10	significant at
11	BY MR. BAUM:
12	Q. There's only one statistically
13	significant number in all of these outcome measures.
14	The secondaries were all greater than .05. The Table 6
15	with the patients excluded was greater than .05. The
16	only one all the secondaries were greater than .05.
17	The only one that's below .05 is that .038 with the
18	patients exposed to the dispensing error included,
19	correct?
20	MR. ROBERTS: Objection. You're
21	testifying and you're mischaracterizing the
22	testimony and the document.
23	THE WITNESS: No.
24	BY MR. BAUM:

1	Q. I'm not correct? There was another
2	there was another statistically significant outcome
3	measure?
4	MR. ROBERTS: Objection.
5	THE WITNESS: There was we just saw
6	an significant difference at Week 1 on the
7	observed case analysis of the CDRS.
8	BY MR. BAUM:
9	Q. So at Week 8 there were no other
10	there were no positive outcomes greater than at Week
11	8 for the secondary outcomes, observed cases and CDRS-R $% \left({{\left({{{\rm{D}}{\rm{R}}} \right)}} \right)$
12	were all greater than .05, correct?
13	MR. ROBERTS: Objection.
13 14	MR. ROBERTS: Objection. THE WITNESS: At Week 8, what analysis?
14	THE WITNESS: At Week 8, what analysis?
14 15	THE WITNESS: At Week 8, what analysis? BY MR. BAUM:
14 15 16	THE WITNESS: At Week 8, what analysis? BY MR. BAUM: Q. Week 8, secondary outcomes, observed
14 15 16 17	THE WITNESS: At Week 8, what analysis? BY MR. BAUM: Q. Week 8, secondary outcomes, observed cases and CDRS-R with the dispensing error patients
14 15 16 17 18	THE WITNESS: At Week 8, what analysis? BY MR. BAUM: Q. Week 8, secondary outcomes, observed cases and CDRS-R with the dispensing error patients excluded were all greater than .05 P-values, correct?
14 15 16 17 18 19	THE WITNESS: At Week 8, what analysis? BY MR. BAUM: Q. Week 8, secondary outcomes, observed cases and CDRS-R with the dispensing error patients excluded were all greater than .05 P-values, correct? MR. ROBERTS: Objection.
14 15 16 17 18 19 20	THE WITNESS: At Week 8, what analysis? BY MR. BAUM: Q. Week 8, secondary outcomes, observed cases and CDRS-R with the dispensing error patients excluded were all greater than .05 P-values, correct? MR. ROBERTS: Objection. THE WITNESS: Well, we only looked
14 15 16 17 18 19 20 21	THE WITNESS: At Week 8, what analysis? BY MR. BAUM: Q. Week 8, secondary outcomes, observed cases and CDRS-R with the dispensing error patients excluded were all greater than .05 P-values, correct? MR. ROBERTS: Objection. THE WITNESS: Well, we only looked we've only looked at tables with the LOCF

significance. 1 2 BY MR. BAUM: 3 And the only result that was less than 0. .05 in any of these tables we've looked at was the one 4 5 result that included the patients subject to the 6 dispensing error with the .038 P-value, correct? 7 MR. ROBERTS: Objection. 8 THE WITNESS: No. 9 BY MR. BAUM: 10 Q. At Week 8? MR. ROBERTS: Objection. 11 12 THE WITNESS: At Week 8 in the LOCF 13 analysis, the CDRS was .038, yes. 14 BY MR. BAUM: 15 0. With the unblinded patients included? 16 MR. ROBERTS: Objection. 17 THE WITNESS: In the ITT population. 18 BY MR. BAUM: 19 That included the nine patients who were 0. exposed to the dispensing error, correct? 20 21 MR. ROBERTS: Objection, asked and 22 answered. 23 THE WITNESS: Yes. 24 BY MR. BAUM:

1 So let's go to Exhibit 13 -- we're going 0. 2 to eat food. 3 MR. ROBERTS: Break for food, okay. 4 THE VIDEOGRAPHER: We will be going off 5 the record at 12:43 p.m. This marks the end of Media 6. 6 7 (Luncheon recess.) 8 (Document marked for identification as 9 Flicker Deposition Exhibit No. 13.) 10 THE VIDEOGRAPHER: We are back on the 11 record at 1:05 p.m. This marks the beginning 12 of Media 7. 13 Go ahead, Counselor. 14 BY MR. BAUM: 15 Ο. Okay. I'm going to hand you what we're 16 marking as Exhibit 13, which is MDL-FORP0018664. This is a memorandum from Bill Heydorn to you, James Jin, 17 Julie Kilbane, Paul Tiseo, Jane Wu dated October 17, 18 19 2001 regarding review of first draft of CIT-MD-18 study 20 report. 21 You have to go into the third page to 22 see that e-mail. It's right here, there. 23 MR. ROBERTS: The memo you mean? 24 MR. BAUM: Yeah, the memo.

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BY MR. BAUM: 1 2 0. And it says to Charlie Flicker, do you see that? 3 4 Α. Yes. 5 Q. And it's from Bill Heydorn, and it says, "Attached for your review is the first draft of the б CIT-MD-18 study report." 7 8 Do you see that? 9 Α. Yes. 10 Q. Do you recall receiving a draft of the CIT-MD-18 study report? 11 12 Α. No. 13 Do you have any reason to doubt that you Q. 14 received this memorandum --15 MR. ROBERTS: Objection. 16 BY MR. BAUM: 17 -- with the study report draft? Q. Well, the study report appears to have 18 Α. 19 my handwriting on it, so if these were associated. 20 Ο. Does this appear to you that these were 21 produced in the ordinary course of Forest business? 22 MR. ROBERTS: Objection. 23 THE WITNESS: Yes. 24 BY MR. BAUM:

1	Q.	All right. So there's some handwriting
2	on the memo it	self at 11/27/01.
3		Do you see that?
4	Α.	Yes.
5	Q.	Is that your handwriting?
6	Α.	Might be.
7	Q.	And then if you go over to the
8	attachment, yo	ou see some strikings out, like there's a
9	strike out of	flexible dose study, pediatric
10	depression.	
11		Is that your handwriting?
12	Α.	I think it is, yes.
13	Q.	And if you flip through here, you'll see
14	there's some h	andwriting throughout.
15		Does that appear to be your handwriting?
16		MR. ROBERTS: Objection.
17		THE WITNESS: Those look like my
18	scribb	oles.
19	BY MR. BAUM:	
20	Q.	So does it appear to you that you edited
21	this draft of	CIT-MD-18 study report?
22	Α.	Provided comments, yes.
23	Q.	Well, it looks like there's some things
24	being stricker	out and some replacement language being
	ow Tochnologiag	Ing Dage 255

Charles Flicker, Ph.D. suggested, correct? 1 2 MR. ROBERTS: Objection. 3 THE WITNESS: Yes. 4 BY MR. BAUM: 5 Q. So if you go to Page 8 of -- all right. 6 So at Page 8, at the second to the last 7 paragraph, there's some lines striking through the 8 second to the last paragraph. 9 Do you see that? 10 Α. Yes. 11 And the paragraph that's being stricken Ο. 12 out has as the second sentence, it says, "If the blind was broken for any reason, Forest Laboratories was to 13 14 be notified immediately. Any patient for whom the 15 blind had been broken was to be immediately 16 discontinued from the study and no further efficacy 17 evaluations were to be performed." 18 Do you see that? 19 Α. Yes. 20 That's more or less consistent with the Ο. 21 unblinding procedure from the protocol, correct? 22 MR. ROBERTS: Objection. 23 I'm not sure about that. THE WITNESS: 24 As we said, it's somewhat -- it's somewhat

ambiguous. 1 2 BY MR. BAUM: 3 0. Well, take a look at Exhibit 9. It's 4 Page 328. 5 MR. ROBERTS: What page? 6 MR. BAUM: 328. 7 MR. ROBERTS: Thank you. 8 BY MR. BAUM: 9 Ο. And it -- in the Unblinding Procedures in the italicized portions it says, "If the blind is 10 11 broken for any reason, Forest Laboratories must be notified immediately. Any patient for whom the blind 12 has been broken will immediately be discontinued from 13 14 the study and no further efficacy evaluations will be 15 performed." 16 Do you see that? 17 Α. Yes. 18 And that's more or less what it says Q. 19 right here in this paragraph, correct? 20 MR. ROBERTS: Objection. 21 THE WITNESS: Yes. 22 BY MR. BAUM: 23 0. And it looks like you struck that out. 24 Do you see that?

1	Α.	Yes.
2	Q.	And then put in its place, there's to
3	be put in its	place is some handwriting, because of a
4	drug packaging	error, 9 patients assigned to citalopram
5	treatment at s	tudy at blank study centers were
6	initially disp	ensed 20-milligram citalopram
7	20-milligram c	italopram tablets that were
8	distinguishabl	e in color from the placebo tablets. And
9	then you cross	ed out in that they were pink in color
10	rather than wh	ite. All study medication shipments
11	including pote	ntially unblinding information were
12	replaced in fu	11.
13		Do you see that?
14	Α.	Yes.
15	Q.	Did you write that language?
16	Α.	I think so.
17	Q.	Do you know why you struck that language
18	in that paragr	aph that it had the quote from the
19	protocol	
20		MR. ROBERTS: Objection.
21	BY MR. BAUM:	
22	Q.	in the unblinding section?
23	Α.	No.
24	Q.	Okay. If you go to Exhibit 11, Page 44

1	of the study report, and you look at section 5
2	Exhibit 11?
3	MR. ROBERTS: Oh, Exhibit 11.
4	THE WITNESS: Yeah.
5	MR. ROBERTS: Oh, Exhibit 11. This is
6	Exhibit 11. Do you have Exhibit 11?
7	MR. BAUM: I have it, I'm going to give
8	it to him. Here you go. Here's the
9	MR. ROBERTS: You said Page 44.
10	MR. BAUM: Yeah, Page 44, section on
11	Blinding.
12	MR. ROBERTS: It's counted there's
13	two of them. It's doubled, I think. Right?
14	Just making sure I'm not going crazy.
15	MR. WISNER: There's two Page 44s.
16	MR. BAUM: Just the way it got copied.
17	MR. ROBERTS: Okay.
18	BY MR. BAUM:
19	Q. So if you look at the bottom paragraph
20	on that page, you'll see the language "because of a
21	drug packaging error."
22	Do you see that?
23	A. Yes.
24	Q. And if you look over at what your
~ 11	

handwriting is, I think you'll see that they're pretty 1 much the same, correct? 2 3 MR. ROBERTS: Objection. 4 THE WITNESS: Certainly similarities. 5 BY MR. BAUM: 6 And the paragraph or the sentence 0. 7 regarding the protocol violation is not included, 8 correct? 9 MR. ROBERTS: Objection. 10 THE WITNESS: What paragraph? 11 BY MR. BAUM: 12 0. And this sentence here, it starts with, "if the blind was broken for any reason." 13 14 Α. Right. 15 That doesn't appear in this section now, Ο. 16 correct? 17 You mean that starts off with "the Α. tear-off panel"? 18 19 Ο. Right. 20 MR. ROBERTS: Let the record reflect 21 that we're talking about Exhibit 13. 22 MR. BAUM: Yeah. 23 BY MR. BAUM: 24 The third paragraph under "5.3.4 0.

1	Blinding" of Page 8 of Exhibit 13 starts with "the
2	tear-off panel" and it ends with "medication," and that
3	whole paragraph is stricken, correct?
4	MR. ROBERTS: Objection.
5	THE WITNESS: Yes.
6	BY MR. BAUM:
7	Q. And it does not appear in the Section
8	5.3.4 of the final protocol of the final study
9	report, correct?
10	MR. ROBERTS: Objection.
11	THE WITNESS: Yes.
12	BY MR. BAUM:
13	Q. Okay. So your handwritten striking of
14	the protocols on blinding language recommended in this
15	draft resulted in its elimination from the final study
16	report, right?
17	MR. ROBERTS: Objection.
18	THE WITNESS: Yes.
19	BY MR. BAUM:
20	Q. Okay. Do you know where this language
21	but otherwise blinded that's in the study report came
22	from?
23	MR. ROBERTS: Objection.
24	THE WITNESS: Where?

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BY MR. BAUM: 1 2 At Page 44, in that bottom paragraph, it 0. 3 says? 4 MR. ROBERTS: On Exhibit 11? 5 BY MR. BAUM: 6 Ο. On Exhibit 11 it says "although otherwise blinded, " do you see that? 7 8 Α. Yes. 9 0. Do you know what that language came 10 from? MR. ROBERTS: Objection. 11 12 THE WITNESS: No. 13 BY MR. BAUM: 14 Q. It's not in your hand -- it's not part of your handwritten changes. That's why we were 15 16 asking. 17 No, I don't. Α. Okay. Let's go to Page 17 of Exhibit 18 Q. 19 13. At the bottom it has "Secondary Statistical Objectives, the secondary statistical objectives of 20 21 this study were." 22 Do you see that? 23 Α. Yes. 24 And then going over to the next page, Q.

1	"1. To further compare the efficacy of citalopram to
2	placebo in children and adolescents with MDD using,"
3	and then it's crossed out, "the change from baseline to
4	Week 8 in."
5	Do you see that?
6	A. Yes.
7	Q. Did you strike that out?
8	MR. ROBERTS: Objection.
9	THE WITNESS: This looks like my
10	handwriting.
11	BY MR. BAUM:
12	Q. Okay. And then below it shows it
13	lists off the various secondary outcome measures, and
14	then it's CGI score at Week 8 is struck out at Week 8.
15	Do you see that?
16	MR. ROBERTS: Objection.
17	THE WITNESS: Where are we looking? I
18	don't see that. Oh, down here?
19	BY MR. BAUM:
20	Q. Right here, right there.
21	A. Oh, yes.
22	Q. You see CGI-I?
23	A. Yes.
24	Q score at Week 8 has "at Week 8"

stricken off? 1 2 Α. Yes. 3 0. If you look at Exhibit 11, Page 54? 4 MR. ROBERTS: Which is the next page 5 over. That's Exhibit 13. Exhibit 11 is this 6 one, so just turn the page over. 7 BY MR. BAUM: 8 You see under the Secondary Statistical 0. 9 Objectives, it's pretty much the same as what you did 10 with your handwriting, with the Week 8s eliminated. 11 Do you see that? 12 MR. ROBERTS: Objection. THE WITNESS: Yes, they look similar. 13 14 BY MR. BAUM: 15 So each of your edits on that section, 0. 16 appeared in that section, do you know why you crossed 17 out the Week 8 in those two spots? 18 MR. ROBERTS: Objection. 19 THE WITNESS: I could speculate. 20 BY MR. BAUM: 21 Well, what is your impression of why you 0. 22 did that? 23 Objection. MR. ROBERTS: 24 This is a list of the THE WITNESS:

1	outcome measures. It doesn't specify any time
2	points, so it wouldn't be appropriate to
3	specify a time point for that variable in
4	particular.
5	BY MR. BAUM:
6	Q. That wasn't part of the plan to
7	de-emphasize the Week 8 negative outcomes in favor of
8	the positive outcomes for the prior weeks?
9	MR. ROBERTS: Objection.
10	THE WITNESS: It appears to me it was
11	done for consistency.
12	BY MR. BAUM:
13	Q. If you look at the protocol, which is
14	Exhibit 9 at Page 17.
15	MR. ROBERTS: Exhibit 9. That's Exhibit
16	11. I think this is Exhibit nine. Yeah, this
17	is Exhibit 9. What page did you say again?
18	BY MR. BAUM:
19	Q. At the Paragraph 12.1.2 and it's Page
20	329.
21	MR. ROBERTS: 329.
22	MR. BAUM: The big number up at the time
23	is 329.
24	MR. ROBERTS: Talking about 1.2, okay.

1 BY MR. BAUM: Yeah, "Secondary Objectives." It says, 2 Ο. 3 "To further compare the efficacy of citalopram to 4 placebo in depressed children and adolescents patients. 5 The endpoints for the secondary objectives are the 6 CGI-Improvement score and change from baseline in 7 CGI-Severity score, K-SADS-P (depression module) and 8 CGAS score at Week 8." 9 Do you see that? 10 Α. Yes. 11 So at Week 8 is the endpoint for the 0. 12 secondary outcomes, correct? 13 MR. ROBERTS: Objection. 14 BY MR. BAUM: 15 Are you thinking, or did you think you 0. 16 answered? 17 Well, it's somewhat different because Α. here it says -- I mean, in comparing the rest of the 18 study report, it says CGI-I score at Week 8 as opposed 19 20 to here it's CGS at the end. So it's -- just in terms 21 of the consistency with the study report, it's --22 that's different. Yeah, but I do see that. 23 Ο. You do see that the endpoint for the 24 secondary outcomes was Week 8, per the protocol,

Charles Flicker, Ph.D. 1 correct? 2 MR. ROBERTS: Objection. 3 THE WITNESS: Yes. 4 BY MR. BAUM: 5 Q. Okay. And then you struck that language in the study report? 6 7 MR. ROBERTS: Objection. 8 BY MR. BAUM: 9 Q. Draft that you handwrote your changes 10 into, correct? 11 Α. No. 12 0. Well, over here, see you struck out the Week 8 part, right? 13 14 MR. ROBERTS: Objection. 15 THE WITNESS: No, that's what I was just 16 saying is that the study report is quite different. The study report, as I see it, is 17 18 simply listing the variables and not specifying 19 any time point. 20 BY MR. BAUM: 21 Right. 0. 22 Α. Except for the CGI-I, which makes sense, 23 because the CGI-I is you're not measuring change from 24 baseline.

1	Q.	What?
2	Α.	See, these CGI-I there's no baseline.
3	Q.	Okay. But what we're trying what I'm
4	trying to poin	t out to you is that in this draft, which
5	is Exhibit 13,	it essentially mirrors the typewritten
6	portion, essen	tially mirrors the language that's in the
7	secondary obje	ectives. It says "to further compare the
8	efficacy."	
9		Do you see that?
10		MR. ROBERTS: Objection.
11	BY MR. BAUM:	
12	Q.	And so are you saying that because the
13	CGI-I is not a	Week 8 analysis change from baseline
14	in Week 8, tha	t's why you struck that out?
15		MR. ROBERTS: Objection.
16		THE WITNESS: Yes. They're different.
17	BY MR. BAUM:	
18	Q.	You don't think that was to enable
19	discussion of	the prior weeks instead of Week 8, which
20	is not mention	hed here?
21		MR. ROBERTS: Objection.
22	BY MR. BAUM:	
23	Q.	Right?
24		MR. ROBERTS: Objection.

1 THE WITNESS: The prior weeks are going to be examined no matter what. 2 BY MR. BAUM: 3 4 Q. What's the endpoint, Week 8 or Week 1? 5 MR. ROBERTS: Objection. 6 THE WITNESS: In this paragraph of the 7 protocol Week 8 is identified as an endpoint. BY MR. BAUM: 8 9 Ο. Okay. Let's take Page 26 of Exhibit 13 10 and under Section "7.0 Changes in the Conduct of the 11 Study and Planned Analyses." 12 Do you see that? 13 MR. ROBERTS: So Page 26, yeah, right 14 there. 15 THE WITNESS: Yes. 16 BY MR. BAUM: 17 And there's some of your handwritten Q. revisions to that section regarding the conduct of the 18 study with planned analyses, and it says there in the 19 20 original wording, nine patients (105, 113, 114, 505, 21 507, 506, 509, 513 and 514) accidentally received 1 22 week of unblinded study drug treatment (tablets had the 23 incorrect color coating). 24 Do you see that?

1 Α. Yes. So there it said they received one week 2 0. 3 of unblinded study drug treatment, not potentially unblinded or potentially -- potentially caused bias, 4 right? It said that they received one week of 5 unblinded study treatment, right? 6 7 MR. ROBERTS: Objection. 8 THE WITNESS: Yes. 9 BY MR. BAUM: And then your handwriting inserted 10 Q. 11 "medication with potentially unblinding information," 12 correct? 13 MR. ROBERTS: Objection. 14 THE WITNESS: Yes, that's my 15 handwriting. 16 BY MR. BAUM: Q. 17 Did you do that handwriting to under-emphasize the fact that the patients received 18 19 unblinded study drug treatment? 20 MR. ROBERTS: Objection. 21 THE WITNESS: It would require some 22 speculation on my part, but I put that in, I would believe, to provide more accurate 23 24 information.

1	BY MR. BAUM:
2	Q. You thought it was more accurate to say
3	potentially unblinding instead of unblinded?
4	A. Yes.
5	Q. You think you were the one that
6	introduced the language potentially unblinded
7	potentially unblinding information?
8	MR. ROBERTS: Objection.
9	THE WITNESS: Well, I wrote this, I
10	wrote this phrase.
11	MR. BAUM: Let's go to Exhibit 14.
12	MR. ROBERTS: Should we keep all these?
13	MR. BAUM: Keep them all handy.
14	MR. ROBERTS: Why don't you turn them
15	all to the front so we can see.
16	(Document marked for identification as
17	Flicker Deposition Exhibit No. 14.)
18	BY MR. BAUM:
19	Q. So Exhibit 14 is MDL-FORP0175697, it's
20	an e-mail from Paul Tiseo to Joan Barton, Charlie
21	Flicker, Ivan Gergel, Lawrence Olanoff and others dated
22	March 2, 2000, re: CIT-18.
23	Do you recall receiving this e-mail and
24	the attached fax?

1 Α. No. 2 Ο. Have you seen this before? 3 MR. ROBERTS: Objection. 4 THE WITNESS: Yes. 5 BY MR. BAUM: 6 You saw it yesterday? Ο. 7 Α. Yes. 8 Do you have any reason to believe that Q. 9 you did not receive it at the time? 10 MR. ROBERTS: Objection. 11 THE WITNESS: I don't know that I received it on March 2nd but --12 BY MR. BAUM: 13 14 Do you think you might have --Q. 15 -- I imagine I got it. Α. 16 Ο. Okay. And do you agree that this document was produced in the ordinary course of 17 18 business at Forest? 19 MR. ROBERTS: Objection. 20 THE WITNESS: I don't know how ordinary. 21 I'd say in the course of business. 22 BY MR. BAUM: 23 Ο. Okay. And then it says, Dear all, for your information, a copy of the fax that went out to 24

1	all CIT-MD-18 Pediatric Investigational Sites this
2	morning is attached. All sites have been also been
3	contacted by telephone and given verbal instructions on
4	how to proceed with both drug shipment as well as their
5	patients who have been screened and/or randomized.
б	Do you see that?
7	A. Yes.
8	Q. So Dr. Tiseo is saying that this
9	attachment that is attached to this e-mail was sent out
10	to all of the CIT-MD-18 sites, right?
11	MR. ROBERTS: Objection.
12	THE WITNESS: Yes.
13	BY MR. BAUM:
14	Q. And they each received telephone calls
15	regarding it, correct?
16	MR. ROBERTS: Objection.
17	THE WITNESS: That's what this says.
18	BY MR. BAUM:
19	Q. Do you know who would have received the
20	fax at the sites?
21	MR. ROBERTS: Objection.
22	THE WITNESS: No.
23	BY MR. BAUM:
24	Q. Okay. Let's go to the next page, and it
L	

1	says, "Fax Transmission Cover Sheet" with like four
2	asterisks Urgent, bolded in big print "Urgent Message"
3	and then four asterisks, re: CIT-MD-18 Citalopram
4	Pediatric Depression Study.
5	Have you seen this fax before?
6	A. Yes.
7	Q. And when did you see that?
8	A. Yesterday.
9	Q. Okay. Here it says, "It has come to our
10	attention that an error was made during the packaging
11	of the clinical supplies for the above-noted study. A
12	number of bottles of 'active' medication were
13	mistakenly packed with the pink-colored commercial
14	Celexa tablets instead of instead the standard white
15	citalopram tablets used for blinded clinical studies.
16	As a result, dispensing these tablets would
17	automatically unblind the study. This medication needs
18	to be replaced with the appropriate white tablets
19	immediately to maintain the study blind."
20	Did I read that correctly?
21	A. Yes.
22	Q. So the pink-colored commercial tablets
23	got dispensed to CIT-MD-18 patients, correct?
24	MR. ROBERTS: Objection.

1 THE WITNESS: According to this, there were pink tablets given to some patients. 2 BY MR. BAUM: 3 4 And --0. 5 Α. Well, I mean, we know that based on other information. б 7 And per the MD-18 protocol, all the 0. 8 pills dispensed in CIT-MD-18 were supposed to be white, 9 correct? 10 MR. ROBERTS: Objection. 11 THE WITNESS: I'd have to go back to the 12 protocol to verify that, but that sounds 13 correct. 14 BY MR. BAUM: 15 0. We read that into the record earlier, 16 but so do you have any reason to dispute that they 17 ought to have been white, correct? 18 MR. ROBERTS: Objection. 19 THE WITNESS: No, I don't. No, I don't 20 dispute that. 21 BY MR. BAUM: 22 0. Okay. So the fact that some of them 23 were not white was protocol violation, correct? 24 MR. ROBERTS: Objection.

1 THE WITNESS: Yes. 2 BY MR. BAUM: 3 0. So here, according to Dr. Tiseo, the study was automatically unblinded for the patients 4 5 subject to dispensing error, correct? 6 MR. ROBERTS: Objection. 7 THE WITNESS: He writes "automatically 8 unblind the study." 9 BY MR. BAUM: "As a result, dispensing these tablets 10 Q. would automatically unblind the study." So if the 11 12 patients were dispensed those pink tablets, they would be automatically unblinded, correct? 13 14 MR. ROBERTS: Objection. 15 THE WITNESS: That's what he writes 16 here. 17 BY MR. BAUM: Okay. So do you know why those 18 0. unblinded patients weren't excluded from the study at 19 20 that point? 21 MR. ROBERTS: Objection. 22 THE WITNESS: First of all, we don't 23 know that the patients were unblinded. We know 24 that there was information that could impact

the blinding of the study that was conveyed to 1 the site. 2 BY MR. BAUM: 3 4 0. Well, upon -- as of March 2nd, 2002, 5 upon receiving this fax, the investigators were advised that the pink-colored tablets were Celexa, correct? 6 7 MR. ROBERTS: Objection. 8 THE WITNESS: That's how I would 9 interpret this fax, yes. BY MR. BAUM: 10 11 0. So that would indicate that the 12 investigators knew what those patients were getting, 13 correct? 14 MR. ROBERTS: Objection. 15 THE WITNESS: Well, no, it doesn't 16 completely indicate that. The patients -- the 17 investigator would also have to know what color tablets the patient received. 18 19 BY MR. BAUM: 20 0. The patients that received the pink 21 commercial Celexa would have been exposed to the 22 investigators who gave them those tablets, and they 23 would know that they were receiving Celexa at that 24 point, correct?

1	MR. ROBERTS: Objection.
2	THE WITNESS: I don't recall too many
3	investigators who would hand patients tablets.
4	BY MR. BAUM:
5	Q. All right. So the investigators that
6	were notified of this had to do something with respect
7	to the pink tablets that had been given to their
8	patients to hand out?
9	A. Yes.
10	MR. ROBERTS: Objection.
11	BY MR. BAUM:
12	Q. So at that point they knew which of
13	their patients had been assigned to receive Celexa
14	because they had been assigned to receive Celexa pink
15	tablets, correct?
16	MR. ROBERTS: Objection.
17	THE WITNESS: No, that wouldn't be my
18	understanding.
19	BY MR. BAUM:
20	Q. So when they returned the pink tablets,
21	they wouldn't know that their patient that had those
22	tablets was assigned Celexa?
23	MR. ROBERTS: Objection.
24	THE WITNESS: Under if an

1	investigator were to look at a return look
2	at returned medication and he saw that the
3	tablets were pink in the within this time
4	frame, then I would think the investigator
5	would be able to draw the conclusion that the
6	patient was on active drug.
7	BY MR. BAUM:
8	Q. And why bother to replace these tablets
9	if it weren't an issue that would unblind the study?
10	MR. ROBERTS: Objection.
11	THE WITNESS: Well, the protocol
12	specifies that the color coating of the tablets
13	should be blinded, should be the same,
14	identical in the placebo and treatment groups.
15	BY MR. BAUM:
16	Q. Was it your understanding that all nine
17	of these patients received pink-colored commercial
18	tablets?
19	MR. ROBERTS: Objection.
20	THE WITNESS: Well, was it my
21	understanding? I mean, I have no understanding
22	what my understanding is, but if you're
23	referring to that, what I wrote in the study
24	report, I would say there's evidence of that.

1	BY MR. BAUM:
2	Q. Okay. That's actually what the report
3	says at Page 63, Section 7.0 in Exhibit 11. It says
4	it lists Patients 105 through 514 and says that the
5	nine patients were mistakenly dispensed one week of
6	medication with potential unblinding information,
7	tablets had incorrect color coating.
8	A. That's different though.
9	MR. ROBERTS: Objection.
10	BY MR. BAUM:
11	Q. Oh, how is it different?
12	MR. ROBERTS: Objection.
13	THE WITNESS: Well, it seems that I'd
14	made the mistake of saying that nine patients
15	got pink tablets.
16	BY MR. BAUM:
17	Q. Yeah.
18	A. My current understanding is that that is
19	not correct.
20	Q. Oh, so you think this study report is
21	incorrect when you wrote it at the time?
22	MR. ROBERTS: Objection.
23	THE WITNESS: I think I made a mistake,
24	yeah.

1 BY MR. BAUM: 2 Ο. What do you think actually happened? 3 MR. ROBERTS: Objection. 4 THE WITNESS: My current impression is 5 that the placebo patients received white tablets. 6 7 BY MR. BAUM: 8 And the citalopram patients received 0. 9 pink tablets? 10 MR. ROBERTS: Objection. 11 THE WITNESS: For those nine, yes. 12 BY MR. BAUM: 13 0. And so in either case, the investigators 14 would know which patients were either on citalopram or 15 on placebo among those nine patients, correct? 16 MR. ROBERTS: Objection, 17 mischaracterizes the document and 18 mischaracterizes his testimony. 19 THE WITNESS: If the investigator --20 MR. ROBERTS: And requires speculation. 21 THE WITNESS: -- read the fax and they 22 reviewed the patient's medication bottles, then 23 they would be able to draw a conclusion 24 regarding the assigned treatment group.

1 BY MR. BAUM: That would be an unblinding, correct? 2 Ο. 3 MR. ROBERTS: Objection. 4 That would affect the --THE WITNESS: 5 that would affect the investigator's blinding. BY MR. BAUM: б 7 Okay. Do you recall that you testified 0. 8 in your 2007 deposition that as the medical director, 9 that your primary mandate in the CNS research was 10 overseeing the process of registering CNS compounds 11 gaining regulatory approval. 12 Does that ring a bell? 13 MR. ROBERTS: Objection. 14 THE WITNESS: No. 15 BY MR. BAUM: 16 0. Do you think that was what your primary 17 mandate was? 18 Objection. MR. ROBERTS: 19 THE WITNESS: Yes. 20 BY MR. BAUM: 21 Do you believe that in your role as a 0. 22 medical director of the clinical research department at 23 Forest that you had an obligation to be truthful with the FDA in all communications about CIT-MD-18? 24

1 MR. ROBERTS: Objection. 2 THE WITNESS: Yes. BY MR. BAUM: 3 And do you believe that Forest had an 4 0. obligation to be truthful with the FDA in all 5 б communications about CIT-MD-18? 7 MR. ROBERTS: Objection. 8 THE WITNESS: Yes. 9 MR. BAUM: Can you give me Exhibit 16. 10 We're going to skip 15 and we're going to come 11 back to it. 12 MR. ROBERTS: Okay. 13 (Document marked for identification as 14 Flicker Deposition Exhibit No. 16.) 15 BY MR. BAUM: 16 0. Okay. So handing over what we've marked as 16, and this is an e-mail MDL-FOREM0030386 from 17 18 Dr. Tiseo to Lawrence Olanoff, Dr. Gergel, Amy Rubin, 19 Anjana Bose as well as Tracey Varner, Julie Kilbane and you dated March 8, 2000, regarding letter to FDA for 20 21 CIT-18. 22 Do you see that your name is on the CC 23 there? 24 Α. Yes.

1	Q.	Do you have any reason to believe that
2	you were not -	that you did not receive this e-mail?
3		MR. ROBERTS: Objection.
4		THE WITNESS: Yeah, there were quite a
5	few e-	mails I didn't received, yeah, I'm
6	sure l	received it.
7	BY MR. BAUM:	
8	Q.	And does it appear this document was
9	produced in th	ne ordinary course of Forest business?
10		MR. ROBERTS: Objection.
11		THE WITNESS: Essentially.
12	BY MR. BAUM:	
13	Q.	And this March 8 date is a few days
14	after Dr. Tise	eo sent the memorandum and fax to the
15	clinical trial	investigators informing them of the
16	dispensing err	cor, correct?
17		MR. ROBERTS: Objection.
18	BY MR. BAUM:	
19	Q.	That was March 2nd, six days later.
20		Do you see that?
21	Α.	Yes.
22	Q.	And have you seen this document before?
23		MR. ROBERTS: Objection.
24		THE WITNESS: I might have seen this

yesterday. 1 2 BY MR. BAUM: 3 Ο. Okay. So in the e-mail on the cover of the attachment, it says attached -- "Dear all, attached 4 please find the letter that Charlie and I put together 5 for the purpose of informing the FDA of our packaging 6 mishap in the citalopram pediatric study." 7 8 Do you see that? 9 Α. Yes. Do you recall putting together a letter 10 Q. with Dr. Tiseo to be delivered to the FDA? 11 12 MR. ROBERTS: Objection. 13 THE WITNESS: No. 14 BY MR. BAUM: 15 Was it part of your duties to do Ο. something like that? 16 17 MR. ROBERTS: Objection. 18 It wouldn't be out of THE WITNESS: 19 line. 20 BY MR. BAUM: 21 Then attached is a letter to the FDA in 0. 22 draft, correct? 23 Α. Yes. 24 And in the first paragraph here it says Q.

that there was a clinical supplies package willing 1 2 error for CIT-MD-18. 3 Do you see that? 4 Α. Yes. 5 Q. And it's for eight randomized patients at two investigational sites? 6 7 Α. Yes. 8 And in the second paragraph it says, Q. 9 "For reporting purposes, the primary efficacy analysis 10 will exclude the eight potentially unblinded patients, with a secondary analysis including them also to be 11 conducted, " correct? 12 13 Α. Yes. 14 Would you agree that excluding the Q. 15 unblinded or potentially unblinded patients from the 16 primary efficacy analysis was the scientifically appropriate thing to do? 17 18 MR. ROBERTS: Objection. Not necessarily. 19 THE WITNESS: 20 BY MR. BAUM: 21 This is not what was actually done in Ο. 22 the final study report, though, correct? 23 MR. ROBERTS: Objection. 24 Both analyses -- well, no, THE WITNESS:

1	I guess it was nine, right? But both analyses
2	were conducted.
3	BY MR. BAUM:
4	Q. Yeah, but one was doesn't ask primary
5	efficacy analysis and that here the primary efficacy
6	analysis was the one that excluded the eight
7	potentially unblinded patients, correct?
8	MR. ROBERTS: Objection.
9	THE WITNESS: Yes.
10	BY MR. BAUM:
11	Q. And the one that included them was going
12	to be a secondary analysis?
13	MR. ROBERTS: Objection.
14	THE WITNESS: In this proposal, yes.
15	MR. BAUM: Okay. Let's go to the next
16	document. Mark it as Exhibit 17.
17	(Document marked for identification as
18	Flicker Deposition Exhibit No. 17.)
19	BY MR. BAUM:
20	Q. And if you look at the top, it says
21	letter to FDA - draft, March 8, 2000, which is right
22	the same day as the prior e-mail.
23	Do you recall that? Prior exhibit was
24	dated March 8 as well.

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1 MR. ROBERTS: Objection. 2 BY MR. BAUM: 3 0. And then there's some handwriting at the top. Is that your handwriting? 4 5 Α. That looks like my handwriting. б Okay. So have you seen this document Ο. before? 7 8 MR. ROBERTS: Objection. 9 THE WITNESS: No. 10 BY MR. BAUM: 11 0. Okay. Does it appear to have been 12 something you did while you were working at Forest in the ordinary course of Forest business? 13 14 MR. ROBERTS: Objection. 15 THE WITNESS: Yes. 16 BY MR. BAUM: 17 If you look at the typed portion of the Q. paragraph, you see the paragraph starts by saying, "The 18 19 purpose of this letter is to inform the agency that an error was made during the packaging of the clinical 20 21 supplies for the above-noted study." 22 Do you see that? 23 Α. Yes. 24 And then "Two of our investigational Q.

1	sites called in to report that some of their patients
2	were receiving white tablets and others were receiving
3	pink tablets."
4	Do you see that?
5	A. Yes.
6	Q. And then "These reports were passed onto
7	Forest Clinical Packaging where it was discovered that
8	a number of bottles of 'active' medication were
9	mistakenly packed with the pink-colored commercial
10	Celexa tablets instead of the standard white citalopram
11	tablets used for blinded clinical trials."
12	Do you see that?
13	A. Yes.
14	Q. So based on this letter, it appears the
15	dispensing error was discovered after two clinical
16	investigators called Forest inquiring about why some of
17	their patients were receiving white tablets and others
18	were receiving pink ones, right?
19	MR. ROBERTS: Objection.
20	THE WITNESS: That's how it looked to
21	me.
22	BY MR. BAUM:
23	Q. And they were supposed to all be
24	receiving white tablets, right?

1 MR. ROBERTS: Objection. 2 THE WITNESS: I think we concluded that. BY MR. BAUM: 3 4 0. So the letter continues, "On March 2nd, all sites were notified of this error by telephone and 5 by fax." 6 7 Do you see that? 8 Α. Yes. 9 Ο. And that's consistent with what we read earlier, right? 10 11 MR. ROBERTS: Objection. 12 THE WITNESS: Yes. 13 BY MR. BAUM: 14 Q. And in the March 2nd letter Dr. Tiseo said that dispensing of the pink tablets would 15 16 automatically unblind the study, correct? 17 MR. ROBERTS: Objection. 18 THE WITNESS: His fax? 19 BY MR. BAUM: 20 Yeah. 0. 21 That's what it says. Α. 22 Q. Returning to Exhibit 17, if you look at 23 the bottom of the page, it says -- no. 24 This is 17. We're still MR. ROBERTS:

on 17. 1 2 BY MR. BAUM: 3 0. "As only 8 of 160 patients had been randomized at the time this error was discovered, the 4 5 impact upon the integrity of the study is suggested to be minimal." б 7 Do you see that? 8 Α. Yes. 9 At this time it was supposed that 0. 10 pulling these eight out would not affect anything, so 11 it was okay to not include them in the primary 12 analysis, correct? 13 MR. ROBERTS: Objection. 14 THE WITNESS: I'm not sure what you 15 mean. 16 BY MR. BAUM: 17 It says, "As only 8 of 160 patients had Q. been randomized at the time this error was discovered, 18 19 the impact upon the integrity of the study is suggested to be minimal." So that it's suggested we're not going 20 21 to count them and only eight -- and only eight of them 22 were not going to be counted, so it's not going to be a 23 big deal because you've got 160 patients anyway? 24 MR. ROBERTS: Objection.

1 THE WITNESS: Was this letter even sent? 2 BY MR. BAUM: 3 0. Well, that's what we're going to find 4 out. 5 MR. ROBERTS: Objection. 6 THE WITNESS: So this is just one 7 person's opinion what they drafted here. 8 BY MR. BAUM: 9 0. Well, this is, I think, a draft that you and Dr. Tiseo worked on together. 10 11 MR. ROBERTS: Objection. You're 12 testifying. BY MR. BAUM: 13 14 Q. All right. So at the next to last 15 paragraph it's -- there would be -- it says, there's 16 going to be a full set of 160 patients -- no. Let me 17 just backtrack. 18 Let me go up to the handwriting. It 19 says -- first it says reconsider no letter. 20 What did you mean by that? 21 MR. ROBERTS: Objection. 22 THE WITNESS: I don't know. 23 BY MR. BAUM: 24 Were you suggesting that they just hide Q.

from it the FDA? 1 2 MR. ROBERTS: Objection. 3 THE WITNESS: I don't know what reconsider no error -- no letter. 4 5 BY MR. BAUM: 6 Ο. Okay. Then next it says, "Due to a 7 packaging error, 8 randomized patients at 3 8 investigational sites had access to potentially unblinding information." 9 10 Do you see that? Are you talking about my handwriting? 11 Α. 12 Ο. Yeah, your handwriting. 13 Α. Potential -- yes. 14 And then by adding potentially, you were Q. 15 toning down Dr. Tiseo's automatically unblinded language, right? 16 17 MR. ROBERTS: Objection. 18 THE WITNESS: Well, I don't know who 19 wrote this draft. 20 BY MR. BAUM: 21 Q. Okay. So let's go on to the next thing. 22 "Drug has been repackaged and a full complement of 160 23 additional patients will be enrolled under standard double-blind conditions." 24

1		Do you see that?
2	Α.	Yes.
3	Q.	And that's your handwriting, right?
4		MR. ROBERTS: Objection.
5		THE WITNESS: Yes.
6	BY MR. BAUM:	
7	Q.	And were you suggesting that a full set
8	of 160 patient	s would be enrolled under standard
9	double-blind c	conditions, right?
10		MR. ROBERTS: Objection.
11		THE WITNESS: Well, that's what it says.
12	BY MR. BAUM:	
13	Q.	And by implication, you were suggesting
13 14		And by implication, you were suggesting patients subject to the dispensing error
	that the nine	
14	that the nine	patients subject to the dispensing error
<mark>14</mark> 15	that the nine	patients subject to the dispensing error
14 15 16	that the nine were not stand	patients subject to the dispensing error lardly double-blinded, correct? MR. ROBERTS: Objection.
14 15 16 17	that the nine were not stand	patients subject to the dispensing error ardly double-blinded, correct? MR. ROBERTS: Objection. THE WITNESS: It doesn't directly
14 15 16 17 18	that the nine were not stand	patients subject to the dispensing error ardly double-blinded, correct? MR. ROBERTS: Objection. THE WITNESS: It doesn't directly
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1	Q. And then next you say, "For reporting
2	purposes, the primary efficacy analysis will exclude
3	the potentially unblinded patients, and a secondary
4	analysis including them will also be conducted."
5	Do you see that?
6	A. Yes.
7	Q. And so you were suggesting that the
8	primary efficacy measure would exclude the patients
9	exposed to the dispensing error, correct?
10	MR. ROBERTS: Objection.
11	THE WITNESS: Yes.
12	BY MR. BAUM:
13	Q. That was your handwriting?
14	MR. ROBERTS: Objection.
15	THE WITNESS: That's my handwriting.
16	BY MR. BAUM:
17	Q. You thought that was a good idea at the
18	time, right?
19	MR. ROBERTS: Objection.
20	THE WITNESS: That was a proposed
21	solution.
22	BY MR. BAUM:
23	Q. Go to the next exhibit, 18 oh, in
24	Exhibit 17 where it says, "Two of our investigational

1	sites called in to report that some of their patients
2	were receiving white tablets and others were receiving
3	pink tablets," do you see that?
4	A. Yes.
5	Q. Those investigators were unblinded,
6	right?
7	MR. ROBERTS: Objection.
8	THE WITNESS: Well, it doesn't specify
9	investigators, someone at the site.
10	BY MR. BAUM:
11	Q. So someone at the site in dealing with
12	the pills and the patients was unblinded, correct?
13	MR. ROBERTS: Objection,
14	mischaracterizes the document.
15	THE WITNESS: They were potentially
16	unblinded. They would have had to associate
17	the
18	MR. BAUM: Let's go to Exhibit 18.
19	MR. ROBERTS: Hold on. Are you
20	finished?
21	THE WITNESS: Yeah.
22	(Document marked for identification as
23	Flicker Deposition Exhibit No. 18.)
24	BY MR. BAUM:

1	Q.	They got the memo, though, from
2	Dr. Tiseo, con	rrect?
3		MR. ROBERTS: Objection.
4		THE WITNESS: How would I know?
5	BY MR. BAUM:	
6	Q.	Let's take a look at 18. This is
7	MDL-FOREM00303	884, and it's an e-mail response to
8	Dr. Tiseo's e-	-mail from Amy Rubin, and when I say
9	response to Dr	r. Tiseo's memo, he sent a memo out
10	requesting sug	gestions to the revisions to the letter
11	to go to the B	DA. Then Amy Rubin sends to Lawrence
12	Olanoff, Ivan	Gergel Anjana Bose, Paul Tiseo, Tracey
13	Varner, Julie	Kilbane and you this proposed draft of
14	the letter to	the FDA.
15		Do you see that?
16	Α.	Yes.
17	Q.	And it's dated March 9th, 2000.
18		Do you see that? Yes?
19	Α.	I'm looking.
20	Q.	It's right up at the top, up here.
21	Α.	Oh, yeah, yeah.
22	Q.	You see that?
23	Α.	Yes.
24	Q.	Okay. And that's a day after Dr. Tiseo

asked for some comments? 1 2 Α. Okay. 3 Ο. And Amy Rubin, do you know what her job 4 was? 5 Α. No. You don't know whether or not she was in б 0. 7 regulatory affairs? 8 MR. ROBERTS: Objection. 9 THE WITNESS: Based on this, she --10 well, I assume she was in regulatory. 11 BY MR. BAUM: 12 O. Okay. So in this e-mail Ms. Rubin states, "I have taken the liberty of editing your 13 14 letter as follows: Please make any other changes you 15 feel are necessary." 16 Do you see that? 17 Α. Yes. And then below she appears to have made 18 Q. 19 some edits or cut and pasted a version of the draft that you and Dr. Tiseo had worked on. 20 21 Do you see that? 22 MR. ROBERTS: Objection. 23 THE WITNESS: That seems to be a 24 reasonable scenario.

1	BY MR. BAUM:
2	Q. Now, she changed the line from that you
3	or Dr. Tiseo or in your handwriting you said 8
4	randomized patients at 2 investigational sites were
5	dispensed medications that could have potentially
6	unblinded the study, and that now it's been changed by
7	Amy Rubin to say medication was dispensed to eight
8	randomized patients in a fashion that had the potential
9	to cause patient bias.
10	Do you see that?
11	A. Yes.
12	MR. ROBERTS: Objection.
13	BY MR. BAUM:
14	Q. And that phrase, "potential to cause
15	patient bias" is different from what Dr. Tiseo had in
16	mind when he said that it was mistakenly unblinded,
17	correct?
18	MR. ROBERTS: Objection.
19	THE WITNESS: I don't see where
20	Dr. Tiseo said that.
21	BY MR. BAUM:
22	Q. Right here, he says, "As a result,
23	dispensing these tablets would automatically unblind
24	the study."

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1	A. So he didn't say mistakenly unblinded.
2	He said if they were dispensed. So what's the
3	question?
4	Q. Her phrasing is different than this
5	language, correct?
6	MR. ROBERTS: Objection.
7	THE WITNESS: Those two are differently
8	different, yes.
9	BY MR. BAUM:
10	Q. And it's different from saying that they
11	were potentially unblinded, correct?
12	MR. ROBERTS: Objection.
13	THE WITNESS: What's different from
14	potentially unblinded?
15	BY MR. BAUM:
16	Q. Potential to cause patient bias.
17	A. That is different.
18	Q. And that's different from saying that
19	the integrity of the blind was unmistakenly violated,
20	correct?
21	MR. ROBERTS: Objection.
22	THE WITNESS: It's definitely different
23	from saying the integrity of the blind was
24	what?

1	BY MR. BAUM:
2	Q. Unmistakenly violated.
3	A. Mistakenly or unmistakenly.
4	Q. Unmistakenly, okay.
5	MR. ROBERTS: Objection.
6	MR. BAUM: Let's go to Exhibit 19.
7	(Document marked for identification as
8	Flicker Deposition Exhibit No. 19.)
9	BY MR. BAUM:
10	Q. This is an e-mail dated an e-mail
11	chain going from March 8 to March 14 between Paul
12	Tiseo, Amy Rubin and you, and if you look at the
13	e-mail look at the e-mail string, you will see that
14	the things that are below are what we just went through
15	the e-mail from March 8 from Paul Tiseo asking for
16	comments and then attached to that is Amy's Amy
17	Rubin's e-mail with her revisions, and then you are
18	commenting on top of that.
19	Do you see that?
20	A. It looks that way.
21	Q. It says, although the patient sorry.
22	Although "potential to cause bias" is a masterful
23	stroke of euphemism, I would be a little more up front
24	about the fact that the integrity of the blind was

unmistakenly violated. 1 2 Do you see that? Α. 3 Yes. 4 Q. Have you seen this before? 5 MR. ROBERTS: Objection. 6 THE WITNESS: I saw this yesterday. 7 BY MR. BAUM: 8 Q. Okay. And do you have any reason to 9 believe you didn't write that? 10 MR. ROBERTS: Objection. 11 THE WITNESS: I probably wrote this. 12 BY MR. BAUM: Q. And this was produced in the ordinary 13 14 course of Forest business, correct? 15 MR. ROBERTS: Objection. 16 THE WITNESS: Yes. 17 BY MR. BAUM: Q. And so you were directly involved in 18 19 resolving the dispensing error problem, correct? 20 MR. ROBERTS: Objection. 21 THE WITNESS: It would appear that I was 22 involved in preparing this communication to the 23 FDA regarding the problem. 24 BY MR. BAUM:

1	Q. Okay. And according to you, using the
2	phrase potential to cause patient bias in a letter to
3	the FDA was a masterful stroke of euphemism, correct?
4	MR. ROBERTS: Objection.
5	THE WITNESS: I think I wrote that.
6	BY MR. BAUM:
7	Q. And according to you, use of the phrase
8	potential to cause bias was not being up front with the
9	FDA, right?
10	MR. ROBERTS: Objection.
11	THE WITNESS: Yes, I felt that it was
12	not a straightforward enough description.
13	BY MR. BAUM:
14	Q. And according to you, Forest should have
15	just been up front about the fact that the integrity of
16	the blind was unmistakenly violated, correct?
17	MR. ROBERTS: Objection.
18	THE WITNESS: I think it was
19	necessary I felt that it was necessary it
20	appears that I felt it was necessary to
21	communicate to the agency that there had
22	been that protocol violations had occurred
23	that affected the blind of the study.
24	MR. BAUM: Can you repeat the question.

1 (The court reporter read back the record 2 as requested.) 3 MR. ROBERTS: I renew my objections, if we're asking it to him again. 4 5 BY MR. BAUM: 6 I think you answered a slightly 0. 7 different question, which I appreciate you're trying to 8 articulate, but I just want a direct answer to that 9 question. 10 Α. Can you repeat the question. 11 (The court reporter read back the record 12 as requested.) 13 MR. ROBERTS: Objection. 14 THE WITNESS: I certainly felt that 15 Forest should be up front about that there had 16 been a protocol violation -- that had been 17 protocol violations that affected the integrity of the blind. 18 19 BY MR. BAUM: 20 0. Now, you're aware that the language 21 regarding potential to cause bias actually ended up in 22 the study report, and your language about unmistakenly 23 violated did not end up in there, correct? 24 MR. ROBERTS: Objection.

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1 THE WITNESS: No. 2 BY MR. BAUM: 3 Q. You think your language made it into the 4 report? 5 MR. ROBERTS: Objection. 6 THE WITNESS: I don't know what was in 7 the report. The report or the letter? 8 BY MR. BAUM: 9 0. Oh, sorry. The letter. Sorry. 10 We'll get to that. 11 Do you know whether or not ultimately 12 the phrase potential to cause bias is what ended up in the letter that Forest sent to the FDA? 13 14 MR. ROBERTS: Objection. 15 THE WITNESS: No, I do not. 16 MR. BAUM: Let's go to Exhibit 19. 17 MR. ROBERTS: Twenty. 18 MR. BAUM: Oh, 20, sorry. 19 (Document marked for identification as 20 Flicker Deposition Exhibit No. 20.) 21 BY MR. BAUM: 22 0. This is FOREM0030382, and it's from Amy Rubin to you, Charlie Flicker, and CC'd to Paul Tiseo. 23 24 It's dated March 15th, which is the day after your

1	e-mail to her dated March 14th and the subject is the
2	letter to the FDA for CIT-18.
3	Do you see that?
4	A. Yeah.
5	Q. Do you think it was Amy Rubin's job to
6	create masterful euphemisms in letters to the FDA?
7	MR. ROBERTS: Objection.
8	THE WITNESS: No.
9	BY MR. BAUM:
10	Q. And do you think she used the phrase
11	potential to cause patient bias because she considered
12	it her job to protect marketing and medical by using
13	masterful euphemisms?
14	MR. ROBERTS: Objection.
15	THE WITNESS: I think she was softening
16	the language.
17	BY MR. BAUM:
18	Q. That made it misleading, correct?
19	MR. ROBERTS: Objection.
20	THE WITNESS: No, I don't think it's
21	misleading. I think potential to cause bias is
22	accurate, but at least when I wrote my comment,
23	I thought the statement should be a more
24	straightforward statement that the impact was

upon the study blind should have been included. 1 2 BY MR. BAUM: 3 Q. Okay. So have you seen this e-mail 4 before that's Exhibit 20? MR. ROBERTS: Objection. 5 6 THE WITNESS: Twenty? 7 BY MR. BAUM: 8 It's the one you've got in your hand Q. 9 there? 10 Α. Yes. 11 Q. When did you see it? 12 Α. Yesterday. Okay. And you see it's addressed to 13 Q. 14 you. 15 Does this appear to have been produced in the ordinary course of Forest business? 16 17 MR. ROBERTS: Objection. 18 THE WITNESS: Yes. 19 BY MR. BAUM: 20 And Ms. Rubin responds to your e-mail 0. 21 from the day before, "Thanks for the compliment. Part of my job is to create 'masterful' euphemisms to 22 23 protect medical and marketing." 24 Do you see that?

Α. Yes. 1 Were you bothered that Ms. Rubin had 2 0. 3 appeared to ignore your concern that the language she 4 suggested was not being up front with the FDA? 5 MR. ROBERTS: Objection. 6 THE WITNESS: Well, obviously, I don't remember this interaction. It looks to me as 7 8 if she was joking. 9 BY MR. BAUM: 10 In your opinion, do you think it was Q. 11 appropriate for Ms. Rubin to be creating masterful euphemisms to protect medical and marketing in her 12 13 communications with the FDA? 14 MR. ROBERTS: Objection. 15 THE WITNESS: Do I think it was 16 appropriate for her to create a euphemism? BY MR. BAUM: 17 18 Masterful euphemisms to protect medical 0. and marketing in her communications with the FDA. 19 20 MR. ROBERTS: Objection. 21 THE WITNESS: I don't think that was 22 part of her job description. 23 BY MR. BAUM: 24 She was essentially bragging about 0.

1	misleading the FDA, wasn't she?
2	MR. ROBERTS: Objection.
3	THE WITNESS: I think she was joking.
4	BY MR. BAUM:
5	Q. So if the language actually ended up in
6	the letter to the FDA, wasn't she actually performing
7	the act of conveying something less up front to the FDA
8	than you thought ought to have been conveyed?
9	MR. ROBERTS: Objection.
10	THE WITNESS: I would have to see the
11	letter that actually went to the FDA.
12	BY MR. BAUM:
13	Q. All right. But she's joking about
14	misleading the FDA, essentially, correct?
15	MR. ROBERTS: Objection,
16	mischaracterizes the document, causes for
17	speculation.
18	THE WITNESS: I think she's joking about
19	her linguistic dexterity.
20	BY MR. BAUM:
21	Q. And that linguistic dexterity or
22	wordsmithing was resulted in creating a masterful
23	euphemism to protect medical and marketing
24	MR. ROBERTS: Objection.

BY MR. BAUM: 1 2 -- in her communications with the FDA, Ο. 3 correct? 4 Α. Well, I think it's a joke, but I think 5 the language could be described as euphemistic. 6 MR. BAUM: Okay. So let's take a look at Exhibit 21. 7 8 (Document marked for identification as 9 Flicker Deposition Exhibit No. 21.) 10 BY MR. BAUM: 11 Ο. Which is the letter that actually went to the FDA dated March 20th, 2000 addressed to Russell 12 Katz from Forest, Tracey Varner, and manager of 13 14 regulatory affairs for Forest. 15 Do you see that? 16 Α. Yes. 17 Q. Have you seen this before? 18 Objection. MR. ROBERTS: THE WITNESS: 19 No. 20 BY MR. BAUM: 21 So let's take a look at this. 0. 22 Do you recall that Ms. Varner was in the line of e-mails regarding the unblinding problem? 23 24 MR. ROBERTS: Objection.

1 THE WITNESS: No. 2 BY MR. ROBERTS: Q. Let's take a look at Exhibit 14. Do you 3 4 see it? 5 MR. ROBERTS: Do you have it? This is 6 what it looks like. 7 THE WITNESS: Which one? 8 MR. BAUM: Fourteen. MR. ROBERTS: Exhibit 14. Here, I see 9 it, Exhibit 14. 10 11 BY MR. BAUM: 12 0. So this is the e-mail cover letter with the urgent message memo that went out on March 2nd. 13 14 Α. Okay. 15 MR. ROBERTS: Objection. 16 BY MR. BAUM: 17 Q. And if you see on the addressee lines, you've got Tracey Varner and Amy Rubin. 18 19 Do you see that? 20 Yeah. Α. 21 Do you see them both? 0. 22 Α. Yeah. 23 Ο. Okay. So here Tracey Varner is now 24 informing the FDA essentially what happened as

1	reflected in this March 2nd, 2000 memo that went out to
2	the investigator sites, correct?
3	MR. ROBERTS: Objection.
4	THE WITNESS: Excuse me?
5	BY MR. BAUM:
6	Q. This letter from Tracey Varner to the
7	FDA dated March 20th, 2000 is informing the FDA about
8	the dispensing error problem that was discussed in the
9	March 2nd letter that went out to the investigator
10	sites?
11	A. Yes.
12	MR. ROBERTS: Objection.
13	BY MR. BAUM:
14	Q. So the first line says, "Dear Dr. Katz,
15	we are taking this opportunity to notify the Division
16	of a clinical supply packaging error for study
17	CIT-MD-18 (site $#2$ - Dr. Busner and site $#16$ -
18	Dr. Wagner). Due to this error, medication was
19	dispensed to eight randomized patients in the fashion
20	that had the potential to cause patient bias."
21	Did I read that correctly?
22	A. Yes.
23	Q. And that's Amy Rubin's language that
24	made it into the letter that went to the FDA, correct?
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1	MR. ROBERTS: Objection.
2	THE WITNESS: The potential to cause
3	patient bias is the same phrase that was in Amy
4	Rubin's e-mail.
5	BY MR. BAUM:
6	Q. And that's what you characterize as a
7	masterful euphemism for the blind having been
8	unmistakenly violated, correct?
9	MR. ROBERTS: Objection.
10	THE WITNESS: I made a statement that it
11	was a masterful euphemism, yeah.
12	BY MR. BAUM:
13	Q. For what you said was the blind had
14	unmistakenly been violated, correct?
15	MR. ROBERTS: Objection.
16	THE WITNESS: I have to look at it.
17	BY MR. BAUM:
18	Q. Find it?
19	A. Yeah. Well, there are two separate
20	statements. One is that it's a euphemism. The other
21	is that there was a violation of the study blind.
22	Q. And when you wrote that e-mail, you were
23	attempting to be accurate at the time, correct?
24	MR. ROBERTS: Objection.

1 THE WITNESS: I was always attempting to 2 be accurate. BY MR. BAUM: 3 4 Ο. Okay. All right. So next it says, "A 5 full complement of 160 patients will be enrolled under standard double-blind conditions." 6 7 Do you see that? 8 Α. Yes. 9 And that's the line that you wrote, 0. handwrote in the draft that you edited, correct? 10 11 MR. ROBERTS: Objection. 12 BY MR. BAUM: 13 Q. Right here. 14 Yes, that's -- that's my handwriting. Α. 15 So by implication, again, what you Ο. 16 conveyed to the FDA was that these eight patients subject to the dispensing error were not standardly 17 18 double-blinded, right? 19 MR. ROBERTS: Objection. 20 THE WITNESS: Well, it's not really 21 exactly what I wrote. 22 BY MR. BAUM: 23 0. What did you write? 24 And a full complement of 160 additional Α.

patients will be enrolled. 1 So were you thinking that there would be 2 0. a new group of patients that would be enrolled that 3 would not be subject to the dispensing error? 4 5 Α. I don't know what I was thinking, but I don't think that's what I was thinking. 6 What did that line mean? 7 Ο. 8 MR. ROBERTS: Objection. 9 THE WITNESS: That there would be -- I'd 10 have to speculate. 11 BY MR. BAUM: 12 Ο. Well, you were the author. 13 MR. ROBERTS: Objection. 14 BY MR. BAUM: 15 That was your handwriting; that was your 0. 16 thoughts. 17 MR. ROBERTS: Objection. 18 It was my thoughts 20 THE WITNESS: 19 years ago, but -- and if you want me to 20 speculate, I can speculate on --21 BY MR. BAUM: 22 0. I wouldn't call it speculation when I'm 23 talking to the guy who actually wrote it, but you give 24 me your best impression of what you thought you meant.

1 MR. ROBERTS: Objection, 2 mischaracterizing the witness' statement. 3 THE WITNESS: What's the question again? 4 BY MR. BAUM: 5 Q. What did you think you meant by that line? 6 7 MR. ROBERTS: Objection. 8 That there would be at THE WITNESS: 9 least 160 more patients enrolled in the study. 10 BY MR. BAUM: 11 Ο. And they would not have the problem of a 12 dispensing error, correct? 13 MR. ROBERTS: Objection. 14 THE WITNESS: Yes. 15 BY MR. BAUM: 16 Ο. Okay. So next it says, in this letter to the FDA, "For reporting purposes, the primary 17 efficacy analysis will exclude the eight potentially 18 19 unblinded patients, with a secondary analysis including 20 them also to be conducted." 21 Do you see that? 22 Α. Yes. 23 Ο. So that, again, is what actually went to 24 the FDA saying that the primary efficacy analysis would

exclude the patients exposed to the dispensing error, 1 2 correct? 3 MR. ROBERTS: Objection. 4 THE WITNESS: Yes. 5 BY MR. BAUM: 6 0. And that's not what was done, correct? 7 MR. ROBERTS: Objection. 8 THE WITNESS: That's correct. 9 BY MR. BAUM: 10 Q. Do you know why there was a change? I would have to speculate. 11 Α. 12 0. Okay. So, ultimately, what Forest promised the FDA was going to do, it didn't do, 13 14 correct? 15 MR. ROBERTS: Objection, you're 16 testifying. 17 THE WITNESS: They conducted both of the 18 analyses. 19 BY MR. BAUM: 20 All right. But which one was designated 0. 21 as the primary analysis? 22 MR. ROBERTS: Objection. 23 THE WITNESS: The analysis of the ITT 24 population was the primary analysis.

BY MR. BAUM: 1 2 0. And what it says here is that they were 3 going to have the analysis with the eight unblinded patients, potentially unblinded patients excluded, 4 5 correct? 6 MR. ROBERTS: Objection. 7 THE WITNESS: Yes. 8 BY MR. BAUM: 9 0. That was a more scientifically 10 appropriate thing to do, wasn't it? 11 MR. ROBERTS: Objection. 12 THE WITNESS: I would characterize it is 13 a proposed solution to the unblinding problem. 14 MR. BAUM: Okay. Let's go to Exhibit 15 22. 16 (Document marked for identification as 17 Flicker Deposition Exhibit No. 22.) BY MR. BAUM: 18 19 So Exhibit 22 is MDL-FORP0168046. It's 0. an e-mail from Joan Barton to you, Paul Tiseo, Joan 20 21 Howard Jane Wu and Carlos Cobles dated December 6, 2000 22 regarding CIT-MD-18 study drug. 23 Do you see that? 24 Α. Yes.

1	Q. Does it appear to have been produced in
2	the ordinary course of business?
3	MR. ROBERTS: Objection.
4	THE WITNESS: Yes.
5	BY MR. BAUM:
6	Q. Do you have any reason to believe that
7	you didn't receive it?
8	MR. ROBERTS: Objection.
9	THE WITNESS: No.
10	BY MR. BAUM:
11	Q. Okay. So here it says, "Attached is a
12	table showing which patients were randomized when the
13	problem was discovered that the study drug was
14	unblinded. A total of 6 adolescents and 3 children had
15	already been randomized. Please let me know if this
16	will alter the total number of child or adolescent
17	patients to be randomized for this trial."
18	Did I read that correctly?
19	A. Yes.
20	Q. So you had recommended that another 160
21	patients be brought in to create a trial that didn't
22	have any patients exposed to the dispensing error,
23	correct?
24	MR. ROBERTS: Objection.

Charles Flicker, Ph.D.

1 THE WITNESS: No. 2 BY MR. BAUM: 3 0. That's what you wrote in your 4 handwriting, right? 5 MR. ROBERTS: Objection. 6 THE WITNESS: No. 7 BY MR. BAUM: 8 What did you write? Q. I wrote that 160 more patients would be 9 Α. enrolled. 10 11 Ο. Okay. Maybe I misunderstood. That's 12 what I thought I was saying. 13 So and here Ms. Barton says, the study 14 drug was unblinded, not potentially unblinded, correct? 15 MR. ROBERTS: Objection. 16 THE WITNESS: It says "study drug was unblinded." 17 18 BY MR. BAUM: 19 It doesn't say potentially unblinded or 0. potential to cause bias? 20 21 MR. ROBERTS: Objection. 22 BY MR. BAUM: 23 Ο. It says they were unblinded, right? 24 Well, the study drug was not blinded. Α.

1	Q. This says the study drug was unblinded,
2	correct?
3	MR. ROBERTS: Objection.
4	THE WITNESS: Right. That's not the
5	same as the study being unblinded or the
6	patients being unblinded.
7	BY MR. BAUM:
8	Q. Okay. So let's but this
9	A. The study drug was not it would be
10	more accurate to say the study drug was not blind.
11	Q. So that would be a protocol violation,
12	though, right?
13	MR. ROBERTS: Objection.
14	THE WITNESS: I would regard that as a
15	protocol violation.
16	(Document marked for identification as
17	Flicker Deposition Exhibit No. 23.)
18	BY MR. BAUM:
19	Q. We're going to go to the next exhibit,
20	Exhibit 23. This is dated January 5th, 2001. It's a
21	Forest Labs inter-office memorandum from James Jin,
22	draft statistical analysis plan, and it's addressed to
23	Ed Lakatos, Jane Wu, Wendy Ma, Shanshan Wang and Julie
24	Kilbane.

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1 MR. ROBERTS: They're on the CC line. 2 BY MR. BAUM: 3 Q. On the CC line. And then if you --4 well, do you recall being involved in any of the citalopram clinical trial meetings? 5 6 MR. ROBERTS: Objection. 7 THE WITNESS: I must have been. These 8 particular meetings? Oh, the citalopram clinical team? 9 BY MR. BAUM: 10 11 Q. There were multiple clinical team 12 meetings. 13 Do you recall having like weekly 14 meetings? 15 Α. I don't know. 16 0. Did you attend any of them? 17 MR. ROBERTS: Objection. 18 THE WITNESS: I don't know. 19 BY MR. BAUM: 20 Okay. Here -- do you know who James Jin 0. 21 was? 22 Α. Vaguely. 23 Ο. Do you recall he was a biostatistician 24 on the MD-18?

1	A. Yeah.
2	Q. Do you recall corresponding with him
3	about getting drafts of the tables done?
4	MR. ROBERTS: Objection.
5	THE WITNESS: No.
6	BY MR. BAUM:
7	Q. Have you seen documents going back and
8	forth between you regarding drafts of the efficacy
9	tables?
10	MR. ROBERTS: Objection.
11	THE WITNESS: No.
12	BY MR. BAUM:
13	Q. All right. So here he's saying,
14	"attached for your review is draft statistical analysis
15	plan," and please return your comments, and there were
16	nine patients who were randomized at the beginning of
17	the study but not blinded.
18	Do you see that?
19	A. Yes, I see that.
20	Q. So right there he's saying they were not
21	blinded, correct?
22	MR. ROBERTS: Objection.
23	THE WITNESS: That's what it says.
24	MR. BAUM: Let's go to the next exhibit.

1	(Document marked for identification as
2	Flicker Deposition Exhibit No. 24.)
3	BY MR. BAUM:
4	Q. This is Exhibit 24, and this is an
5	inter-office memorandum from James Jim to Paul Tiseo,
6	Charles Flicker and Ivan Gergel dated January 5th,
7	2001, MDL-FORP0175632.
8	Do you see that?
9	MR. ROBERTS: No, that's not. Can you
10	read the MDL again? I think we're looking at
11	different things, but maybe we're not. What's
12	your number again? Is it 49936?
13	MR. WISNER: We're looking at the same
14	thing, it's just the script is
15	MR. BAUM: I've got 49936. Did I read
16	something off wrong?
17	MR. ROBERTS: You didn't read 49936, I
18	don't think, did you?
19	MR. WISNER: Go off the record.
20	MR. BAUM: No, here, I got it, Exhibit
21	24 you have is FORP0049936; is that correct?
22	MR. ROBERTS: Yes.
23	BY MR. BAUM:
24	Q. And this is a memorandum from Dr. Jin to
·	

you, Paul Tiseo, Scott McDonald, Ed Lakatos and Jane Wu 1 dated July 10, 2001, correct? 2 3 A. Yes. 4 Q. And it has a test run 3 tables: 5 CIT-MD-18. 6 Do you recall this document? 7 Α. No. 8 Have you seen this document before? Q. 9 MS. KIEHN: He just says he doesn't recall it. 10 11 MR. ROBERTS: Objection. 12 THE WITNESS: No. 13 BY MR. BAUM: 14 Q. Was this document produced in the 15 ordinary course of Forest business? MR. ROBERTS: Objection. 16 17 THE WITNESS: Looks that way. 18 BY MR. BAUM: 19 Q. Do you have any reason to believe that you didn't receive it? 20 21 MR. ROBERTS: Objection. He doesn't 22 recall it. 23 THE WITNESS: No. BY MR. BAUM: 24

1	Q.	So the subject of this memo that you
2	sent was test	run 3 tables.
3		What does that mean?
4		MR. ROBERTS: Objection.
5		THE WITNESS: Where does it say that?
6	BY MR. BAUM:	
7	Q.	It's in the subject line, test run 3
8	tables CIT-MD-	18.
9	Α.	What does that mean?
10	Q.	Yeah.
11	Α.	I don't know.
12	Q.	Do you recall a run being done of the
13	tables for MD-	18 to see if the program worked?
14		MR. ROBERTS: Objection.
15		THE WITNESS: No.
16	BY MR. BAUM:	
17	Q.	Okay. Do you see the handwriting below?
18	Α.	Yes.
19	Q.	Is your handwriting?
20		MR. ROBERTS: Objection.
21		THE WITNESS: Yes.
22	BY MR. BAUM:	
23	Q.	And it has this instructions, it looks
24	like, to James	Jin; is that correct?
L		

1 MR. ROBERTS: Objection. 2 THE WITNESS: Yes. BY MR. BAUM: 3 4 Ο. And among those instructions is please 5 provide draft appendix tables and plots: 1 primary efficacy analysis - ITT subpopulation, asterisk, 6 7 asterisk, patients with drug dispensing error excluded. 8 Do you see that? 9 Α. Yes. 10 Q. That's your handwriting, and that's what 11 you were instructing at the time? 12 MR. ROBERTS: Objection. 13 THE WITNESS: Yes. 14 (Document marked for identification as 15 Flicker Deposition Exhibit No. 25.) 16 BY MR. BAUM: 17 Q. We're just going to go to the next exhibit, 25, which is MDL-FOREM0010201 from Jane Wu to 18 19 James Jin and Qiong Wang, and it says, "We need to 20 generate Tables 4.1A and 4.1B for ITT population, 21 excluding the 9 patients who were unblinded at the 22 beginning of the study. Can you please tell Qiong who 23 they are and try to get the results before 9:30, Friday morning?" This was sent at 12:30 a.m. on August 10th. 24

1 Do you see that? 2 Α. Yes. And then below there's an e-mail from 3 0. Jane Wu to Paul Tiseo and you regarding CIT-MD-18. It 4 5 says, Paul, Charlie, we will meet with you to talk about the results of CIT-18 in R&D conference room at б 9:30 to 10:30 on August 10th. 7 8 Do you recall attending that meeting? 9 MR. ROBERTS: Objection. 10 THE WITNESS: No. 11 BY MR. BAUM: 12 0. Do you recall that August 10th is the date, according to Mary Prescott, you sent her positive 13 14 results for CIT-MD-18, from that earlier e-mail? 15 MR. ROBERTS: Objection. 16 THE WITNESS: No. 17 BY MR. BAUM: Q. Was it a coincidence they're the same 18 19 dates? 20 MR. ROBERTS: Objection. 21 MS. KIEHN: He just said he doesn't 22 remember being the same date. 23 THE WITNESS: No. 24 BY MR. BAUM:

So does this appear to be produced in 1 0. the ordinary course of business? 2 3 MR. ROBERTS: Objection. 4 This memo? THE WITNESS: 5 BY MR. BAUM: 6 Yeah, this e-mail here, this e-mail Ο. 7 string. 8 Α. Yeah. 9 0. Do you have any reason to doubt you received the e-mail that was addressed to you? 10 11 MR. ROBERTS: Objection. He doesn't 12 remember. 13 THE WITNESS: No. 14 BY MR. BAUM: 15 Ο. Okay. So at this point, per this 16 e-mail, the analysis excluding the unblinded patients was appearing as Tables 4.1A and 4.1B and not in the 17 appendix, right? 18 19 MR. ROBERTS: Objection. He's talking 20 about Exhibit 25 in here. 21 THE WITNESS: No, but he's saying -- no, 22 this is a request to --23 MR. ROBERTS: You can ask him to clarify 24 if you don't understand.

1 THE WITNESS: Let me just look at this. 2 BY MR. BAUM: 3 0. Well, that document is going to be a little confusing to you because that was a --4 5 Α. No, that's not confusing at all. 6 MS. KIEHN: Give him time to look at the 7 documents. 8 BY MR. BAUM: 9 0. All right, go ahead. My understanding of this document 10 Α. No. is that Jane Wu is telling James Jin to do a reanalysis 11 12 in which the eight patients are excluded, but Table 4.1A is an ITT analysis. It's right in here. 13 14 Q. Yeah. 15 So this is a subpopulation analysis. Α. 16 Okay. So here let me just move on to 0. another subject. I got your answer there. 17 18 You're saying that this is -- the 19 reanalysis may not have ended up as a 4.1A or 4.4B; is 20 that correct? 21 MR. ROBERTS: Objection. 22 THE WITNESS: No, that's not what I'm 23 I'm saying the ITT analysis in this saying. 24 analysis plan is 4.1A.

1 BY MR. BAUM: 2 0. Okay. Now, next she says that that 3 analysis was being done "excluding the 9 patients who were unblinded at the beginning of the study." 4 5 Do you see that? 6 Α. Yes. And she's saying who were unblinded, not 7 Ο. potentially unblinded or with the potential to cause 8 9 patient bias. This is saying that excluding the nine 10 patients who were unblinded at the beginning of the 11 study, correct? 12 MR. ROBERTS: Objection. 13 THE WITNESS: That is the language that 14 she used. 15 MR. BAUM: Okay, let's go to the next 16 exhibit. 17 (Document marked for identification as 18 Flicker Deposition Exhibit No. 26.) 19 BY MR. BAUM: 20 Exhibit 26, MDL-FORP0049697. This is an Ο. 21 undated document from your custodial file, and these 22 are efficacy tables for CIT-MD-18, and if you flip a 23 couple pages in to one, two, three -- the fourth page 24 in, you'll see some handwriting up at the top of Table

1	4.1A.		
2			MR. ROBERTS: Are you talking the one
3		that er	nds in 703.
4			THE WITNESS: Oh, yeah, it ends in Bates
5		Number	703. Thanks.
6			MR. ROBERTS: So the Bates numbers are
7		in the	bottom right corner. It should say 703
8		at the	bottom of it.
9			MR. WISNER: 4.1A.
10			MR. ROBERTS: Right there. So this is
11		what he	e's talking about.
12			THE WITNESS: Okay.
13	BY MR.	BAUM:	
13 14	BY MR. 3		You see the handwriting in the upper
	BY MR.		You see the handwriting in the upper
14			You see the handwriting in the upper Yes.
14 15		Q.	
14 15 16		Q. A.	Yes.
14 15 16 17		Q. A. Q.	Yes. It says "excluded 9 patients."
14 15 16 17 18		Q. A. Q. A.	Yes. It says "excluded 9 patients." Yes.
14 15 16 17 18 19		Q. A. Q. A.	Yes. It says "excluded 9 patients." Yes. That's your handwriting, isn't it?
14 15 16 17 18 19 20		Q. A. Q. A. Q.	Yes. It says "excluded 9 patients." Yes. That's your handwriting, isn't it? No.
14 15 16 17 18 19 20 21		Q. A. Q. A. Q. A.	Yes. It says "excluded 9 patients." Yes. That's your handwriting, isn't it? No. That's not your handwriting?

Okay. So it's dated August 10, 2001. 1 Ο. You see the table date there? 2 3 Α. Yes. 4 Q. Does this appear to have been produced 5 in the ordinary course of Forest business? 6 MR. ROBERTS: Objection. 7 THE WITNESS: Yes. 8 BY MR. BAUM: 9 Ο. If you look at the -- if you look across 10 the top, the total N numbers were 85 and 89 for the participants in the trial. That ended up to 174. 11 12 Do you see that? 13 Α. Yes. 14 That number is the number with the Q. 15 unblinded patients included, and if you take them out, 16 you end up with a number of 166, correct? 17 MR. ROBERTS: Objection. 18 THE WITNESS: Okay. 19 BY MR. BAUM: 20 And if you look down at the N numbers in 0. 21 the body of this table, you'll see that the N for the 22 total placebo patients is 81, and the N for the total 23 citalopram patients is 85. 24 Do you see that?

Where are you looking, in the actual 1 Α. tables? 2 3 Ο. Right there, this N. 4 Yeah, yeah. Α. 5 Q. And if you go here, that's 81. б Α. Right. 7 And then over here, it's 85. And Ο. 8 throughout each of these weeks it's 81 and 85. 9 Α. Got you. 10 Q. And that adds up to 166, correct? 11 Α. Yes. 12 So that's the number of patients when 0. you exclude the nine patients who were subject to the 13 14 dispensing error, correct? 15 MR. ROBERTS: Objection. 16 THE WITNESS: Yes, it's consistent with 17 the comment. 18 BY MR. BAUM: And if you go over to the next page, 19 Ο. you'll see that at Week 8 there's a P-value of .052, 20 21 correct? Right there, yes? 22 Α. Yes. 23 Ο. And so that's -- this is the table that 24 ended up becoming essentially Appendix 6 in the study

Charles Flicker, Ph.D. report, correct? 1 2 Α. Yes. 3 MR. ROBERTS: Objection. 4 BY MR. BAUM: And it was not made 3.1, which was the 5 Q. primary efficacy outcome, correct? 6 7 MR. ROBERTS: Objection. 8 THE WITNESS: Excuse me? 9 BY MR. BAUM: 10 Q. This table was not used as the primary outcome measure; it was placed in the appendix of the 11 12 study report, correct? 13 MR. ROBERTS: Objection. 14 THE WITNESS: Yes. 15 MR. BAUM: So now we can take a break. 16 THE VIDEOGRAPHER: We will be going off 17 the record at 2:32 p.m. This marks the end of 18 Media 7. 19 (Brief recess.) 20 THE VIDEOGRAPHER: We will be going back 21 on the record at 2:43 p.m. This marks the 22 beginning of Media 8. 23 Go ahead, Counsel. 24 BY MR. BAUM:

So there was a meeting that was being 1 0. held on August 10 in one of the earlier e-mails. 2 3 Do you recall that? 4 Α. No. 5 Q. All right. So that -б Oh, do I recall the e-mail that we Α. looked at? 7 8 Yeah, yeah. Q. 9 Α. Yes. 10 Q. That there was a meeting that was being held the morning of August 10 --11 12 Α. Yes. 13 -- and that needed to get a run done Q. 14 with the unblinded patients excluded for that meeting. 15 Α. Yes. 16 0. Do you recall that? 17 MR. ROBERTS: Objection. 18 BY MR. BAUM: 19 And then this is a run that's dated Ο. August 10 for that. Do you --20 21 MR. ROBERTS: Objection. 22 BY MR. BAUM: 23 0. -- see that? 24 Well, yes, I know what you mean. Α.

1 0. And so do you -- was it at that moment 2 when you first learned that the -- with the excluded 3 dispensing error patients, the P-value was greater than 4 .050? 5 MR. ROBERTS: Objection. 6 I'm assuming that this THE WITNESS: 7 meeting held on August 10th was held, it would 8 appear that that would be the first time that 9 those -- that that analysis was available. 10 BY MR. BAUM: 11 Is that the reason why the analysis Ο. 12 excluding the patients was not used as the primary efficacy measure? 13 14 MR. ROBERTS: Objection. 15 That requires speculation THE WITNESS: 16 on my part. 17 BY MR. BAUM: Well, you and Amy Rubin and Tracey 18 0. Varner essentially promised the FDA that the primary 19 20 efficacy measure would exclude those patients, correct? 21 MR. ROBERTS: Objection. 22 THE WITNESS: We -- there was a proposal 23 to the FDA that a primary efficacy analysis 24 would be done in which those patients were

excluded. I don't know what the response to 1 2 the agency was. BY MR. BAUM: 3 4 Ο. Okay. 5 Α. Response of the agency was. And it wasn't a proposal. It said we 6 Ο. 7 will not include them, correct? 8 MR. ROBERTS: Objection. 9 THE WITNESS: I'm not exactly sure, but it was -- but there is a description of a 10 11 primary efficacy analysis excluding the eight 12 patients. 13 BY MR. BAUM: 14 Ο. Okay. And that says, for reporting 15 purposes, the primary efficacy analysis will exclude the eight potentially unblinded patients. 16 17 Do you see that? 18 Α. Yes. It doesn't propose that, it says it will 19 Ο. not be included, correct? 20 21 MR. ROBERTS: Objection. 22 BY MR. BAUM: 23 They will not be included, correct? Ο. 24 Objection. MR. ROBERTS:

1 THE WITNESS: Still a proposal. 2 BY MR. BAUM: 3 0. It doesn't say may, it says will, 4 doesn't it? 5 MR. ROBERTS: Objection. 6 THE WITNESS: Yes, it does say will. 7 MR. BAUM: Let's go to the next exhibit. 8 (Document marked for identification as 9 Flicker Deposition Exhibit No. 27.) 10 BY MR. BAUM: 11 Ο. This is Exhibit 27, which is MDL-FORP0050230, and it's to Paul Tiseo and Charlie 12 Flicker from James Jin and Jane Wu, final draft tables, 13 14 CIT-MD-18 dated August 10, 2001, which is the same date 15 that we've been dealing with, correct? 16 MR. ROBERTS: Objection. 17 BY MR. BAUM: In these last two or three e-mails, the 18 0. 19 August 10, see there's a date of August 10? 20 August 10th, yes, August 10th. Α. 21 Okay. And then in the upper right 0. there's handwriting 9/13/01. 22 23 Do you see that? 24 Α. Yes.

1 Q. And does that appear to be your handwriting? 2 3 Α. Yes. 4 And then there's a circle around Charlie Q. Flicker with an arrow going down to James Jin. 5 6 Do you see that? 7 Α. Yes. 8 Did you do that? Q. 9 MR. ROBERTS: Objection. 10 That looks like my THE WITNESS: handwriting. 11 12 BY MR. BAUM: Does this appear to be a document 13 0. 14 produced in the ordinary course of Forest business? 15 MR. ROBERTS: Objection. 16 THE WITNESS: Yes. 17 BY MR. BAUM: Q. And do you have any doubt that you 18 19 received this document and sent something back to James 20 Jin? 21 MR. ROBERTS: Objection. 22 THE WITNESS: It seems likely. 23 BY MR. BAUM: 24 And if you look at the next page, you 0.

		Charles Flicker, Ph.D.
1	see your handw	writing again on the next page?
2	Α.	Yeah.
3	Q.	And that up in the upper right, there's
4	a 7/17/01 date	2.
5		Do you see that?
6	Α.	Yeah.
7	Q.	So it appears that your interchanging
8	some drafts ba	ick and forth with James Jin with some
9	suggestions of	things to do, and one of the things
10	suggested in J	uly 17th was to provide an analysis with
11	the subpopulat	ion with these patients with the drug
12	dispensing err	or excluded, then here's James Jin saying
13	that he's retu	rning to you a final analysis.
14		Do you see that?
15		MR. ROBERTS: Objection.
16	BY MR. BAUM:	
17	Q.	It's actually probably from James Jin
18	and Jane Wu, a	and she's saying please let James know or
19	it says please	e let James know, so it's probably
20	actually writt	en by Jane Wu in conjunction with James
21	Jin.	
22		Do you see that?
23		MR. ROBERTS: Objection.
24		THE WITNESS: Yeah, I mean, these are

1 two separate memos at different times but... 2 BY MR. BAUM: 3 Q. Okay. So in this third paragraph here of the memo it says, "However, for the ITT population 4 5 minus" --6 MR. ROBERTS: First page. Hold on. 7 He's on the second page. 8 BY MR. BAUM: 9 0. It says, However, for the ITT population 10 minus the nine patients for which the treatment was 11 unblinded at the beginning of the study, there were 12 statistically significant treatment-by-age interaction with the CDRS-R, CGI-I, K-SADS-P. 13 14 Do you see that? 15 Α. Yes. 16 0. So it looks like Jin and Wu were 17 complying with your request to have a run done with the nine patients excluded, correct? 18 MR. ROBERTS: Objection. 19 20 THE WITNESS: Didn't we already see 21 that? 22 BY MR. BAUM: 23 0. Well, I'm just reading to you what this 24 line says; is that correct?

1	MR. ROBERTS: Objection.
2	THE WITNESS: Well, this looks like a
3	different set of table. This is obviously a
4	much I mean, I'm assuming that these if
5	this is associated with this, this is obviously
6	a much larger set of tables.
7	BY MR. BAUM:
8	Q. Yeah. Okay. What I'm trying to get at
9	is this is saying that they did a run with the nine
10	patients excluded, per this cover e-mail, correct?
11	MR. ROBERTS: Objection.
12	THE WITNESS: Well, this is a full set
13	of tables. The run with the guys excluded was
14	that little memo.
15	BY MR. BAUM:
16	Q. Okay. The one we just looked at before
17	that said excluded nine patients, correct?
18	MR. ROBERTS: Objection.
19	THE WITNESS: Yeah.
20	BY MR. BAUM:
21	Q. Here it says, "However, for the ITT
22	population minus the nine patients for which the
23	treatment was unblinded at the beginning of the study."
24	Do you see that?

Yes. 1 Α. 2 Ο. And it says "was unblinded" as opposed 3 to potentially unblinded, correct? 4 MR. ROBERTS: Objection. 5 THE WITNESS: That's the language they 6 use, yes. 7 BY MR. BAUM: 8 Q. And that was Jane Wu and James Jin, 9 correct? 10 Α. Yes. 11 MR. BAUM: We're going to go to Exhibit 12 28. 13 (Document marked for identification as 14 Flicker Deposition Exhibit No. 28.) 15 BY MR. BAUM: 16 0. Okay. This is Exhibit 28, 17 MDL-FOREM0002742. It's an e-mail from Bill Heydorn to Evelyn Kopke dated 10/24/2001, notes from the 18 19 conference call October 4 with attachment notes from conference call with PharmaNet, October 4, 2001. 20 21 Do you see that? 22 Α. Yes. 23 Ο. Okay. And then if you look at the 24 e-mail down below, it has you as one of the recipients

on the CC. 1 2 Do you see that? Α. 3 Yes. 4 And then if you look on the attachment Q. it has as attendees for a conference call with 5 PharmaNet dated October 4, 2001. Forest is Charles б 7 Flicker, Bill Heydorn, James Jin and Jane Wu, and 8 Evelyn Kopke and Gundi LaBadie for PharmaNet. 9 Do you see that? 10 Α. Yes. 11 0. Does it appear that you were involved 12 with a telephone conference with PharmaNet on 13 October 24, 2001? 14 MR. ROBERTS: Objection. You mean 15 October 4th? 16 BY MR. BAUM: 17 Q. October 4, sorry, October 4, 2001. 18 MR. ROBERTS: Objection. 19 THE WITNESS: Yeah, it looks that way. 20 BY MR. BAUM: 21 Q. And does this appear to have been 22 produced in the ordinary course of Forest business? 23 Objection. MR. ROBERTS: 24 THE WITNESS: Yeah.

1 BY MR. BAUM: Do you have any doubt that you 2 Ο. participated in or sent or received any of the 3 correspondence attached to this e-mail? 4 5 MR. ROBERTS: Objection. 6 THE WITNESS: A little bit. 7 BY MR. BAUM: 8 What's that? 0. 9 I don't know. I could have walked out Α. 10 on a meeting. I could have never gotten it. Ιt 11 doesn't look very familiar. 12 Ο. Okay. So let's take a look at some of the things that are itemized on the points that Bill 13 14 Heydorn sent to you and Natasha Mitchner and James Jin 15 and Jane Wu. 16 It says at Paragraph 9, "For secondary efficacy measures, no significant difference at the 17 week 8 LOCF analysis. There are some significant 18 19 findings early on in treatment. Forest looking at individual patient listings to see if there are any 20 21 clues as to why week 8 findings were not positive. For 22 now, emphasize the positive findings at earlier time 23 points for the secondary efficacy variables." 24 Do you see that?

Α. Yes. 1 Do you see here that they're saying that 2 0. the Week 8 findings were not positive for the secondary 3 4 endpoints? MR. ROBERTS: Objection. 5 THE WITNESS: It says no significant 6 7 difference. 8 BY MR. BAUM: It says as to why the Week 8 findings 9 0. were not positive, correct? This is Bill Heydorn --10 11 Α. "As to why week 8 findings were not 12 positive, yes. 13 Q. Okay. So it's characterizing the 14 secondary outcome measures as not being positive, 15 correct? 16 MR. ROBERTS: Objection. 17 THE WITNESS: It says the Week eight LOCF shows no significant difference on 18 19 secondary efficacy measures. 20 BY MR. BAUM: 21 Q. And it also refers to them as not being 22 positive, correct? 23 MR. ROBERTS: Objection. 24 THE WITNESS: Yes, he says here not

positive. 1 BY MR. BAUM: 2 3 Q. Okay. And so here there is a plan of emphasizing the positive findings at earlier time 4 points and for the secondary efficacy variables, 5 б correct? 7 MR. ROBERTS: Objection. 8 THE WITNESS: It says, "emphasize the 9 positive findings at earlier time points." 10 BY MR. BAUM: 11 0. That's a little misleading, isn't it? 12 MR. ROBERTS: Objection. 13 THE WITNESS: I'd say it's putting a 14 best foot forward. 15 BY MR. BAUM: 16 0. And not emphasizing the failure at Week 17 8, correct? 18 MR. ROBERTS: Objection. 19 THE WITNESS: There's no -- there's no 20 indication that those differences would be 21 concealed. It's saying that the emphasis will 22 be placed on where there was significant 23 differences. BY MR. BAUM: 24

That's what ended up happening in the 1 Q. 2 study report, right? 3 MR. ROBERTS: Objection. 4 BY MR. BAUM: 5 Q. Yes? I have no idea. 6 Α. 7 You don't recall what we just went over Ο. today showing you that that's what --8 9 Α. Oh, the study report? 10 Q. Yes. 11 MR. ROBERTS: Objection. 12 THE WITNESS: I thought we were talking 13 about --14 BY MR. BAUM: 15 0. That plan was --16 Α. Is this a publication? 17 This is the -- this Exhibit 28 are notes Q. for -- points of note in study report for CIT-MD-18. 18 19 Oh, this refers to the study report? Α. 20 Yes. And so this --Ο. 21 I thought it was a publication. Α. 22 Q. No. This is what was notes from a 23 meeting that resulted in a draft of the study report 24 that -- and there were plans here to refer to these

1	secondary endpoints, emphasize the positive findings at
2	earlier time points for the secondary efficacy
3	variables.
4	That's what was done in the study
5	report, correct?
6	MR. ROBERTS: Objection.
7	THE WITNESS: In the efficacy writeup,
8	the focus was on where there was a positive
9	effect.
10	BY MR. BAUM:
11	Q. And omission of the Week 8 negative
12	effect, correct?
13	MR. ROBERTS: Objection.
14	THE WITNESS: That was available in the
15	tables, but the writeup does emphasize where
16	there were significant differences.
17	BY MR. BAUM:
18	Q. Okay. So next in Paragraph 11 says,
19	"dosing error - some citalopram tables were not
20	blinded."
21	Do you see that? Paragraph 11?
22	A. Yes.
23	Q. And "the 9 patients who received
24	unblinded medication were included in the main

1	analyses; a secondary post-hoc analysis of the ITT
2	subpopulation was done. Refer to these analyses
3	briefly in methods and results and reference the reader
4	to the appendix table."
5	Do you see that?
6	A. Yes.
7	Q. That's what actually happened in the
8	study report, correct?
9	MR. ROBERTS: Objection.
10	THE WITNESS: It's certainly they're
11	certainly referred to, and it did look as if
12	the relevant analyses were in the appendix.
13	BY MR. BAUM:
14	Q. And that's different than what Forest
15	told they were going to do with the primary efficacy
16	analysis relative to the nine patients who received
17	unblinded medication, correct?
18	MR. ROBERTS: Objection, asked and
19	answered.
20	THE WITNESS: Could you repeat that?
21	BY MR. BAUM:
22	Q. Paragraph 11 saying that the post-hoc
23	analysis of the ITT subpopulations with the nine
24	patients being excluded being placed in the appendix is
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1	different than what Forest told the FDA it was going to
2	do when it excluded the nine patients and said that
3	they were going to have that analysis be the primary
4	efficacy analysis; this is different than that, isn't
5	it?
6	A. Forest
7	MR. ROBERTS: Objection,
8	mischaracterizes the document, asked and
9	answered.
10	THE WITNESS: Yeah, Forest proposed to
11	the FDA to conduct the analysis of with the
12	patients excluded as the primary.
13	BY MR. BAUM:
14	Q. And this paragraph is saying doing
15	something different, correct?
16	MR. ROBERTS: Objection.
17	THE WITNESS: This paragraph is not in
18	agreement with that.
19	BY MR. BAUM:
20	Q. Okay. And also here it says "9 patients
21	who received unblinded, " not potentially unblinded,
22	correct?
23	MR. ROBERTS: Objection.
24	THE WITNESS: The language here is

unblinded. 1 2 BY MR. BAUM: 3 0. And then it says, "dosing error - some citalopram tables were not blinded." 4 5 Do you see that? It doesn't say potentially unblinded, it says were not blinded, 6 7 correct? 8 MR. ROBERTS: Objection. THE WITNESS: Well, I don't know what an 9 10 unblinded table is. 11 BY MR. BAUM: 12 Q. Well, here it's directly saying they were not blinded, which is more consistent with your 13 14 saying that the blind was unmistakenly violated, 15 correct? 16 MR. ROBERTS: Objection, 17 mischaracterizes the witness' testimony, 18 mischaracterizes the document. THE WITNESS: What? 19 20 BY MR. BAUM: 21 Q. You said that you thought that the blind 22 had been unmistakenly violated, correct? 23 MR. ROBERTS: Objection, 24 mischaracterizes the witness' testimony.

1 THE WITNESS: I said that the integrity of the blind -- that there was a violation of 2 the integrity of the blind. 3 4 BY MR. BAUM: 5 Q. Is this language here more consistent with what ended up in the study report? 6 7 Objection. MR. ROBERTS: 8 MR. BAUM: Never mind. Strike that. 9 MS. KIEHN: So it's 2:59. 10 MR. ROBERTS: It's 2:59. 11 BY MR. BAUM: 12 Ο. Take a look at Paragraph 7. It says, "Note that study was not powered to look at differences 13 14 within two subgroups (children and adolescents). The 15 sample size was calculated based on the anticipated 16 effect size for the primary efficacy variable." 17 Do you see that? 18 Α. Yes. 19 Do you recall now that the MD-18 was not Ο. 20 powered to look at the subgroup separately? 21 MR. ROBERTS: Objection. 22 BY MR. BAUM: 23 Ο. It was powered to look at them together? 24 Α. No.

1	Q. Does this indicate that, though?
2	MR. ROBERTS: Objection.
3	THE WITNESS: That's yeah, that's
4	what this suggests.
5	MR. BAUM: Okay.
6	MS. KIEHN: We're going to ask a couple
7	questions in the event we don't reconvene so
8	that we have it on the record.
9	MR. WISNER: Sorry, in the event we
10	don't reconvene, is that a possibility?
11	MR. ROBERTS: Well, why don't we stay on
12	record
13	MS. KIEHN: Anything is a possibility.
14	MR. ROBERTS: ask the questions and
15	then we can talk about this off record, all
16	right?
17	MR. BAUM: All right. Go ahead.
18	BY MR. ROBERTS:
19	Q. Okay. Dr. Flicker, do you have an
20	understanding as to why the primary efficacy analysis
21	included the nine patients?
22	A. Do I have an understanding, excuse me?
23	Q. As to why the primary efficacy analysis
24	did include the nine patients?
L	

I believe so. I mean, it is -- it's 1 Α. not -- it's somewhat speculative, but I believe so. 2 Okay. Do you recall what that is? 3 Ο. What I think it was is that the 4 Α. 5 statistical group insisted upon using the study's ITT population. 6 7 Okay, thank you. Ο. 8 You gave testimony earlier that 9 suggested that both Table 3.1 and Appendix Table 6 should be examined, quote, by anyone receiving this 10 11 study. 12 Who were you referring to when you referenced, quote, anyone reviewing the study? 13 14 For regulatory reviewers should examine Α. 15 the entire -- all the details. 16 0. The FDA concluded that MD-18 met the 17 threshold for statistical significance on the primary 18 outcome measure, correct? 19 Α. Yes. 20 And the FDA had both tables, both 3.1 0. 21 and Table 6, correct? 22 Α. Yes. 23 0. Does presenting the primary efficacy 24 endpoint of 0.3 -- of .038 in a poster or publication

1	and omitting mention of the post-hoc secondary analysis
2	of the intent-to-treat subpopulation result in a
3	misleading portrayal of the study results?
4	A. No. Post-hoc secondary analysis was
5	supportive, overwhelming body of evidence in the study
6	clearly is indicative of a treatment effect.
7	Q. Because the result of the post-hoc
8	secondary analysis is supportive of the result of the
9	primary efficacy parameter, correct?
10	A. Yes.
11	Q. The difference is, quote, trivial, as
12	you put it, correct?
13	A. I regard the difference as trivial, yes.
14	MR. BAUM: I just
15	MS. KIEHN: Hold on. No, not until we
16	turn it back over.
17	MR. BAUM: I'm objecting. You are
18	leading this guy.
19	MR. ROBERTS: Okay. Your objection is
20	noted.
21	MS. KIEHN: You're the master of
22	leading.
23	BY MR. ROBERTS:
24	Q. The results of the post-hoc secondary

1	analysis do not undermine the results of the primary
2	efficacy parameter; is that fair?
3	MR. BAUM: Objection, leading.
4	THE WITNESS: Yes.
5	BY MR. ROBERTS:
6	Q. Now, I would like to direct you back to
7	Exhibit 14. If you remember, this is Exhibit 14. We
8	lost it a couple times ago, but now it is found.
9	I turn you to the top of Page 2 of the
10	fax. So it says "Return of medication" is where I'm
11	directing you to. It says, "please return all patient
12	kits," correct?
13	A. Yes.
14	Q. So the sites did not know which bottles
15	contained pink pills, they were instructed to return
16	all of the patient kits, correct?
17	A. Yes, they would have returned all the
18	medication they had.
19	Q. Okay. So now I'm going to direct you to
20	Exhibit 21. This is the FDA letter dated March 20th.
21	You can try and find it within your pile, I actually
22	think it's right over there, Exhibit 21.
23	Does this letter inform the FDA that
24	there had been a deviation in the protocol procedure,
	Dage 259

it affected the integrity of the blind? 1 2 Α. Yes. Because it specifically says that they, 3 0. quote, excluded the eight potentially unblinded 4 5 patients, right? MR. BAUM: Objection, leading. 6 7 BY MR. ROBERTS: 8 0. You can answer. Yes, it does refer to eight patients, 9 Α. 10 eight potentially unblinded patients. 11 MR. ROBERTS: Thank you, Doctor, that's 12 all. 13 BY MR. BAUM: 14 Do you have to leave now? 0. 15 Α. Yeah. 16 MR. BAUM: Okay. So we're going to 17 reserve our right to get the rest of our 18 minutes and follow up and finish our 19 deposition. 20 MR. ROBERTS: Let's go off the record. 21 MS. KIEHN: We understand your position. 22 We'll take it under advisement. 23 THE VIDEOGRAPHER: This marks the end of 24 Media 8 and also the conclusion of today's

1	questioning of Charles Flicker. Media of
2	today's deposition will be transferred to the
3	custody of Golkow. We are going off the record
4	at 3:05 p.m. on Friday, November 4th, 2016.
5	(Witness excused.)
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1	CERTIFICATION
2	I, MARGARET M. REIHL, a Registered
3	Professional Reporter, Certified Realtime
4	Reporter, Certified Shorthand Reporter,
5	Certified LiveNote Reporter and Notary Public,
6	do hereby certify that the foregoing is a true
7	and accurate transcript of the testimony as
8	taken stenographically by and before me at the
9	time, place, and on the date hereinbefore set
10	forth.
11	I DO FURTHER CERTIFY that I am
12	neither a relative nor employee nor attorney
13	nor counsel of any of the parties to this
14	action, and that I am neither a relative nor
15	employee of such attorney or counsel, and that
16	I am not financially interested in the action.
17	
18	
19	
	Margaret M. Reihl, RPR, CRR, CLR
20	CSR #XI01497 Notary Public
21	
22	
23	
24	

In Re: Celexa and Lexapro Marketing and Sales Practices Litigation, MDL No. 2067, No. 09-MD-2067 (NMG)

Errata Sheet to the Deposition of Charles Flicker, Ph.D. Deposition Date: November 4, 2016

Page	Line(s)	Now Reads	Suggested Reading	Reason
10	7	It was definitely	There was definitely	Stenographic error
23	5	I was surprised I believe so.	I don't know I was surprised I believe so.	Stenographic error
31	9-10	Q. And Clara was a good buffer? A. I would often correct what she had	Q. And Clara was a good buffer? MR. ROBERTS: Objection A. I would often correct what she had	Stenographic error
59	15	Yeah, like PowerPoint presentations	Or, yeah, like PowerPoint presentations	Stenographic error
79	12-13	prepared by Natasha Mitchner and Mary Prescott?	prepared by Natasha Mitchner or Mary Prescott?	Stenographic error
111	12	ask you is is that based	ask you is that based	Stenographic error
122	21	please sign and return to me shortly."	please sign and return to me."	Stenographic error
126	16	look at the I	look at the protocol - I	Stenographic error
130	10	clean record.	clean record, that's all.	Stenographic error
182	23	"Change from Baseline	"Change from Baseline in	Stenographic error
209	8-10	Q. Let's go to Page 100, which is Table 3.1. So if you look at Table 3.1 it says the	Q. Let's go to Page 100, which is Table 3.1. Ms. KIEHN: Is someone on the phone? Q: I was just turning off my phone. So if you look at Table 3.1	Stenographic error

CLARA WAS MY SECRETHRY AT PEIZER !

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Page	Line(s)	Now Reads	Suggested Reading	Reason
			it says the	
214	13	do I well,	do I know well,	Stenographic error
238	24	Weeks 1, 4 and 6	Weeks 1, 4, and 6	Stenographic error
239	20	actually assessed.	actually assessed at the time.	Stenographic error
241	19	Week 8, yes, or were assessed	Week 8, yes, were assessed	Stenographic error
244	3	A P-value of .6;	A P-value of .06;	Attorney error
252	13	the CDRS was .038, yes.	the CDRS-R was .038, yes.	Stenographic error
265	24	Talking about 1.2, okay.	Talking about 12.1.2, okay.	Stenographic error
277	4	March 2nd, 2002,	March 2nd, 2000,	Attorney error
305	22	This is FOREM0030382	This is MDL- FOREM0030382	Stenographic error
309	16	causes for	calls for	Stenographic error
324	21	24 you have is FORP0049936;	24 you have is MDL- FORP0049936;	Stenographic error

I, the undersigned, declare under penalty of perjury that I have read the deposition transcript; that I have made any corrections, additions, or deletions that I was desirous of making in the errata sheet above; and that the deposition transcript is otherwise a true and correct transcript of my testimony contained therein.

2

(Signature)

Subscribed and sworn before me this

, 2016

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(Date)

