-	IN THE UNITED STATES DISTRICT COURT
	DISTRICT OF MASSACHUSETTS
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	IN RE: CELEXA AND LEXAPRO :MDL NO. 2067
	MARKETING AND SALES PRACTICES : Master Docket No.
	LITIGATION :09-MD-2067-(NMG)
4	4
	DELANA S. KIOSSOVSKI and :Hon. Nathaniel M Gorton
į	RENEE RAMIREZ, on behalf of :
	themselves and all others : Case No.
(similarly situated, :14-CV-13848 (NMG)
	:
-	7 Plaintiff, :
	:
8	8 v. :
	:
9	9 FOREST PHARMACEUTICALS, INC. :
	and FOREST LABORATORIES, INC.,:
10	
	Defendants. :
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	OCTOBER 6, 2016
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1 THE VIDEOGRAPHER: Good morning. 2 now on the record. My name is Kevin Pollard, 3 and I am a videographer for Golkow Technologies. Today's date is October 6th, 4 5 2016, and the time its 9:27 a.m. This video deposition is being held in New York, New York 6 in the matter of Delana S. Kissovski v. Forest 7 8 Laboratories, et al. 9 The deponent is Steve Closter. 10 counsel will be noted on the stenographic 11 record. The court reporter is Peg Reihl and 12 will now swear in the witness. 13 ... STEVEN L. CLOSTER, having been duly 14 sworn as a witness, was examined and testified 15 as follows ... 16 BY MR. WISNER: 17 Q. Good morning. My name is Brent Wisner. What's your name? 18 19 Steven Closter. Α. 20 Have you ever had your deposition taken 0. 21 before? 22 Α. I have. 23 MR. WISNER: Okay. Just back up. 24 everyone made their appearances on the record

That's what I was --1 yet? 2 MS. KIEHN: It's going to be recorded. 3 MS. THORNE: It's going to be on the --4 MR. WISNER: Got you. That's what I was confused with the start of this. 5 BY MR. WISNER: 6 7 All right. Have you ever had your 0. 8 deposition taken before? 9 Α. I have. 10 And how many times has that occurred? Q. I believe three times. 11 Α. 12 0. And what was the context of those depositions? 13 14 Α. General cases, liability. I can't 15 remember exactly what the focus of the -- you know, 16 exactly what the cases were. 17 Q. Do you recall what courts they transpired in? 18 19 Α. No. 20 One of them was in the securities case Ο. 21 involving Celexa and Lexapro. 22 You're familiar with that? 23 Α. Yes. 24 Do you recall what the other two were Q.

about? 1 2 Α. Not exactly, no. 3 Ο. Do you recall generally when they 4 occurred? 5 Α. Generally, in the last few years. 6 Ο. What's the last few years mean to you? 7 Three, four years or so. Α. 8 Okay. So it's been in the last five Q. 9 years; is that fair to say? I believe so, but I would have to check. 10 Α. I'm sure counsel would know for sure. 11 12 0. Did either of those depositions relate to Celexa or Lexapro? 13 14 I believe they did. Α. 15 Ο. Both of them? 16 Α. Yes, I can't recall if it was both drugs or one of the drugs, but it was certainly one or the 17 other or both. 18 19 And is that different than any testimony Ο. you may have provided to the Department of Justice in 20 21 2007? 22 MS. THORNE: Objection.

THE WITNESS:

Golkow Technologies, Inc.

BY MR. WISNER:

23

24

Is it different topics?

1 Mm-hmm. Q. 2 Α. I'm sure there was some overlap in topics. 3 Were those previous depositions 4 Q. specifically related to pediatric use of Celexa and/or 5 6 Lexapro? 7 I don't recall. Α. 8 Okay. Do you recall what the Ο. 9 circumstances were of those depositions in any context? You know, we reviewed documents, it 10 Α. talked about my experiences at the company as it 11 relates to both of those products, along a range of --12 a range of topics. 13 14 Ο. And was it focused on any particular 15 type of theory or issue of liability that you're aware 16 of? 17 I really can't recall. Α. Okay. Was there a focus on off-label 18 Q. promotion, for example? 19 20 I don't recall. Α. 21 Okay. You're familiar with off-label 0. 22 promotion? 23 Α. Yes.

All right. Were either of those

Q.

- depositions related to birth defects associated with
- 2 Celexa and/or Lexapro?
- A. I recall that was a topic, yes.
- 4 Q. Did any of them involve potential
- 5 suicidality associated with Celexa and/or Lexapro?
- 6 MS. THORNE: Objection.
- 7 THE WITNESS: Yeah, I don't recall.
- 8 BY MR. WISNER:
- 9 Q. Okay. Do you know what suicidality is?
- 10 A. Yes, I do.
- 11 Q. Okay. All right. Since you've had your
- deposition taken before, I'm not going to go through
- 13 all the particulars once more.
- 14 A. Sure.
- 15 Q. The only one that I do stress, however,
- is that if I ask you a question and you don't
- 17 understand it, please make sure to say I don't
- 18 understand your question, please repeat, okay?
- 19 A. Sure.
- 20 Q. I will rephrase it, repeat it until you
- 21 feel like you understand the question, okay?
- 22 A. Got it.
- Q. With that caveat, however, if you
- 24 answer, I'm going to assume you understood my question.

1 Is that okay? Sounds fair. 2 Α. 3 Ο. And I guess the other rule I should probably mention right now is that all answers should 4 be audible. 5 6 Good. Α. 7 So head nods, usually although they can Ο. be taken down in the transcript, are usually not seen 8 9 by the court reporter, so she needs to hear audible answers, okay? 10 Sounds fair. 11 Α. 12 Okay, great. O. 13 (Document marked for identification as 14 ForestC Deposition Exhibit No. 1.) 15 BY MR. WISNER: 16 I'm going to hand you what I've marked 17 as Exhibit 1 to your deposition. 18 Have you seen this document before? 19 I have. Α. 20 What is it? Ο. 21 I don't know exactly, you know, what Α. 22 it's called. Looking for a title on it, but I believe 23 this is the request to -- you know, for me to 24 participate in a deposition in regards to the case that

- I can see here on the paper. And if you look at the -- there's an 2 Ο.
- Exhibit A attached to the document on Page 3. You
- 4 skipped it.

- 5 Α. Sorry.
- 6 When I refer to page numbers throughout Ο.
- 7 this deposition, I put numbers in the top right corner
- 8 of every exhibit to help facilitate direction.
- 9 You see on Page 3 there?
- 10 Α. Yes.
- 11 Q. You see that Exhibit A?
- 12 Α. I do.
- And there's a bunch of definitions; you 13 Q.
- 14 see that?
- 15 Α. Yes.
- 16 And there's subject matters? Q.
- 17 Α. Yes.
- Have you gone over all the subject 18 Q.
- 19 matters in preparing for your deposition today?
- 20 Α. Have I gone over? What do you mean?
- 21 Have you prepared to testify about these 0.
- 22 topics that are listed in this notice?
- 23 Α. I have.
- 24 Okay. And you've prepared -- how have Q.

you prepared for them? 1 I met with counsel for two days 2 Α. reviewing the topics and went over a number of materials as it relates to the topics. 4 5 Q. And what days did you meet? 6 Α. I met yesterday and the past Friday. 7 How long were those meetings? O. 8 Most of the day. Α. 9 When does your day start? Ο. 10 Α. When does my day start? When do I get 11 out of bed or --12 Let me ask you a better -- a clearer O. question. 13 14 Α. Okay. 15 When did those days start? O. 16 Α. Approximately 8:30, 9:00. They differed. Perhaps Friday started at 8:30, yesterday 17 started at 9:15. 18 19 Okay. And about when did they end? Ο. 20 Probably around 4:00. Α. 21 Okay. So they were essentially full 0. 22 work days; is that right? 23 Α. Yes.

Okay. Who was present -- let's start

Q.

with the first meeting last Friday. 1 Uh-huh. 2 Α. 3 Ο. Who was present at that meeting? 4 The three individuals that are here, 5 Danielle, Kristin and Darcelle. 6 Were they the same individuals who were Ο. 7 present yesterday as well? 8 Α. Yes. 9 Ο. Okay. You said you reviewed materials. 10 Do you recall what materials you 11 reviewed? 12 I do. Α. 13 What materials were those? Ο. 14 Study reports, published papers, press Α. 15 releases, other documents. 16 Were the materials that you reviewed specific in reference to the topics mentioned on this 17 notice? 18 19 Yes, they were. Α. 20 Okay. I want to get a little bit Ο. 21 background on your work history. 22 Α. Sure. 23 (Document marked for identification as 24 ForestC Deposition Exhibit No. 2A.)

- 1 BY MR. WISNER:
- 2 Q. I'm going to enter in as Exhibit 2A, you
- 3 recognize this document?
- 4 A. Yes.
- 5 Q. What is this?
- 6 A. Looks like it's my LinkedIn page.
- 7 Q. Okay. And previously before the
- 8 deposition we requested a Curriculum Vitae, a resume.
- 9 I understand you do not have one; is that correct?
- 10 A. I do not have an updated CV.
- 11 Q. Okay. So this is the closest thing we
- 12 have to a resume or CV; is that right?
- 13 A. Correct.
- Q. Okay. Let's start off with your
- 15 education. What is your educational background?
- 16 A. I attended college at Cornell
- 17 University, got a Bachelor's degree in business in
- 18 1991. I then continued on for my MBA at the Stern
- 19 School of Business graduating in 1999.
- Q. And that was a graduate degree, an MBA?
- 21 A. Correct.
- Q. Okay. And your undergrad was that a
- 23 Bachelor of Science or Bachelor of Arts?
- A. Bachelor of Science.

- 1 Q. Okay. In the context of your
- 2 undergraduate degree, did you ever get any specific
- 3 training or education in the context of medicine or
- 4 clinical trials?
- 5 A. Meaning did I take any classes?
- 6 O. Mm-hmm.
- 7 A. I took some life science classes,
- 8 biology, chemistry.
- 9 Q. The science aspect of your degree, did
- 10 that focus in on biology or medicine or applied
- 11 sciences?
- 12 A. My focus was a business major.
- Q. Okay. So it was focused primarily on
- 14 the application of, I guess, math and economics to
- 15 business; is that fair?
- 16 A. If you would like to characterize it
- 17 that way, that's fine.
- 18 Q. Okay. And in your MBA context, did you
- 19 spend any time focusing on medicine?
- A. No, not in my MBA coursework.
- Q. Now, obviously, you have been working
- for various pharmaceutical companies for a while?
- A. Correct.
- Q. It looks like for the bulk of your

- 1 professional career; is that right?
- 2 A. Yes, 22 years.
- 3 Q. Have you had any formal training in
- 4 medicine in that context?
- 5 A. I mean, are you asking what the training
- 6 was at these positions that I held at these companies?
- 7 Q. Well, I just want to know generally,
- 8 have you received medical training in your positions at
- 9 these pharmaceutical companies?
- 10 A. When you say "medical training,"
- 11 training like a doctor would have or --
- 12 Q. I'm trying to understand -- I'm trying
- 13 to understand what educational background you have in
- 14 science. That's what I'm trying to gather.
- 15 A. Sure.
- 16 Q. Can you give me sort of a general bird's
- 17 eye view understanding of what education or training
- 18 you may have received in the context of your positions
- 19 at these pharmaceutical companies?
- 20 A. Sure. Well, my first position was at
- 21 Dura Pharmaceuticals, where I began as a sales
- 22 representative. At the time we sold cough and cold
- 23 products, asthma products. There may have been some
- other categories. I was trained as a sales

- 1 representative to sell them, so, you know, a fairly
- 2 comprehensive training background on whether it was
- disease state or on the products themselves, on the
- 4 package insert and any sales material that we had, you
- 5 know, access to. That's something that would be
- 6 supplemented over time with sales training meetings.
- 7 I was then a divisional manager, where
- 8 there was similar ongoing training.
- 9 And then as I transitioned in 1999 to at
- 10 the time was Forest Laboratories, it was certainly some
- 11 emersion just by doing my job as it relates to the
- 12 disease state. You know, I began on the brand team for
- 13 Celexa and Lexapro so, certainly, some background on
- 14 depression and other mood disorders, you know, attended
- 15 scientific congresses, reviewed poster sessions, went
- 16 to CME sessions and interacted with thought leaders.
- 17 So that is a process that occurs over time as you're
- 18 emersed in the data.
- 19 Q. And I guess you've continued on at
- 20 Forest Laboratories as it was acquired by various
- 21 entities. I guess currently it's owned by Allergan; is
- 22 that right?
- A. Forest was purchased by Actavis.
- 24 Q. Okay.

- 1 A. And then Actavis purchased Allergan and
- then assumed the Allergan name, so that's the sequence
- 3 of events.
- 4 Q. And through all of those changes, you've
- 5 maintained an executive level position in the company;
- 6 is that fair to say?
- 7 A. If you're saying I'm a vice president,
- 8 if we want to call that executive, that's fine. You
- 9 know, when most of those changes occurred, I may have
- 10 been an assistant vice president and then, you know,
- 11 made a vice president at some point along the way.
- 12 Q. Okay. Now, when you were working at
- 13 Dura Pharmaceuticals, did you spend any time working on
- 14 antidepressants or SSRIs?
- 15 A. I did not.
- 16 Q. Okay. What sort of products did you
- 17 focus on?
- 18 A. As I mentioned, cough and cold products,
- 19 products for asthma, allergies. Those were the bulk of
- 20 the products that we had at the time.
- 21 Q. So it would be fair to say, then, when
- 22 you started working at Forest Pharmaceuticals in 1999,
- that was your first exposure to the marketing or sales
- 24 related to antidepressants?

- That's right. 1 Α. You understand one of the topics today 2 0. involves discussions of clinical trials that have been 3 conducted on both Celexa and Lexapro? 4 5 Α. I'm aware of that. 6 And you are prepared to testify on Ο. behalf of Forest Pharmaceuticals about those clinical 7 8 trials? 9 To the extent my expertise can help, 10 sure. 11 MS. KIEHN: To the extent he agreed to 12 testify to high level details about the 13 studies. 14 BY MR. WISNER: 15 You are -- you understand your role Ο. 16 today as a rule 30(b)(6) witness? 17 Α. I do. What is your understanding of that role? 18 Q. 19 That I'll be representing the company. Α. 20 You understand that you'll be speaking O. 21 for the company, correct?
- 24 allegations in this case?

Α.

O.

Correct.

What is your understanding of the basic

22

```
1
                    MS. THORNE: Objection. Are you asking
             him in his individual capacity, or are you
 2
             asking him now in his capacity as a 30(b)(6)
 3
             witness for the company?
 4
 5
                    MR. WISNER: I'm asking him in his
 6
             capacity as a 30(b)(6) witness for the company.
 7
                                  Sorry. Could you repeat
                    THE WITNESS:
 8
             the question.
 9
    BY MR. WISNER:
10
             Q.
                    Sure. What is your understanding of the
11
    basic allegations in this case?
12
             Α.
                    The basic allegations are that there's
    accusations, I believe, of off-label promotion of
13
14
    Celexa for pediatric use.
15
                    Do you understand that this case also
             Ο.
16
     involves the drug Lexapro as well?
17
             Α.
                    Yes.
18
                    Okay. Have you reviewed the Complaint
             Q.
19
     filed in this matter?
20
                   Is this the Complaint?
             Α.
21
             Ο.
                    It is not.
                    I'm not aware if I've reviewed it. If I
22
             Α.
23
     saw it, I would probably tell you, but I don't know if
24
     I'm -- we're thinking of the same thing so...
```

- 1 Q. Have you reviewed a document that is 115
 2 pages long and repeats a bunch of legalese over and
 3 over again?
 - 4 A. I saw several documents like that, so
 - 5 unless I saw it, I literally would need to see it, I
 - 6 think, to confirm whether I've seen it or not.
 - 7 Q. Fair enough. Have you reviewed any
 - 8 pleadings?
 - 9 I'm sorry. Strike that.
- 10 Have you reviewed any expert reports
- 11 that have been submitted by the plaintiffs in this
- 12 case?
- 13 A. Expert reports. Could you clarify what
- 14 those would be?
- 15 Q. Sure. Have you reviewed any document
- 16 purporting to offer opinions, expert opinions by people
- 17 that have been retained by the plaintiffs in this case?
- MS. THORNE: Objection.
- 19 THE WITNESS: On any topic in
- 20 particular?
- 21 BY MR. WISNER:
- Q. Yeah, have you looked at any of them?
- A. I believe I've seen one.
- Q. Do you recall which expert report that

1 was? 2 Α. It was a report that was published 3 fairly recently on I believe it was the conduct of a 4 clinical trial and how it was disseminated. 5 Q. I got you. 6 You're talking about a publication? 7 Yes, appears to be a publication. Α. 8 By Jureidini, is that the name? Q. 9 Α. That is the one, yes. 10 Q. Okay. We'll get to that later. 11 Α. Okay. 12 I'm asking about something a little O. different. 13 14 Α. Okay. 15 I'm asking about documents that are on Ο. 16 pleading paper like that, that have the Court case on it and reflect expert opinions rendered for the 17 18 purposes of litigation; have you seen any documents 19 like that? 20 MS. THORNE: Objection. 21 THE WITNESS: Yeah, again, I think I 22 would need to see it to let you know if I've 23 seen it or not.

BY MR. WISNER:

1 Ο. So your answer is you don't know? I don't know. 2 Α. Okay. Have you seen any expert reports 3 0. 4 generated by Forest's experts? 5 MS. THORNE: Objection. 6 THE WITNESS: Yeah, again, I would need 7 to see the documents to let you know whether 8 I've seen them or not. 9 BY MR. WISNER: 10 Ο. All right. Let me just ask you the 11 question. Have you, for example, seen any declaration written by Joseph Glenmullen? 12 Not that I'm aware of. 13 Α. 14 Okay. I want to start the deposition Q. 15 focusing on some events that transpired in 2010. 16 You understand that Forest -- Forest 17 Pharmaceuticals pled guilty to various counts under the Food, Drug and Cosmetic Act in 2010? 18 19 MS. THORNE: Objection. 20 THE WITNESS: Yeah, I'm aware there is 21 an arrangement and an acknowledgment of -- to a 22 misdemeanor of off-label promotion of Celexa in 23 an agreement with the government.

BY MR. WISNER:

And by "acknowledgment" you mean a plea 1 Ο. of guilty, correct? 2 3 A. Correct. 4 Q. Okay. (Document marked for identification as 5 ForestC Deposition Exhibit No. 3.) 6 7 BY MR. WISNER: 8 I'm handing you a document that I've marked as Exhibit 3. 9 10 Have you seen this document before? 11 Α. I don't believe I've seen this. 12 This appears to be -- the first page is 0. a secretary's certificate signed by Lawrence S. 13 14 Olanoff. 15 Do you see that? 16 Α. Yes. 17 Do you know who Lawrence Olanoff is? Q. I do. 18 Α. 19 Who is he? Ο. 20 He was at one point the chief medical Α. 21 officer of Forest and ultimately the president of the 22 company. 23 Okay. And then Annex A, which is Ο. starting on Page 2, is a resolution of the Board of 24

- 1 Directors of Forest Pharmaceuticals, Inc. dated
- 2 September 14th, 2010.
- 3 A. Right.
- 4 Q. Do you see that?
- 5 A. I do.
- 6 Q. And you don't recall ever having seen
- 7 this document before?
- A. I don't believe so.
- 9 Q. Okay. Well, if you go down to the
- 10 paragraph, third one from the bottom, do you see that?
- 11 Starts with "further resolved," the first one that says
- 12 "further resolved."
- 13 A. Yes.
- Q. It says, "that the company is authorized
- and directed to plead guilty to the charges specified
- 16 in the Information."
- Do you see that?
- 18 A. I do.
- 19 Q. Do you understand what the Information
- 20 is referring to here?
- 21 A. I'm not clear.
- Q. Okay. Have you reviewed the Criminal
- 23 Information that was filed against pharmaceutical in
- 24 preparation for your testimony today?

1 MS. THORNE: Objection. 2 THE WITNESS: So this would have been 3 the government allegations? 4 BY MR. WISNER: 5 Q. Mm-hmm. I have reviewed that document. 6 7 Okay. And do you understand that that 0. 8 document is called the Criminal Information? 9 MS. THORNE: Objection. 10 I believe so. I would THE WITNESS: 11 need to see it to completely verify. 12 BY MR. WISNER: Okay. The next paragraph reads, it's 13 Ο. 14 further resolved, "that the company is authorized and 15 directed to enter into the Settlement Agreement and 16 Release and settlement agreements with individual states as contemplated by the Settlement Agreement and 17 18 Release and the State Settlement Agreement." 19 Do you see that? 20 I do. Α. 21 Are you familiar with the Settlement 0. 22 Agreement and Release that was entered into by Forest in 2010? 23 24 MS. THORNE: Objection.

1 I believe I've seen it, THE WITNESS: 2 but, again, I would need to verify. BY MR. WISNER: 3 4 Ο. And, in fact, that's actually one of the 5 topics that's on the list today; isn't that true? 6 MS. THORNE: Objection. 7 THE WITNESS: Yes. 8 BY MR. WISNER: 9 Okay. The next paragraph is "Further 10 resolved, that the Officers of the Company, or their 11 authorized representatives (specifically including but 12 not limited to Herschel S. Weinstein, Esquire, Vice President - General Counsel of FLI), are hereby 13 14 authorized and directed to take all actions and deliver 15 any agreements, certificates, and documents and instruments with respect to or contemplated by the 16 Agreements," and there is a parenthetical that I'm 17 18 going to skip. 19 Α. Yep. 20 Ο. "And matters set forth above, including, 21 without limitation, the payment of all amounts, fees, 22 costs, and other expenses, necessary or appropriate to 23 effectuate the purpose and intent of the foregoing

resolutions and effectuate and implement the

resolutions contemplated hereby." 1 Did I read that generally correctly? 2 3 Α. You read it, yes, verbatim, except for the parenthetical. 4 5 Q. Is your understanding that Mr. Weinstein 6 was, in fact, authorized to enter a plea and resolve allegations related to the Criminal Information 7 8 settlement? 9 MS. THORNE: Objection. 10 THE WITNESS: That's what it generally 11 says on the paper. 12 BY MR. WISNER: And resolutions by the Board of 13 0. 14 Directors, that is an expression and authorization 15 issued by Forest, correct? 16 MS. THORNE: Objection. 17 THE WITNESS: I believe so. 18 (Document marked for identification as 19 ForestC Deposition Exhibit No. 4.) 20 BY MR. WISNER: 21 I'm handing you a document, what I've 22 marked as Exhibit 4. It's going to be a lot of these 23 today, so you should probably find a way to keep them

orderly.

- 1 A. I have them in order face down.
- Q. And, again, for the record, I apologize
- 3 that I read so quickly.
- 4 Okay. Have you seen this document
- 5 that's been marked as Exhibit 4?
- A. Just give me a minute to look at it.
- 7 (Witness reviews document.) I believe I have seen this
- 8 document.
- 9 Q. This document is the plea agreement
- 10 entered into between Forest Pharmaceuticals and United
- 11 States Department of Justice.
- 12 A. Right.
- 13 Q. Turn to the last page on this
- 14 agreement -- pardon me -- second to last page, it's
- 15 Number 14 on the top right.
- 16 A. Yep.
- 17 Q. It's signed by Herschel Weinstein.
- Do you see that?
- 19 A. I do.
- 20 O. And he's the individual we saw in
- 21 Exhibit 3 that was authorized to enter into these
- 22 agreements on behalf of Forest, correct?
- 23 A. Yes.
- Q. All right. Turn back to the first page.

```
1
                   MS. THORNE: Brent, sorry to interrupt,
 2
            do you happen to have a second copy with you?
 3
                   MR. WISNER: I do not. I only made
 4
            three. I'm sorry.
 5
                   MR. BAUM: You can have mine. Do you
 6
            need a plea agreement?
 7
                   MR. WISNER: Yeah.
 8
                   MS. THORNE: Thank you.
 9
                   MR. WISNER: Very chivalrous of you,
10
            Michael.
11
                   MS. KIEHN: A good example.
12
    BY MR. WISNER:
13
            Q. All right. So under the paragraph that
14
    starts -- that's titled "Change of Plea."
15
                   Do you see that?
16
            Α.
                   Yes.
17
            Q.
                   There's a sentence that reads, at the
    earliest practical date Forest shall waive indictment
18
19
    and plead guilty to the three-count Information
20
    attached hereto as Exhibit A.
21
                   Right.
            Α.
22
            Q.
                   Do you see that?
23
            Α.
                   Yes.
24
                   Was it your understanding that part of
            Q.
```

- 1 this plea agreement was that Forest would agree to
- 2 waive any indictment and, in fact, plead guilty to the
- 3 Criminal Information that had been issued against it?
- 4 MS. THORNE: Objection.
- 5 THE WITNESS: And it says, yes, "plead
- 6 guilty to the three-count Information attached
- 7 hereto as Exhibit A." I don't have Exhibit A
- 8 to look at.
- 9 BY MR. WISNER:
- 10 Q. I didn't want to create unnecessary
- 11 documents so I'll show that information shortly. Don't
- worry.
- 13 A. Okay.
- 14 Q. If you go to the sentence at the bottom
- of Page 1, it's the second to last sentence, it starts
- 16 "Forest expressly."
- Do you see that?
- 18 A. Yes I do.
- 19 Q. It reads, "Forest expressly and
- 20 unequivocally admits that it committed these offenses
- 21 and further admits, with respect to Count One, it acted
- 22 knowingly and corruptly. Defendant expressly and
- 23 unequivocally further admits that it is in fact guilty
- of these offenses, and agrees that it will not make any

statements inconsistent with this explicit admission." 1 Do you see that? 2 I do. 3 Α. Is it your understanding that Forest 4 Q. agreed to admit that it committed the offenses charged 5 in the Criminal Information? 6 7 Α. Yes. 8 Is it also your understanding that 9 Forest expressly and unequivocally admits that it is quilty of those offenses? 10 11 MS. THORNE: Objection. 12 THE WITNESS: That's was written on the 13 page. 14 BY MR. WISNER: 15 0. That's Forest's understanding, correct? 16 Α. Yes. 17 Okay. And you also understand that Q. Forest agreed that it will not make any statements 18 19 inconsistent with this explicit admission. 20 Do you understand that? 21 MS. THORNE: Objection. 22 THE WITNESS: Forest agrees, yes. 23 BY MR. WISNER: 24 0. Okay. If you can just turn to Page 5

under Section 4a it reads, "a criminal fine." 1 2 Do you see that? 3 Α. Yes. 4 It reads "A criminal fine of Q. 5 \$150,000,000 to be imposed as follows." 6 Do you see that? 7 Α. Yes. 8 And now Count Three, that's the one that 0. 9 relates to Celexa, right? 10 MS. THORNE: Objection. 11 THE WITNESS: I believe so. 12 MR. WISNER: Sorry. Did I state it 13 incorrectly? 14 BY MR. WISNER: 15 Ο. It reads, a criminal fine of 16 150 million, right? I think I might have said 17 something different. 18 It does say 150 million. I'm not sure Α. 19 what you said previously. 20 Okay. And then for Count Three the Ο. 21 criminal fine listed here in this plea agreement was 22 \$39,500,000; is that right? 23 Α. Correct. 24 Is it your understanding that that was Q.

- 1 the fine imposed on Forest with regards to Count Three?
- 2 A. Yes.
- Q. Okay. If you turn to Page 6, the first
- 4 full paragraph reads "The United States."
- 5 Do you see that?
- 6 A. Yes.
- 7 Q. And it says, "The United States may, at
- 8 its sole option, be released from its commitments under
- 9 this Agreement, including, but not limited to, its
- 10 agreement that this paragraph constitutes the
- 11 appropriate disposition of this case, if at any time
- between Forest's execution of this Agreement and
- 13 sentencing Forest," and I'm going to read these first
- 14 four bullet points, okay?
- 15 A. Sure.
- 16 Q. Either fails to admit a complete factual
- 17 basis for the plea; fails to truthfully admit its
- 18 conduct in the offenses of conviction; falsely denies,
- or frivolously contests, relevant conduct for which
- 20 Forest is accountable under U.S.S.G. Section 1B1.3; or
- 21 gives false, misleading testimony in any proceeding
- 22 related to the criminal conduct charged in this case
- 23 and any relevant conduct for which Forest is
- 24 accountable, under U.S.S.G 1B1.3.

1		Do you	see that?	
2	A	. Yes.		
3	Q	. Is it y	our understand	ling that Forest was
4	obligated	by this plea	agreement to	admit a complete
5	factual b	asis for the p	plea?	
6		MS. THO	RNE: Objectio	on. This
7	М	r. Closter is	not an attorr	ney, and we
8	a	llowed we	agreed to have	e Forest testify on
9	t.	ne factual in	formation that	is contained in
10	t.	ne plea. We	did not agree	to allow the
11	С	ompany to tes	tify as to leg	gal conclusions
12	d	rawn based on	a legal docum	ment. So to the
13	e.	xtent that Mr	. Closter can	speak to this from
14	h	is own person	al knowledge,	he can, but he is
15	n	ot going to to	estify on beha	alf of the company
16	0	n the legal m	eaning of the	document.
17		MR. WIS	NER: Mr. Clos	ster has been called
18	t	o testify on 1	behalf of Fore	est. One of the
19	n	oticed topics	, specifically	Topic Number 36,
20	r	elates to thi	s agreement.	I asked him if it's
21	F	orest's under	standing that	it had to admit a
22	С	omplete factua	al basis for t	the plea. Please
23	a	nswer that que	estion, Mr. Cl	oster.
24		MS. THO	RNE: I'm just	going to state for

the record that the topic --1 I believe the record has 2 MR. WISNER: been made. I don't have time for this. 3 4 MS. THORNE: I'm going to state for the 5 record that the topic that we agreed to in the meet and confer was the factual -- we agreed to 6 7 allow Forest to speak to the factual statements 8 made within the plea agreements we did not 9 agree to allow Forest to testify to the legal 10 conclusions. 11 I will allow the witness to answer the 12 question, but I want the objection stated for 13 the record. 14 MR. WISNER: I appreciate the objection, 15 and I think this falls within the purview of 16 the factual predicates of the agreement. 17 BY MR. WISNER: 18 So, Mr. Closter, I'll ask you again, is it Forest's understanding that it is required to admit 19 a complete factual basis for the plea? 20 21 MS. THORNE: Objection. 22 MS. KIEHN: Was required. 23 THE WITNESS: Just ask me one more time. 24 MR. WISNER: We're going to go off the

record for a second. 1 2 THE VIDEOGRAPHER: We are now off the record. The time is 9:55. 3 (Discussion off the record.) 4 5 THE VIDEOGRAPHER: We are now back on the record. The time is 9:56. 6 7 BY MR. WISNER: 8 Is it Forest's understanding that it 9 must admit to a complete factual basis for the plea? 10 MS. THORNE: Objection, misleading, 11 mischaracterizes the document, assumes facts 12 not in evidence, outside the scope. 13 THE WITNESS: It's, you know, my 14 understanding based on what I'm reading off the 15 page. 16 BY MR. WISNER: 17 Q. I'm sorry. Was that a yes? Yes, based on my personal interpretation 18 Α. of reading the document, yes. 19 20 Ο. Okay. So, for example, today do you 21 believe Forest is obligated to admit a complete factual 22 basis for the plea? 23 MS. THORNE: Objection. Again, that is 24 outside the scope of the deposition notice.

1	mba dan ani ki an di dan aka anla
1	The deposition did not ask
2	MR. WISNER: That's it. Just stop. We
3	don't have time for the speaking objections.
4	MS. THORNE: No, no. This isn't a
5	speaking objection. This is a 30(b)(6)
6	deposition. You should look at the transcript
7	of your own 30(b)(6) deposition if you really
8	want to raise issues with speaking objections.
9	We agreed to let Mr. Closter speak on behalf of
10	the company with respect to the factual
11	contents of the plea agreement. We did not
12	agree to allow the company to interpret the
13	legal document in front of you. That is for
14	counsel.
15	MR. WISNER: I understand you've made
16	this objection already. Can you just say
17	outside the scope and instruct him either to
18	answer it or not.
19	MS. THORNE: It is outside the scope.
20	To the extent that Mr. Closter can answer the
21	question based on his own personal knowledge,
22	he can do so. I am going to instruct him not
23	to answer on behalf of the company. So any
24	testimony that you get on this question is

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based on Mr. Closter's personal knowledge and
 1
            is not on behalf of Forest.
 2
    BY MR. WISNER:
 3
 4
            Q. Mr. Closter, would you like me to repeat
 5
    the question?
 6
            Α.
                   Yes.
 7
                   All right. Is it Forest's understanding
            0.
 8
    that today it is not obligated to admit a complete
9
    factual basis for the plea?
10
                    MS. THORNE: Objection. I'm going to
11
             instruct the witness not to answer on behalf of
12
            the company. If you have an understanding
            based on your own personal knowledge, you may
13
14
            answer the question.
15
                    THE WITNESS: On my own, you know,
16
            personal reading of this document, it would
17
            appear, I'm not sure on the time frame, I'm not
18
            a lawyer to really interpret the document, but
19
             it would seem to, you know -- that we would be
20
            required to admit a complete factual basis for
21
            the plea.
22
    BY MR. WISNER:
23
            0.
                   Because that's the truth, right; the
24
    truth is important?
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1 MS. THORNE: Objection. 2 THE WITNESS: I'm simply reading off the 3 page. 4 MR. WISNER: I know, but you obviously 5 want to tell the truth, right? 6 MS. THORNE: Objection. 7 THE WITNESS: Of course. 8 BY MR. WISNER: 9 Okay. And so regardless of whether or 10 not this agreement required that you admit a complete 11 factual basis pursuant to the agreement, you, speaking 12 for Forest, obviously want to tell the truth of what actually happened, right? 13 14 Α. Sure. 15 O. Okay. Turn to Page 8. Under a section 16 that says "Cooperation," do you see that? 17 Α. Yes. 18 All right. I'm just going to read the first sentence. It says, "Forest shall cooperate 19 20 completely and truthfully in any trial or other 21 proceeding arising out of any ongoing civil, criminal 22 or administrative investigation of its current and 23 former officers, agents, employees, and customers in 24 connection with the matters described in the

1 Information." 2 Did I read that correctly? 3 Α. Yes. This is a section of the agreement that 4 Ο. 5 you have previously reviewed, correct? 6 I have reviewed this before. Α. 7 Okay. If you go down to the last Ο. paragraph on Page 8. 8 9 Α. Yes. 10 Q. It again reads, "Forest expressly and 11 unequivocally further admits that it committed the 12 offenses charged in the Information and is in fact guilty of those offenses. Forest agrees that it will 13 14 not make any statements inconsistent with this explicit 15 admission of guilt to these offenses. This agreement 16 concerning inconsistent statements is not intended to apply to any statement made by any individual in the 17 course of any criminal, regulatory or civil matter 18 19 against such individual, unless such individual is speaking on behalf of Forest." 20 21 Do you see that? 22 Α. Yes. 23 Ο. And isn't it true you, in fact, are 24

speaking on behalf of Forest today?

1 Α. Today I am. 2 O. Okay. Turn to Page 11, Section 14, "Breach of Agreement." 3 4 Do you see that? 5 Α. Yes. I'll just read the first sentence, "If 6 Ο. 7 the United States determines that Forest has failed to 8 comply with any material provision of this Agreement, 9 or has committed any crime following its execution of 10 this Agreement, the United States may, at its sole 11 option, be released from its commitments under this 12 Agreement in its entirety by notifying Forest, through counsel or otherwise, in writing. The United States 13 14 may also pursue all remedies available under the law, 15 even if it elects not to be released from its 16 agreements under this Agreement." Did I read that correctly. 17 18 MS. THORNE: Objection. I'm going to 19 state that this is, again, outside the scope of 20 the notice of the deposition as negotiated 21 between the parties. You identified sections 22 of this document that you would address with 23 the witness. We agreed to let the witness 24 testify on behalf of Forest only to those

```
sections. This is not a section that you
 1
 2
             identified. This is outside the scope.
 3
                   MR. WISNER: Again, this is a very long
 4
            speaking objection, just listen to my question.
 5
                   MS. THORNE: No, this is not a speaking
 6
            objection.
 7
                   MR. WISNER: My question was did you
 8
            read it correctly -- did I read that it
9
            correctly?
10
                    MS. THORNE: Again, you're not even
11
            allowed to ask him.
12
                   MR. WISNER: That's not correct.
13
                   MS. THORNE: You're not even allowed to
14
            ask him about --
15
                    MR. WISNER: Listen to my questions and
16
            make the objection --
17
                   MS. THORNE: -- something outside the
18
            scope of --
19
                   MR. WISNER: -- when it's appropriate.
20
            You are wasting my time and his time.
21
                   MS. THORNE: I'm not wasting your time.
22
    BY MR. WISNER:
23
            0.
                   Mr. Closter, did I read that correctly?
24
                   MS. THORNE: My objection stands.
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1 MR. WISNER: I understand. I'm going to press forward with the question. 2 3 MS. THORNE: If -- you can answer. You're not answering on behalf of --4 5 MR. WISNER: Are you instructing him not to answer if I read it correctly? 6 7 MS. THORNE: He's not answering on 8 behalf of the company. 9 MR. WISNER: Okay. 10 MS. THORNE: As a person, he can tell 11 you whether you read the document. 12 BY MR. WISNER: 13 Q. Did I read that correctly, Mr. Closter, 14 personally? 15 Personally, you read it correctly. Α. 16 0. And would that somehow differ if you were speaking for the company? 17 18 MS. THORNE: Objection. 19 BY MR. WISNER: 20 Ο. Does the English language change when 21 you're speaking for Forest as opposed to when you're 22 speaking for yourself? 23 MS. THORNE: Objection. 24 THE WITNESS: I'm not sure it matters.

1 MR. WISNER: Talk about frivolous 2 objections. 3 MS. THORNE: Talk about frivolous 4 questions. 5 BY MR. WISNER: 6 My only question to you about this is Ο. 7 did you read those two sentences in preparation for 8 your testimony today? 9 I reviewed the document, yes. 10 Q. So you did read them? Yes, I did. 11 Α. 12 Q. Okay, thank you. That's literally all I wanted to ask. 13 14 (Document marked for identification as 15 ForestC Deposition Exhibit No. 5.) 16 BY MR. WISNER: 17 Q. I'm going to hand you another document. This is Exhibit 5 to your deposition. 18 All right. Are you familiar with this 19 20 document, Mr. Closter? 21 A. I believe I've seen this document 22 before. 23 This is, in fact, a side letter 0. 24 agreement between Forest Laboratories and the US

Department of Justice? 1 2 Α. Right. And this was signed contemporaneously 3 0. 4 with the plea agreement that was Exhibit 4? 5 Α. Okay. That's a yes? 6 Ο. 7 Α. If you're telling me that, yes. 8 I mean, look at the dates, if you'd Q. like. 9 10 Α. So I'm comparing this to the plea 11 agreement, which we've just looked at? 12 Ο. Yeah. 13 Yes, the dates are exactly the same. Α. 14 Okay. So then it was signed Q. 15 contemporaneously with the plea agreement? 16 Α. Yes. 17 MS. THORNE: Objection. The document 18 speaks for itself. 19 MR. WISNER: Really? 20 MS. THORNE: Really. 21 BY MR. WISNER: 22 0. All right. Turn to Page 2. I guess 23 it's the fourth paragraph down, starting with "it is understood." 24

1 Α. Okay. 2 Okay. And it reads, it is understood Ο. 3 among the parties to this Side Letter Agreement that the United States' promise not to prosecute Forest 4 Laboratories -- sorry, let me state that again -- that 5 the United States' promise not to prosecute Forest 6 7 Laboratories is dependent upon and subject to Forest 8 Pharmaceuticals fulfilling its material obligations in 9 the Plea Agreement and Forest Laboratories fulfilling its material obligations herein and in this related 10 11 Civil Settlement Agreement attached hereto as Exhibit 12 Two. 13 Do you see that? 14 Α. Yes. 15 Is it your understanding that Ο. satisfaction of the Settlement Agreement and Forest 16 Pharmaceuticals' satisfaction of the plea agreement 17 were a material condition to this side letter 18 19 agreement? 20 Objection. That calls for MS. THORNE: 21 a legal conclusion. Again, that is outside the 22 scope of the 30(b)(6) deposition notice. 23 agreed to let the witness testify to the 24 factual information contained within the

1 document. We did not agree to allow the company to testify as to legal conclusions that 2 require counsel. So to the extent that 3 4 Mr. Closter can interpret the document from a 5 legal perspective in his own personal capacity, he can feel free to do so, but he is not going 6 7 to testify on behalf of the company to legal 8 conclusions. 9 MR. WISNER: So you're instructing him 10 not to answer the question? MS. THORNE: I am instructing him not to 11 12 answer the question on behalf of the company, that is accurate. 13 14 BY MR. WISNER: 15 Okay. Mr. Closter, are you going to Ο. 16 follow your counsel's instruction not to answer my 17 question? 18 Α. I'm going to, yes. 19 Okay. So you refuse to answer my Ο. question on behalf of Forest; is that right? 20 21 Α. Yes. 22 MS. THORNE: Objection. 23 That's correct. THE WITNESS: 24 MR. WISNER: Objection to what?

the grounds of your objection? 1 2 MS. THORNE: Seriously, Brent? 3 MR. WISNER: Yeah, I'd like to know the actual grounds for your objection. You just 4 5 objected to me asking if he's going to follow your instruction. I'd like to know the grounds 6 7 for that objection. 8 MS. THORNE: You're mischaracterizing 9 his testimony. That's the grounds for my 10 objection. 11 BY MR. WISNER: 12 0. Mr. Closter, I'm asking you a question, I'm not characterizing your testimony. 13 14 Α. Okay. 15 Are you going to follow your counsel's 16 instructions not to answer my question regarding that sentence and whether or not those were material 17 preconditions to the side letter agreement on behalf of 18 19 Forest? 20 I'm taking counsel's advice. Α. 21 Okay. Would you be willing to answer Ο. 22 them on a personal level? 23 Α. I'd prefer not to. 24 Why is that? Q.

- 1 A. I'm not a lawyer. These are legal
- documents that are beyond the scope of what I am
- 3 trained to do and understand.
- 4 Q. Okay. So based on the sentence I just
- 5 read to you, you don't feel comfortable answering
- 6 whether or not the satisfaction of the plea agreement
- 7 signed by Forest Pharmaceuticals and the Settlement
- 8 Agreement signed by Forest Laboratories were a material
- 9 condition to the side letter agreement; is that right?
- 10 A. That's right.
- MS. KIEHN: He can confirm what's stated
- on the page, if that's what you're looking for.
- MR. WISNER: I got his testimony. It's
- 14 fine.
- MS. KIEHN: He can't draw -- okay.
- 16 MR. WISNER: He doesn't feel comfortable
- answering the question I get it. I understand
- 18 English can be very scary.
- 19 BY MR. WISNER:
- Q. All right. "Cooperation of Forest
- 21 Laboratories, "Section 2, do you see that?
- 22 A. Yes.
- Q. All right. It says, "Forest
- Laboratories shall cooperate completely and truthfully

in any trial or other proceeding arising out of any 1 ongoing civil, criminal or administrative investigation 2 of its current and former officers, agents, and 3 employees and customers in connection with matters 4 5 described above in Paragraph One." 6 Do you see that? 7 Α. Yes. 8 Do you understand that Forest is Q. 9 required to cooperate -- was required -- was required to cooperate completely and truthfully as part of the 10 11 side letter agreement? 12 MS. THORNE: Objection, calls for a 13 legal conclusion. Mr. Closter is not a 14 lawyer --15 MR. WISNER: We know the objection. 16 understand it. 17 MS. THORNE: Yeah, we do know the objection. 18 19 MR. WISNER: Are you instructing him to 20 answer the question or not? 21 MS. THORNE: So I'm going to instruct 22 him not to answer the question to the extent 23 that it calls for a legal conclusion, which it 24 does. The document speaks for itself. If you

want him to confirm what's on the page, he can 1 2 confirm what's on the page. 3 THE WITNESS: I can confirm what's on 4 the page. 5 BY MR. WISNER: 6 I'm sorry. That wasn't my question. Ο. 7 question was --8 What is your question? Α. -- was it your understanding that Forest 9 was required to cooperate completely and truthfully? 10 11 Α. That is my personal opinion, yes. 12 Q. Okay. Is that the opinion of Forest 13 Pharmaceuticals? 14 MS. THORNE: Objection. 15 THE WITNESS: I mean, I'm not speaking 16 on behalf of the company in regards to the 17 question. BY MR. WISNER: 18 19 So you refuse to answer the question of 0. whether or not Forest believes it had to act 20 21 truthfully? 22 MS. THORNE: Objection, mischaracterizes 23 the testimony. 24 THE WITNESS: That's right.

- 1 BY MR. WISNER:
- Q. Okay. Turn to Page 3. The first -- the
- 3 third paragraph down starting with "Forest Laboratories
- 4 acknowledges, do you see that?
- 5 A. Hang on one second. Forest Laboratories
- 6 -- I'm sorry. This is --
- 7 Q. Page 3.
- 8 A. Page 3.
- 9 Q. And I guess it's the fourth paragraph
- 10 down.
- 11 A. Okay, I got you. Okay, I got it.
- 12 "Forest Laboratories acknowledges," yeah.
- Q. There was a hanging paragraph.
- 14 A. Yep.
- 15 Q. Okay. "Forest Laboratories acknowledges
- 16 that Forest Pharmaceuticals expressly and unequivocally
- 17 admits that it committed the offenses charged in the
- information, that, with respect to Count One, Forest
- 19 Pharmaceuticals acted knowingly and corruptly, and that
- 20 Forest Pharmaceuticals is in fact guilty of those
- 21 offenses. Forest Laboratories agrees that it will not
- 22 make any statements inconsistent with this explicit
- 23 admission of guilt by Forest Pharmaceuticals to these
- offenses."

1	Did I read that correctly?				
2	A. Yes.				
3	Q. Okay. Forest Laboratories, in fact,				
4	acknowledges that Forest Pharmaceuticals was expressly				
5	and unequivocally guilty of the offenses charged in the				
6	information, correct?				
7	MS. THORNE: Objection, calls for a				
8	legal conclusion. I'm going to instruct the				
9	witness not to answer. We agreed to allow the				
10	witness to testify as to the factual subject				
11	matter in these documents. We did not agree to				
12	allow the witness to draw legal conclusions for				
13	you based on the document. The document speaks				
14	for itself. Mr. Closter can confirm what's on				
15	the page.				
16	MR. WISNER: Ms. Thorne, is it your				
17	position that whether or not someone is guilty				
18	of an offense is not a factual question.				
19	MS. KIEHN: He already answered that				
20	question.				
21	MS. THORNE: He's already answered that				
22	factual question.				
23	MR. WISNER: So your objection is asked				
24	and answered; is that right?				

1 MS. THORNE: No, because at this point you're asking him to interpret the document. 2 MR. WISNER: I asked you whether or not 3 Forest Pharmaceuticals is guilty --4 5 MS. THORNE: First of all, I'm not the 6 one testifying here, so you don't get to 7 announce your questions to me that way. If you 8 have question for the basis of my objection, 9 I'm giving it to you. You already asked him 10 the factual question. 11 MR. WISNER: I'm asking you is the 12 question of whether or not Forest 13 Pharmaceuticals is guilty, is it your position 14 that that's not a factual question? 15 MS. THORNE: That's not the question you 16 just asked. 17 BY MR. WISNER: 18 All right. Let me ask the question to you, Mr. Closter. Is Pharmaceuticals unequivocably and 19 expressly guilty of the offenses charged in the 20 21 Criminal Information? 22 MS. THORNE: Objection, asked and 23 answered. 24 THE WITNESS: From what I can read on

the document, yes. 1 2 BY MR. WISNER: 3 O. In fact, on behalf of Forest, that's 4 factually true, correct? 5 MS. THORNE: Objection, asked and 6 answered. 7 THE WITNESS: Yes. 8 BY MR. WISNER: 9 Q. Okay. All right. I'm handing you a document which I've marked as Exhibit 6 to your 10 deposition. 11 (Document marked for identification as 12 13 ForestC Deposition Exhibit No. 6.) 14 BY MR. WISNER: 15 Q. Do you recognize this document? 16 Α. I do. 17 Q. What is it? I believe this was the arraignment with 18 Α. 19 the government, also known as the allocution. 20 Q. Okay. And this arraignment occurred on 21 November 19th, 2010, correct? 22 A. Correct. 23 Q. And it was before the Honorable Nancy 24 Gertner?

1 Α. Yes. And this was in the United States 2 Ο. District Court for the District of Massachusetts, 3 4 correct? Yes. 5 Α. 6 All right. If you turn to Page 3, I'm Ο. 7 going to start on Line 17. 8 Α. Okay. 9 Ο. The Court asks, all right. suppose Mr. Weinstein should stand first. Please 10 before you take the plea, Mr. Weinstein, tell me again 11 and put on the record what your position is and how you 12 bind the company. 13 14 He responds, I am vice president, 15 general counselor of Forest Pharmaceuticals and its 16 parent, Forest Laboratories. 17 The Court asks, do you have the authority to bind the company to this plea agreement 18 19 and this plea? 20 Mr. Weinstein says, yes, I do. 21 Did I read that correctly? 22 Α. You read a couple words that were --23 MS. THORNE: There were one or two that were off, for the record. 24

1 THE WITNESS: You had a please before in 2 the Court in Line 2, and then I think the last 3 line, Line 24, instead of so you have, you said 4 do you have. 5 MR. WISNER: I'm sorry. Thank you for correcting my words. 6 7 BY MR. WISNER: 8 With those corrections, did I read them Q. 9 correctly? 10 Α. Yes. 11 0. Was it your understanding that Mr. Weinstein was, in fact, empowered to enter a plea 12 on behalf of Forest Pharmaceuticals at this 13 14 arraignment? 15 Α. That is true. 16 O. Okay. Turn down to Line 13 and 14. 17 Do you see that? 18 MS. THORNE: On which page, Brent? 19 MR. WISNER: On Page 4, sorry. 20 THE WITNESS: Yes. 21 BY MR. WISNER: 22 Ο. It says, "Forest Laboratories, Inc. through Herschel Weinstein was sworn." 23 24 Do you see that?

1 Α. Yes. So Mr. Weinstein was, in fact, placed 2 Ο. 3 under oath speaking on behalf of Forest Laboratories? 4 Α. It appears --5 MS. THORNE: Objection. 6 THE WITNESS: It appears that way. 7 BY MR. WISNER: 8 Okay. Then as you see from Lines 15 Ο. 9 through 22, the clerk reads the offenses in the 10 Information and Mr. Weinstein pleads guilty, correct? 11 MS. THORNE: Objection. 12 THE WITNESS: Yes, on Line 23. 13 BY MR. WISNER: 14 Exactly. All right. And then if you Ο. 15 look at Line 25 going on the next page, the Court says, 16 "Why don't you take the stand, Mr. Weinstein." 17 Do you see that? 18 Α. Yes. 19 Is it your understanding that O. 20 Mr. Weinstein, in fact, not only was under oath but 21 that he actually took the stand during this 22 arraignment? 23 MS. THORNE: Objection.

THE WITNESS:

24

It appears that way from

the document. 1 2 BY MR. WISNER: 3 O. Now, if you turn to Page 6 on Line 5. 4 Α. Okay. 5 Q. The Court says, counsel, will you give me a description of the charges and what the facts are. 6 7 Do you see that? 8 Α. Yes. 9 And in response to that question, Ο. 10 Mr. Arnold begins speaking. 11 Do you see that? 12 Α. Yes. And then if you look at the line -- the 13 Q. 14 end of his -- starting on Page 14, Mr. Arnold says, 15 "I'm also going to give you Count 2 because I'm going 16 to be discussing certain facts pertaining to both 17 Counts 1 and 2 together." 18 Do you see that? 19 Line 14, right. Α. 20 Yeah, sorry, 14 through 16; is that Ο. 21 right? 22 Α. Yes. 23 Ο. And the Court says okay, right? 24 MS. THORNE: Brent, what page are we on

at this point? I'm sorry. 1 2 MR. WISNER: Page 6. 3 THE WITNESS: He said Page 14. He meant 4 Line 14. 5 BY MR. WISNER: 6 Ο. Page 6, Line 17 at this point. 7 Α. Seventeen. 8 The Court says okay, right? Q. 9 Α. Yes. 10 Q. And then Mr. Arnold then proceeds for 11 several pages all the way until Page 14, Line 13. 12 Do you see that? 13 Α. Yes. 14 And then at the very end on Line 12, Q. Mr. Arnold says, "With respect to Count 3, I'm going to 15 16 ask that Mr. Steger provide that to the Court." 17 Do you see that? 18 Α. Yes. 19 The Court says, "that's fine. Go on." Q. 20 And then Mr. Steger begins speaking, do 21 you see that? 22 Α. I do. 23 Ο. And then Mr. Steger then proceeds to 24 discuss the allegations and facts related to Count 3?

1 MS. THORNE: Objection. 2 THE WITNESS: Yeah, I mean, I have to 3 read forward if it refers to allegations and 4 facts, then --5 BY MR. WISNER: 6 You haven't read this? Ο. 7 Α. I have. 8 Okay. And you've read in anticipation Q. 9 of testifying today, right? 10 I did. Α. 11 Okay. And so you've -- I assume you've 0. 12 read, starting on Line 15 through to Page 18, Line 19; is that fair? 13 14 I have. I mean, I haven't memorized it. Α. 15 0. Sure. 16 Α. I am familiar with the information. And, generally, a bunch of allegations 17 Q. and facts are relayed in those pages, correct? 18 19 MS. THORNE: Objection. 20 THE WITNESS: I believe so. I'd prefer 21 to read it and give you a firm conclusion, but 22 I believe you're characterizing the 23 information. 24 BY MR. WISNER:

Sure. We'll get into the facts in a 1 Ο. minute. I just wanted to sort of get to the next part 2 before that. 3 4 Sure. Α. 5 Q. All right. Then in response on Page 18, Line 22, the Court says, so there are two questions 6 that I will ask with respect to that --7 8 Α. One second, so Page 18, Line 22. 9 Ο. Yeah. 10 Α. Okay. 11 Q. The Court says, "So there are two 12 questions that I will ask with respect to that presentation." 13 14 Do you see that? 15 Α. Yes. 16 And then there is a discussion here Ο. 17 about -- don't worry about that. Turn to Page 20, Line 18 18. 19 Α. Okay. 20 Line 18, the Court then asks, "Then Ο. 21 likewise the allegations that were made by both 22 counsel, are these facts true?" 23 Did I read that correctly?

Α.

You did.

24

- 1 Q. And Mr. Weinstein responds, "they're
- 2 consistent with what I believe the facts to be, "
- 3 correct?
- 4 A. Correct.
- 5 Q. Mr. Weinstein at that point was speaking
- on behalf of Forest Laboratories?
- 7 MS. THORNE: Objection. He was speaking
- on behalf of Forest Pharmaceuticals.
- 9 THE WITNESS: Repeat the question.
- 10 BY MR. WISNER:
- 11 Q. No. Actually, my question is Forest
- 12 Laboratories. He was speaking on behalf of Forest
- 13 Laboratories?
- MS. THORNE: Objection, mischaracterizes
- the document, assumes facts not in evidence.
- 16 BY MR. WISNER:
- 17 Q. I draw your attention to Page 4, Line 13
- 18 through 14 states that Mr. Weinstein was sworn in on
- 19 behalf of Forest Laboratories, right?
- That's what it says, right?
- 21 A. That is what it says.
- Q. Okay. So I'll ask the question again.
- When Mr. Weinstein said -- let's go back
- 24 to Page 20 -- the Court asks, "Then likewise the

allegations that were made by both counsel, are these 1 facts true?" Mr. Weinstein responds, "they're 2 consistent with what I believe the facts to be." 3 4 Do you see that? 5 Α. Yes. At that point, based on these 6 0. 7 transcripts, Mr. Weinstein was speaking on behalf of 8 Forest Pharmaceuticals -- I'm sorry -- Forest 9 Laboratories? 10 MS. KIEHN: Objection. The plea was 11 being entered by Forest Pharmaceuticals. 12 MR. WISNER: I understand. My question 13 still stands. 14 THE WITNESS: Based on the transcript, 15 it appears that way. 16 BY MR. WISNER: 17 0. Okay. But it's your understanding that Mr. Weinstein was actually supposed to be speaking on 18 19 behalf of Forest Pharmaceuticals; is that right? 20 MS. KIEHN: Objection. 21 MS. THORNE: Objection. 22 THE WITNESS: I'm not -- you know, based 23 on my -- you know, general knowledge, I 24 couldn't say for sure whether he was speaking

on behalf of Forest Pharmaceuticals or 1 2 Laboratories, that's just beyond the scope of what I would know. 3 4 BY MR. WISNER: 5 Q. We saw the resolution by the company, right? 6 7 MS. THORNE: Objection. 8 BY MR. WISNER: Do you want to go back and look at it? 9 Ο. 10 MS. KIEHN: He testified he doesn't 11 know. Move on. 12 BY MR. WISNER: 13 Okay. Let's go back to Exhibit --0. 14 MS. KIEHN: He's not going to interpret 15 this document with your questions about titles, 16 et cetera. Everyone knows the plea was entered 17 by FPI. You're trying to trick him into saying --18 19 MR. WISNER: I asked --20 MS. KIEHN: -- that FLI entered the 21 I'm not going allow it. It's what I'm plea. 22 concerned about. 23 MR. WISNER: I asked him his 24 understanding was in fact that Forest

Pharmaceuticals -- he was speaking on behalf of 1 Forest Pharmaceuticals. 2 MS. KIEHN: He doesn't have an 3 4 understanding about that. He said he doesn't 5 know. MS. THORNE: The document is --6 7 MR. WISNER: I was trying to clarify the 8 record for you. 9 MS. THORNE: The document speaks for 10 itself. 11 MS. KIEHN: All of these documents speak 12 for themselves. 13 BY MR. WISNER: 14 Okay, okay. So my question to you is Ο. you said a second ago that the document appears to say 15 16 that Mr. Weinstein was speaking on behalf of Forest Laboratories, right? 17 18 Based on what the document says. 19 But it's your understanding that 0. 20 Mr. Weinstein was entering an allocution plea on behalf 21 of Forest Pharmaceuticals, correct? 22 MS. THORNE: Objection. 23 MS. KIEHN: You're asking him legal 24 questions, but to the extent you can answer, go

ahead and answer. 1 2 MR. WISNER: That's a factual question 3 about what happened. 4 MS. KIEHN: No, it's not, no, who's 5 speaking on behalf of who now? MR. WISNER: Enough speaking objections. 6 7 BY MR. WISNER: 8 Are you going to answer my question? Q. 9 I don't know the answer. Okay. You don't know who Mr. Weinstein 10 Q. 11 was speaking on behalf of? 12 It's not clear to me. Α. 13 Q. Okay. Then the Court asks, okay --14 I'm sorry. Which page are we on? Α. 15 Oh, we're still on Page 20. Now we're Ο. on Line 22. 16 17 Α. Okay. The Court then asks, "Okay. So 18 Q. essentially the corporation is pleading guilty to these 19 20 charges because it is quilty and for no other reason?" 21 And Mr. Weinstein says, "that's 22 correct." 23 Do you see that? 24 I do. Α.

- Q. Okay. All right. I want to go back to the facts that were presented that Mr. Weinstein
 - 3 admitted were true, okay?
 - 4 A. Okay.
 - 5 Q. Let's start on Page 15, Lines 4 -- Line
 - 6 4. Let me know when you're there.
 - 7 A. I'm there.
 - Q. Okay. Now, just for context, if you
- 9 want to look at Page 14 to get oriented, this is during
- 10 Mr. Steger's presentation.
- 11 Do you see that?
- 12 A. Yes.
- Q. Okay. So on Page 15, Line 4 it says,
- 14 "In 1998, FDA approved Celexa for the treatment of
- 15 adult depression."
- Do you see that?
- 17 A. Yes.
- 18 Q. That's true?
- 19 A. That is true.
- Q. Okay. "The FDA never approved Celexa
- 21 for the treatment of any condition other than adult
- depression or for any use in children or adolescents."
- That's true, right?
- MS. THORNE: Objection. Was that true?

1 MR. WISNER: Whether that's true today. 2 BY MR. WISNER: 3 O. Is that true? 4 All right. So your question is is it 5 true today that Celexa was never approved for the 6 treatment of any condition other than adult depression or for any use in children or adolescents? 7 8 Q. Yeah. 9 I believe that's true. 10 Q. Okay. The next sentence reads, 11 "Following FDA approval, Forest began promoting, 12 distributing and selling Celexa through the United States, including the District of Massachusetts." 13 14 Is that true? 15 Α. I believe it is. 16 Ο. Okay. Great. 17 The next sentence reads, "The United States would have shown that Forest was aware that the 18 FDA had not approved Celexa for treatment of any 19 condition other than adult depression." 20 21 Is that true? 22 MS. THORNE: Objection. 23 MS. KIEHN: Objection. He's not going 24 to testify as to what the United States would

- have shown. If you're asking him if Forest was aware, he can answer that question.
 - 3 BY MR. WISNER:
 - 4 Q. Was Forest aware that the FDA had not
 - 5 approved Celexa for the treatment of any condition
 - 6 other than adult depression?
 - 7 A. That is true.
 - Q. Okay. "In or about April 2002, Forest
 - 9 Labs in an attempt to obtain, among other things, a
- 10 pediatric indication for Celexa submitted data to the
- 11 FDA from two double-blind placebo controlled study
- 12 involving the use of Celexa in children."
- Is that statement true?
- 14 A. That is true.
- Okay. "One of these studies, the Forest
- 16 study, was sponsored by Forest Labs."
- 17 Is that true?
- 18 A. Yes.
- 19 Q. Okay. "The Forest study indicated that
- 20 Celexa was more effective than placebo in treating
- 21 pediatric patients suffering from depression."
- 22 Is that true?
- 23 A. Yes.
- Q. "The other study, the European study,

- 1 had been conducted in Europe and sponsored by the
- 2 Danish company that had developed and owned the rights
- 3 to Celexa."
- 4 Is that true?
- 5 A. That's true.
- 6 Q. All right. "The European study had
- 7 negative results, that is, the study did not show
- 8 Celexa to be any more effective than placebo in
- 9 treating pediatric depression."
- 10 That is true, right?
- 11 A. That is true.
- 12 Q. Okay. "On or about September 23rd,
- 13 2002, the FDA denied Forest Labs' request for a
- 14 pediatric indication for Celexa."
- That is true, correct?
- 16 A. I believe that's true.
- 17 Q. All right. Now, I'm just going to ask
- 18 you if you read the next sentence, it ends with "Forest
- 19 was aware that promoting a drug product for indications
- other than those approved by the FDA was illegal."
- Is that something that Forest was aware
- 22 of?
- A. We were aware of that.
- Q. Okay. Then it reads beginning in -- I'm

- 1 skipping the United States, whatever they're
- demonstrating because I'm not interested in what the
- 3 United States would or would not have done. I'm
- 4 interested in what is true.
- 5 Beginning in 1998 and continuing
- 6 thereafter through at least September 2002, Forest
- 7 promoted Celexa for use in treating depression in
- 8 adolescents suffering from depression, even though
- 9 Celexa was not FDA approved for pediatric use.
- 10 Is that true?
- MS. THORNE: Brent, you misread that one
- 12 a little bit.
- MR. WISNER: I'll read it again.
- MS. THORNE: Yeah, sorry.
- MR. WISNER: Sorry. Didn't get all my
- 16 coffee this morning.
- 17 BY MR. WISNER:
- 18 Q. "Beginning in 1998 and continuing
- 19 thereafter through at least September 2002, Forest
- 20 promoted Celexa for use in treating children and
- 21 adolescents suffering from depression, even though
- 22 Celexa was not FDA approved for pediatric use."
- 23 Is that true?
- A. I mean, are you asking as a corporate

- 1 entity Forest, or there were some representatives
- 2 within the company that were doing it in a fashion that
- 3 wasn't consistent with how we promoted our products?
- 4 Q. I'm asking if the sentence that was
- 5 alleged here by the United States against Forest during
- 6 the arraignment was true?
- 7 A. I believe we agreed to this.
- Q. Okay. It continues, Forest's off-label
- 9 promotion consisted of various sales techniques
- 10 including directing Forest sales representatives who
- 11 promoted Celexa to make sales calls to physicians who
- 12 treated children and adolescents promoting Celexa by
- 13 various Forest's sales representatives for use in
- 14 children and adolescents, hiring outside speakers to
- talk to pediatricians, child psychiatrists and other
- 16 medical practitioners who specialized in children and
- 17 adolescents about the benefits of prescribing Celexa to
- that patient population and for publicizing and
- 19 circulating the positive results of the double-blind
- 20 placebo controlled Forest study on the use of Celexa in
- 21 adolescents while at the same time failing to disclose
- the negative results of the second double-blind placebo
- 23 controlled European study on the use of Celexa in
- 24 adolescents.

1 MS. THORNE: Brent, you said disclosed but it should have been discuss. 2 MR. WISNER: 3 Thank you. 4 BY MR. WISNER: 5 Q. Changing that word to discuss as opposed to disclosed, is that true? 6 This is true. 7 Α. 8 Okay. With respect to the speaking Ο. 9 engagements, for example, the United States would have 10 introduced evidence -- with respect to the speaking 11 engagements, for example, four sales representatives 12 and division managers identified speakers from lists maintained and approved by Forest to organize 13 14 promotional lunches and dinners as part of which 15 speakers were paid to give a talk about Celexa. 16 MS. THORNE: You said four, not Forest, 17 right? 18 MR. WISNER: Yes. 19 BY MR. WISNER: 20 Is that true? Ο. 21 You're saying would the United States Α. have introduced that evidence, or is there evidence? 22 23 I'm asking is there evidence Ο. 24 establishing that four sales representatives --

1 MS. KIEHN: Well, I wouldn't ask if there's evidence establishing, just does he 2 3 agree with that statement. 4 MR. WISNER: Fine. 5 BY MR. WISNER: 6 Do you agree that that statement is Ο. 7 true? 8 Α. I agree the statement is true. 9 Ο. Okay. "Certain of Forest approved 10 speakers were medical practitioners who specialized in 11 treating children and adolescents suffering from 12 depression, and Forest paid these practitioners to give promotional talks on the use of Celexa in children and 13 14 adolescents." 15 Is that true? This is true. 16 Α. 17 Okay. "In or about mid-2001, Forest Q. learned of the positive results from the Forest study 18 19 and the negative results from the European study, and Forest Labs shared these results with the FDA." 20 21 Is that true? 22 Α. That is true. "Forest treated the studies 23 Ο. 24 differently." I'm just going to -- because I think --

- 1 I'm going to read the next sentence as well because I
- 2 think that sentence by itself is a bit ambiguous.
- 3 A. Okay.
- 4 Q. "Forest treated the studies differently.
- 5 Forest publicized and promoted the results from the
- 6 positive Forest study while at the same time Forest did
- 7 not publicize or disclose the results of the negative
- 8 study to persons outside the FDA or the Danish company
- 9 which sponsored the negative study."
- 10 Is that true?
- 11 A. This is true.
- 12 Q. "Forest did this in various ways
- including via certain discussions that Forest sales
- 14 representatives had with medical practitioners about
- 15 the use of Celexa in treating children, via certain
- 16 promotional speeches made by pediatric specialists who
- 17 were hired by Forest to talk about the use of Celexa in
- 18 treating children and adolescents and via letters sent
- 19 by Forest Professional Affairs Department to medical
- 20 practitioners who had requested from Forest all
- 21 available information and data concerning the use of
- 22 Celexa in treating children and adolescents."
- 23 Is that true?
- 24 A. This is true.

- Q. Okay. And is it also true that this violation occurred beginning as early as 1998 and
- 4 during this time period Forest delivered for
- 5 introduction into interstate commerce and caused the
- 6 delivery for introduction into interstate commerce into

continued through in or about December 2002 and that

- 7 Massachusetts and elsewhere various quantities of
- 8 Celexa for unapproved use in pediatric and adolescent
- 9 patients which was misbranded in that Celexa's labeling
- 10 lacked adequate direction for use. Is that true?
- 11 A. Yes.

3

- 12 Q. All right.
- 13 (Document marked for identification as
- 14 ForestC Deposition Exhibit No. 7.)
- 15 BY MR. WISNER:
- 16 Q. All right. I'm going to hand you a
- document that's been marked Exhibit 7.
- 18 Are you familiar with this document?
- 19 A. I am.
- 20 O. You, in fact, reviewed this document in
- 21 preparation for your testimony today?
- 22 A. I did.
- Q. This is the Information that was filed
- 24 against Forest Pharmaceuticals, correct?

- 1 A. I believe so.
- Q. And this was filed by the US Department
- 3 of Justice?
- 4 A. United States -- I assume so. It says
- 5 the United States of America.
- 6 Q. Fair enough. It was filed by the United
- 7 States of America?
- 8 A. Yes.
- 9 Q. All right. I'm just going to draw your
- 10 attention to Page 22 of -- sorry 21 of the Information.
- 11 A. Okay.
- 12 Q. And starting on Page 21 and continuing
- through to Page 28, Paragraphs 35 through 71?
- 14 A. I'm sorry, Paragraphs?
- 15 Q. Fifty-five through 71 reflect Count
- 16 Three of the Information, correct?
- MS. THORNE: Objection, calls for a
- 18 legal conclusion.
- 19 THE WITNESS: Appears that way.
- 20 BY MR. WISNER:
- Q. Okay. And you have reviewed the various
- 22 allegations made in these paragraphs in preparation for
- your testimony today?
- 24 A. I have.

Q. Can you please identify which one of 1 2 these allegations are untrue? 3 So you want me to look through this entire document? 4 5 Q. I assume you already have. 6 MS. KIEHN: You're going have to go line 7 by line --8 THE WITNESS: Well, I'd have --9 MS. KIEHN: -- if you want to do that. 10 THE WITNESS: Yeah, I would need to read 11 through it. 12 BY MR. WISNER: 13 Ο. Okay. So you're telling me you can't 14 identify which ones are untrue in this --15 If you'd like me to read through it, I Α. 16 can do that. 17 Okay. Great. We'll go off the record. Q. It's going to take some time. 18 Α. 19 MR. WISNER: We'll go off the record. 20 THE VIDEOGRAPHER: We are now off the 21 record. The time is 10:31. 22 (Brief recess.) 23 THE VIDEOGRAPHER: We are now back on the record. The time is 11:05. 24

- 1 BY MR. WISNER:
- Q. Mr. Closter, did you have a chance to
- 3 review the Criminal Information regarding the
- 4 allegations in Count Three?
- 5 A. I have.
- 6 Q. Are you prepared to specify which ones
- 7 Forest believes are incorrectly stated or untrue?
- A. Yes.
- 9 Q. All right. Which ones are those?
- 10 A. So we can begin on Page 23.
- 11 Q. Okay.
- 12 A. This would be Number 60.
- 13 Q. All right. Is it under the block quote?
- 14 A. Yeah. I mean, I think the part of it
- 15 that we would object to is "Forest Pharmaceuticals did
- 16 not adopt this draft document, nor did it for several
- 17 years thereafter require sales representatives to sign
- 18 a document that discussed the prohibition against
- 19 off-label marketing."
- 20 O. What is incorrect about that allegation?
- 21 A. I guess the fact that it's true, we did
- 22 not adopt the draft of the document, but that's only
- because we had a policy in place that was well
- 24 characterized that was well known by the sales force

- 1 and reiterated many, many times over the years. So it
- 2 was felt that we didn't -- we didn't need to adopt that
- 3 document for the purposes as described.
- 4 Q. Would it be fair to say that it's
- 5 Forest's position that they had a policy or -- a policy
- 6 in place that was essentially the same prohibiting
- 7 off-label promotion?
- 8 A. Yes.
- 9 Q. Okay. What other paragraphs do you
- 10 disagree with?
- 11 A. So we can move to Page 24, so this would
- 12 be -- I guess Number 63.
- 13 Q. Okay.
- 14 A. So reading down, there's a
- characterization of "thousands of child psychiatrists,"
- 16 it's about the fifth or sixth line down in that
- 17 paragraph.
- 18 Q. Yes, it says, these -- I'll just read it
- into the record. "These Celexa 'call panels' included,
- among others, thousands of child psychiatrists and
- 21 pediatricians who specialized in treating children and
- 22 adolescents."
- A. Yes, so the use of the word thousands,
- 24 I'm not -- I don't know what that's referring to. Is

- 1 that tens of thousands, hundreds, thousand? So I don't
- believe that's an accurate characterization.
- 3 O. What would be an accurate
- 4 characterization? Would it be under 10,000?
- 5 A. Absolutely, much below 2,000 all in.
- 6 Q. So it would be fair to say between 1 and
- 7 2,000?
- 8 A. Yes.
- 9 Q. So it is over 1,000, but it's not above
- 10 2,000; is that a fair characterization?
- 11 A. That's right.
- 12 Q. Okay. Is there the next issue?
- 13 A. The next one is really the line after
- 14 that, "Forest Pharmaceuticals also directed its Celexa
- sales representatives to call on physicians on worked
- in the pediatric wards of hospitals."
- 17 Q. Okay. Is that incorrect?
- 18 A. I believe that's incorrect.
- 19 Q. So it's your testimony that Forest
- 20 Pharmaceuticals did not direct Celexa sales
- 21 representatives to call on physicians who worked in the
- 22 pediatric wards of hospitals?
- 23 A. That's right.
- Q. Did Forest direct its sales

- 1 representatives to call on physicians that worked at
- pediatric hospitals?
- 3 A. I would have to double check to see if
- 4 those physicians were on the call panel that worked at
- 5 pediatric hospitals, so I don't know.
- Q. And how do you know that that allegation
- 7 is incorrect? Have you reviewed the call panels to see
- 8 whether or not there was any physicians within a
- 9 pediatric ward within the hospitals that were called?
- MS. KIEHN: Objection. He prepared for
- this deposition through reviewing documents as
- well as conversations with counsel, but he's
- not going to testify as to what he may have
- learned through counsel.
- MR. WISNER: Absolutely.
- 16 BY MR. WISNER:
- 17 Q. If your answer to that question would
- involve conversations you had with counsel, I'm not
- 19 interested.
- 20 A. Right.
- 21 Q. I'm just asking, did you look -- is it
- 22 your understanding that why that sentence is wrong
- 23 based on conversations you've had with counsel?
- A. I haven't seen any information whereby

we directed representatives to call on pediatric wards 1 of hospitals. 2 3 O. Okay. And independent of any 4 conversations you had with counsel regarding the truth or accuracy of that sentence --5 6 Right. Α. 7 -- do you have any independent knowledge Ο. about whether or not Forest directed sales 8 9 representatives to call on physicians at pediatric 10 hospitals, slightly different than this sentence there? 11 Α. Yeah, I'm not aware of any. 12 Okay. But you are aware that Forest did O. direct sales representatives to call upon pediatric 13 14 psychiatrists as well as pediatricians, correct? 15 Objection, leading. MS. THORNE: There were physicians on 16 THE WITNESS: 17 the panel that IMS had designated, probably based on their academic training, that they 18 19 were -- had some sort of child specialty, and 20 they were on the overall call panel, along with 21 tens of other types of physicians, including 22 psychiatrists and primary care physicians. 23 MR. WISNER: Okay. I just want to 24 respond to your objection of leading.

declaring this witness a hostile witness 1 pursuant to Federal Rule of Evidence 611(c)(2), 2 as he is testifying on behalf of an adverse 3 4 party, so I do believe I am entitled to lead? 5 MS. THORNE: We would disagree with 6 that, but that's fine. MR. WISNER: Okay. All right. If you 7 8 want to keep making leading objections, you're 9 welcome to, but you can say that objection is 10 standing. I just would like to avoid, but it's 11 your call. 12 BY MR. WISNER: 13 Ο. All right. What other paragraphs or 14 sentences do you disagree with in these sections? 15 So 64, which is immediately after Α. 16 what we just talked about, during sales calls, various Forest Pharmaceuticals sales representatives, acted at 17 times with the knowledge and encouragement of their 18 19 Division Managers and Regional Directors. 20 I don't know what it means by "various." 21 Any use of, you know, the plural sales representatives, 22 you know, I believe we're aware of a couple division 23 managers and perhaps one regional director was 24 involved. This makes it appear that there are many

- 1 more than that.
- 2 Q. How many divisional managers were
- 3 involved?
- 4 A. We're aware of two.
- 5 Q. Okay. And how many regional directors
- 6 were involved?
- 7 A. One.
- Q. Just one, okay.
- 9 So Forest -- so you're saying that
- 10 Forest admits that at least two division managers and
- 11 at least one regional director were involved, but
- 12 you're not willing to admit that there was any
- 13 additional ones; is that fair?
- MS. THORNE: Objection.
- THE WITNESS: That's fair.
- 16 BY MR. WISNER:
- Q. Okay. What else?
- 18 A. Further down on that page at the bottom,
- 19 "Forest Pharmaceuticals sales representatives often
- documented these details through 'call notes,'
- 21 thousands of which reflected off-label promotional
- 22 activity directed at the use of Celexa in children and
- 23 adolescents.
- You know, I don't know what evidence

- 1 that, you know, the government had in this regard. You
- 2 know, we talk about, you know, call notes. They
- 3 weren't mandatory. There was no acceptable format.
- 4 The call notes, if you looked at them, were very
- 5 different from representative to representative. We
- 6 don't know if those were things that actually happened.
- 7 We don't know the context. It also reflects thousands,
- 8 but understand that's against the panel of upwards of
- 9 50 million call notes. So in the end whatever those
- 10 notes would have suggested, there's not very many of
- 11 them as it relates to the whole body of call notes that
- 12 exists for all their activity that happened to be
- 13 recorded through call notes.
- Q. So just to clarify, it's Forest's
- 15 position that it cannot endorse the veracity of any
- 16 statements made in a particular call note because
- 17 Forest was not there; is that right?
- 18 A. That's correct. There's no actual
- 19 recording other than what the representative may have
- 20 recorded.
- Q. Okay. Now, when a call note is made,
- though, it is made generally at around the time that
- the call on the physician occurred, right?
- MS. THORNE: Objection.

1 THE WITNESS: Yeah, we don't know that. 2 BY MR. WISNER: 3 Q. Okay. That was the training -- sales representatives were trained to input their call notes 4 shortly thereafter a call on a physician? 5 6 MS. THORNE: Objection. 7 THE WITNESS: I mean, I haven't seen any 8 training on call notes, personally. 9 BY MR. WISNER: 10 Q. I mean, you worked in marketing for a 11 long time, right? 12 Yes, I have. A. 13 And, in fact, you helped develop Q. 14 tactical plans related to sales of Celexa -- I'm 15 sorry -- of Lexapro, right? 16 MS. THORNE: Objection. Are you asking 17 Mr. Closter in his personal capacity at this 18 point, or are you asking him as a company 19 representative? 20 MR. WISNER: Obviously, I'm asking in 21 his personal capacity. 22 MS. THORNE: Just to make the record 23 clear. 24 MR. WISNER: Sure.

1 THE WITNESS: Yes. 2 BY MR. WISNER: 3 Ο. Okay. And during the time in your involvement in those planning and strategy sessions, 4 5 was it understood amongst people within sales as well as in marketing that sales representatives were 6 7 supposed to document their sales calls in call notes 8 contemporaneously with their calling upon that physician? 9 10 MS. THORNE: Objection. Again, are you 11 asking Mr. Closter in his personal capacity at 12 this point, or are you asking him as a Forest 13 30(b)(6) witness? 14 MR. WISNER: Both. 15 MS. THORNE: Okay. 16 THE WITNESS: Personally, I'm on the 17 marketing and not on the sales end, but I'm not aware of any formal or written training on call 18 19 notes. 20 BY MR. WISNER: 21 Okay. But my question was was it 22 generally understood within Forest that sales notes or 23 call notes were to be made contemporaneously with 24 visits on those calls?

1	MS. THORNE: Objection.
2	THE WITNESS: I don't know if there was
3	a direction as to when to record those call
4	notes, which means they could have occurred
5	after the call, immediately after, they could
6	have occurred at the end of the day, the end of
7	the week or even the end of the month, and part
8	of that depended on the local level, you know,
9	what was the expectation of the divisional
10	manager, and for some representatives it was,
11	you know, merely to appease their manager. So,
12	you know, you could question what was in those
13	call notes if they were merely doing it so
14	their boss could see that they had some record
15	of activity.
16	BY MR. WISNER:
17	Q. Again, I guess my question is was it
18	generally understood, though, that sales
19	representatives would make call notes contemporaneously
20	with their calls?
21	MS. THORNE: Objection, asked and
22	answered. Mr. Closter has already answered the
23	question.
24	BY MR. WISNER:

My question is pending, Mr. Closter. 1 Ο. Yeah, I don't think it's generally 2 accepted. I don't -- I think it was too variable. 3 And the variation was either at that 4 5 same day or within a month? 6 MS. THORNE: Objection. THE WITNESS: Or longer. I couldn't --7 8 I wasn't in that capacity. You have to 9 interview a series of sales reps to see what 10 their behavior was. 11 BY MR. WISNER: 12 Ο. Have you ever heard of a sales rep who entered in his call note six months after the fact? 13 14 MS. THORNE: Objection, objection. I'm 15 going to object because that's, at this point, 16 outside the scope of the 30(b)(6) notice. 17 are clearly Mr. Closter a question based on his 18 own personal knowledge, so to the extent 19 Mr. Closter can answer based on his own 20 personal knowledge, he can answer, but I'm not 21 going to ask him to testify as to whether the 22 company has ever heard of a sales rep who 23 entered in his call note six months after the 24 fact.

1 THE WITNESS: Yeah, I don't know the 2 answer to the question. BY MR. WISNER: 3 4 You don't know if you know whether or not you've ever heard of a sales rep who entered in 5 call notes six months after the fact? 6 7 MS. THORNE: Objection. 8 THE WITNESS: Like I said, I'm not close 9 enough to it to know the range in which a 10 representative --11 BY MR. WISNER: 12 Q. My question to you is have you ever heard of that happening? That was my question. 13 14 MS. THORNE: Objection. Again, I'd like 15 to make clear for the record that any answer 16 Mr. Closter gives to this question is in his 17 own personal capacity. 18 THE WITNESS: Right. I don't believe 19 I've asked anyone when they recorded their call 20 notes, whether it was that day, a month later 21 or six months later. 22 BY MR. WISNER: 23 O. Mr. Closter, that wasn't my question.

Just listen to my question.

24

1 Have you ever heard of a sales rep entering his call notes six months after the fact? 2 3 Have you ever heard of that before? 4 MS. THORNE: Objection. 5 MR. WISNER: I understand it's pursuant in your individual capacity. 6 7 MS. THORNE: Yeah. 8 That's fine. I've never THE WITNESS: 9 heard them -- whether or not they've entered them a month later either. 10 BY MR. WISNER: 11 12 Ο. Okay. So your testimony, then, about whether or not sales notes, call notes are made 13 14 contemporaneously with the sales visits is not based on 15 any conversations you've ever had with sales 16 representatives? 17 MS. THORNE: Objection. For the record, are you asking whether Mr. Closter's testimony 18 19 in his --20 MR. WISNER: My question stands. 21 MS. THORNE: No, and I'm clarifying it 22 for the record. Is your question whether 23 Mr. Closter's testimony on behalf of the 24 company or on behalf of himself is based on his

	7
1	personal knowledge?
2	MR. WISNER: Both. Call notes were a
3	topic of the 30(b)(6), so, please, Mr. Closter.
4	MS. THORNE: No, the general process,
5	the general process or the general
6	MR. WISNER: Danielle, please stop
7	coaching the witness. I asked a question.
8	MS. THORNE: I'm not coaching the
9	witness.
10	MR. WISNER: Your objection is noted.
11	MS. THORNE: No, I'm not coaching the
12	witness.
13	MR. WISNER: Please answer the question.
14	MS. THORNE: You're not putting the
15	topics in front of Mr. Closter and asking him
16	to speak to the specific topics. We negotiated
17	topics, so I'm making clear on the record what
18	the topic we agreed to is. That is not
19	coaching the witness.
20	MR. WISNER: I understand your
21	objection. Can you please answer my question,
22	Mr. Closter.
23	THE WITNESS: I'm trying to remember the
24	question, but I did not talk to anybody in

regards to call notes and when they were 1 2 recorded. BY MR. WISNER: 4 Now, call notes have dates on them, 5 right? 6 MS. THORNE: Objection, assumes facts not in evidence. 7 8 THE WITNESS: Yeah, I mean, I'd have to 9 look at the output of the call notes to know 10 whether or not they were dated. BY MR. WISNER: 11 12 0. Did you look at call notes in preparation for your testimony today? 13 14 I have seen call notes in the past. Α. 15 They have a date on them, don't they? O. 16 MS. THORNE: Objection, assumes facts not in evidence. 17 THE WITNESS: Again, I'd have to look at 18 19 what was logged and captured, but, yes, I 20 believe there'd be a date on the call note. 21 BY MR. WISNER: 22 Okay, all right. So my question, I don't know if I got a clear answer, and I apologize if 23 you've already answered this, there have been a lot of 24

- 1 objections, your testimony earlier that you don't know
- 2 how contemporaneously call notes were made relative to
- 3 the call is not based on conversations you have
- 4 personally had with sales representatives?
- 5 A. That's right.
- 6 O. Okay. What is the basis of that
- 7 testimony?
- 8 A. Just general knowledge of talking to
- 9 managers, understanding the business, being involved in
- 10 it for the last 22 years.
- 11 Q. Have you ever conducted an audit to see
- 12 how frequently sales call notes are not
- 13 contemporaneously done with the call?
- MS. THORNE: Objection.
- THE WITNESS: No, back then I don't
- believe we did that on that.
- 17 BY MR. WISNER:
- 18 Q. Have you ever had a conversation with a
- 19 manager who expressed concern that sales
- 20 representatives were taking too long to enter in their
- 21 call notes?
- MS. THORNE: Objection.
- THE WITNESS: No.
- 24 BY MR. WISNER:

- 1 Q. Okay. All right. What is the next part
- 2 you have disagreement with?
- 3 A. Sure. The next is on Page 25, Number
- 4 65, and an objection to "in certain regions of the
- 5 country, including New England, various Forest
- 6 Pharmaceuticals Division Managers actively encouraged
- 7 off-label promotion of Celexa for use in children and
- 8 adolescents."
- 9 I'm not sure what the government meant
- 10 by "various." I don't know what the number is that
- 11 they were referring to, and I would disagree with the
- 12 term of actively encouraged.
- Q. Okay. So it's your testimony to this
- 14 jury that you don't believe that there were various
- 15 pharmaceutical division managers that actively
- 16 encouraged off-label; is that right?
- 17 A. Right, and my specific -- my specific
- issue is with, again, the plural division managers,
- 19 it's not known whether that's 2 or 20.
- Q. Plural means two or more, right?
- 21 A. Correct.
- MS. THORNE: Objection.
- 23 BY MR. WISNER:
- Q. And that's a plural division managers,

- 1 right?
- 2 A. Yes.
- Q. Okay. So it doesn't specify the number,
- 4 it just says two or more, right?
- A. Right, but it may mischaracterize the
- 6 term.
- 7 MS. THORNE: Objection.
- 8 BY MR. WISNER:
- 9 Q. Okay. And then what's the problem with
- 10 the word "actively"?
- 11 A. You know, I think there's a difference
- between actively encouraged and perhaps permitted
- 13 passively. I think there's different levels of focus
- 14 and effort.
- 15 Actively encouraged meaning this is a
- 16 primary objective, this should take up the bulk of your
- 17 time, lots of communication on it versus -- and this
- is, you know, in reference to off-label promotion, it's
- or allowing it to happen or, you know, seeing it in a
- 20 sales call but not correcting it, right. So to me
- 21 those are two different things, and I don't believe
- 22 what occurred was, you know, I would have characterized
- or the company would characterize as actively
- 24 encouraged off-label promotion.

- Q. Who are the two division managers that
- 2 you're referring to?
- 3 A. One of them is Chris Clermont. I'm not
- 4 sure of the name of the other one.
- 5 Q. And those two division managers, were
- 6 they terminated from Forest?
- 7 A. I'm not sure. I know they were
- 8 disciplined.
- 9 Q. Okay. Anything else in Paragraph 65?
- 10 A. No.
- 11 Q. Okay. The next paragraph that you have
- 12 a disagreement with?
- 13 A. Sure, this would be on Page 26, Number
- 14 67.
- 15 Q. Okay.
- 16 A. And it's a similar I think
- 17 mischaracterization that I've pointed out. At various
- 18 times in New England, certain Forest Pharmaceuticals
- 19 Regional Directors and Division Managers -- and, again,
- 20 not being comfortable with the plural, so I've already
- 21 discussed the division managers, and I'm he aware of
- one regional director who was involved.
- 23 Q. So other than the potential plural
- 24 ambiguity here, everything else is fine?

- 1 A. Up to that point, yes. There are things
- 2 afterwards which I would point out.
- Q. Okay. Please tell me.
- 4 A. The next one is various pharmaceuticals
- 5 divisional managers also directed sales representatives
- 6 to show off-label studies to physicians, but not leave
- 7 copies of those studies with the physicians so as to
- 8 avoid detection that would get the sales
- 9 representatives and Forest Pharmaceuticals in trouble.
- 10 Again, the use of word "various," plural
- 11 Division Managers. We're aware of one instance where
- 12 that occurred.
- 13 Q. So, again, your concern here is the
- 14 ambiguity of the plural?
- MS. THORNE: Objection.
- 16 THE WITNESS: Correct.
- 17 BY MR. WISNER:
- 18 Q. Okay. Next dispute?
- 19 A. In Number 68, again, at the top it
- 20 refers to sales representatives and Division Managers
- 21 identified speakers from lists maintained and approved
- 22 by Forest Pharmaceuticals, and this is in regards to
- the coordination of speaker programs of which division
- 24 managers did not coordinate those programs. That was

solely by the representatives. 1 2 Ο. Mr. Closter, we're going to go through the rest of these, but is your general disagreement with the various elements of these dealing with the use 5 of the words various and the plurals of district 6 managers and regional managers? I have to look forward to see if that's 7 Α. the only part. 8 9 Sure. Please tell me when you find one 10 that's beyond that issue. 11 Α. Sure. 12 MS. THORNE: Objection. 13 MS. KIEHN: He should still note for the 14 record his views. 15 MR. WISNER: Sure, that's fine. I just 16 don't want to spend time going over the word 17 various over and over again. 18 THE WITNESS: The next part is within 19 68, where it starts, "and Forest 20 Pharmaceuticals paid these practitioners to 21 give promotional talks on the use of Celexa in 22 children and adolescents." So, you know, this

is a fee for service that we pay speakers

giving up their time to speak to audiences. We

23

24

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1
             didn't know -- we were not aware corporately
             that these speakers were giving talks on Celexa
 2
             use in children and adolescents. You know, the
 3
             speakers themselves signed contracts that
 4
 5
             would, you know, compel them to speak on label.
 6
             We also gave them content that was on label,
 7
             but despite that, those speakers, the
 8
             government alleges, spoke on topics related to
 9
             children and adolescents.
10
             Ο.
                    I just want to be clear.
                                               It's your
11
     testimony to this jury that Forest Pharmaceuticals or
12
     Forest Laboratories did not know that members of the
     speaker bureau were talking about the off-label use of
13
14
     Celexa and Lexapro in children and adolescents?
15
             Α.
                    I mean, in instances where it was
16
     alleged to have occurred, we did not know.
17
             Q.
                    That really wasn't my question.
18
                    My question is is it your testimony to
     this jury that Forest didn't know that members of its
19
20
     speaker program were giving presentations about the use
21
    of adolescents in children specifically with regard to
22
     Celexa and Lexapro?
23
             Α.
                    That's right.
24
             O.
                    Is it your testimony to this jury that
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- 1 Forest didn't know that Karen Wagner was giving a
- 2 continuing medical education program sponsored by
- 3 Forest Pharmaceuticals specifically about the use of
- 4 SSRIs, including citalopram, and their use in pediatric
- 5 depression?
- 6 MS. THORNE: Objection.
- 7 THE WITNESS: We were aware, but
- 8 understand that, you know, CME is not a
- 9 promotional venue --
- 10 BY MR. WISNER:
- 11 Q. So it's your testimony --
- 12 A. -- like speaker programs.
- 13 Q. Sorry, didn't mean to interrupt you.
- 14 A. It's all right.
- 15 Q. So it's your testimony to this jury that
- 16 CMEs are not a form of promotion?
- 17 A. That's right.
- 18 Q. Okay. So is there any -- another issue
- 19 beyond the various plural issue?
- 20 A. Yes, further down on the page on 26
- 21 there is a host of programs that the government alleges
- 22 had occurred or were conducted in some capacity. Other
- than two of them, we're not aware of what these titles
- 24 mean or reference.

- 1 Q. That's good to know, because I haven't
- 2 been able to find them either.
- Which two are you aware of?
- 4 A. The title "Adolescent Depression."
- Q. Okay.
- A. And Treatment Options in Depressive
- 7 Disorders in Adolescents -- I'm sorry, new treatment
- 8 options. So it's the first one --
- 9 Q. I got it.
- 10 A. -- we're aware of and then the one that,
- 11 you know, overlaps the second to last line to the last
- 12 line.
- Q. Okay. So those were the only two that
- 14 Forest was aware of?
- 15 A. Yes.
- Q. Okay. And so the rest of these, just to
- 17 be clear, you don't know what the government is talking
- 18 about?
- 19 A. We don't.
- 0. Okay. The next substantive nonvarious
- 21 plural issue?
- 22 A. I mean, I'm going to point those out,
- 23 just for the record.
- Q. Just point them.

- 1 A. In 69 there is some discussion about to
- 2 obtain funding support for these promotional programs,
- 3 Forest Pharmaceuticals sales representatives were
- 4 required to submit paperwork to the Division Managers,
- 5 so on and so on, it goes on to predict the expected
- 6 return on investment from the attendees.
- 7 I mean, this is something we don't -- we
- 8 just don't have record of corporately. You know, these
- 9 are field initiated programs and field approved
- 10 programs, so we're not aware of any forms that haven't
- 11 been able to locate any that speak to this.
- 12 Q. Putting aside whether or not you could
- 13 find any forms or documents related to these, is it
- 14 Forest's understanding that sales representatives did,
- in fact, conduct return on investment analysis
- 16 regarding medical practitioners who were invited to
- 17 various programs?
- 18 A. I can't say -- I can't say that that's
- 19 true, and I don't believe it was required to be filled
- out on the form to approve the program. We have to see
- 21 them.
- Q. To be clear, are you saying it's not
- 23 true or you just don't know if it's true or not?
- A. I don't know if it's true.

- 1 Q. Okay. The next one?
- 2 A. You know, it further goes on to say "and
- 3 others within Forest Pharmaceuticals consistently
- 4 approved these requests for funding, "we won't -- we
- 5 don't know if they were approved or denied, since
- 6 that's something that resided with the field management
- 7 team.
- Q. Okay.
- 9 A. The next one is I guess C.
- 10 Q. So the top Paragraph 70?
- 11 A. Yeah, communicating incomplete and
- 12 potentially misleading information concerning the
- 13 efficacy of Celexa in treating children and
- 14 adolescents. This is in regards to what follows, which
- is the results of the two studies, one conducted by
- 16 Forest, I believe, and then the other conducted by our
- 17 partner based in Denmark. We do not believe that that
- 18 was misleading. That is an unfair characterization of
- 19 that.
- 20 Okay. So to be clear, you do admit that
- 21 Forest publicized Study 18, which is the one that was
- 22 allegedly positive?
- A. Was positive, not allegedly positive.
- Q. I'm going to disagree with you on that.

- 1 A. That's fine.
- 2 Q. But that you would claim is positive,
- 3 right? They did promote --
- 4 A. The FDA claims is positive.
- 5 Q. Okay. My question to you is did Forest
- 6 promote Study 18?
- 7 A. No, we didn't promote it.
- 8 Q. Fair enough. Did Forest publicize Study
- 9 18?
- 10 A. Study 18 was presented in poster format
- 11 at a major scientific meeting.
- 12 Q. Forest issued a press release about it?
- 13 A. Yes, we issued a press release.
- 14 Q. They publicized Study 18?
- 15 A. We issued a press release. If you would
- 16 like to call that publication, you can. I wouldn't,
- we'd call publicized by issuing the release.
- 18 Q. So a press release is not a form of
- 19 publicity?
- A. For sake of argument, yes.
- Q. Okay. But my question for you then is
- 22 Forest did not publicize or issue a press release about
- 23 Study 94404 when they originally got the results,
- 24 correct?

1 That's right. It was not our study. Α. 2 And you don't think that it was O. misleading for Forest to publicize or disseminate in a press release a positive result while failing to 4 mention or discuss the negative one? 5 6 MS. THORNE: Objection. 7 THE WITNESS: That's right. 8 BY MR. WISNER: 9 Ο. That's -- okay. 10 Regarding the -- these CME programs, I think they called them or the --11 12 Α. Do you want me to -- I can continue the document, because there's further --13 14 I just want to -- I just want a Q. follow-up question before we move on? 15 16 Α. Sure. 17 On Number 68 all these programs you said Q. you're not familiar, you're only familiar with two of 18 19 them; is that what you said? 20 Α. Right. 21 Do you know who would be familiar with 0. 22 these? 23 MS. THORNE: Objection. 24 I don't.

THE WITNESS:

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1
    BY MR. WISNER:
 2
            O.
               Okay. And on these return on
    investments that you were discussing --
 4
                   Yeah.
            Α.
 5
            Q.
                   -- that you haven't seen forms of --
 6
            Α.
                   Right.
 7
            0.
                   -- who would know?
 8
                   MS. THORNE: Objection.
9
                   THE WITNESS: Perhaps someone in sales
10
            administration. I believe you've talked to
11
            some expert in that area, they may have some
            further insight if you haven't gotten any from
12
13
            them.
14
    BY MR. WISNER:
15
                  Now, you specified that they were in the
            O.
16
    field, right?
17
            A. Correct.
            Q. Who would know where those field
18
19
    documents would be?
20
                   Someone in document retention. I don't
            Α.
21
    know.
22
            Q. All right. You want to continue with
23
    that.
24
            A. Yeah, so just the characterization of
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- 1 the dissemination of the data aggressively publicized
- 2 and promoted, I would not say issuing a press release
- 3 is aggressively publicizing, and I would not agree that
- 4 we promoted the results from the positive Forest study.
- 5 Q. So to be clear, you understand that
- 6 Forest did more than issue a press release, right?
- 7 A. Like, what are you suggesting?
- 8 Q. Well, they drafted a poster
- 9 presentation, correct, for Karen Wagner?
- 10 A. Right, presented at --
- MS. THORNE: Objection.
- 12 THE WITNESS: -- ACNP of that year.
- 13 BY MR. WISNER:
- 14 Q. Okay. They also prepared a presentation
- that she delivered at the ACNP conference, right?
- MS. THORNE: Objection.
- 17 THE WITNESS: I'm actually not aware of
- 18 that.
- 19 BY MR. WISNER:
- Q. Okay. We'll get to that later.
- 21 Forest also sponsored CME education
- 22 events throughout the United States where Karen Wagner
- 23 presented the results of Study 18, correct?
- MS. THORNE: Objection.

1 I'm aware of a series of THE WITNESS: 2 CME events. BY MR. WISNER: 3 4 Ο. And you're also aware that various sales 5 representatives used the Wagner study in promoting -strike that, because you don't like the word various. 6 7 You are aware that at least one or two sales representatives used the Wagner study to promote 8 the use of Celexa in children? 9 10 MS. THORNE: Objection. 11 THE WITNESS: We're aware of a handful 12 of representatives doing that. BY MR. WISNER: 13 14 Okay. And all of that activity, in your Ο. 15 opinion, doesn't qualify as aggressively publicizing or 16 promoting the results; is that right? 17 That's right. Α. 18 Do you have another issue, next issue? Ο. 19 Yeah, the next one is on the following Α. 20 page, on 28, and it's a rather long, generalizing 21 statement begins with, "As a result, doctors and 22 psychiatrists received incomplete and misleading 23 information," and then it goes on to cite three

different things, and I don't know if the allegation is

24

- 1 applying incomplete and misleading to all of these, to
- one of them, but I disagree with -- I disagree with the
- 3 paragraph.
- 4 Q. Okay. Putting aside the issue of
- 5 whether or not they were incomplete or misleading, the
- facts alleged in 1, 2 and 3, are those correct?
- 7 MS. THORNE: Objection, compound.
- THE WITNESS: One, we're aware of a
- 9 handful of instances where that occurred, and
- Number 2, similar, we're aware of
- 11 representatives initiating promotional programs
- with speakers who are alleged to have covered
- these topics, and I can agree with the facts of
- 14 3.
- 15 BY MR. WISNER:
- 16 O. Okay.
- 17 A. Although I'm not -- I'm not really
- 18 sure -- there's a request from Forest Pharmaceuticals
- 19 all available information and data concerning the use
- of Celexa in treating children and adolescents, I don't
- 21 know, I haven't seen what the actual requests were. It
- 22 was for some information. Was it information on a
- 23 particular study or all of the information, which is
- 24 what the document alleges.

- 1 Q. But the actual letter that was used that
- 2 they're referring to here did not disclose the results
- 3 of 94404, correct?
- 4 MS. THORNE: Objection.
- 5 THE WITNESS: I understand that's true.
- 6 BY MR. WISNER:
- 7 Q. Is there any other issues you have with
- 8 the remainder of 71?
- 9 A. No.
- 10 Q. Okay. I see that some of the issues you
- 11 took with the Criminal Complaint -- sorry, the Criminal
- 12 Information -- related specifically to the
- 13 characterization of Forest's conduct as incomplete and
- 14 misleading; is that fair?
- 15 A. Yes.
- 16 O. It's your belief that the off-label
- 17 promotion activity that is alleged in the Information
- 18 specifically related to a handful of sales
- 19 representatives; is that right?
- 20 A. That's right.
- Q. And involved, as you said, one regional
- 22 manager; is that right?
- 23 A. One regional director.
- Q. One regional director and two district

```
managers; is that right?
 1
                    Right.
 2
             Α.
 3
             0.
                    And that very small group of people,
    Forest ended up paying approximately $40 million in
 5
     fines; is that right?
 6
                    MS. THORNE: Objection.
 7
                    THE WITNESS: I would have to look at
 8
             the exact doc -- you know, figures but that
 9
             sounds about right.
    BY MR. WISNER:
10
                   And not only did they pay $40 million in
11
12
     fines, but they also were required to enter into a
    corporate integrity agreement, correct?
13
14
                    MS. THORNE: Objection.
15
                    THE WITNESS: That's true.
16
    BY MR. WISNER:
17
                   And, actually, a condition to the plea
             Q.
     agreement actually was entering into a civil Settlement
18
19
    Agreement as well, correct?
20
                    MS. THORNE: Objection.
21
                    THE WITNESS: I believe that's true.
22
    BY MR. WISNER:
23
             Ο.
                    Ultimately, all said and done, with
```

fines and settlement amounts, Forest ended up paying

24

```
$313 million, right?
 1
 2
                    MS. THORNE: Objection. Objection.
 3
            the --
                    MR. WISNER: The objection is noted.
 4
                    MS. THORNE: For the record I'd like to
 5
 6
            state that that figure refers to all three
 7
            counts, two of which had nothing to do with
 8
            Celexa promotion.
 9
                    MR. WISNER: I really appreciate you
10
            coaching the witness. Please answer my
            question, sir.
11
12
                   MS. KIEHN: She's making sure the record
13
            is clear.
14
                    THE WITNESS: Right. I would have to
15
            look at the numbers and verify the figure.
16
                    MR. WISNER:
                                Okay.
                    (Document marked for identification as
17
            ForestC Deposition Exhibit No. 8.)
18
19
    BY MR. WISNER:
20
                    I'm handing you a document, which is
            0.
21
    Exhibit 8. To be clear, Mr. Closter, the criminal fine
22
    was $39,500,000 related to Count Three, correct?
23
            Α.
                   Yep.
24
                   The document I handed you is the
            Q.
```

Settlement Agreement and Release, correct? 1 2 Α. Yes. 3 Ο. And this is related to allegations that -- allegations that Forest caused false claims to 4 5 be submitted to various governmental programs for the pediatric use of Celexa and Lexapro, correct? 6 7 Α. Yes. 8 And this covers a time frame between Ο. 9 1998 and 2005? Page 4, Paragraph 2. 10 Α. Thank you, yes. 11 If I draw your attention to Page 6, Ο. 12 Paragraph 1, related to this covered conduct involving Celexa and Lexapro, Forest agrees to pay the United 13 14 States and Medicaid participating states, collectively, 15 the total amount of \$149,158,057.66; is that right? 16 Α. Yes. 17 MS. THORNE: Objection. Again, for the record, I'd like to point out that that does 18 19 not refer merely to conduct involving Celexa. 20 It also refers to conduct involving a drug that 21 is not at issue in this action. 22 (Document marked for identification as 23 ForestC Deposition Exhibit No. 9.)

BY MR. WISNER:

24

- 1 Q. I'm handing you a document marked as
- 2 Exhibit 9. This is the Corporate Integrity Agreement
- 3 that was entered into between Forest Laboratories and
- 4 the Office of Inspector General, US Department of
- 5 Health and Human Services?
- 6 A. Yes.
- 7 Q. This also was signed contemporaneously
- 8 both with the criminal plea, the settlement, correct?
- 9 A. Right.
- 10 Q. And if you look on the first paragraph
- on Page 1, the last part of the sentence says, Forest
- 12 Laboratories' agreement to the CIA is a condition
- 13 precedent to those agreements.
- Do you see that?
- 15 A. Yes.
- 16 Q. Okay. Now, this document involves
- 17 prospective regulation of Forest's conduct in promoting
- 18 drugs, correct?
- MS. THORNE: Objection.
- THE WITNESS: I mean, I'll take your
- word for it. I have to read through it. I
- haven't read this document in quite some time.
- 23 BY MR. WISNER:
- O. Okay. You did not review it in

preparation for your testimony today? 1 2 Α. No. 3 Ο. Okay. You understand, based upon your position at the company, that this document governed 4 5 for a period of five years how the rules and policies that Forest should implement in promoting all forms of 6 7 drugs starting in 2010? 8 MS. THORNE: Objection, mischaracterizes 9 the document. 10 THE WITNESS: Ask the question again. 11 BY MR. WISNER: 12 0. Sure. You understand that this document specifies the policies, procedures and activities to 13 14 regulate Forest's promotion of drugs for five years 15 following the entry of the agreement in 2010? 16 MS. THORNE: Objection. The document 17 speaks for itself, mischaracterizes the 18 document. THE WITNESS: I'm sure it covers that 19 20 and a whole lot more. 21 BY MR. WISNER: 22 Ο. Okay. In fact, while you were working at Forest, you got trained on this, didn't you? 23 24 T did. Α.

1 And, in fact, you were required to abide Q. by the provisions of it as an employee at Forest, 2 3 correct? 4 MS. THORNE: Objection. Are you asking 5 Mr. Closter in his individual capacity for that 6 question? 7 MR. WISNER: I believe I said as an 8 employee at Forest. 9 MS. THORNE: Making the record clear. 10 BY MR. WISNER: 11 Q. That's a yes? 12 Α. Yes. Okay. I'm handing you a document --13 Q. 14 well, actually, we can put that away for now. 15 All right. I'd like to turn to the 16 issue of efficacy of Celexa and Lexapro, all right? 17 Α. Okay. Are you familiar with something called a 18 Q. 19 clinical trial? 20 Α. Yes. 21 What is a clinical trial? Ο. 22 Α. You know, it's a scientific study of, 23 you know, in a certain population with a, you know,

given disease state and an indication, and, you know,

24

- 1 there's a hypothesis of the active drug, typically
- 2 versus a placebo, and you want to demonstrate that
- 3 either the active drug works or it doesn't and whether
- 4 it's safe or not.
- 5 Q. You are familiar with, as you mentioned,
- 6 a placebo-controlled clinical trial?
- 7 A. Yes.
- Q. Are you also familiar with an active
- 9 controlled clinical trial?
- 10 A. Yes.
- 11 Q. And you're also familiar with open label
- 12 clinical trials?
- 13 A. Yes.
- 14 Q. In the context of placebo-controlled
- 15 clinical trials, you would agree that those are the
- 16 sort of gold standards for evaluating the efficacy of a
- 17 particular medication?
- MS. THORNE: Objection. This is outside
- the scope of the 30(b)(6) deposition notice.
- We agreed to put forth a witness to testify on
- behalf of the company to specific enumerated
- clinical trials, so Mr. Closter can continue to
- testify in his personal capacity to the extent
- that he knows, but he cannot testify on behalf

1 of the company in response to this question. 2 Are we talking about THE WITNESS: depression trials or other trials? 3 BY MR. WISNER: 4 5 Q. My question was just placebo-controlled clinical trials are the gold standard for determining 6 7 the efficacy of any drug? 8 MS. THORNE: Reiterating my objection. 9 THE WITNESS: I mean, it's not true. 10 depends on the drug class, right. There's 11 certain classes that they do not do 12 placebo-controlled trials, for instance, for 13 the FDA to evaluate efficacy. They'll do 14 active control trials, and there are others 15 where they'll do placebo-controlled trials. 16 BY MR. WISNER: 17 Q. Thank you. You would agree, though, that for in the 18 19 context of depression or antidepressants, 20 placebo-controlled trials are the -- generally 21 considered the gold standard for assessing the efficacy 22 of a compound? 23 MS. THORNE: Objection. I'm going to 24 reiterate my objection. To the extent

Mr. Closter can testify to this in his personal 1 2 capacity, he can feel free to answer the question, but I'm going to instruct him to not 3 4 answer on behalf of the company, as this is outside the notice. 5 6 THE WITNESS: My personal experience, 7 yes. 8 BY MR. WISNER: 9 Okay. Are you familiar with something 10 called a protocol? 11 Α. Yes. 12 0. What is a protocol? 13 MS. THORNE: Objection. Again, to the 14 extent that Mr. Closter can testify on behalf 15 of his personal experience, he can go ahead and 16 testify. 17 MR. WISNER: Can you just say renew my 18 objection. This is wasting so much time. 19 Sure. I renew my objection MS. THORNE: 20 and I instruct the witness not to answer on 21 behalf of the company. 22 MR. WISNER: Let me reask the question. 23 I'll withdraw the question. 24 BY MR. WISNER:

- 1 Q. Are you familiar with the protocols for
- 2 Celexa Study 18, 94404, Lexapro Study 15 and 32?
- A. I've looked at the protocol for MD-18.
- 4 I have not recently seen the protocols on the other
- 5 studies.
- 6 0. What is a protocol?
- 7 A. A protocol is really how the study is
- 8 going to be conducted, right, how many patients, the
- 9 design of the trial, inclusion, exclusion criteria may
- 10 include -- it's going to include different variables
- 11 that may be assessed during the trial to assess whether
- 12 the drug works or not.
- Q. And you would agree that protocols are
- 14 written before the trial begins, correct?
- 15 A. Yes.
- Q. And they're, in fact, approved by the
- 17 FDA?
- 18 A. We do submit them for approval.
- 19 Q. And once the clinical trial begins, it
- is supposed to adhere to the specifications outlined in
- 21 the protocol?
- MS. THORNE: Objection. Again, this
- 23 question is outside the scope of the 30(b)(6)
- deposition notice. I'm going to renew my

objection and instruct Mr. Closter not to 1 answer on behalf of the company. To the extent 2 3 that you have personal knowledge on the topic, 4 you can answer. 5 THE WITNESS: So I'm not a clinical expert. I don't liaise directly with FDA, so I 6 7 don't profess to be an expert, but, to my 8 understanding, protocols can change over time 9 depending on the conduct of the study and 10 things that may arise, and often the dialogue 11 between FDA and a sponsor is fluid, meaning 12 things are corresponded before, during and after trials. 13 14 BY MR. WISNER: 15 Ο. And, in fact, if a change to a protocol 16 occurs, that change has to be specified as an amendment to the protocol, correct? 17 18 MS. THORNE: Objection. I renew my 19 objection and instruct Mr. Closter to answer in 20 his personal capacity. 21 MR. WISNER: Strike the question. 22 BY MR. WISNER: 23 Ο. With regards to Celexa Study 18, the protocol was changed, it had to be reflected in the 24

```
amendment as an amendment to that protocol, correct?
 1
 2
                    MS. THORNE: Objection to extent the
 3
             question calls for a hypothetical. It is
             outside the scope of the 30(b)(6) deposition
 4
 5
             notice, and so, Mr. Closter, if you have the
 6
             ability in your personal capacity to answer the
 7
             hypothetical, you can do so, but your answer
 8
             will not be on behalf of the company.
 9
                    THE WITNESS:
                                  Technically, I'm not sure.
10
             While I have general knowledge of this topic, I
11
             am not certain about protocol amendment
12
             changes.
13
    BY MR. WISNER:
14
                    So you don't know how a protocol gets
             Ο.
15
     amended; is that right?
16
                    MS. THORNE: Objection. Again, any
17
             answer you give is not on behalf of the
18
             company.
19
                    MR. WISNER: I'm asking what he knows.
20
                    MS. THORNE: Are you asking for his
21
             personal knowledge?
22
                    MR. WISNER: Obviously.
23
                    MS. THORNE:
                                 Well, then say that in your
24
             question and then it will be obvious on the
```

1 record. 2 THE WITNESS: My personal knowledge, I'm 3 not sure. 4 BY MR. WISNER: 5 Q. Okay. Do you happen to know in your 6 knowledge capacity as a person speaking for Forest? 7 Α. No. 8 MR. WISNER: Let's go off the record. 9 THE VIDEOGRAPHER: We are now off the record. The time is 11:47. 10 11 (Brief recess.) 12 THE VIDEOGRAPHER: We are now back on the record. The time is 11:55. 13 14 BY MR. WISNER: 15 Mr. Closter, there have been four 16 placebo-controlled clinical trials for Celexa and Lexapro studying the efficacy of the medications, the 17 treatment of pediatric populations, correct? 18 19 MS. THORNE: Objection. 20 THE WITNESS: Correct. 21 BY MR. WISNER: 22 Q. Okay. And those four studies are I'm 23 going to call Celexa Study 94404, are you familiar with 24 that one?

1 Α. Yes. 2 Ο. Celexa Study 18? 3 Α. MD-18, right. Okay. Would you prefer that I call it 4 Q. 5 MD-18; would that be easier for you? 6 Α. It would, strange enough. 7 Any time I refer to Study 18 or MD-18, Ο. I'm referring to that one, okay? 8 9 Α. Okay. 10 Q. You're familiar with Lexapro Study 15? 11 Α. Yes. 12 And is that MD15 for you? Ο. 13 Α. Yes. 14 Okay. And then are you familiar with an Q. 15 MD32? 16 Α. Yes. 17 Q. Okay. And that's for Lexapro as well? 18 Yes, and just to be clear, you mentioned Α. 19 the four studies that were sponsored by the companies 20 that own the rights to citalogram and escitalogram, but 21 there may have, in fact, been other studies that habe 22 been done on those drugs by other parties. 23 Ο. Are you aware of any? 24 I mean, not specifically, but I'm sure Α.

- 1 there is a body of evidence, case reports and things
- 2 like that.
- Q. Okay. But I'm specifically referring to
- 4 placebo-controlled clinical trials. Are you aware of
- 5 any other placebo-controlled?
- A. I mean, not specifically, but the drug
- 7 has been out for quite some time, it's possible some
- 8 academic center or someone else may have generated some
- 9 things.
- 10 Q. But you're not aware of any?
- 11 A. No, not specifically. I'm just making a
- 12 point.
- 13 (Document marked for identification as
- 14 ForestC Deposition Exhibit No. 10.)
- 15 BY MR. WISNER:
- Q. All right. I'm handing you a document
- 17 it's marked as Exhibit 10 to your deposition. This is
- 18 a document entitled "Integrated Clinical Study Report."
- Do you see that?
- 20 A. Yes.
- Q. And this is referring to study 94404,
- 22 correct?
- 23 A. Correct.
- Q. I just want to, for the record, indicate

- 1 that I've taken excerpts of the study report because
- 2 it's fairly lengthy, and I didn't feel I wanted to
- 3 clutter the record, okay?
- 4 A. Okay.
- 5 Q. And to help facilitate the situation,
- 6 I've actually put a Bates number on the top right of
- 7 each document -- of each page, so that you can
- 8 easily -- hopefully easily find out which pages we're
- 9 talking about, okay?
- 10 A. I don't see a Bates number. I see
- 11 numbers.
- 12 Q. Sorry, a number, that's what I meant, a
- 13 number on the top right hand.
- A. Yep, yep.
- Q. And it doesn't necessarily correspond
- 16 with the actual page numbers of the report, okay?
- 17 A. Got you.
- 18 Q. So when I say Page 1, I'm referring to
- 19 the one on the top right corner, all right?
- A. All right.
- Q. And that's going to be for all these
- 22 documents moving forward.
- MS. THORNE: Just for the record, this
- document does not have a Bates number for this

```
action, or does it?
 1
 2
                    MR. WISNER: I'm pretty confident you've
 3
            produced this document in about 55 versions,
            but this one I did not get from our production,
 4
 5
             I got elsewhere. So it's a publicly available
            document.
 6
 7
                    THE WITNESS: And just to note, the
 8
             document indicates it's 345 pages in total.
 9
    BY MR. WISNER:
10
             0.
                   Okay, looks right. All right. So this
11
    was a clinical trial --
12
                    MS. KIEHN: We're handing his sheet.
13
                    THE WITNESS: The cheat sheet and --
14
                    MR. WISNER: Sure, let's actually put
15
             that into the record as well.
16
                    MS. THORNE: Wait, there's -- yeah,
17
             that's the version that he had.
                    (Document marked for identification as
18
19
             ForestC Deposition Exhibit No. 2B.)
20
    BY MR. WISNER:
21
                   Marking this as Exhibit 2B, this is a
22
    chart that was prepared prior to your testimony to help
23
    you keep track of all the clinical trials; is that
24
     right?
```

Yes. 1 Α. 2 Ο. Okay. Did you personally prepare that chart? 3 4 Α. No. 5 Q. Okay. All right. So this study 94404 was sponsored by Lundbeck, correct? 6 7 Α. Correct. 8 Lundbeck was Forest's partner with Q. 9 regards to Celexa and Lexapro, correct? 10 MS. THORNE: Objection. 11 THE WITNESS: That's correct. 12 BY MR. WISNER: 13 This says the last patient visit was Q. 14 April 23rd, 2001. 15 Do you see that? 16 Α. Yes. 17 And you would agree with me that this Q. study occurred primarily in Europe? 18 19 MS. THORNE: Objection. 20 THE WITNESS: Yeah, it looks like 21 exclusively in Europe, right, unless some of 22 these countries are not European, but I believe 23 they are. 24 BY MR. WISNER:

- 1 Q. I'm not sure about Astonia, but the rest
- of them, I think are in Europe.
- But you understand that this study did
- 4 not occur in the US, correct?
- 5 A. That is correct.
- 6 O. Okay. And it was monitored and
- 7 controlled by Lundbeck, not Forest, correct?
- A. That's correct.
- 9 Q. Now, Forest did play a role in helping
- 10 to develop the protocol as well as the final study
- 11 report for this study, correct?
- MS. THORNE: Objection.
- THE WITNESS: I'm not aware who was
- involved in the study protocol or the final
- report from the Forest side.
- 16 BY MR. WISNER:
- 17 Q. Okay. Do you know whether or not
- 18 Forest -- anybody at Forest was involved in preparing
- 19 the report at all?
- 20 A. I can't answer the question. I don't
- 21 know the answer.
- Q. You don't know?
- 23 A. No.
- Q. All right. Turn to Page 2. Let me ask

- 1 you, who would know if Forest was involved in
- 2 preparation of this study report?
- A. I mean, certainly someone on the
- 4 clinical end.
- 5 Q. Okay. Do you have a name in mind that
- 6 would be someone who would know the answer to that
- 7 question?
- 8 A. Larry Olanoff, Charlie Flicker, these
- 9 are folks who were here, I believe, at that time.
- 10 Q. All right. So Study Objectives, Primary
- 11 Objective, the first says to study the efficacy and
- 12 tolerability of citalogram compared to placebo in
- 13 adolescent study -- adolescent patients suffering from
- 14 major depression.
- I sort of said that right, right?
- 16 A. Yes.
- 17 Q. Okay. So the purpose of the study was
- 18 to study the potential efficacy and the tolerability of
- 19 Celexa in treating adolescent depression; is that fair?
- 20 A. Yes.
- 21 Q. This was exclusively related to
- 22 adolescents, not younger children, right?
- A. Adolescents as, you know, defined by the
- 24 age population, which I'm assuming is in here

- 1 somewhere.

 2 Q. Consult your chart. Do you know what

 3 the age range was for this study?

 4 A. Thirteen to 18.
- 5 Q. Okay. Now, you would agree with me that
- 6 this study was negative for efficacy?
- 7 A. There were negative results in the
- 8 study, yes.
- 9 Q. Okay. And isn't it true that you have
- 10 previously testified that when a prospectively defined
- 11 primary endpoint does not show statistical
- 12 significance, that means that a study is negative?
- MS. THORNE: Objection. Are you asking
- Mr. Closter in his capacity as 30(b)(6), when
- you say that you have previously testified, are
- 16 you referring to prior testimony by Forest or
- prior testimony by Mr. Closter?
- MR. WISNER: By Mr. Closter.
- MS. THORNE: Okay.
- THE WITNESS: That's my understanding.
- 21 BY MR. WISNER:
- Q. Okay. And the primary efficacy endpoint
- 23 here -- if you turn to Page 7 of the study report,
- 24 Section 6.7.1 Efficacy Parameters.

1 You see that? 2 Α. Yes. 3 O. Okay. And it lists out the primary efficacy endpoint and the secondary efficacy endpoints, 4 5 right? 6 Α. Yes. 7 And it lists out all these different 0. 8 endpoints that are going to be measured as part of the 9 study, correct? 10 Α. Correct. 11 And the first one says "change from baseline in the Kiddie-SADS-P total score over time." 12 13 You see that? 14 Α. Yes. 15 Kiddie-SADS-P total score over time, 0. 16 that's referring to a depression checklist specifically designed to assess a child or adolescent's depression, 17 18 correct? 19 MS. THORNE: Objection. 20 Yeah, I'm not that THE WITNESS: 21 familiar with the Kiddie-SADS-P, so -- but 22 that's the basic goal. 23 BY MR. WISNER: 24 If you just look on Page 6, the first 0.

paragraph. Let's take a look there and see if that 1 will help you answer my question. 2 3 Α. (Witness reviews document.) 4 Okay. 5 Q. So the Kiddie-SADS-P is just a rating scale used to diagnose or assess a particular 6 7 adolescent's depression; is that fair to say? 8 Yeah, it says school-aged children in Α. 9 the -- that is literally part of the scale. 10 Q. The acronym? 11 Α. Yes. 12 Ο. Okay. 13 Α. Thank you. 14 And then the secondary efficacy out Q. 15 points -- efficacy endpoints there is a bunch of bullet 16 points here. 17 Do you see that? 18 Α. Yes. 19 And some of them refer to various O. assessments on the Kiddie-SADS-P. 20 21 Do you see that? 22 Α. Yes. 23 And some of them refer to the MADRS Ο. 24 total score over time, for example?

- 1 Α. Yes. And these are all various forms of 2 Ο. 3 secondary efficacy assessments that are specifically to assess whether or not there's any efficacy -- strike 4 5 that. 6 What is your understanding of a 7 secondary efficacy endpoint? 8 Secondary efficacy endpoint, I mean, Α. 9 it's not part of your primary. Primary is going to 10 determine whether the study produced positive or 11 negative results, and the secondary endpoints are 12 basically supportive. They give you some interesting information, but they're not designed with the same 13 14 sort of robustness and rigor that you would treat a 15 primary efficacy endpoint. 16 Okay. The primary efficacy endpoint in 17 this clinical trial was negative, correct? 18 Α. The result was negative, yes. 19 Okay. And every other single secondary Ο. 20 efficacy endpoint was also negative, correct?
- MR. WISNER: Let's go off the record.

I'd have to just see the results to

THE VIDEOGRAPHER: We are now off the

confirm that.

Α.

21

22

record. The time is 12:05. 1 2 (Brief recess.) 3 THE VIDEOGRAPHER: We are now back on the record. The time is 12:07. 4 5 BY MR. WISNER: 6 Mr. Closter, all of the secondary 7 endpoints specified on Page 7 were, in fact, negative, 8 based on the information in this report, correct? 9 Yeah, based on the analyses that are presented here in mostly table form and some in graph 10 11 form, I would confirm that. 12 0. Thank you. 13 (Document marked for identification as 14 ForestC Deposition Exhibit No. 11.) 15 BY MR. WISNER: 16 Okay. I'm handing you a document that's 17 been marked as Exhibit 11. 18 Are you familiar with this document? 19 Α. I am. 20 What is this document? Ο. 21 It's a brief report that was published, Α. 22 which includes the results of Lundbeck Study 94404. 23 0. And this document was published in 2006, 24 correct?

1 Α. Correct. 2 Ο. The final study report was completed, 3 however, on March 21st, 2002, right? 4 MS. THORNE: Objection. 5 THE WITNESS: Study report -- I know the 6 study period ended in April 23rd of 2001. 7 BY MR. WISNER: 8 Go back to the previous exhibit. If you Ο. 9 look at the bottom on the first page, report number and 10 date, March 21st, 2002. 11 Do you see that? 12 Α. Yes. 13 So the study report was completed on Q. 14 March 21st, 2002, right? 15 MS. THORNE: Objection. 16 THE WITNESS: 17 BY MR. WISNER: Why did it take so long for the results 18 Ο. of this study to be published in a journal? 19 20 MS. THORNE: Objection. That's outside 21 the scope of the 30(b)(6) notice, so to the 22 extent that Mr. Closter can answer the question 23 based on his own personal knowledge and not on

the information given to him by counsel, he can

24

```
To the extent that the only information
 1
             do so.
             that he has on that topic he has from counsel,
 2
             he should not answer the question in either his
 3
 4
             personal knowledge or his capacity as a
 5
             30(b)(6) witness, but I instruct you not to
 6
             answer this question on behalf of the company.
                    THE WITNESS: So the question.
 7
    BY MR. WISNER:
 8
 9
                    The question is still pending, sir.
10
             Α.
                    So, in my personal knowledge, I don't --
11
     I don't know why it took so long. This study wasn't
12
     conducted by Forest, so I'm not sure why it took them
    so long to publish it.
13
14
                    Isn't it true that actually Lundbeck
15
     investigators were eager to publish this study back in
     2002?
16
17
                    MS. THORNE: I renew my objection.
18
             Again, testimony is in your personal capacity.
19
                                  I don't know the answer to
                    THE WITNESS:
20
             that question.
21
                    (Document marked for identification as
22
             ForestC Deposition Exhibit No. 12.)
23
    BY MR. WISNER:
24
                    Handing you a document I've labeled as
             0.
```

- 1 Exhibit 12.
- 2 Mr. Closter, have you seen this document
- 3 before?
- 4 A. I don't believe I've seen this exact
- 5 one, no.
- 6 Q. This appears to be an e-mail exchange
- 7 between William Heydorn and Kerstin Fredricson Overo.
- 8 Do you see that?
- 9 A. Yes.
- 10 Q. And if you look down at the bottom of
- 11 the page, you can see that Kerstin's e-mail address is
- 12 at Lundbeck.com.
- Do you see that?
- 14 A. I do.
- 15 Q. All right. The beginning of -- this is
- an e-mail string, so you have to read from the bottom
- 17 up, okay?
- 18 A. Sure.
- 19 Q. Okay. So the first e-mail reads "Bill,
- 20 hope this finds you well. I just wanted to check on
- 21 the status of the Wagner pediatric manuscript. Last I
- 22 heard Forest was discussing journals, but I assume it
- 23 has been submitted by now? The reason I ask is that
- investigators in the Lundbeck sponsored study seem

```
eager to submit a manuscript of their -- on their
 1
     study. They are working on it. We have not yet seen
 2
    any draft, and I wanted to make sure that the positive
    data are in the public domain before their negative
 4
 5
    data get out.
 6
                    Do you see that?
 7
             Α.
                    Yes.
 8
                    It appears that an individual from
             Q.
 9
    Lundbeck has e-mailed Mr. Heydorn and has indicated
10
     that the investigators at Lundbeck were eager to submit
11
     an manuscript on Study 94404, correct?
12
                    MS. THORNE: Objection. This document
             is outside the scope of the 30(b)(6), so to the
13
14
             extent that Mr. Closter can answer the question
15
             based on his personal knowledge, he may do so,
16
             but he's not testifying on behalf of the
17
             company.
18
                    THE WITNESS: And your question was
19
             exactly?
20
                    MR. WISNER: Repeat the question.
21
                    (The court reporter read back the record
22
             as requested.)
23
                    THE WITNESS:
                                  Yeah, that's correct,
24
             that's what the -- how the e-mail reads.
```

```
1
    BY MR. WISNER:
 2
             Ο.
                    Based on your personal knowledge at the
 3
     company, do you know why -- sorry.
 4
                    Later on in the e-mail she says, I
 5
    wanted to make sure that the positive data are out in
     the public domain before the negative data get out;
 6
     that's how it reads, right?
 7
 8
             Α.
                    Yes.
 9
                    Isn't it true that Forest -- isn't it
10
    true that Forest wanted to delay the publication of any
11
    negative pediatric data for Celexa while simultaneously
12
    promoting the positive data from MD-18?
13
                    MS. THORNE: Objection.
14
                    THE WITNESS: I can't agree with that
15
             statement.
16
    BY MR. WISNER:
17
                    Isn't it also true that the positive
             Ο.
    data being out in the marketplace before the negative
18
19
    data would have helped increase Celexa sales?
20
                    MS. THORNE:
                                 Objection.
21
                    THE WITNESS: Yeah, I don't agree with
22
             that statement either.
```

Golkow Technologies, Inc.

BY MR. WISNER:

0.

23

24

Why don't you agree with that statement?

I mean, the study, first of all, wasn't 1 Α. going to be promoted. There's already use of all these 2 3 drugs, Celexa, ultimately Lexapro and other drugs in the class in a variety of patients, including the 4 5 pediatric population, even in the absence when none of the products had an indication, so I don't believe it 6 7 would have had any -- any impact. 8 Are you familiar with Bill Heydorn? Q. 9 Α. I know Bill. 10 Who is he? 0. 11 He left the company some time ago. I Α. believe he was on the medical affairs team that 12 13 supported the antidepressants. 14 Was he at Forest -- in 2002 were you Ο. 15 working at Forest? 16 Α. Yes. 17 Q. In what capacity? 18 I was on the Lexapro marketing team. Α. 19 Okay. Did you have any interactions Ο. 20 with Mr. Heydorn regarding the publications of Study 18 21 or 94404? 22 MS. THORNE: Objection. I'm just making 23 clear for the record that when you say you in 24 this instance, I assume you're referring to

```
Mr. Closter.
 1
 2
                   MR. WISNER: Yes.
 3
                   THE WITNESS: I did not.
 4
    BY MR. WISNER:
 5
            Q.
                   You are -- are you familiar with Irvin
 6
    Gergel?
 7
                   MS. THORNE: I'm renewing that
 8
            clarification until you indicate that you're
 9
            asking him questions on behalf of the company
10
            again.
11
                   MR. WISNER: Sure.
12
                   THE WITNESS: I know Ivan Gergel.
13
    BY MR. WISNER:
14
            Q. Does Forest know Ivan Gergel?
15
            A.
                   Yes.
            Q.
16
                  Does Forest know Charlie Flicker?
17
            Α.
                   Yes.
                   And do you personally know Charlie
18
            Q.
19
    Flicker as well?
20
            A.
                   I do.
21
                    (Document marked for identification as
22
            ForestC Deposition Exhibit No. 13.)
23
    BY MR. WISNER:
24
            Q. Okay. I'm handing you a document that
```

- 1 has been marked as Exhibit 13 to your deposition. This
- is an excerpt of the deposition of Bill Heydorn, okay.
- 3 This was taken on August 29th, 2007, okay?
- 4 A. Okay.
- 5 Q. Now, if I can draw your attention to
- 6 Page 77 -- sorry -- it's Page 3 on the top right, but
- 7 it's 77 in the deposition itself.
- 8 A. Got it.
- 9 Q. On Line 23 I'm just going to read along
- 10 for a bit, and then I'm going to ask you some
- 11 questions. The question was were you aware of anyone
- 12 at Forest Labs who shared the view it would be best if
- 13 the positive data of CIT 18 was in the marketplace
- 14 before the negative data of 94404 was put in the
- 15 marketplace. Objection. Answer --
- 16 A. Where are you reading from? I just want
- 17 to --
- 18 Q. It goes from the top to the bottom, it's
- 19 kind of weird 77, 78, 79, 80?
- A. All right. And you're starting on line?
- Q. Starting on Line 23 on Page 77.
- 22 A. Okay, thank you.
- 23 O. So I'll read that again.
- Were you aware of anyone at Forest Labs

who shared the view that it would be best if the 1 2 positive data of CIT 18 was in the marketplace before 3 the negative data of 94404 was put in the marketplace? 4 Objection. 5 Answer, yes. 6 Question, and who did you understand to 7 share that view? 8 Objection to form. 9 Answer, I think most of the individuals 10 associated with the citalogram project held that view. 11 Question, would that include Dr. Gergel? 12 Yes. 13 Question, and Dr. Flicker? 14 Answer, yes. 15 And would that include yourself? 16 Answer, yes. 17 Question, and why was it that you would have preferred at the time that the positive data be 18 put in the public domain before the negative data of 19 944 was put in that domain? 20 21 Answer, clearly from the company's 22 perspective, having the positive data published was a 23 positive move for the compound. At the same time 24 generating a publication and getting a publication on

- 1 negative data in the public domain is a bit
- 2 challenging. There are investigators who are not
- 3 interested in publishing negative data in many cases
- 4 and it's difficult to get journals to publish negative
- 5 data.
- I'm going to skip down to Line 23 on
- 7 that page.
- 8 A. Okay.
- 9 Q. This question, and that -- okay, Line
- 10 22 -- sorry, Line 23. And that positive data put out
- in the marketplace over negative data will do better
- 12 for the sales of Celexa?
- Objection to form.
- Answer, I certainly wasn't in sales and
- 15 the marketing department -- and marketing department,
- 16 but that would be my understanding, yes.
- 17 Do you see that?
- 18 A. Yes.
- 19 Q. Do you have any reason to believe that
- 20 Mr. Heydorn was lying under oath in his deposition?
- MS. THORNE: Objection. That's outside
- the scope of the 30(b)(6) deposition notice.
- We agreed to put forth a witness to testify on
- the contents of the publications, not the

circumstances surrounding their publication. 1 So to the extent that Mr. Closter has personal 2 3 knowledge as to whether Mr. Heydorn was lying or any other circumstances surrounding the 4 5 publication, he can testify to those to the 6 extent that he has that knowledge, but he 7 cannot testify on behalf of the company. 8 So I'm going to instruct you not to 9 testify on behalf of the company. 10 BY MR. WISNER: 11 Ο. Hard to remember the question after all 12 that, right? 13 Α. So the question is was Mr. Heydorn 14 lying, right; was that your question? 15 Do you have any reason to believe O. 16 that Mr. Heydorn was lying in his deposition? 17 I have no idea. Α. Okay. Did you work closely with 18 Q. 19 Dr. Gergel or Dr. Flicker? 20 MS. THORNE: Objection. Again, this is 21 in Mr. Closter's individual capacity? 22 MR. WISNER: 23 THE WITNESS: At times. 24 BY MR. WISNER:

- 1 Q. And previously you testified on behalf
- 2 of Forest earlier in this deposition --
- 3 A. Right.
- 4 Q. -- that the existence of positive data
- 5 and the nonexistence of negative data would not have an
- 6 impact on sales.
- 7 Do you recall that testimony?
- 8 MS. THORNE: Objection. The testimony
- 9 speaks for itself.
- THE WITNESS: Yes.
- 11 BY MR. WISNER:
- 12 Q. You would agree that Dr. Heydorn
- disagrees with you in his testimony here, correct?
- MS. THORNE: Objection.
- 15 THE WITNESS: I don't know. He's not
- responding to my theory or my assertion
- 17 directly.
- 18 BY MR. WISNER:
- 19 Q. Well, the question was asked, and that
- 20 positive data being put out in the marketplace over
- 21 negative data would be better for the sales of Celexa?
- 22 And the answer is, I certainly wasn't in sales and
- 23 marketing department, but that would be my
- 24 understanding, yes.

1 Do you see that? 2 Α. Yes. So he's saying that he does believe it 3 Ο. would have an impact on sales and marketing? 4 5 MS. THORNE: Objection. BY MR. WISNER: 6 7 Q. And you testified a minute ago that you 8 do not believe it would have one, correct? MS. THORNE: Objection, mischaracterizes 9 10 the testimony. 11 THE WITNESS: Yeah, I can't speak to the 12 testimony of Mr. Heydorn. BY MR. WISNER: 13 14 It's right in front of you, Mr. Closter. 0. 15 I can't speak to his assertions or Α. 16 really what he intended here. 17 Q. But you'd agree with me that his testimony contradicts what you just testified on behalf 18 19 of Forest a few minutes ago? 20 MS. THORNE: Objection. The witness 21 already testified he can't answer the question. 22 THE WITNESS: I can't answer the 23 question. 24 BY MR. WISNER:

```
You can't answer whether or not this
 1
             Ο.
     testimony in front of you contradicts what you said a
 2
 3
     second ago?
 4
                    MS. THORNE: Objection, asked and
 5
             answered.
 6
    BY MR. WISNER:
 7
             O.
                    Sorry, what's your answer, Mr. Closter?
 8
             Α.
                    I can't answer.
 9
             Ο.
                    You can't answer that question?
10
             Α.
                    No.
11
             Q.
                    Okay. Now, isn't it true -- you can put
     that testimony of Dr. Heydorn away.
12
13
             Α.
                    Sure.
14
                    Isn't it true that according to the
             Q.
15
    publication that I showed you, which I believe was
    Exhibit --
16
17
                    MS. THORNE: Eleven.
18
    BY MR. WISNER:
19
                    -- eleven.
             Ο.
20
             Α.
                    Should I pull it out?
21
                    That was -- sure, if you need to to
             0.
22
    answer the question. It was not even submitted for
23
    publication until December 2004; isn't that right?
24
                    MS. THORNE: Objection. Again, we
```

agreed to put forth a witness to testify to the 1 contents of the publication, not the 2 circumstances surrounding their publication. 3 So to the extent Mr. Closter has personal 4 5 knowledge, he can speak to it. 6 I'm going to instruct you not to answer 7 on behalf of the company. BY MR. WISNER: 8 9 I direct you to the first page of the document where it says when it was submitted, it's on 10 the face of the document, so I'll ask the question --11 12 MS. KIEHN: It speaks for itself. 13 BY MR. WISNER: 14 So I'll ask you the question again, Ο. 15 isn't it true that the document was not submitted until 16 December 21st, 2004? 17 Α. That's when it says it was received. 18 Okay. And that was approximately two Ο. and a half years after the completion of the final 19 20 study report? 21 MS. THORNE: Objection. I reiterate my 22 objection. 23 THE WITNESS: Yeah, so the time frame is 24 from March '02 to December of '04 when it was

received, approximately two and a half years. 1 BY MR. WISNER: 2 3 0. Okay. Isn't it true that the reason why the manuscript was not submitted for publication until 4 5 December of 2004 is because Forest was deliberately trying to conceal the results of Study 94404 from the 6 7 public domain? 8 MS. THORNE: Objection. I renew my 9 objection. Same instruction to the witness. 10 THE WITNESS: Yeah, my personal 11 experience, it's not true. 12 BY MR. WISNER: Okay. And you're testifying --13 0. 14 MR. WISNER: Your position is that he 15 cannot testify about whether or not Forest 16 deliberately tried to conceal the results of 17 94404 from the public domain? 18 MS. THORNE: My position is that we put 19 forth a witness to testify as to the contents 20 of the publications, not the circumstances 21 surrounding their publication. That's what you 22 agreed to, that's what we agreed to. 23 MR. WISNER: So you're instructing him 24 not to answer that question? Do you want me to

file another motion to compel? 1 MS. THORNE: We'll allow the witness to 2 3 answer this particular question. 4 BY MR. WISNER: 5 Q. Mr. Closter, isn't it true that Forest 6 deliberately attempted to conceal the distribution of 7 the contents of 94404 from the public domain? 8 Not that I'm aware of. Α. 9 Okay. Isn't it true, though, that it 10 wasn't until the New York Times issued an exposé of Forest criticizing its failure to disclose the results 11 12 of 94404 that this manuscript was ever submitted for publication? 13 14 MS. THORNE: Objection. 15 THE WITNESS: My understanding is that 16 as part of that article in the New York Times, 17 we did issue -- or at least disclosing the information. 18 BY MR. WISNER: 19 20 0. Fair enough, but my question was a 21 little more specific, and that was isn't it true that 22 Forest -- sorry, strike that. 23 Isn't it true that 944 was not submitted

for publication until after the New York Times issued

24

```
an exposé criticizing Forest for failing to disclose
 1
    94404 to the medical community?
 2
 3
                   MS. THORNE: Objection.
 4
                    MR. WISNER: Just let me finish my
 5
            question, please.
 6
                    MS. THORNE: I thought you were done.
 7
            It was a long question.
 8
                    THE WITNESS: I'd have to look at the
 9
            timing of the events from the New York Times
10
            article to when the article was -- or the brief
            report was submitted to the journal by
11
12
            Lundbeck.
13
                    (Document marked for identification as
14
            ForestC Deposition Exhibit No. 14.)
15
    BY MR. WISNER:
16
            Q. Sure. I'm handing you a document that's
    Exhibit 14 to your deposition. This is a copy of The
17
18
    New York Times article, correct?
19
                   MS. THORNE: Objection, vague, outside
20
            the scope.
21
                    THE WITNESS: It is a New York Times
22
            article.
23
    BY MR. WISNER:
24
            Q. Okay. The one that we were just talking
```

```
about that was published in The New York Times related
 1
    to this issue, this is a copy of that article, correct?
 2
 3
                    MS. THORNE: Objection.
 4
                    THE WITNESS:
                                  Okay.
 5
    BY MR. WISNER:
 6
                    That's correct, right; this is a copy of
             O.
 7
    it?
 8
                    MS. THORNE: Objection.
 9
                    MS. KIEHN: You need to look at it.
10
                    THE WITNESS:
                                  Appears to be.
11
                    MS. THORNE: And, also for the record,
12
             the two of you were not just talking about it.
13
             You were characterizing a New York Times
14
             article in your question, so if you would like
15
             to tell the witness that this is the article
16
             you were referring to in your question, you can
17
             do that.
18
    BY MR. WISNER:
19
                    So, Mr. Closter, this is dated
             Ο.
    June 21st, 2004, correct?
20
21
             Α.
                   Correct.
22
             Q.
                    All right. The submission of the
23
    manuscript did not occur until December of 2004,
```

correct?

24

- That's when Lundbeck submitted it, yes. 1 Α. So it would appear, based on the 2 O. documents in front of you, that the manuscript was not 3 submitted for publication until after the New York 4 5 Times article came out, correct? 6 MS. THORNE: Objection. 7 THE WITNESS: Yeah, the timing suggests 8 that. 9 BY MR. WISNER: 10 Ο. And isn't it true that the only reason 11 Forest agreed to allow Lundbeck to publish the 12 manuscript 94404 was because the cat was out of the bag because of The New York Times? 13 14 MS. THORNE: Objection. 15 THE WITNESS: Yeah, I don't believe 16 that's true. 17 BY MR. WISNER: 18 Ο. Okay. Isn't it true that prior to the publication of The New York Times article, Forest had 19 20 no plan or publication plan specifically designed to
- 22 journal?
- MS. THORNE: Objection.
- THE WITNESS: Two things. One is it's

have the results of 94404 published in a medical

21

1 not our study, it's a partner study. Second is I'd have to look back at the plans that you 2 3 refer to and see what was mentioned, and I haven't -- I have not seen those. 4 5 BY MR. WISNER: 6 Well, we just looked at an e-mail 7 between Bill Heydorn and someone from that partner, the 8 Lundbeck company, correct? 9 Α. Correct. 10 Q. And in that e-mail she is saying that 11 the investigators at Lundbeck are eager to get this manuscript submitted, correct? 12 13 MS. THORNE: Objection. 14 THE WITNESS: That's what the e-mail 15 stated. 16 BY MR. WISNER: 17 And that's back in 2002, right? Q. MS. THORNE: Objection. Would you like 18 19 the witness to look at the document? 20 MR. WISNER: If he needs to. He can 21 answer the question if he can answer the 22 question. 23 THE WITNESS: Yes, late November 2002. 24 BY MR. WISNER:

So in late November 2002, Mr. Heydorn is 1 0. 2 getting a request about an eagerness of the Lundbeck 3 researchers to submit this manuscript --4 MS. THORNE: Objection. 5 MR. WISNER: I'm not done with my 6 question. 7 BY MR. WISNER: 8 Q. -- and it doesn't get submitted until 9 December of 2004, correct? 10 MS. THORNE: Objection, mischaracterizes 11 the document. 12 THE WITNESS: That's when the 13 publication was submitted for review, yes. 14 BY MR. WISNER: 15 And you'd agree in testifying to this Ο. 16 jury that that e-mail from Mr. Heydorn suggests that Forest had at least some control over the publication 17 schedule of Lundbeck? 18 19 MS. THORNE: Objection, mischaracterizes 20 the document, assumes facts not in evidence. 21 THE WITNESS: Yeah, there's a lot of 22 data that supports including multiple studies across multiple indications, that then feed 23 24 into a publication plan. So when you say there

```
were no plans to disseminate it, you need to
 1
 2
             see the plans, and I wouldn't characterize a
             three line e-mail between colleagues from one
 3
 4
             company to the other to give even a hint as to
 5
             what the plans are around the publication of a
 6
             study, let alone all the data that exists
 7
             supporting a drug.
 8
    BY MR. WISNER:
 9
                   Celexa Study 18 was issued in a press
     release before the final study report was ever
10
     completed; isn't that true?
11
12
                    MS. THORNE: Objection.
13
                    THE WITNESS: I'd have to see the
14
             timing.
15
                    (Document marked for identification as
16
             ForestC Deposition Exhibit No. 15.)
    BY MR. WISNER:
17
                    I'm handing you a document that's been
18
             Ο.
19
    marked Exhibit 15.
20
                    Are you familiar with this document?
21
    Let me clarify because it might be a little confusing
22
    at first glance. This is the protocol for MD-18.
23
                    Do you see that?
24
                    MS. THORNE: Objection, that is
```

inaccurate. This is an excerpted form of the 1 2 protocol. It does not contain every page of 3 the protocol. It omits sections. 4 MR. WISNER: Okay. Sorry. 5 BY MR. WISNER: Mr. Closter, this is an excerpt of 6 7 MD-18's protocol, correct? 8 And if you say it is. I mean, I've seen Α. 9 parts of this, but it doesn't say protocol, but I'll 10 take your word for it. 11 Q. Turn to the second page. 12 Α. Okay. Final Protocol Authorization Sign-off 13 Q. 14 Sheet, you see there? 15 Α. Yes. 16 Bunch of signatures, right? Q. 17 Α. Yes. Paul Tiseo? 18 Q. 19 Paul Tiseo. Α. 20 Ο. Tiseo. Thank you. 21 MS. THORNE: Objection. This is outside 22 the scope of the 30(b)(6) deposition notice. 23 Let's go off the record. MR. WISNER: 24 We are now off the THE VIDEOGRAPHER:

record. The time is 12:29. 1 2 (Discussion off the record.) 3 THE VIDEOGRAPHER: We are now back on 4 the record. The time is 12:32. 5 BY MR. WISNER: 6 So I believe the question I asked you 7 that was objected to and we hadn't gotten a response 8 was this was signed by Paul Tiseo in September 1st, 9 1999; is that right? 10 Α. Yes. 11 Ο. Okay. And that's because that's what it says right here in this document, right? 12 13 Right. Α. 14 Okay. Now, it always says "Authorized Q. 15 By." 16 Do you see that? 17 Α. Yes. And there's a bunch of other names 18 Q. 19 listed here as well, right? 20 Correct. Α. 21 The first name is actually Charles 0. 22 Flicker, Ph.D. 23 Do you see that? 24 Α. Yes.

1 Q. Who is Charles Flicker? 2 At the time he was the medical director **A**. 3 on the CNS group. What would his responsibilities involve 4 Q. to the best of your knowledge personally? 5 6 To the best of my knowledge, you know, **A**. conducting clinical trials, making sure they were 7 8 proceeding as planned, reviewing some of the documents that would, you know, be developed as a result of a 9 10 clinical trial. 11 Q. Like, for example, a final study report? 12 **A**. Yes. 13 Okay. Lawrence Olanoff is also listed Q. 14 here. 15 Do you see that? 16 **A**. Yes. 17 And he was the executive vice president Q. of scientific affairs at that time? 18 19 **A**. Right. 20 Do you generally know what his **O**. 21 responsibilities were personally? 22 **A**. I believe at the time he was head of all 23 the R&D activities at the company. 24 Q. Okay. And then Ivan Gergel, who is he?

- A. Similar, from what I recall, he reported
- 2 to Larry and Charles Flicker reported to Ivan. So
- Ivan, I believe, at the time oversaw all the programs,
- 4 including CNS and other programs that we had ongoing at
- 5 the company.
- Now, correct me if I'm wrong, I'm not
- 7 trying to mischaracterize your testimony, but would it
- 8 be fair to say that at the top of the pyramid for these
- 9 three people, it would be Dr. Gergel, then Dr. Olanoff
- and then Dr. Flicker?
- 11 A. No. It would be Dr. Olanoff, Dr.
- Gergel, Dr. Flicker.
- Q. Okay. Sorry. Thank you.
- 14 And then who are these other two people,
- 15 Edward Lakatos?
- 16 A. I believe he was in the stats
- 17 department.
- 18 Q. Okay. Did you know him personally?
- 19 A. I can't recall. Yeah, I don't know.
- 20 O. And Keith Rotenberg, do you know who
- 21 that is?
- 22 A. Only by what it says on the page, that
- 23 apparently he was in regulatory affairs, perhaps the
- 24 head of regulatory affairs, I don't know.

Okay. And you don't know either Edward 1 Ο. 2 or Keith personally, correct? 3 Α. Keith I don't. Edward it was a long 4 time ago, perhaps I do, but it's too long to remember. 5 Q. All right. Do you know what Mr. Flicker's responsibilities were with regards to 6 Study 18 at that time? 7 8 No, not specifically. 9 0. But he was overseeing -- would be overseeing the clinical trials related to 10 antidepressants, correct? 11 12 MS. THORNE: Objection. 13 THE WITNESS: I believe that's true. 14 BY MR. WISNER: 15 Ο. All right. On Page 6 here, there's the objective of the clinical trial -- sorry, Page 3. 16 felt my own mistake there. Page 3, Section 5 it says 17 Objective. 18 19 Do you see that? 20 Α. Yes. 21 And would it be fair to say that the 0. 22 objective of this clinical trial was to measure the 23 efficacy and safety of citalogram in treating both

children and adolescents with major depressive

24

disorder? 1 2 That's what it says on the page. 3 Ο. Okay. That's, in fact, what the purpose of the study was, correct? 5 Α. That's the objective, the primary 6 objective. 7 All right. It says Study Design and O. 8 Duration -- well, skip that. We'll move it on. 9 All right. Turn to Page 4. 10 Α. Okay. 11 Ο. Here there's a section that says 12 "Primary Efficacy Measure." 13 Do you see that? 14 Α. I do. 15 And then there's also groupings of 0. 16 "Secondary Efficacy Measures." 17 Do you see that? I do. 18 Α. 19 Would it be fair to say that there is Ο. one primary efficacy measure and four separate 20 21 secondary efficacy measures specified in this protocol? 22 Α. One primary -- one, two, three -- yes. 23 Ο. Okay. I want to draw your attention to 24 Page 5 under the Section 9.2 "Dosing Regimen."

```
1
                    Do you see that?
 2
             Α.
                    Yes.
 3
             O.
                    All right. It says, "Patients who meet
     all of the eligibility criteria at the end of the
 4
 5
     single-blind lead-in period (Baseline visit) will be
 6
     assigned a randomization number and dispensed the
 7
     corresponding bottle of study medication for Week 1 of
 8
    double-blind treatment."
 9
                    And then the next paragraph reads, "At
10
     the end of Week 1, patients will return to the clinic
11
    bringing their unused study medication with them for
12
    drug accountability. Henceforth, patients must return
     their unused study medication at each clinic visit."
13
14
                    Tell me if I'm reading this correctly,
15
     at Week 1 after they've had their baseline visit,
16
     they're given a bottle of medication, are told to take
     it a certain amount each day, and then at the end of
17
    Week 1 they come back to the clinic and give them all
18
19
     the medication they have left over; is that fair to
20
     say?
21
                                 Objection. To the extent
                    MS. THORNE:
22
             you're asking for a detail that is not
23
             contained in the study report, I'm going to
24
             object to this as outside the scope, but to the
```

```
extent you're asking him to confirm what's in
 1
             the study report, I will let the witness answer
 2
 3
             the question.
 4
                    THE WITNESS: Yeah, that's what I'm
 5
             reading.
    BY MR. WISNER:
 6
 7
                    It says at the end of week visit -- the
             Ο.
 8
     first -- at the end of Week 1 visit, patients will be
 9
    dispensed another bottle, this time containing ten
10
     tablets of either placebo or active medication, and
11
     they will continue to take one tablet daily during Week
12
     2 of the study.
13
                    Do you see that?
14
             Α.
                    Yes.
15
                    So from my understanding of that, and
             Q.
16
     correct me if I'm wrong, after Week 1 they're given
     another bottle containing ten tablets and they take
17
     that and they come back at the end of Week 2?
18
19
                    MS. THORNE: Objection. I'm going to
20
             renew my objection with the same instruction.
21
                    THE WITNESS: That's what I'm reading
22
             off the paper.
23
    BY MR. WISNER:
24
                    And then at the end of Week 2 patients
             0.
```

- 1 will be dispensed two bottles of medication, each
- 2 containing ten tablets of either placebo or
- 3 20 milligrams citalopram and will be instructed to
- 4 continue taking one tablet daily during Weeks 3 and 4
- 5 of the study.
- 6 Do you see that?
- 7 A. Yes.
- Q. And then it specifies what happens at
- 9 the end of Week 4 and Week 6, they would be getting
- 10 dispensed one bottle containing 40 tablets of either
- 11 placebo or active medication.
- Do you see that?
- 13 A. Yes.
- 14 Q. So this dosing regimen part of the
- 15 protocol specifies at which point and at which visits
- 16 various patients will be dispensed either the drug or
- 17 the placebo pills, correct?
- MS. THORNE: Renewing my objection with
- 19 the same instruction.
- THE WITNESS: That's the way it reads.
- 21 BY MR. WISNER:
- Q. All right. Now, if you turn to Page 7
- 23 under "Statistical Evaluation," there's the
- 24 "Objectives" section.

1 Do you see that? 2 Α. Yes. 3 Ο. And then primary objective the last sentence reads, "The primary endpoint is change from 4 baseline and CDRS-R score at Week 8." 5 6 Do you see that? 7 Α. I do. 8 So isn't that saying that the primary Q. 9 endpoint is how much change has happened on the CDRS 10 score from the baseline and at the end of Week 8? Objection, renewing the 11 MS. THORNE: 12 same objection with the same instruction. 13 THE WITNESS: That's the way it reads. 14 BY MR. WISNER: 15 Ο. Okay. And then if you look at the 16 secondary objectives under 1 it has -- the second sentence reads, the endpoints for the secondary 17 objectives are the CGI-Improvement score, the change of 18 19 baseline and CGI-Severity score, K-SADS-P (depression 20 module) score and CGAS score at Week 8. 21 You see that? 22 Α. Yes. 23 Ο. So, again, the secondary endpoints are 24 being measured at Week 8, correct?

1 MS. THORNE: Renewing my objection with the same instruction. 2 3 THE WITNESS: Yes. I mean, there may be other time points they were evaluated, but it 4 5 does specify Week 8. BY MR. WISNER: 6 7 Ο. Okay. If you turn the next page on Page 8 under the efficacy analysis, well, look at the 8 9 primary efficacy analysis. Again, it says the primary 10 efficacy parameters is change from baseline in CDRS-R 11 score at Week 8 will be used at the primary efficacy 12 parameter. 13 Do you see that? 14 I do. Α. 15 So it's saying that the actual parameter Ο. 16 is at Week 8 there, correct? 17 Α. Yes. And then for the secondary efficacy 18 parameters it lists all the parameters there, and then 19 20 it says, "descriptive statistics will be calculated by 21 visit. Comparison between citalopram and placebo will 22 be performed using the same approach as for the primary 23 efficacy parameter." 24 You see that?

1 Α. Yes. 2 Ο. So, again, this is confirming that the secondary efficacy parameters are going to be measured at Week 8? 4 5 MS. THORNE: Objection to the extent that you're asking the witness to draw 6 7 conclusions that are not in this document and 8 that get into further detail, I'm going to 9 instruct the witness not to answer on behalf of 10 the company as it's outside the scope, but to 11 the extent you're asking the witness to confirm 12 what's written in the report, he can go ahead and do that. 13 14 THE WITNESS: I can confirm what's 15 written in the report. 16 BY MR. WISNER: 17 0. And that's what's written in the report, 18 correct? 19 MS. THORNE: Objection, mischaracterizes 20 the document. 21 THE WITNESS: Right. It says "using the 22 same approach as for the primary efficacy 23 parameter." It doesn't necessarily -- you're 24 asking does it say Week 8? It doesn't say Week

8. 1 2 BY MR. WISNER: 3 Ο. Okay. But it says the same efficacy 4 parameter, right? 5 Α. It says the same approach. 6 Ο. Okay. And the approach for the primary 7 efficacy analysis is -- will be used as the primary 8 efficacy parameter at Week 8, right? 9 MS. THORNE: Objection. Again, to the 10 extent you're are asking the witness to draw 11 conclusions, I'm going to instruct him not to 12 answer on behalf of the company, but he can 13 speak as to what's in the document. 14 THE WITNESS: It would appear that way, 15 but if you wanted to ask the person who wrote 16 the document, they'd be better than I would to 17 answer the question. 18 BY MR. WISNER: 19 So it's your testimony that you can't Ο. 20 testify on behalf of Forest right now about what the 21 secondary outcomes in MD-18 were to be measured at Week 22 8? 23 MS. THORNE: Objection. That completely mischaracterizes the witness' testimony. 24

1 MR. WISNER: I asked him a question. 2 MS. KIEHN: He already answered that 3 question. 4 MR. WISNER: And your objection is asked 5 and answered. 6 MS. THORNE: No, the objection is you 7 just mischaracterized the witness' testimony. 8 That's not what he said. 9 BY MR. WISNER: 10 Q. Okay. So I asked the question then; is 11 that true? 12 MS. KIEHN: Ask it again. 13 MR. WISNER: Can you read the question 14 back, please. 15 (The court reporter read back the record 16 as requested.) 17 MS. THORNE: Renew my objection. 18 THE WITNESS: Based on reading the 19 document, if the document suggests that the 20 same approach is for the primary efficacy 21 parameter is referring back to 12.5.1, which I 22 believe we're getting that information, 23 suggests that it would be at Week 8. 24 BY MR. WISNER:

- 1 Q. Okay. In preparing for to your
- 2 testimony today, did you look at the secondary
- 3 endpoints for Study 18?
- 4 A. In what way do you mean?
- 5 Q. Did you look at the results of the
- 6 secondary endpoints?
- 7 A. I looked at them at some point, either
- 8 in this abbreviated document or within the paper
- 9 itself.
- 10 Q. Okay. So you have actually looked at
- 11 the secondary endpoints, correct?
- 12 A. Yes.
- Q. Okay. And, finally, on Page 9, "12.7"
- 14 Sample Size Considerations, "do you see that section?
- 15 A. I do.
- 16 Q. It states that "The primary efficacy
- variable is the change from baseline CDRS-R score Week
- 18 8. Assuming an effect size (treatment group difference
- 19 relative to pooled standards deviation) of 0.5, a
- 20 sample size of 80 patients in each treatment group will
- 21 provide at least 85% power at an alpha level of 0.05
- 22 (two-sided)."
- Do you see that?
- 24 A. Yes.

Do you have any understanding of what 1 Ο. that paragraph means? 2 3 Not really. 4 Okay. You do understand generally, Ο. 5 though, that a study has to be sufficiently powered, 6 correct? 7 MS. THORNE: Objection. Are you asking 8 Mr. Closter in his individual capacity or in 9 his capacity as 30(b)(6)? BY MR. WISNER: 10 11 Q. You understand that Celexa Study 18 has 12 to be sufficiently powered, correct? 13 MS. THORNE: Objection. Are you asking 14 the witness in his individual capacity or in --15 MR. WISNER: Yes, I'm asking him as a 16 representative of Forest. 17 MS. THORNE: Okay. Well, then I object 18 to this as outside the scope of the deposition 19 notice. 20 MR. WISNER: I specifically specified 21 powering as the topic. 22 MS. THORNE: That's not what we agreed 23 to. MR. WISNER: Off the record. Can I see 24

```
the letter?
 1
 2
                    THE VIDEOGRAPHER: We are now off the
 3
             record. The time is 12:45.
 4
                    (Luncheon recess.)
 5
                    THE VIDEOGRAPHER: We are now back on
 6
             the record. The time is 1:29.
 7
                    (Document marked for identification as
 8
             ForestC Deposition Exhibit No. 16.)
 9
    BY MR. WISNER:
10
             Q.
                   Handing you a document marked Exhibit 16
11
    to your deposition. This appears to be a copy of
    excerpts of the final study report for study MD-18,
12
13
    correct?
14
                    It looks it. It doesn't say final on
             Α.
15
     it, but I'll take your word that it's final.
16
                    This was completed -- the study was
    completed in April of 2001, correct?
17
18
             Α.
                    Yes.
19
                    And this report was generated in April
             O.
20
    of 2002?
21
                   Yes.
             Α.
22
             Q.
                    All right. Turn to Page 7.
23
                    Are you there?
24
             Α.
                    Yes.
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- 1 Q. Under "Statistical Objectives," again,
- 2 this reads very similar to the protocol we looked at a
- 3 minute ago. You have the primary statistical objective
- 4 and the secondary statistical objectives.
- 5 Do you see that?
- 6 A. Yes.
- 7 Q. And, again, I want to focus first on the
- 8 secondary objectives, and then we'll go to the primary
- 9 ones, okay?
- 10 A. Okay.
- 11 Q. The secondary ones were listed in b, c,
- d and e in this document, they are CGI-S, CGI-I,
- 13 K-SADS-P and CGAS.
- 14 You see that?
- 15 A. Yes.
- MS. THORNE: For the record, there is
- also an A that pertains to the secondary
- objectives.
- 19 BY MR. WISNER:
- Q. Sure, but that's not specifically an
- objective, per se, right? That's just something that
- 22 characterizes the other four, correct?
- MS. THORNE: Objection.
- 24 BY MR. WISNER:

Mr. Closter? 1 Q. I mean, I don't know who wrote the 2 3 document. It would appear that that would -- you know, I wouldn't have indented it this way. 4 5 Q. Sure. There is a colon after A, right? 6 Α. Yes, it would appear that those four 7 are, you know, secondary statistical objectives to further compare the efficacy of citalogram and so on. 8 9 All right. Why don't you turn to Page Ο. 30 in the document. Towards the latter half of the 10 11 document it becomes tables so --12 Α. Yes. 13 -- it would be Page 30. Let me know Q. 14 when you're there. 15 Α. I'm there. 16 This reads Table 3.2, correct? Q. 17 Table 3.2. Α. And this is -- has a date on it, it's 18 Q. 19 generated October 30th, 2001? 20 Α. Yes. 21 And this states it's the "Secondary Ο. 22 Efficacy, CGI Improvement after 8 Weeks." 23 You see that?

Α.

Yes.

24

This is one of the secondary endpoints, 1 Q. 2 correct? 3 MS. THORNE: Objection. 4 THE WITNESS: As, you know, specified on 5 an earlier page, yes. BY MR. WISNER: 6 7 O. Okay. And here the P value for the 8 endpoint is 0.257? 9 Α. That's what it says on the page. That is not statistically significant, 10 Q. 11 correct? 12 MS. THORNE: Objection. 13 THE WITNESS: I mean, it's not indicated 14 as such on the page. 15 BY MR. WISNER: 16 Statistical significance is something 17 that's below .05, correct? 18 That's my understanding. Α. 19 That is not below .05, correct? 0. 20 A. Right. 21 Q. All right. Turn to the next table on the next page, Table 3.3. This is change of baseline 22 23 in CGI severity after 8 weeks.

You see that?

24

Α. Yes. 1 2 And if you look down again at Week 8 0. compared to baseline, the P value between citalogram 3 4 and placebo is .266. You see that? 5 6 MS. THORNE: Objection. 7 THE WITNESS: Yes. 8 BY MR. WISNER: 9 0. That is not statistically significant, 10 correct? 11 MS. THORNE: Objection. 12 THE WITNESS: It is not below .05, 13 right. 14 BY MR. WISNER: 15 0. Turn to the next page, Page 32, Table 3.4. 16 17 You see this? 18 Α. Yes. 19 This is another secondary efficacy 0. endpoint, correct? 20 21 A. Correct. 22 Q. This is change of baseline in CGAS after 23 8 weeks. 24 You see that?

1 Α. Yes. 2 O. And that also has a P value of .309. 3 You see that? 4 MS. THORNE: Objection. 5 THE WITNESS: That's what it says on the 6 page. 7 BY MR. WISNER: 8 Q. Okay. And that is not statistically 9 significant, correct? 10 MS. THORNE: Objection. 11 THE WITNESS: Correct. 12 BY MR. WISNER: 13 Q. All right. The last one here, Table 14 3.5. 15 You see it? 16 Α. Yes. 17 All right. That is a secondary efficacy Q. 18 as well endpoint? 19 A. Correct. 20 And, again, that has a P value of 0.105, 0. 21 correct? 22 Α. Right. 23 0. And that is also not statistically significant? 24

```
1
                   MS. THORNE: Objection.
 2
                   THE WITNESS: Right.
    BY MR. WISNER:
 3
4
            Q. So based on the results in these tables,
    none of the secondary endpoints reached statistical
5
    significance, correct?
6
7
                   MS. THORNE: Objection.
8
                   THE WITNESS: At Week 8, correct.
9
    BY MR. WISNER:
10
            Q. And the secondary endpoint was the
    difference between citalogram and placebo at Week 8,
11
12
    correct?
13
                   MS. THORNE: Objection.
14
                   THE WITNESS: Right.
15
    BY MR. WISNER:
16
            Q. All right. So none of the secondary
    endpoints as pre-defined in the protocol met
17
    statistical significance?
18
19
                   MS. THORNE: Objection.
20
                   THE WITNESS: That's right.
21
    BY MR. WISNER:
22
            Q. Turn to Page 14, Section "10.5 Efficacy
23
    Conclusions."
                   You see that?
24
```

I see it. 1 Α. 2 Ο. All right. Go to the second paragraph 3 in there, I'm going to read it to you. It says, significant differences, P value of less than 0.05, 4 5 indicative of greater improvement in citalogram patients -- let me read that again. 6 7 Significant differences, P value less 8 than 0.05, indicative of greater improvement in 9 citalopram patients than placebo patients were also observed in the CGI, CGS and CGAS. 10 11 Do you see that? 12 Α. Yes. Now, is it true, actually, that all of 13 Q. 14 the endpoints at Week 8 were not statistically 15 significant? 16 MS. THORNE: Objection. This is outside 17 the scope of the 30(b)(6) notice. To the extent that you're asking the witness to draw 18 19 conclusions comparing one portion of the study 20 report to another portion of the study report, 21 I'm going to object to him answering the 22 question. 23 THE WITNESS: Yeah, I mean, I'm not an 24 expert on the studies. I mean, you've shown me

1 a couple of pages in a study report of which I didn't write or review in as much detail as it 2 would take to draw conclusions. 3 4 BY MR. WISNER: 5 Q. All of the secondary negative endpoints were negative, correct? 6 7 MS. THORNE: Objection. 8 THE WITNESS: Based on what you showed 9 me in the document, those were negative. 10 BY MR. WISNER: 11 Okay. This first sentence here suggests 12 that they're indicative of significant greater improvement in citalogram relative to placebo patients, 13 14 doesn't it? 15 MS. THORNE: Objection, mischaracterizes 16 the document, and to the extent that you are 17 asking the witness to testify to your characterization of the document, that is 18 19 outside the scope of the 30(b)(6) notice, I'm 20 going to instruct him not to answer on behalf 21 of the company. He can answer on behalf of his 22 personal knowledge, if he has a view. 23 THE WITNESS: You know, personally 24 speaking, I don't know what this is exactly

referring to. You know, it doesn't say Week 8. 1 It doesn't reference secondary efficacy 2 3 parameters even leading into these parameters that were mentioned. 4 5 BY MR. WISNER: 6 Secondary efficacy parameters are CGI-I, 7 CGI-S and CGAS, correct? 8 MS. THORNE: Objection. 9 THE WITNESS: You know, as indicated 10 earlier in the document, they are. BY MR. WISNER: 11 12 Q. Okay. This sentence says that significant differences indicative of greater 13 14 improvement in citalogram patients than placebo 15 patients were also observed on those various metrics. 16 You see that? 17 MS. THORNE: Objection. That's not what 18 the document says. 19 THE WITNESS: I can read what's in the 20 document. 21 BY MR. WISNER: 22 0. That's what it says, right? 23 MS. THORNE: Objection. Significant differences 24 THE WITNESS:

indicative of greater improvement in citalogram 1 2 patients than placebo patients were also 3 observed on the following three measures. 4 BY MR. WISNER: 5 Q. Okay. Nowhere in that paragraph, and 6 you can feel free to read the rest of the paragraph, 7 does it ever state that all the secondary endpoints as 8 specified in the protocol were negative for efficacy? 9 MS. THORNE: Objection. 10 THE WITNESS: Yeah. I mean, I would 11 need to spend a moment to read the entire 12 paragraph if you're asking me to comment on it. 13 BY MR. WISNER: 14 Please read the entire paragraph and let Ο. 15 me know when you're done. 16 (Witness reviews document.) 17 Q. Sorry, Mr. Closter, I see you flipping through pages there. Are you through the paragraph? 18 19 MS. THORNE: Objection. 20 THE WITNESS: Well, I mean, there's 21 2,135 pages in this document. 22 BY MR. WISNER: 23 0. I'm sorry. I asked you to read that 24 paragraph.

1 Did you read the paragraph? 2 Α. That's fine. In order to --MS. THORNE: Objection. Are you saying 3 the witness is not entitled to see the context 4 5 of the document before answering your question? 6 MR. WISNER: No. I asked him to let me 7 know when he was done reviewing the paragraph, and I saw him flipping through pages, so I just 8 9 asked him if he's finished reviewing the 10 paragraph. 11 Right. So it helps me THE WITNESS: 12 when I'm going to review that paragraph, I need to see what comes before and what comes after 13 14 it and then what the document is, because, as I 15 mentioned, there's over 2,100 pages in the 16 original document, yet what's here I'm going to 17 imagine is maybe, you know, 15% of that. 18 So I'm sure some of them are tables, but 19 even some of the written report, I'm assuming, 20 is missing in places. So without seeing the 21 entire document, it's going to be difficult to 22 understand where exactly this fits in. 23 BY MR. WISNER: 24 Ο. Mr. Closter, my pending question to you

- 1 is have you finished reviewing that paragraph?
- A. And I have not.
- Q. Okay. So let me know when you're done
- 4 finishing reviewing that paragraph.
- 5 A. Absolutely. (Witness reviews document.)
- 6 Q. Mr. Closter, I'll just read you the
- 7 paragraph. I think that will be quicker.
- 8 The paragraph reads, significant
- 9 differences, P value less than 0.5 -- 0.05, indicative
- 10 of greater improvement in citalogram patients than
- 11 placebo patients, were observed on the CGI, CGIS and
- 12 CGAS. Statistically significant effects were not found
- as consistently across study timepoints for the
- 14 secondary efficacy parameters as for the primary
- 15 efficacy parameter, but numerically greater improvement
- in the citalogram group was observed on every efficacy
- 17 parameter at every clinic visit in both the LOCF and OC
- 18 analysis. Results from the LOCF and OC analysis were
- 19 similar.
- 20 Do you see that?
- 21 A. Yeah. I'm not going to be able to give
- 22 you commentary on this paragraph alone because the data
- 23 that precedes it is all relevant to my answer. So if
- 24 you'd like to expand my answer on the data that in this

section that is relevant to this paragraph, I'd be 1 2 happy to give you a read on from what I am reading, but 3 I am unable to give you an answer on just 10.5 because 4 it's incomplete. 5 Q. Okay. So my question for you, 6 Mr. Closter, is a relatively simple one, and that is in 7 that paragraph, does it state that every secondary 8 outcome specified in the protocol was negative for 9 efficacy? 10 Objection, misleading, MS. THORNE: 11 mischaracterizes the document. 12 THE WITNESS: Yeah, I mean, it doesn't -- here's the challenge, and I 13 14 encourage you to read what precedes this, 15 because I think you will come to the right 16 conclusion, that these efficacy conclusions are 17 that, they are summarizing the body of the efficacy results, and it's not just talking 18 19 about Week 8 because there were earlier time 20 points where all of these things were measured 21 at every study visit, and those are fully 22 described in the paragraphs leading up to this. 23 So this is merely a summary of what was 24 just presented, and I think you're going to

find that the data, from what I am reading, 1 2 this paragraph accurately characterizes that 3 data from my point of view, which is not of a clinician, which is of someone who has worked 4 5 in the business for quite some time and has 6 read these reports from time to time, which is 7 why I went back to read them, because any 8 sentence or paragraph in and of themselves 9 aren't going to give you the full picture. 10 BY MR. WISNER: 11 Mr. Closter, I appreciate your answer. 12 My question didn't ask for any of that. 13 Of course you didn't. Α. 14 My question simply asked whether or not Ο. 15 in that paragraph that I just read you it states that 16 the endpoints, the secondary endpoints at Week 8 were negative for efficacy? 17 18 MS. THORNE: Objection, misleading, 19 asked and answered. 20 You can answer the question, but you can 21 feel free to give a complete answer. 22 THE WITNESS: Yeah, I mean, I'm not 23 going to answer the question because it's -- in 24 my mind, it's not an appropriate question to

- 1 ask.
- 2 BY MR. WISNER:
- 3 Q. So you're refusing to answer my question
- 4 about whether something is contained in that paragraph?
- 5 A. I can tell you if something is contained
- or not, an actual sentence, but I'm not going to
- 7 interpret the sentence.
- Q. Okay. So you refuse to answer my
- 9 question whether or not in that paragraph it states
- 10 that the secondary endpoints at Week 8 were negative
- 11 for efficacy?
- MS. THORNE: Objection, misleading.
- 13 Your question is misleading.
- 14 THE WITNESS: Yeah, it does not
- literally say that.
- 16 BY MR. WISNER:
- 17 Q. Okay. Does it literally say that
- 18 anywhere in the entire efficacy conclusions written
- 19 here in the narrative starting on Page 11 through page
- 20 15, and I have given you the entire narrative that
- 21 contained in the final study report?
- 22 A. Yeah, I've read what's on Page 13, and
- 23 it talks about at certain data points the study did not
- 24 show statistical significant.

1 Please tell me what paragraph you're Ο. referring to? 2 3 Α. Okay. I'll start at 10.2.1. 4 Ο. Okay, second paragraph? 5 Α. I mean, okay, so it says significant improvement on CGI-S, second paragraph. 6 7 significant at earlier time points 1, 2, 4 and 6 but 8 not the end of Week 8, okay. So that's pretty clear to 9 me that it was not significantly -- statistically 10 significantly better than placebo at Week 8. 11 Okay. So let's stop right there. I Ο. 12 appreciate you saying that. Does it ever say that this was an -- the secondary endpoint was negative for 13 14 efficacy? 15 Objection. MS. THORNE: 16 THE WITNESS: No, but it's not 17 informative. It doesn't have to say that. mean, one can read the line and understand it 18 19 was not significant at Week 8. It says that. 20 BY MR. WISNER: 21 So you think a person reviewing this 22 couldn't get confused and think that the secondary 23 endpoints were, in fact, positive because it never once 24 says that the secondary endpoints are negative?

1	MS. THORNE: Objection.
2	THE WITNESS: Lucky enough, it's not
3	people like me or you that read these
4	documents, but it's people that are fully
5	trained in them, whether they're at a sponsor
6	company like Forest was at the time or at the
7	FDA. I mean, these are people that are very
8	smart, they have the right background, and they
9	are trained to understand and read documents
10	that are generated like this. This is the
11	format that the FDA wants them in.
12	BY MR. WISNER:
13	Q. So you'd agree with then that an FDA
14	reviewer won't get mixed up here in thinking that the
	reviewer won e gee mined up here in eniming ende ene
15	secondary endpoints were all positive?
15	
	secondary endpoints were all positive?
16	secondary endpoints were all positive? MS. THORNE: Objection.
16	secondary endpoints were all positive? MS. THORNE: Objection. THE WITNESS: I don't believe in my
16 17 18	secondary endpoints were all positive? MS. THORNE: Objection. THE WITNESS: I don't believe in my own experience, I do not believe they would be
16 17 18 19	secondary endpoints were all positive? MS. THORNE: Objection. THE WITNESS: I don't believe in my own experience, I do not believe they would be confused by and this is generally speaking
16 17 18 19 20	secondary endpoints were all positive? MS. THORNE: Objection. THE WITNESS: I don't believe in my own experience, I do not believe they would be confused by and this is generally speaking by this document.
16 17 18 19 20 21	secondary endpoints were all positive? MS. THORNE: Objection. THE WITNESS: I don't believe in my own experience, I do not believe they would be confused by and this is generally speaking by this document. MR. WISNER: Thank you. One second.

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1
                    (Pause.)
 2
                    THE VIDEOGRAPHER: We are now back on
             the record. The time is 1:46.
 3
                    (Document marked for identification as
 4
 5
             ForestC Deposition Exhibit No. 50.)
    BY MR. WISNER:
 6
 7
                  Mr. Closter, I'm handing you a
             0.
 8
    document -- unfortunately this is out of sequence, was
    planning to get to this later, but it's Exhibit 50 for
10
    this deposition.
11
             Α.
                   Okay.
12
                    This is a memorandum prepared by the
             0.
    Food and Drug Administration, specifically by Thomas
13
14
    Laughren.
15
                    Do you see that?
16
            Α.
                    Yes.
17
                    Okay. Now, if you just turn to Page 3
             Q.
    of the document. Page 3, if you go down, all the way
18
19
    down just before the paragraph that reads "Comment."
20
                    Do you see that paragraph?
21
                    Yeah.
            Α.
22
             Q.
                    It says, "Results also significantly
23
     favored citalogram over placebo in most secondary
24
     outcomes."
```

1 Do you see that? 2 Α. Yes. This is an FDA reviewer who has stated 3 Ο. 4 in his report that the results significantly favored 5 citalopram over placebo on most secondary outcomes, 6 when, in fact, every single secondary outcome was 7 negative pursuant to the protocol? 8 MS. THORNE: Objection. Are you asking 9 a question. Or are you testifying, counsel? 10 Was there a question? Because I didn't see a 11 question mark. 12 BY MR. WISNER: 13 Ο. Mr. Closter, I believe I have a question 14 pending, if you could answer, please. 15 I actually don't think you MS. THORNE: do have a question pending, so if you would 16 17 like to read back your statement and then ask correct at the end of it, feel free to do so, 18 19 but there is not a question pending. 20 MR. WISNER: Ms. Thorne, I'd ask you to 21 stop interfering with my deposition. I have a 22 question pending. Can you please answer it. 23 If you could please repeat the question. (The court reporter read back the record 24

1	as requested.)
2	MS. THORNE: So I don't see a question
3	there.
4	MR. WISNER: So isn't that true?
5	MS. THORNE: Okay. Now you want to
6	finish your question. So now I'll object to
7	your question as outside the scope of the
8	30(b)(6) deposition notice, because we didn't
9	put up a witness to testify as to what
10	Mr. Laughren believed or intended when he wrote
11	this document. So Mr. Closter can go ahead and
12	he can answer in his personal capacity, but
13	he's not going to answer this question on
14	behalf of the company.
15	THE WITNESS: You know, so in my own
16	opinion, I mean, you'd be best served asking
17	Dr. Laughren what he meant by that. Was he, in
18	fact, referring to the secondary endpoints at
19	Week 8? Was he referring to the study visits
20	over time, which were described usually as
21	descriptive statistics per the protocol? So I
22	don't know.
23	BY MR. WISNER:
24	Q. You would agree that it would be

```
incorrect to state that the secondary endpoints in
 1
 2
     citalopram Study 18 were positive?
 3
                    MS. THORNE: Objection.
 4
                    THE WITNESS: Again, I'm not the expert,
 5
             I don't participate in the trial. I'm
 6
             obviously not a clinical expert, so it would be
 7
             difficult for me to say that or not say that.
    BY MR. WISNER:
 8
 9
                    I'm sorry, Mr. Closter, a second ago you
    testified under oath that all the secondary outpoints
10
11
    were negative, correct?
12
             Α.
                    Based on the study report you showed me.
13
                    MS. THORNE: Objection.
14
                    MR. WISNER: I'm sorry. Are you done
15
             with your objection?
16
                    MS. THORNE:
                                 Yes.
17
    BY MR. WISNER:
                    Okay. So it would be incorrect then to
18
             Ο.
     say the opposite, i.e., that the secondary endpoints
19
20
    were positive, correct?
21
                    MS. THORNE: Objection, misstates the
22
             document to the extent you're referring to
23
             Mr. Laughren's document, it doesn't make any
24
             reference to the time point that he is
```

referring to, first of all. 1 Second of all, to the extent you are not 2 3 referring to the document and you are asking a hypothetical, that hypothetical is outside the 4 5 scope of the deposition notice, and I'm going to instruct the witness not to answer on behalf 6 7 of the company. 8 Mr. Closter, to the extent that you are 9 able to answer it in your personal capacity, 10 you can feel free to do so. 11 MS. KIEHN: Thirdly, the document makes 12 no reference to secondary endpoints. 13 THE WITNESS: Yeah, again, it's 14 difficult to know what he's referring to. 15 MR. WISNER: Please repeat my question. 16 (The court reporter read back the record 17 as requested.) 18 MS. THORNE: I'm going to renew my 19 objection, and I'm going to renew Ms. Kiehn's 20 objection, with the same instruction. 21 THE WITNESS: I really don't know how to 22 answer the question. 23 BY MR. WISNER: 24 I'm sorry, Mr. Closter, let's try this 0.

again. 1 2 Α. Sure. 3 Ο. You previously testified based on your review of the final study report on behalf of Forest 4 that all the secondary outcomes were negative, correct? 5 6 MS. THORNE: Objection, asked and 7 answered, misstates the testimony. 8 THE WITNESS: Right. Based on what you 9 shared with me in the tables from the redacted 10 report that you shared with me, we went over 11 each of those endpoints at Week 8. 12 BY MR. WISNER: 13 And they were all negative, correct? Q. 14 MS. THORNE: Objection. 15 THE WITNESS: Again, based on what I saw 16 the P values were all greater than .05. 17 BY MR. WISNER: So it would be incorrect then to state 18 0. 19 that those outcomes were positive, right? 20 Α. Again, if that's what Dr. Laughren is 21 referring to, but we don't know unless you ask him. 22 0. I'm not asking about Dr. Laughren right

I'm asking you, Mr. Closter.

And I'm saying I don't know.

Α.

23

24

```
So you don't know if it's incorrect to
 1
             Ο.
 2
     say all the secondary outcomes were positive?
 3
                    MS. THORNE: Objection, again, going to
             object to this as outside the scope to the
 4
 5
             extent that you're asking for -- that you're
 6
             posing a hypothetical. If you want to ask him
 7
             the outcomes of the secondary endpoints, we
 8
             have put up a witness who can speak to what the
 9
             outcomes of the secondary endpoints are, but if
10
             you want to phrase -- if you want to ask all of
             these misphrased questions and hypotheticals,
11
12
             that's outside the scope, Brent.
    BY MR. WISNER:
13
14
                    I believe I have a question pending,
             Ο.
15
    Mr. Closter.
16
             Α.
                    I told you three times now, I can't
17
     answer the question.
18
                    So you can't answer whether or not that
             Q.
    would be incorrect to say; that's your testimony,
19
20
     correct?
21
             Α.
                    Yes.
22
                    I want to make sure I get your answer.
             Q.
23
             Α.
                    Yes.
24
                    MS. KIEHN: You keep switching between
```

outcomes and endpoints. 1 2 MR. WISNER: If you could please make an 3 objection or not, but please stop coaching the witness. 4 5 MS. THORNE: Nobody is coaching the 6 witness. 7 MS. KIEHN: We want to make sure the 8 testimony is clear, which you are intent on 9 making sure it is not clear. 10 MR. WISNER: Please stop wasting my 11 time. 12 BY MR. WISNER: 13 Q. Can you please turn to Exhibit 16. 14 Α. Okay. 15 Okay. Isn't it true that Forest 0. contracted with a contract research organization 16 PharmaNet to help draft the initial draft of Celexa 17 Study 18 final study report? 18 19 MS. THORNE: Objection. I'm going to 20 object to that as outside the scope of the 21 30(b)(6) notice. 22 Mr. Closter, to the extent you have 23 personal knowledge on that topic you can 24 testify, but I'm going to instruct you not to

testify on behalf of the company. 1 2 THE WITNESS: I have no knowledge of 3 that. 4 MR. WISNER: Take a break. 5 THE VIDEOGRAPHER: We are now off the 6 record. The time is 1:53. 7 (Brief recess.) 8 THE VIDEOGRAPHER: We are now back on 9 the record. The time is 2:06. 10 BY MR. WISNER: 11 Mr. Closter, did you prepare today to 12 testify on behalf of Forest regarding how the protocol -- final study report for Study 18 was 13 14 drafted? 15 I don't know the steps by how it was Α. 16 drafted, no. 17 Q. You don't know who Forest may or may not have contracted with to generate the report? 18 19 I don't know. Α. 20 Do you know who had a hand in editing 0. 21 the report? 22 A. I am sure it would be those on the 23 clinical team. 24 Have you actually seen any of those 0.

edits? 1 2 Have I seen any edits to the report, no. 3 Ο. So you're not prepared to testify about any of that today; is that fair? 4 5 Α. Not regarding the edits or who we contracted with to draft the report. 6 7 Okay. You also understand that the Ο. plaintiffs have alleged that the primary efficacy 8 9 endpoint in the study was not, in fact, positive because we believe certain of those patients were 10 unblinded? Do you understand that, that's our 11 allegations? 12 13 MS. THORNE: Objection. 14 THE WITNESS: I'm aware that that is a 15 point of contention. 16 BY MR. WISNER: 17 Are you prepared today to testify about Q. the unblinding that occurred in Study 18? 18 19 MS. THORNE: Objection. I'm going to 20 object to that as outside the scope of the 21 30(b)(6) to the extent that you referred to an 22 actual unblinding. If you would like to 23 recharacterize your question, Mr. Closter can 24 testify on behalf of the company to high level

1	details regarding a potential unblinding issue.
2	MR. WISNER: While I hear you on this
3	objection, and I apologize for questioning you
4	and putting you on the spot, and if you don't
5	feel comfortable doing so, please let me know,
6	but I want to clarify what you're going to
7	object to because I want to know if I need to
8	end this deposition or not so or not address
9	this topic and wait for a court order
10	compelling it.
11	MS. THORNE: To the extent that you
12	would like to ask the witness about a potential
13	unblinding that plaintiffs perceive occurred,
14	you can ask him about high levels detail on
15	that. I will let you know if you get into a
16	level of detail that goes beyond the witness'
17	preparation, but he is able to testify to that
18	at a high level.
19	MR. WISNER: And when you say "a high
20	level," what does that mean.
21	MS. THORNE: I mean I'm not going to
22	testify I'm not going to put the testimony
23	on the record right now.
24	MR. WISNER: I have 400 questions about

1	the unblinding issue. Are you going to object
2	to all of them beyond the first one is did an
3	unblinding occur?
4	MS. THORNE: No.
5	MS. KIEHN: We agreed to general high
6	level details about the study, so that's what
7	we agreed to.
8	MR. BAUM: So who would we get to
9	testify about the more granular details on the
10	unblinding issue?
11	MS. KIEHN: Aren't you deposing Dr. Jin
12	for that very reason?
13	MS. THORNE: Yeah, didn't you already
14	move to compel like several deponents on that
15	issue, in fact?
16	MR. WISNER: No, I think it was just
17	Jin was for the statistics. I don't think he
18	has any information about the unblinding.
19	MR. BAUM: He has somewhat of an issue
20	with
21	MS. KIEHN: It's the same issues that
22	related. Do we want to go off the record?
23	MS. THORNE: Can we go off the record.
24	THE VIDEOGRAPHER: We are now off the
I .	

record. The time is 2:10. 1 2 (Brief recess.) 3 THE VIDEOGRAPHER: We are now back on the record. The time is 3:04. 4 5 BY MR. WISNER: 6 Ο. All right. Sorry for that delay, Mr. 7 Closter. 8 Α. No problem. 9 Ο. All right. So I want to just ask you 10 some sort of general questions about Study 18, to the 11 best of your knowledge, that you're prepared to testify 12 today. 13 Α. Yeah. 14 You understand that there was a Ο. 15 potential -- there was a dispensing error that occurred 16 with nine patients in Study 18, correct? 17 MS. THORNE: Objection. 18 I'm aware of patients THE WITNESS: 19 getting, I guess, the wrong colored tablets. 20 BY MR. WISNER: 21 And you know because you read that in 22 the study report, right? 23 Α. Yes. 24 So, to be clear, I just want to make Q.

```
sure this is clarified, your understanding of what
 1
    happened with the unblinding is based on what's
 2
 3
    contained in the study report; is that right?
 4
                    MS. KIEHN: Objection.
                                  I don't know if I'd
 5
                    THE WITNESS:
 6
            characterize it as unblinding. I think
 7
            patients just got the wrong color product.
 8
    BY MR. WISNER:
 9
            Ο.
                   Fair enough. I keep calling it
10
    unblinding. Should I say potential unblinding; is that
    better?
11
12
                   MS. KIEHN: Incorrect color coding.
13
                    THE WITNESS: Right, that's exact -- I
14
            mean --
15
                   MR. BAUM: Or how about subject to a
16
            dispensing error?
    BY MR. WISNER:
17
18
            Q. We'll just -- let's look at the language
19
    from the study report. I don't want to fight about
20
    this.
21
                   Just turn to Page 10.
22
            Α.
                   This is within -- so Exhibit 16, right?
23
            Ο.
                   Yeah.
24
            Α.
                    Just to make sure, okay. Page 10.
```

- 1 Okay. I'm there.
- Q. In the second paragraph it says, "nine
- 3 patients" and then it lists the patients' numbers.
- 4 You see that?
- 5 A. Yep, yep.
- 6 Q. "Were mistakenly dispensed 1 week of
- 7 medication with potentially unblinding information."
- 8 Do you see that?
- 9 A. Yes.
- 10 Q. So if I refer to this incident as
- 11 potentially unblinding information, is that okay?
- 12 A. Yeah, that's the way it's written, so
- 13 that's fine.
- Q. Okay. Now, you understand that the
- 15 plaintiffs have alleged that this is not a potential
- 16 unblinding but that it was, in fact, an unblinding of
- 17 these patients.
- Do you understand that?
- MS. THORNE: Objection.
- THE WITNESS: I understand that's the
- 21 assertion made.
- 22 BY MR. WISNER:
- Q. Okay. And Forest disagrees with that
- 24 assertion, correct?

1 MS. THORNE: Objection. 2 That is correct. THE WITNESS: BY MR. WISNER: 3 4 Ο. All right. Just looking at here this 5 list of patient numbers on Page 10, do you know which one of those patients got the wrong colored tablets? 6 7 MS. THORNE: Objection. 8 THE WITNESS: Do I know which of the 9 patients? 10 BY MR. WISNER: 11 Q. Yeah. 12 No, it just has a list of patients. Α. 13 Q. Okay. Did all of them get them; do you 14 know? 15 MS. THORNE: Objection. 16 THE WITNESS: If we read nine patients 17 they list the -- I guess the nine, one, two, three, four, five, six, seven, eight, nine, 18 19 were mistakenly dispensed 1 week of medication. 20 So it appears as though all nine were dispensed 21 the incorrectly colored tablets. 22 BY MR. WISNER: 23 Ο. Okay. I'm just a little confused. 24 just want to make sure I understand.

1 Some of these patients were actually in the placebo arm, right? 2 3 MS. THORNE: Objection. 4 THE WITNESS: I don't know. I couldn't 5 say for certain. BY MR. WISNER: 6 7 0. Okay. We'll save this for the 30(b)(6) 8 deposition witness with Mr. Olanoff. 9 So when I refer to -- okay. So let's 10 move on. 11 Shortly after the results of Study MD-18 12 were made known within Forest, Forest made plans to promote the results of the study; isn't that true? 13 14 MS. THORNE: Objection. THE WITNESS: Yeah, there were no plans 15 16 to promote the study results. Should I be 17 looking at a document right now? BY MR. WISNER: 18 19 No, no. I'm just asking you some 0. general questions. 20 21 Α. Okay. So I saw you read something. 22 So, no, there were no plans to promote 23 the results of the study. 24 MR. BAUM: Are we going to put something

1	C	on the record actually about what we're doing
2	V	with respect to these questions that are being
3	1	reserved for Olanoff or Jin or whatever?
4		MS. KIEHN: Brent, did you want to put
5	S	something on the record?
6		MR. WISNER: Yes, I would like to.
7		So my understanding is consistent to our
8	Ċ	discussions during the previous break, please
9	C	correct me where I'm wrong, we agreed that
10	F	Forest would designate Lawrence Olanoff, whose
11	Ċ	deposition is presently scheduled for
12	C	October 24th, to testify specifically in
13	1	regards to the details of the drafting of
14	S	study final study report of Study 18 and any
15	F	potential unblinding that occurred relating
16	r	potential unblinding that occurred relating to
17	t	that study in detail.
18		MS. KIEHN: To the extent the company
19	k	knows the responses or the information is
20	1	reasonably accessible to the company, yes.
21		(Document marked for identification as
22	F	ForestC Deposition Exhibit No. 33.)
23	BY MR. WI	ISNER:
24	Ç	Q. Handing you a document I marked as

```
Exhibit 33.
 1
 2
                    MS. THORNE: Sorry. For the record,
 3
             Brent, we're skipping --
 4
                    MR. WISNER: A lot of documents.
                    MS. THORNE: -- a lot of exhibit
 5
 6
            numbers, so just so the record is clear when we
 7
             look back at this transcript later, the last
 8
             exhibit in the record is Exhibit 16. We are
 9
            now on Exhibit 33.
10
                    MR. WISNER: That's correct.
11
    BY MR. WISNER:
12
             Q. So this is an e-mail exchange, appears
    at the top of it's dated October 15th, 2001.
13
14
                   Do you see that?
15
            Α.
                   Yes.
16
             Ο.
                   And this is to Paul Tiseo and it's from
    Jeffrey Lawrence.
17
18
                   You see that?
19
            Α.
                   Yes.
20
             0.
                   At least the top e-mail is?
21
             Α.
                   Yep.
22
             Q.
                   Okay. All right. If you look at the
23
    bottom, there is actually a series of e-mails and the
24
    original starts at the last page on Page 2, that's from
```

Jeffrey Lawrence to M. Prescott and N. Mitchner. 1 2 Do you see that? 3 Α. Yes. 4 Q. That's Mary Prescott and Natasha 5 Mitchner, right? 6 I believe so. Α. 7 Mr. Lawrence reads -- writes "Mary, Ο. 8 Natasha, I apologize, but I've forgotten some of the 9 details we've talked about with regards to the pediatric data and Karen Wagner. First of all, did we 10 11 decide who would be writing the manuscript? Have you 12 been in contact with Karen Wagner at all? As you know, we don't want to compromise the publication but we 13 14 would like to wrap some PR and CME around this data. 15 Let me know your thoughts when you get a chance, thanks." 16 17 Did I read that correctly? 18 Α. Yes. 19 Who is Jeff Lawrence? O. 20 Jeff Lawrence worked at Forest on the Α. 21 marketing team for Celexa. 22 Ο. So he was in the marketing group specifically on Celexa? 23

Α.

Correct.

2.4

And here he's writing in this e-mail 1 Ο. that he would like to wrap some PR and CME around the 2 3 pediatric data, correct? 4 MS. THORNE: Objection, asked and 5 answered. 6 THE WITNESS: That's what it says. It 7 looks like that's what he's referring to. 8 BY MR. WISNER: 9 Ο. Okay. So Mr. Lawrence then is actually contemplating conducting some promotional activities 10 around the publication of the pediatric data? 11 12 MS. THORNE: Objection. 13 THE WITNESS: Yeah, I mean, we would not 14 consider those promotional activities. 15 BY MR. WISNER: 16 0. What does PR stand for? 17 Public relations. Α. And PR isn't a form of promotional 18 Q. 19 activities? 20 We do not consider it promotional. Α. 21 What is PR then to you? 0. 22 Α. We consider it data dissemination, 23 nonpromotional activities. 24 So you put data dissemination under the 0.

umbrella of public relations; is that right? 1 2 That's right. O. Okay. Continuing medical education 3 also, is that similar to PR? 4 5 MS. THORNE: Objection. In what way? 6 THE WITNESS: Yeah, I mean, I wouldn't 7 consider it similar to PR, no. 8 BY MR. WISNER: O. You would not? 9 10 Α. No. Q. So why would a man in the marketing 11 group be talking about wrapping PR and CME around this 12 data? 13 14 MS. THORNE: Objection. 15 THE WITNESS: Because at that time, I 16 mean, there were activities that the marketing 17 team was involved in that were not solely related to promotion. 18 19 BY MR. WISNER: 20 Q. Okay. Would you consider PR and CMEs 21 marketing? 22 MS. THORNE: Objection. 23 THE WITNESS: Would I consider them 24 marketing?

```
1
    BY MR. WISNER:
 2
             Ο.
                  Mm-hmm.
 3
             Α.
                    In what way?
                    Well, being done by a guy who was in
 4
             Q.
 5
    marketing, correct?
 6
                    MS. THORNE: Objection.
 7
                                  I mean, if you're saying
                    THE WITNESS:
 8
             everything that a marketer does is considered
 9
             marketing, that's fine. I mean, it goes well
10
            beyond developing promotional materials,
11
            working on public relations, at that time
12
            working on CME, working on training materials
             for the fields, working with supply team,
13
14
             developing forecasts. I mean, marketing does a
15
            broad range of activities.
16
    BY MR. WISNER:
17
             0.
                    I understand, but would you consider
    distributing PR about a particular study to be a form
18
19
    of marketing?
20
                    MS. THORNE: Objection.
21
                    THE WITNESS: Not in a classic sense,
22
            no.
23
    BY MR. WISNER:
24
                    It would be considered part of the
             0.
```

```
marketing budget, though, right?
 1
 2
                    MS. THORNE: Objection.
 3
                    THE WITNESS:
                                  I think in a way the
             company allocated funds, yes, it came out of
 4
 5
             what was called the marketing budget, but it
 6
             was a range of activities that spanned from
 7
             promotional activities like developing sales
 8
             materials, funding promotional programs to
 9
             funding nonpromotional activities, like CME,
10
             PR, publication efforts, and it was merely a
11
             way to capture in the budget, as per finance,
12
             the activities that were devoted against a
            particular brand.
13
14
    BY MR. WISNER:
15
                   Okay. All right. Let's move on to the
             Ο.
16
    next exhibit.
                    (Document marked for identification as
17
18
             ForestC Deposition Exhibit No. 34.)
19
    BY MR. WISNER:
20
             Ο.
                    Handing you a document, Exhibit 34.
21
    This is an e-mail exchange with the top date of
22
     September 29th, 2001 -- sorry, September 25th, 2001.
23
                    Do you see that?
24
             Α.
                    Yes.
```

- Q. All right. If you turn to the second
- 2 page -- sorry -- the third page, you see there's an
- 3 e-mail from John MacPhee to two recipients starting on
- 4 Page 2 and ending on Page 3.
- 5 Do you see that?
- 6 A. I do.
- 7 O. Who is John MacPhee?
- A. At the time I don't know of John's exact
- 9 title, but, at a minimum, he was the head of the
- 10 marketing team for Celexa and Lexapro.
- 11 Q. Okay. And, typically -- I'm just
- 12 curious -- did the head of the marketing team for
- 13 Celexa or Lexapro oversee the creation of continuing
- 14 medical education programs?
- MS. THORNE: Objection.
- THE WITNESS: I mean, he's responsible
- for whatever the marketing team does, right.
- So is he directly involved in maybe some
- 19 activities and others not?
- 20 BY MR. WISNER:
- Q. Let me ask you clear -- a simpler
- 22 question.
- 23 CMEs, continuing medical education,
- they're in the marketing group for Forest; is that

right? 1 2 MS. THORNE: Objection. What time 3 period are you referring to, Brent? BY MR. WISNER: 4 5 Q. In 2001 CMEs were over -- or supervised or overseen in the marketing group; is that right? 6 7 MS. THORNE: Objection. 8 It was really a group THE WITNESS: 9 effort, so marketing was involved, but so was the rest of the organization, medical affairs 10 and clinical, so it was a multi-disciplinary 11 12 sort of management of the CME activity. BY MR. WISNER: 13 14 And, again, it's your testimony that CME Ο. 15 programs were not designed to promote a product? 16 That was the company position, yes. Α. 17 Is that truth, though? Is that actually Q. what happened? 18 19 That's their position. Α. 20 I understand that's their position, but 0. 21 isn't it true that CMEs were used by Forest to promote 22 drugs like Celexa for use in various indications, 23 including children? 24 MS. THORNE: Objection.

- 1 THE WITNESS: They were not -- they were
- 2 not used for promotional purposes.
- 3 BY MR. WISNER:
- Q. Let me just read this e-mail. It says,
- 5 let me present issues re: presentation of ped data at
- 6 upcoming meetings and use of such data in CME programs.
- 7 I want to make sure my thoughts are understood.
- 8 1. I believe that ACNP does not allow
- 9 the referencing of presentations made at their meeting.
- 10 This would eliminate the ability to reference the
- 11 presentation in slides as used in a CME program. We
- 12 need to learn/confirm if this is true or not.
- 2. If it is true, we need to find
- 14 another venue to present the data so that it is
- 15 referencable. In doing this, we need to find a meeting
- occurring soon that will present previously presented
- 17 materials. Sometimes, meetings will not accept data
- 18 presented at a previous meeting.
- 19 3. We then need to make sure that a CME
- 20 program/accrediting body would allow the inclusion of
- 21 data that is not yet published. In other words, make
- 22 sure that a poster presentation is fair game for an
- 23 inclusion in the program/presentation. In addition, we
- would need to check the target journal (I believe JAMA)

- 1 for their rules regarding dissemination of data prior
- 2 to publication. We will probably be restricted to the
- 3 contents of the poster. This needs to be confirmed and
- 4 if true, the poster must be written with a CME program
- 5 in mind.
- 6 4. Once we have more facts a potential
- 7 CME program should be discussed with Karen Wagner to
- 8 see if she agrees and would chair it.
- John MacPhee.
- 10 Did I read that correctly?
- 11 MS. THORNE: Objection. Just for the
- record, Brent, you misspoke in Number 1, you
- said "would" where it should be "could."
- MR. WISNER: Thank you.
- 15 BY MR. WISNER:
- 16 Q. With that correction, did I appear to
- 17 have read it mostly correctly?
- 18 A. You did.
- 19 Q. Okay. Why was the guy who was in charge
- of Celexa marketing so concerned about being able to
- 21 present the pediatric data in a CME as quickly as
- 22 possible?
- MS. THORNE: Objection.
- THE WITNESS: Yeah, I don't know what's

- behind the e-mail. I mean, you'd have to ask
- John what he intended by his e-mail.
- 3 BY MR. WISNER:
- Q. And, to be clear, it's your testimony to
- 5 the jury that the urgency to get this data presented at
- 6 CME presentations was not to help promote the use of
- 7 Celexa for use in children?
- MS. THORNE: Objection.
- 9 THE WITNESS: That's correct, the intent
- 10 was not to promote the data.
- 11 BY MR. WISNER:
- 12 Q. You just said you don't know what
- 13 Mr. MacPhee was referring to, so how do you know that
- 14 was not his intent?
- MS. THORNE: Objection. Your question
- didn't pertain to Mr. MacPhee's intent. Your
- 17 question was about Forest's intent.
- 18 THE WITNESS: That's true. Whatever she
- said is true. The question was not in
- 20 regard --
- 21 BY MR. WISNER:
- Q. Respectfully, I asked you a question.
- 23 If you can answer my question, I would appreciate that.
- A. Do you want to ask the question again?

1 MR. WISNER: Sure. We'll have her read 2 it back. 3 (The court reporter read back the record 4 as requested.) 5 MS. THORNE: Objection. 6 THE WITNESS: I just said I don't know 7 Mr. MacPhee's intent. 8 BY MR. WISNER: 9 Q. Okay. So he could, in fact, have intended to use the CME as a form of promotional 10 material? 11 12 MS. THORNE: Objection, calls for 13 speculation. 14 THE WITNESS: Again, you have to ask 15 John what he meant. 16 BY MR. WISNER: 17 Q. I didn't ask what he meant. I said he could have meant that. 18 19 MS. THORNE: Objection, calls for 20 speculation. 21 THE WITNESS: He could have meant a lot 22 of things. 23 MR. WISNER: Move on to the next 24 exhibit.

1 (Document marked for identification as ForestC Deposition Exhibit No. 35.) 2 BY MR. WISNER: 3 4 This is Exhibit 35. Mr. Closter, I just 5 handed you a document that is Exhibit 35 to your 6 deposition, the first page of the document is an e-mail 7 from Natasha Mitchner to Christina Goetjen, Jeff 8 Lawrence and Bill Heydorn, and the subject is "Wagner 9 Hot Topics slides." 10 Do you see that? 11 Α. Yes. 12 And then attached to this e-mail is, in O. 13 fact, the hot topic slides. 14 Do you see that? 15 Α. T do. 16 And from what you can tell this is, in 17 fact, the presentation that Mrs. Wagner -- Dr. Wagner gave at the ACNP convention? 18 19 MS. THORNE: Objection, assumes facts 20 not in evidence, lack of foundation. 21 THE WITNESS: Yeah, I mean, we know these were sent on the date they were sent in 22 23 advance of the meeting. We don't -- we don't 24 have any confirmation, based on this, that says

these were the exact slides used. 1 2 BY MR. WISNER: 3 Ο. So you don't know whether or not these were the slides used at the ACNP presentation? 4 5 Α. I do not. 6 MR. WISNER: Okay. Let's go off the 7 record. 8 THE VIDEOGRAPHER: We are now off the 9 record. The time is 3:23. 10 (Pause.) 11 THE VIDEOGRAPHER: We are now back on 12 the record. The time is 3:23. BY MR. WISNER: 13 14 Q. Mr. Closter, do you have any reason to dispute that these, in fact, are the slides that were 15 16 given by Karen Wagner at the ACNP convention? 17 MS. THORNE: Objection. 18 THE WITNESS: Based on the e-mail, these 19 appear they could be the final slides of the 20 presentation. 21 BY MR. WISNER: 22 Ο. Okay. Turn to Page 6 of the slide. 23 Before I get into this, this slide was 24 presenting the results of Celexa Study 18, correct?

1 Α. It appears to be true. 2 All right. If you turn to Page 6. O. 3 Α. Okay. This is the results of the primary 4 Q. 5 endpoint in Study 18, correct? 6 Looks to be. Α. 7 Okay. Nowhere on this slide does it 0. 8 indicate that there was a potential unblinding issue 9 with the data, right? 10 MS. THORNE: Objection. 11 THE WITNESS: That is not indicated on 12 this slide, no. 13 BY MR. WISNER: 14 Q. Okay. In fact, nowhere is that 15 indicated in any of these slides? 16 MS. THORNE: Objection. 17 THE WITNESS: Do you want me to look through the whole stack? 18 19 BY MR. WISNER: 20 Sure. Why don't you look through. I'm 0. 21 asking you questions about what's not in there. Okay. (Witness reviews document.) 22 Α. 23 Okay.

0.

24

So nowhere in this slide does it mention

- 1 the information contained in the final study report
- 2 related to the potentially unblinding data underlying
- 3 the primary efficacy results?
- 4 MS. THORNE: Objection.
- 5 THE WITNESS: It's not included in the
- 6 deck.
- 7 BY MR. WISNER:
- Q. It's not in the deck, correct?
- 9 A. Correct.
- 10 Q. Okay. Nowhere in this slide does it
- indicate that all those secondary endpoints were
- 12 negative?
- MS. THORNE: Objection.
- 14 THE WITNESS: It doesn't. I would note
- this is a top line presentation of data.
- There's a lot of aspects of the trial that
- would not be included in a presentation like
- this.
- 19 BY MR. WISNER:
- 20 O. So it's not in the deck, correct?
- 21 A. No.
- Q. Nowhere in the slide does it mention
- 23 that Dr. Wagner had any help preparing these slides,
- 24 does it?

1 MS. THORNE: Objection. 2 THE WITNESS: No. BY MR. WISNER: 3 4 Ο. In fact, these slides were prepared in 5 conjunction with Natasha Mitchner, correct? 6 MS. THORNE: Objection. 7 THE WITNESS: It's likely there was 8 support to present these, to prepare these 9 slides, that's, you know, very standard in presentations like this. 10 11 BY MR. WISNER: 12 0. But Natasha Mitchner is not mentioned anywhere in any of these slides, is she? 13 14 MS. THORNE: Objection. 15 THE WITNESS: No, I'm not sure why she 16 would be. 17 BY MR. WISNER: 18 Ο. Okay. Because she helped create them, 19 right; wouldn't that be why you put her name on? 20 MS. THORNE: Objection. 21 THE WITNESS: That's okay. I mean, 22 Dr. Wagner may have presented this on her own 23 study and gotten help from a fellow or a 24 trainee under her, and they likely wouldn't

have been noted in this either. 1 2 BY MR. WISNER: 3 Ο. Back up. You know that Natasha Mitchner did the first and almost the final draft of these 4 5 slides for Mrs. Wagner, right? 6 MS. THORNE: Objection, assumes facts 7 not in evidence. 8 THE WITNESS: Yeah, I couldn't test all 9 that, but, in general, there are support for presentations like this, and the author, the 10 11 presenter is often involved in every step of 12 the way and, ultimately, has control over the slides. 13 14 BY MR. WISNER: 15 Nowhere in this presentation does it Ο. 16 discuss the effect size of the primary efficacy result? 17 The effect size of the primary efficacy Α. result. 18 19 MS. THORNE: Objection. 20 I mean, it shows the THE WITNESS: 21 primary variable over time, seems pretty 22 relevant. 23 BY MR. WISNER:

Do you know what an effect size is,

Golkow Technologies, Inc.

0.

24

Mr. Closter? 1 2 Α. Generally speaking, yes. Do you know what a Cohen effect size is? 3 O. 4 Α. No, it's beyond my expertise. 5 Q. Okay. Nowhere in here does it specify whether or not the difference between placebo and 6 7 citalopram were clinically significant, does it? 8 MS. THORNE: Objection. 9 THE WITNESS: No, and I'm not really 10 sure what, you know, the role of clinical 11 significance plays in a trial. I know 12 statistical significance. I'm not really familiar with clinical significance in a trial. 13 14 BY MR. WISNER: 15 You're not familiar with the concept of Ο. 16 clinical significance? 17 Α. Concept, yes, but I don't know what role it plays in a clinical trial. 18 19 Well, clinical significance is whether O. or not the difference between the treatment and the 20 21 placebo creates a meaningful effect in the patient's 22 life, right? 23 MS. THORNE: Objection. 24 Right. My understanding, THE WITNESS:

1 that's typically assessed on a patient-to-patient level, difficult to assess 2 3 from the body of a trial where the patients are 4 rather heterogenous. As a whole they may 5 perform in one similar way, but each patient individually is going to perform very 6 7 differently, just like they would in a 8 clinician's practice. 9 BY MR. WISNER: 10 0. Isn't it standard medical practice to 11 look at the Cohen effect size in establishing whether 12 or not the results observed are, in fact, clinically significant? 13 14 MS. THORNE: Objection. 15 THE WITNESS: Yeah, you're asking the 16 wrong guy. I'm not -- I don't have a technical 17 expertise to assess that. 18 BY MR. WISNER: 19 Okay. What about the number needed to Ο. 20 treat, are you familiar with that metric? 21 Yes, in general. Α. 22 Q. And you understand that that is a metric that helps indicate the clinical significance of a 23 24 study result, right?

I'm not sure exactly --1 Α. 2 MS. THORNE: Objection. 3 THE WITNESS: I'm not sure exactly what 4 it measures, but it is a term that clinicians will use about the benefits of a particular 5 6 treatment and allow them to compare it to other 7 treatments. 8 BY MR. WISNER: 9 There is no NNT result listed in this presentation, is there? 10 11 MS. THORNE: Objection. 12 THE WITNESS: No, but I don't even 13 believe that was a parameter in the clinical 14 study. 15 BY MR. WISNER: 16 Q. There is -- I'm sorry. A parameter in a clinical study, is that what you just said? 17 18 MS. THORNE: Objection. THE WITNESS: Yes. 19 20 BY MR. WISNER: 21 Q. NNT is calculated -- do you know how an 22 NNT is calculated? 23 Α. Not exactly. 24 MR. BAUM: To be clear, reserve these

1 things he can't answer. 2 MR. WISNER: That's fine. I don't think 3 that is going to be an issue. 4 MR. BAUM: I think you need to make 5 clear. 6 MR. WISNER: Okay. We reserve the right to ask Dr. Olanoff about effect sizes and NNT 7 8 and clinical significance during his 30(b)(6) 9 deposition, based upon his answers. 10 MS. KIEHN: We understand your position, 11 and we'll take it under consideration. 12 BY MR. WISNER: Okay. Nowhere in this presentation does 13 0. 14 it indicate the results of Study 94404, does it? 15 Α. No. 16 But the study results of 94404 had been made known to Forest before this presentation occurred, 17 18 correct? 19 MS. THORNE: Objection. 20 THE WITNESS: Yes, we would have known 21 about them. 22 BY MR. WISNER: 23 Ο. Do you think it's a bit misleading to present data from a recently completed clinical trial 24

- that purports to have a positive result but not present
 date from a clinical trial that contemporaneously shows
 - 3 there is no positive result?
 - 4 MS. THORNE: Objection.
 - 5 THE WITNESS: We don't believe it's
 - 6 misleading.
 - 7 BY MR. WISNER:
- 8 Q. So just cherry picking the data and
- 9 picking which clinical trial to show to physicians is
- 10 not a -- is not misleading, in your opinion?
- MS. THORNE: Objection.
- 12 THE WITNESS: Yeah, I wouldn't
- characterize it that way.
- 14 BY MR. WISNER:
- Q. All right. I'm handing you a document.
- 16 (Document marked for identification as
- 17 ForestC Deposition Exhibit No. 36.)
- 18 BY MR. WISNER:
- 19 Q. I'm handing you a document Exhibit 36 to
- 20 your deposition. This is an e-mail from William
- Heydorn to William Heydorn dated December 19th, 2001.
- Do you see that?
- 23 A. I do.
- Q. The subject is "ACNP posters Wagner

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(peds), Trivedi (SCT) and Rappaport (SCT)."
 1
 2
                    Do you see that?
                    I do.
 3
             Α.
                    And if you look below, the original
 4
             Ο.
 5
    message was actually from Natasha Mitchner to Bill
    Heydorn. The subject was "ACNP posters."
 6
 7
                    Do you see that?
 8
             Α.
                    Yes.
 9
                    And she writes, "Attached please find
             Ο.
10
    pdfs of the Wagner, Trivedi and Rappaport posters.
    Please do not hesitate to contact me with questions.
11
12
     Thanks."
13
                    You see that?
14
             Α.
                    Yes.
15
                    If you turn the page, this is actually a
             O.
16
     condensed version of that poster.
17
                    Do you see that?
18
             Α.
                    Yes.
19
                    I know the font is small, but I want to
             O.
20
     see if you can read some of the things on here with me,
21
     and this is, to the best of your knowledge, a copy of
22
     the poster that was actually presented at the ACNP
23
     conference in December of 2001?
24
                    MS. THORNE: Objection, lack of
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foundation, assumes facts not in evidence. 1 2 THE WITNESS: This looks to be the 3 poster that may have been presented at the 4 meeting. 5 BY MR. WISNER: 6 Ο. Okay. It's titled "Citalopram Treatment 7 of Pediatric Depression: Results of a 8 Placebo-Controlled Trial." 9 Do you see that? 10 I do. Α. 11 Q. And that's referencing MD-18? 12 Α. I would believe so, yes. 13 All right. The lead author listed on Q. 14 the poster is Karen Wagner. 15 Do you see that? 16 Α. Yes. 17 Q. And then there's some other authors 18 listed there. There's Dr. Robb. 19 Do you see that? 20 Α. Yes. 21 Ο. And then Dr. Findling. 22 Do you see that? 23 Α. Yes. 24 And then Dr. Tiseo? 0.

Tiseo. 1 Α. 2 Tiseo. I keep saying wrong, Tiseo? Ο. Yes. 3 Α. 4 Q. Do you see that? 5 Α. I do. 6 And of all the individuals listed as Ο. 7 authors here, Mr. Tiseo is the only person listed from 8 Forest Laboratories? 9 That is correct. Okay. Natasha Mitchner is not mentioned 10 Q. anywhere in the authorship line here, is she? 11 12 MS. THORNE: Objection. 13 THE WITNESS: No. 14 BY MR. WISNER: 15 Ο. Nor is Charlie Flicker? 16 MS. THORNE: Objection. 17 THE WITNESS: No, he's not. 18 BY MR. WISNER: 19 We do know from the e-mail just before Ο. that Natasha Mitchner had just sent those posters to 20 21 Mr. Heydorn. 22 Do you see that? 23 MS. THORNE: Objection. 24 THE WITNESS: She sent the e-mails, yes.

```
1
    BY MR. WISNER:
 2
             Ο.
                   Don't you think it's a bit misleading to
    not disclose the person who was primarily responsible
 4
     for creating the poster in the authorship line?
 5
                    MS. THORNE:
                                 Objection, assumes facts
            not in evidence, lacks foundation.
 6
 7
                    THE WITNESS: I don't think it's
            misleading at all.
 8
 9
    BY MR. WISNER:
10
             Q.
                   Ms. Mitchner created the poster, didn't
11
     she?
12
                    MS. THORNE: Objection, assumes facts
            not in evidence, lacks foundation.
13
14
                    THE WITNESS: My understanding is that
15
            Natasha Mitchner worked at Weber Shandwick,
16
            which was the medical education publication
17
             support company, and their function would have
            been -- we would have given them data, could
18
19
            have been tables, graphs, copy, you name it,
20
             they would have put that into a format like you
21
             see here in the poster. They would have taken
22
             edits from us, commentary and delivered to us
23
             the final poster, as we had envisioned it.
24
    BY MR. WISNER:
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1 In that role, her role in doing that at Ο. Weber Shandwick is not disclosed anywhere on this 2 3 poster, correct? 4 MS. THORNE: Objection. 5 THE WITNESS: No, and I'm not sure it needs to be or has to be. 6 7 BY MR. WISNER: 8 Why is that? Ο. 9 Whatever the publication guidelines that 10 were in effect at the time would have guided this to be 11 done the exact way it was done. 12 Don't you think physicians have a right O. to know who is behind creating this piece of science 13 14 that they're being presented on? 15 Objection, assumes facts MS. THORNE: 16 not in evidence, lacks foundation and it's 17 outside the scope of the -- and calls for speculation. 18 19 THE WITNESS: So if I was to speculate, 20 you know, what mattered to the individuals who 21 saw this would be the investigators that were 22 involved in the trial, of which Dr. Wagner is 23 one, and perhaps the company that sponsored the 24 study, which would be represented by Dr. Tiseo.

I don't believe there are any other individuals 1 that would be relevant to someone who was 2 3 viewing the poster. 4 MR. WISNER: I'm going to move to strike 5 the answer as nonresponsive. My question to 6 you --7 MS. THORNE: We're going to object to 8 your motion to strike. The answer was 9 responsive. 10 BY MR. WISNER: 11 Mr. Closter, isn't it misleading to 12 present a piece of science to physicians and not disclose that a person who is not even an MD played a 13 14 primary role in creating this poster? 15 MS. THORNE: Objection, assumes facts 16 not in evidence, lacks foundation, calls for 17 speculation, asked and answered. 18 THE WITNESS: My answer stands as it is 19 not misleading, which is exactly how I answered 20 it before. 21 BY MR. WISNER: 22 0. The poster here describes a couple of 23 things, if you look at the last sentence of the 24 abstract, it says, In conclusion, this population

```
of adolescents and children -- sorry -- "In conclusion,
 1
     in this population of adolescents and children,
 2
    citalopram reduced depressive symptoms to a
     significantly greater extent than placebo treatment,
 4
     and was well tolerated."
 5
 6
                    Do you see that?
 7
             Α.
                    I see that.
 8
                    Okay. Nowhere in this abstract or, in
             Ο.
 9
     fact, anywhere on this poster does it indicate that all
10
    of the secondary outcomes were, in fact, negative in
11
     the trial?
12
                    MS. THORNE: Objection.
13
                    THE WITNESS: I mean, I can read it and
14
             just verify that that is true.
15
    BY MR. WISNER:
16
             0.
                   Please do.
17
                    Okay. (Witness reviews document.)
             Α.
18
    Okay.
19
                    So my question that was pending is
             0.
    nowhere on this poster does it indicate that the
20
21
    secondary outcomes for Study 18 were all negative?
```

MS. THORNE: Objection.

secondary outcome measures, efficacy endpoints

THE WITNESS:

22

23

24

There is no assessment of

```
1
            in the poster.
 2
    BY MR. WISNER:
 3
                   Doesn't mention it at all?
            0.
 4
                   MS. THORNE: Objection.
 5
                    THE WITNESS: As I said, it is not
            included.
 6
 7
    BY MR. WISNER:
 8
            0.
                   There is no discussion here of the
 9
    potentially unblinding issues that are discussed in the
    final study report, is there?
10
11
                   MS. THORNE: Objection.
12
                    THE WITNESS: No. I mean, there's a lot
13
            things that are not included here on a poster
14
            that gives you limited space, you know, to
            present your data. So, by nature, it's not
15
16
            going to include everything.
17
    BY MR. WISNER:
               So there's nothing -- there's no
18
19
    discussion of the potentially unblinding data here,
20
    correct?
21
                   MS. THORNE: Objection, asked and
22
            answered.
23
                    THE WITNESS: No, it's not there.
24
    BY MR. WISNER:
```

```
Okay. There's actually no discussion of
 1
             Ο.
    clinical efficacy in here, is there?
 2
 3
                    MS. THORNE: Objection.
 4
                                  There is a graph that
                    THE WITNESS:
 5
             shows by treatment visit the effect that the
             placebo patients had and the citalogram treated
 6
 7
             patients had and showing whether or not at
 8
             those time points the difference was
 9
             statistically significant. Citalopram versus
10
             placebo all the way out, you know, through the
             eight-week endpoint.
11
12
    BY MR. WISNER:
13
             0.
                    I appreciate your answer. My question
14
     is there's actually no discussion of clinical
15
     significance in here, is there?
16
                    MS. THORNE: Objection, asked and
17
             answered.
18
                                  There's no -- literally no
                    THE WITNESS:
19
             words that say clinical significance in the
20
             poster.
21
    BY MR. WISNER:
                    There's no discussion of effect size,
22
             0.
23
    correct?
2.4
                    MS. THORNE: Objection.
```

1 THE WITNESS: No. 2 BY MR. WISNER: There's no discussion of number needed 3 0. to treat, is there? 5 MS. THORNE: Objection. 6 THE WITNESS: No, there isn't. 7 BY MR. WISNER: 8 There is no reference to study 94404 in 0. 9 this poster, is there? 10 MS. THORNE: Objection. 11 THE WITNESS: There's not. There's 12 reference to two other drugs that have similar 13 data in the treatment of depression in the 14 poster. 15 BY MR. WISNER: 16 Absolutely, but there is no reference to a clinical trial specifically designed to study the 17 efficacy of citalopram in pediatric population that was 18 19 available to Forest at this time referenced in this 20 poster, correct? 21 MS. THORNE: Objection. THE WITNESS: No, I believe at that time 22 23 that data was not made public in any form. 24 BY MR. WISNER:

But it was available to Forest, correct? 1 Q. 2 MS. THORNE: Objection. 3 THE WITNESS: When you say "available to Forest," what do you mean? 4 5 BY MR. WISNER: 6 They had the result, top line results of Ο. 7 that, didn't they? 8 I believe we had some, yeah, some of the Α. 9 results would have been accessible to the company. 10 Q. And they knew that the results were 11 negative? 12 Α. Yes, we were aware that the results were negative. 13 14 But Forest did not include the fact that Ο. another clinical trial involving pediatric patients was 15 16 negative in this poster, did it? 17 MS. THORNE: Objection. 18 THE WITNESS: Again, I'm not sure what 19 the obligation would be to include it. 20 BY MR. WISNER: 21 I didn't ask you about the obligation, 22 Mr. Closter. I'm just saying they didn't do it, did 23 they?

MS. THORNE: Objection.

24

1 THE WITNESS: No. 2 BY MR. WISNER: 3 Ο. And according to the testimony of Mr. Heydorn, it was an intentional decision within 4 5 Forest, specifically with Mr. Flicker, Mr. Gergel and Mr. Heydorn himself, to get the positive data out into 6 7 the public domain and conceal the data from 94404? 8 MS. THORNE: Objection. That question 9 is outside the scope of the 30(b)(6) notice. 10 Mr. Closter is not here to testify on behalf of 11 the company as to Mr. Heydorn's prior 12 testimony, so to the extent that Mr. Closter 13 can interpret Mr. Heydorn's prior testimony in 14 his individual capacity, he can do so, but he 15 is not going to testify on behalf of the 16 company on this question. 17 MS. KIEHN: The question also misstates the testimony of Mr. Heydorn. 18 19 THE WITNESS: Yeah, I wouldn't 20 characterize it that way at all. 21 MR. WISNER: Can you please read back 22 the question. 23 (The court reporter read back the record 24 as requested.)

1 MS. THORNE: I renew my objection and my 2 instruction to the witness --3 MR. WISNER: I wasn't reasking the 4 question. I was just asking for it to be read back. 5 6 MS. THORNE: Usually when you read back 7 a question, you are reposing the question. 8 MR. WISNER: I didn't say ask the 9 question again. I asked her just to read it 10 back. I just wanted to hear his answer was 11 responsive, that's all. Thank you. 12 BY MR. WISNER: Q. Did Forest take any effort around this 13 14 time to also get a poster presented on the results of 15 94404? 16 MS. THORNE: Objection. 17 THE WITNESS: I don't know. BY MR. WISNER: 18 19 At the time that these results were 0. 20 being presented at ACNP by Dr. Wagner, Forest wanted to 21 publicize that fact in a press release, correct? 22 MS. THORNE: Objection. 23 THE WITNESS: I believe there was a 24 press release which I've seen which mentioned

that dataset as well as other datasets that 1 were being presented at that meeting. 2 BY MR. WISNER: 3 4 So specifically with -- one second. Ο. (Document marked for identification as 5 ForestC Deposition Exhibit No. 37.) 6 7 BY MR. WISNER: 8 I'm handing you a document Exhibit 37 to 9 your deposition. This is an e-mail exchange, the top of it is from Christina Goetjen to Claire Zinnes. 10 11 Did I say that right? 12 That's Christina Goetjen. Α. 13 Okay. Thank you. Q. 14 And Claire Zinnes. Α. 15 Oh, boy, it's a good thing I'm not O. 16 deposing those people. 17 Α. If you ever do, you should know that. I'm terrible with names, so but it's 18 Q. 19 dated September 26, 2001. 20 Do you see that? 21 Α. Yes. 22 Q. And the subject looks to be a response to "ACNP pediatrics abstract." 23 24 Do you see that?

- 1 A. That's the subject, yes.
- Q. All right. Let's go to the first e-mail
- 3 in the chain. It's on Page 2.
- 4 A. Okay.
- 5 Q. This is from Natasha Mitchner, and she
- 6 says, "Attached please find a Word document of the
- 7 Wagner abstract submitted to ACNP. Please do not
- 8 hesitate to contact me with any questions."
- 9 You see that?
- 10 A. Yes.
- 11 Q. Then in response Christina Goetjen; I
- 12 said it right?
- 13 A. Yes.
- Q. Says "FYI, the latest edition of the
- 15 pediatric data as it was submitted to ACNP for 'hot
- 16 topic' status."
- 17 You see that?
- 18 A. Yes.
- 19 O. Then Claire Zinnes is in -- who is
- 20 Claire Zinnes?
- 21 A. She worked on the digital marketing
- 22 group at Forest back then.
- Q. Okay. Does that mean she focused on
- 24 marketing efforts that were online?

1 Α. Correct. 2 Ο. Okay. She says, John wants CGI to start working on a release and any other way they can spin this data. Are doing that? Or should I? Right, 4 5 that's what she says? 6 Α. Yes. 7 O. Now --8 MS. THORNE: Brent, for the record, it's 9 GCI, not CGI. 10 BY MR. WISNER: 11 GCI. I was going to ask you, what is Ο. 12 GCI; do you know? 13 Division of Grey Advertising that Α. 14 focused on public relations. 15 And was it a customary practice within O. Forest, to the best of your knowledge personally, to 16 consult with a company like GCI to draft press 17 releases? 18 19 MS. THORNE: Just to be clear, when you 20 say "personal," you're asking Mr. Closter now 21 as an individual? 22 MR. WISNER: That's why I used the word 23 personal.

MS. THORNE: No, I just want to make

24

1 sure we're on the same page. THE WITNESS: Yes, we would work with 2 3 GCI to draft a press release. 4 BY MR. WISNER: 5 Q. Okay. Now, she says here, "any other way we can spin this data." 6 7 Are you familiar with the word "spin"? 8 MS. THORNE: Objection. 9 THE WITNESS: In a general sense, yes. 10 I don't know what she means here. 11 BY MR. WISNER: 12 Was it a customary practice within 0. Forest to spin scientific data? 13 14 MS. THORNE: Objection. 15 THE WITNESS: No. I mean, if you can 16 help me define spin, I'll let you know if that 17 was a corporate practice, but I don't believe 18 so. 19 BY MR. WISNER: 20 Ο. Mr. Closter, you work in marketing, 21 right? 22 Α. I do. 23 You don't know what the word spin means? 0. 24 MS. THORNE: Objection.

- THE WITNESS: It can mean a lot of
- things.
- 3 BY MR. WISNER:
- 4 Q. I understand it can mean a lot of
- 5 things, but I think you're kind of spinning the
- 6 definition here.
- 7 MS. THORNE: Objection.
- 8 BY MR. WISNER:
- 9 Q. What is your definition of spin?
- 10 A. You know, spin, my own personal
- 11 definition, you know, get it picked up, get it -- you
- 12 know, news outlets interested in wanting to disseminate
- 13 it.
- Q. Like promote it?
- MS. THORNE: Objection.
- 16 THE WITNESS: I wouldn't use the word
- promote, because we don't really think of -- we
- don't think of public relations as promoting.
- 19 BY MR. WISNER:
- Q. Let me ask you, what is your definition
- of promotion? You keep saying this. I just want to
- 22 make sure I understand what you're saying.
- 23 A. Sure. I mean, promotion would be things
- that, you know, you put in the hands of the field force

- 1 that has claims, you know, that are based on your
- 2 package insert and you're sharing that information
- 3 generally with a clinician. It doesn't have to be a
- 4 clinician. It could be a consumer or other, usually in
- 5 the form of sales materials and ultimately sold by the
- 6 field force. It could be in the form of journal
- 7 advertising. It could be in the form of trained
- 8 speakers who we give promotional on-label content to
- 9 and perhaps they share that information with other
- 10 colleagues of theirs in promotional environments,
- 11 dinner meetings, things like that.
- 12 Q. And the purpose of promotion, right, is
- to help increase sales of your company's product?
- MS. THORNE: Objection.
- THE WITNESS: I mean, the effort, in my
- opinion, is really to educate and share both
- the -- you know, the benefits and the risks of
- the drug so the clinician can make up their own
- mind if they want to use it or not in their
- 20 patients that they treat. In the end, yes,
- 21 that can result in increased sales if done
- appropriately and well.
- 23 BY MR. WISNER:
- Q. So it's your testimony to this jury that

the primary motivation in promotion is not to increase 1 2 sales? 3 MS. THORNE: Objection. It's certainly part of it. 4 THE WITNESS: 5 BY MR. WISNER: 6 Forest is a for-profit company, or at Ο. 7 least was, right? 8 Α. Right. 9 Ο. And they make profits by selling drugs, 10 right? 11 MS. THORNE: Objection. 12 THE WITNESS: Correct. 13 BY MR. WISNER: 14 So if they're going to spend money in 0. 15 engaging in promotional activities, their shareholders 16 would require that it be geared towards increasing profits, correct? 17 18 MS. THORNE: Objection. At this point 19 you're going outside the scope of the 30(b)(6) 20 deposition. 21 If you can answer in your personal 22 capacity, you can feel free to do so. 23 Yes, the intent is that THE WITNESS: 24 promotional efforts will lead to increased

1 sales. 2 BY MR. WISNER: Hand you a document, document 38 to your 3 0. deposition. 4 (Document marked for identification as 5 ForestC Deposition Exhibit No. 38.) 6 7 BY MR. WISNER: 8 Have you seen this document before? Q. 9 Α. I have. 10 What is this document? Q. 11 Α. This is a press release. 12 And this is the press release generated 0. or at least published December 13th, 2001, correct? 13 14 Α. We issued the release on that date, yes. 15 And by "we" you're referring to Forest Ο. 16 Laboratories? 17 Α. Correct. Do you know who drafted this press 18 Q. 19 release? 20 Α. Not specifically, no. 21 Would it be reasonable to assume, based 0. 22 on the last e-mail, that the company GCI played a role 23 in helping draft this press release? 24 MS. THORNE: Objection, calls for

speculation. 1 2 THE WITNESS: Yes. As our vendor and 3 hired agency, they would have likely participated in drafting it. 4 5 BY MR. WISNER: 6 The title of the press release is 7 "Results of Escitalopram and Celexa Studies Presented 8 at Major Scientific Conference." 9 Do you see that? 10 I do. Α. 11 Now, I want to turn your attention to 0. Page 2, and there's a -- at the bottom of there is the 12 para -- is the section that says "Celexa in the 13 14 Treatment of Pediatric Depression." 15 Do you see that? 16 Α. "Celexa in the Treatment of Pediatric 17 Depression." And this press release right here is 18 referring to the presentation that Dr. Wagner gave at 19 ACNP, correct? 20 21 MS. THORNE: Objection. 22 THE WITNESS: Yeah, or would be. 23 is assuming the date was after -- the 24 presentation was after the release date or near

- 1 it, yes.
- 2 BY MR. WISNER:
- 3 Q. So it was at or around the time that
- 4 Dr. Wagner gave her presentation?
- 5 A. That's correct.
- 6 Q. Okay. Now, there is a paragraph, a
- 7 couple paragraphs describing this. You've previously
- 8 reviewed it. I want to ask you some questions about
- 9 what is or is not in there. Are you prepared to do
- 10 that, or do you need to review it again?
- 11 A. I think I can answer, depending on the
- 12 question.
- Q. All right. The first question is --
- 14 well, let's turn to the second paragraph in the
- 15 section, starts off with quote.
- Do you see that?
- 17 A. The second paragraph.
- Q. It's on Page 3.
- 19 A. Page 3. Okay.
- Q. It's a quote that says, "'This study is
- 21 significant because few studies involving any
- 22 antidepressant have shown efficacy compared to placebo
- in the treatment of depression in children and
- 24 adolescents, 'said Karen Dineen Wagner, M.D., Ph.D.,

- 1 Department of Psychiatry and Behavioral Sciences,
- 2 University of Texas Medical Branch at Galveston, and
- 3 the study's lead author. 'Citalopram is now one of the
- 4 few therapies for which we have data showing safety and
- 5 efficacy for this population'."
- Do you see that?
- 7 A. I do.
- 8 Q. By putting that quote from Dr. Wagner
- 9 into a press release specifically having her state that
- 10 citalopram is now one of the few therapies for which we
- 11 have data showing safety and efficacy for this
- 12 population, isn't Forest promoting the use of
- 13 citalopram specifically for use in this population?
- MS. THORNE: Objection.
- THE WITNESS: Yeah, again, there's
- nothing promotional in nature about the
- document.
- 18 BY MR. WISNER:
- 19 Q. It's your testimony to this jury that
- 20 this press release where Dr. Wagner says citalogram is
- 21 now one of the few therapies for which we have data
- 22 showing safety and efficacy for this population is not
- 23 promotional in nature?
- MS. THORNE: Objection.

- Steven L. Closter 1 THE WITNESS: That's correct. 2 BY MR. WISNER: 3 0. The purpose of this press release is to encourage physicians and parents who might be 4 considering citalogram for their child be more 5 comfortable using citalopram in treating pediatric 6 7 depression; isn't that true? 8 MS. THORNE: Objection, lacks 9 foundation, assumes facts not in evidence. 10 THE WITNESS: Yeah, this is for data 11 dissemination purposes only. 12 BY MR. WISNER: 13 0. So it's your testimony to this jury that 14 Forest issued this press release just because they 15 wanted people to have more knowledge?
- MS. THORNE: Objection.
- 17 THE WITNESS: They simply wanted to
- 18 release the data.
- 19 BY MR. WISNER:
- 20 O. Mr. Closter, Forest has admitted, and,
- in fact, you have earlier today, that during this
- 22 period of time, Forest promoted the use of pediatric
- use of Celexa in children up until the end of 2002,
- 24 correct?

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1
                    MS. THORNE: Objection, misstates the
             prior testimony, misstates the document.
 2
 3
                    THE WITNESS:
                                  I mean, we can bring out
             the allocution document, but that's what we
 4
 5
             admitted to, a misdemeanor that a handful of
 6
             representatives sold the drug inappropriately
 7
             for off-label purposes.
    BY MR. WISNER:
 8
 9
                    Just to be clear, yes or no,
10
    Mr. Closter, did Forest promote the use of Celexa in
11
     children between 1998 and 2002?
12
                    MS. THORNE: Objection.
13
                    MS. KIEHN: Asked and answered.
14
                    MS. THORNE: Asked and answered.
15
                    THE WITNESS: What's that?
16
                    MS. KIEHN: I said asked and answered.
17
             You can go ahead and answer, if you can.
18
                    THE WITNESS:
                                  Yeah, again, we
19
             acknowledged and confirmed and the company
20
             acknowledged to a misdemeanor for a handful of
21
             representatives selling the drug in an
22
             inappropriate and off-label fashion for
23
             pediatric use. That's what we agreed, that's
24
             what we admitted to.
```

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1
    BY MR. WISNER:
 2
            0.
                   Mr. Closter, the phrase handful of sales
    representatives, that's nowhere in the Criminal
    Information, right?
 4
 5
                    MS. THORNE: Objection. For the record,
 6
            the Criminal Information is not what the
 7
            company pled to. The company pled to the --
 8
            pled to what's in the --
 9
                    MR. WISNER: Ms. Thorne, he can answer
10
            the question. Your objection is noted. You're
11
            literally just coaching right now.
12
                    MS. THORNE: I'm not coaching.
13
            making sure the record is clear, which you seem
14
             intent on not doing.
15
                    MR. WISNER: The record is fine. I
16
            asked him the question if Forest did it or not,
            and then I asked him about whether or not that
17
            handful of sales reps was in the Information.
18
19
            It's a very simple question.
20
                    MS. KIEHN: No relevance.
21
                    MR. WISNER: Fine. Object to relevance.
22
            Don't coach the witness. So you can please
23
            make your objection, and can I have him answer
24
            the question.
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1 MS. THORNE: You can have him answer the question. I'm stating my objection for the 2 record to make sure that the record is clear. 3 4 MR. WISNER: You are obstructing my 5 deposition, Ms. Thorne. 6 MS. THORNE: Brent, move on. 7 MR. WISNER: Answer my question, please. 8 THE WITNESS: Can you restate the 9 question again or read it. 10 MR. WISNER: Can you please have the 11 question read back. 12 (The court reporter read back the record 13 as requested.). 14 MS. THORNE: Renewing my objection. 15 THE WITNESS: I believe so. I mean, if 16 we want to pull out the allocution document, I 17 would feel more comfortable in agreeing to the language that's in there. 18 19 BY MR. WISNER: 20 Q. Agreeing that it's not in there you 21 mean? 22 Α. That it's not in there, whatever the 23 allocution document says. 2.4 And earlier we went through the 0.

transcripts of Mr. Weinstein's allocution in open 1 2 court. 3 You remember that? 4 Α. Yes. 5 Q. When he testified under oath, you remember that transcript? 6 7 Α. Yes, yes. 8 And in that -- and in that rendition of Ο. 9 the facts, the government stated that Forest promoted the unlawful -- sorry -- promoted the use of Celexa for 10 use in children between 1998 and 2002, correct? 11 12 MS. THORNE: Objection. Would you like to put the document in front of the witness? 13 14 BY MR. WISNER: 15 I have a question pending, Mr. Closter, Ο. 16 if you could please answer it. 17 MS. THORNE: In Mr. Closter feels the need to look at the document to refresh his 18 19 recollection --20 MR. WISNER: He hasn't said anything. 21 MS. THORNE: -- he can do that. 22 MR. WISNER: He can testify he needs 23 help. You can stop coaching him. 24 MS. THORNE: I'm not coaching.

1	MR. WISNER: This is becoming silly.
2	MS. THORNE: No, you gestured at him
3	MR. WISNER: Mr. Closter, please put the
4	document away. I haven't instructed you to
5	pull out the document.
6	THE WITNESS: Okay. I'll answer it when
7	I have the document.
8	MS. THORNE: So you're instructing him
9	not to look at the document.
10	MR. WISNER: No, I'm asking him can you
11	answer the question or not?
12	MS. THORNE: That wasn't the question
13	pending, first of all.
14	MR. WISNER: Oh, my God. Mrs. Thorne
15	sorry, Ms. Thorne, you just not only coached
16	the witness, have now prevented him from
17	answering my question.
18	MS. THORNE: No, I haven't.
19	MR. WISNER: Let me ask my questions and
20	make your objections. Stop coaching.
21	MS. THORNE: Can you stick with the
22	question that's pending
23	MR. WISNER: So thank you.
24	MS. THORNE: at a single time.

- 1 BY MR. WISNER: 2 I asked you a question about whether or not that was stated in the transcript. 4 Do you know the answer to that question, 5 Mr. Closter? 6 I'd have to look at the transcript. 7 Okay. Well, let's show you the 0. transcript then. 8 9 Α. Sounds good. 10 MR. WISNER: That's how it works. 11 MS. THORNE: Oh, you're going to teach 12 me how to take depositions? 13 MR. WISNER: No, I'm just explaining to 14 you why I'm just trying to get an answer to the 15 question. 16 BY MR. WISNER: 17 All right. If I could draw your Q. attention, Mr. Closter, to it's Exhibit 6. 18 19 Α. Okay. 20 Okay. Did you find Exhibit 6? O. 21 Yes. Α. 22 Q. Okay, great. Turn to Page 16, and if
- through 14, and let me know when you're done.

you could just read to yourself quietly Lines 10

23

1 Α. (Witness reviews document.) Okay. 2 Ο. Does that refresh your recollection as 3 to whether or not you can now answer my question? MS. THORNE: Objection. Does it refresh 4 5 his recollection as to whether he can answer 6 your question? 7 THE WITNESS: I believe I can, and what's your question? 8 9 BY MR. WISNER: 10 Q. Okay, great. So my question to you was 11 Mr. Weinstein admitted that Forest promoted the use of Celexa for use in children between 1998 and 2002, 12 13 correct? 14 MS. THORNE: Objection. 15 THE WITNESS: Correct. 16 BY MR. WISNER: Notwithstanding -- you can turn back to 17 Q. Exhibit 38. 18 19 Α. Okay. 20 Notwithstanding that admission under Ο. 21 oath by a company representative, it's your testimony 22 to this jury that this press release where Dr. Wagner 23 says citalogram is not one of the few therapies -- is 24 now one of the few therapies for which we have data

- 1 showing safety and efficacy for this population does
- 2 not constitute promotion?
- MS. THORNE: Objection, asked and
- 4 answered.
- 5 THE WITNESS: I've said I think a few
- times now that is not considered promotion.
- 7 BY MR. WISNER:
- 8 Q. Nowhere in this press release does it
- 9 discuss the potential unblinding of patients?
- MS. THORNE: Objection.
- 11 THE WITNESS: Does not include that.
- 12 BY MR. WISNER:
- 13 Q. Nowhere in this press release does it
- 14 discuss that all the secondary outcomes were negative?
- MS. THORNE: Objection.
- THE WITNESS: Doesn't include any
- information on secondary outcomes.
- 18 BY MR. WISNER:
- 19 Q. It does provide information about, you
- 20 know, the disposition of the study, right?
- 21 A. The disposition of the study.
- MS. THORNE: Objection.
- THE WITNESS: What do you mean?
- 24 BY MR. WISNER:

It talks about rates of discontinuation 1 0. due to adverse events. 2 3 You see that? 4 Yeah, that's a common parameter we evaluate. 5 6 Talks about the mean daily dose of Ο. Celexa in the final week of the study? 7 8 A. Yes. 9 But, again, it does not mention anything whatsoever about secondary outcomes, correct? 10 11 MS. THORNE: Objection. 12 THE WITNESS: No. 13 BY MR. WISNER: 14 0. You are aware that the observed cases 15 results for the primary endcome in Study 18 was also negative? 16 17 MS. THORNE: Objection. THE WITNESS: I would have to see the 18 results to confirm. 19 20 BY MR. WISNER: 21 So you don't know that offhand? 0. 22 Α. No. 23 Just to be clear that there's no 0. reference to the observed cases' results in this press 24

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release?
 1
 2
                   MS. THORNE: Objection.
 3
                   THE WITNESS: No, I'm not sure why they
 4
            would be in here.
 5
    BY MR. WISNER:
 6
               Okay. There's no discussion of effect
            Ο.
 7
    size in here, correct?
8
                   MS. THORNE: Objection.
 9
                   THE WITNESS: No.
10
    BY MR. WISNER:
11
            O. There's no discussion of the number
12
    needed to treat, correct?
13
                   MS. THORNE: Objection.
14
                   THE WITNESS: That's correct.
15
    BY MR. WISNER:
16
            O. There's no discussion in here about
    clinical efficacy at all?
17
18
                   MS. THORNE: Objection.
19
                   THE WITNESS: I mean, we can read this
20
            again, but there is mention of the outcome on
21
            the primary.
22
    BY MR. WISNER:
23
            O.
               But it doesn't disclose whether or not
24
    the difference observed between placebo and citalogram
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was clinically significant, does it?
 1
 2
                   MS. THORNE: Objection, lack of
 3
             foundation, assumes facts not in evidence,
 4
            calls for speculation.
 5
                    THE WITNESS: No. As stated in the
 6
            beginning, it's shown to reduce symptoms of
 7
            depression, right, and then describes the
 8
            primary outcome.
    BY MR. WISNER:
 9
                   But it doesn't actually tell you whether
10
            0.
11
    or not that statistical difference was clinically
    meaningful?
12
13
            A. No, it doesn't say that.
14
                   Okay. There's also no discussion of
            Q.
15
    Study 94404 in here, is there?
16
                   No, there isn't.
17
                   And at this time when this press release
            Q.
    was issued, Forest knew that Study 94404 was negative
18
19
    for efficacy?
20
                   MS. THORNE: Objection.
21
                    THE WITNESS: We were aware of the
22
            results.
23
    BY MR. WISNER:
24
            Q. And those results were negative?
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1 Α. The results were negative. 2 And, again, sorry belaboring all these Ο. questions, but I want to talk about each one of these 3 documents separately, isn't it misleading to people who 4 5 are reading this press release that specifically discloses the results of a positive clinical trial but 6 7 does not disclose the results of a negative clinical 8 trial that was in possession of Forest at the time? 9 MS. THORNE: Objection. 10 THE WITNESS: It's not misleading. 11 BY MR. WISNER: 12 Q. Is it deceptive? 13 MS. THORNE: Objection. 14 THE WITNESS: Not deceptive either. 15 BY MR. WISNER: 16 0. Is it unethical? 17 MS. THORNE: Objection. 18 THE WITNESS: It's not unethical. 19 BY MR. WISNER: 20 I'm handing you a document Exhibit 39 to 0. 21 your deposition. 22 (Document marked for identification as 23 ForestC Deposition Exhibit No. 39.) 24 BY MR. WISNER:

Do you recognize this document? 1 Q. Not specifically. I mean, I can guess 2 Α. what it is. 3 4 MS. THORNE: For the record, does this 5 have a Bates number? 6 MS. KIEHN: It does, but it's cut off. 7 MR. WISNER: Unfortunately, it does 8 appear to be cutoff. Looks like it was printed 9 without proper margins. Would you like me to 10 look at the Bates number? MR. BAUM: I'll find it. 11 12 MS. THORNE: We can locate it. Not --13 you don't have to delay the deposition to 14 locate it. 15 MS. KIEHN: Describe the front page. 16 BY MR. WISNER: 17 This is a document that's titled "A Q. Closer Look at Identifying Depression in Children and 18 19 Adolescents, " right, Mr. Closter? 20 Α. Yes. 21 Q. At the bottom it says "Supported by an 22 unrestricted educational grant from Forest 23 Pharmaceuticals, Inc. " 24 Do you see that?

Yes, I do. 1 Α. 2 O. And it also says "sponsored by CME Inc." 3 Do you see that? 4 Α. Yes. 5 Q. Do you know what CME Inc. is? 6 Α. It's a company. 7 Was it a company that Forest contracted Q. 8 with to develop CME programs? 9 Α. Yes. 10 MS. THORNE: Objection. 11 BY MR. WISNER: 12 0. If you turn to Page 2. This document, in fact, reflects portions of the CME program that 13 14 Dr. Wagner was giving that involved data involving 15 Study 18? 16 MS. THORNE: Objection. 17 THE WITNESS: Okay. 18 BY MR. WISNER: 19 Is that true? 0. 20 I mean, you're asking me if it included Α. 21 MD-18? 22 Q. I'm asking you if that's what this 23 document is, or do you not know? 24 MS. THORNE: Objection.

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1
                    THE WITNESS: I don't know if there is a
             question there. You just said it included it,
 2
             so I was simply --
 3
    BY MR. WISNER:
 4
 5
             Q.
                    I'm trying to ask if this document does
     include -- I'm sorry -- this document reflects the CME
 6
 7
    presentation given by Dr. Wagner related to Study 18
8
    and others studies as well?
9
                    MS. THORNE: Objection, assumes facts
10
             not in evidence, lacks foundation.
11
                    THE WITNESS: I mean amongst the many
12
             slides, there is one slide or a series of
             slides that reference a citalopram study.
13
14
    BY MR. WISNER:
                    Okay. Well, let's -- I mean, let's
15
             Ο.
16
     start at the beginning.
17
                    So turn to Page 4.
18
             Α.
                    Okay.
19
                    Has that the series chair is Karen,
             Ο.
20
    Dr. Wagner.
21
                    Do you see that?
22
             Α.
                    I do.
23
             Ο.
                    Okay. And if you turn to Page 2 it
24
     says, "Join your colleagues at this complimentary
```

- 1 breakfast meeting designed to give you the tools you
- 2 need to help your child and adolescent patients
- 3 overcome the devastating effects of depression."
- 4 Do you see that?
- 5 A. I do.
- Q. It goes on to read, your esteemed panel
- 7 of experts will examine the prevalence of depression in
- 8 the child/adolescent population, as well as the proper
- 9 diagnosis of depression and co-morbid conditions.
- 10 You'll explore the treatment options available to
- 11 improve the quality of life with this special group of
- 12 patients. Plus, you'll enjoy a continental breakfast,
- 13 receive a comprehensive syllabus and earn 4 hours of
- 14 CME credit all at no charge.
- Do you see that?
- 16 A. Yes.
- 17 Q. So this appears to then be a CME program
- 18 that was chaired by Dr. Wagner?
- MS. THORNE: Objection.
- THE WITNESS: It's what it appears to
- 21 be.
- 22 BY MR. WISNER:
- Q. And it was sponsored by Forest
- 24 Pharmaceuticals?

1 MS. THORNE: Objection, misstates the document, misstates the prior testimony, 2 assumes facts not in evidence, lacks 3 foundation. 4 5 THE WITNESS: Yes. BY MR. WISNER: 6 7 Q. And it involved treating pediatric and 8 adolescent depression? 9 MS. THORNE: Objection. 10 THE WITNESS: They label as child and 11 adolescent patients. 12 BY MR. WISNER: Now, if you look here on Page 4, there 13 Q. 14 is a faculty disclosure statement. 15 Do you see that? 16 Α. I do. 17 Q. And it lists for each one of the faculty members their various financial relationships with 18 19 various pharmaceutical companies, right? 20 Α. Yes. 21 And for Karen Wagner it lists all of her various financial associations. 22 23 Do you see that? 24 Α. Yes.

1 One of those includes receives grants Ο. and research support and is a consultant and member of 2 the advisory board for Forest Pharmaceuticals? 3 Forest is one of the many, yes. 4 Α. 5 Q. Yes. 6 Now, if you turn to Page 5, this is the 7 abstract of the presentation "How to Treat Depression 8 in Children and Maximize Their Quality of Life." 9 Do you see that? 10 Α. Yes. 11 Ο. And if you look down here, the outline specifies first psychotherapy? 12 13 Α. Yes. 14 And then it says pharmacotherapy? Q. 15 Α. Yes. 16 Okay. Now, if you turn to Page 12 in Ο. this slide deck of the presentation. Starting at the 17 bottom of the page, you see "Citalopram Treatment for 18 19 Depression in Children and Adolescents." 20 You see that? 21 I do. Α. 22 Q. And it spans through the end of Page 14. 23 Do you see that? 24 Α. Yes.

- 1 Q. Okay. If you need a moment to look
- 2 through, it's fine, but these slides appear to be
- 3 presenting the data from Celexa Study 18.
- 4 A. They do.
- 5 Q. Okay. Now, if you look on Page 12, on
- 6 the bottom slide, I know it's hard to read, but it has
- 7 a reference at the bottom of the slide, it says Wagner
- 8 KD, Robb, Findling, Tiseo, somewhere in Hawaii in 2001.
- 9 You see that?
- 10 A. Waikoloa.
- 11 Q. And that's the ACNP conference?
- 12 Do you see that?
- 13 A. That's right.
- Q. So they're referencing the ACNP
- 15 presentation that we were just discussing a minute ago?
- MS. THORNE: Objection.
- 17 THE WITNESS: Yes.
- 18 BY MR. WISNER:
- 19 Q. Okay. Look through the slides, but I
- just want to ask you some questions about what's in
- 21 there.
- 22 A. Sure.
- Q. Now, again, there's no discussion in any
- of these slides regarding citalogram that suggests that

there was any issues with potential unblinding? 1 2 Objection. MS. THORNE: That is not included. 3 THE WITNESS: 4 BY MR. WISNER: There is no discussion of the fact that 5 Q. all the secondary outcomes were negative? 6 7 MS. THORNE: Objection. 8 THE WITNESS: No. I think you'd find 9 this presentation is consistent with the prior 10 drugs that are also presented, other 11 treatments. 12 MR. WISNER: I appreciate your answer. 13 I move to strike it after the word "no." 14 THE WITNESS: Sure. 15 MS. THORNE: Objection. We object to 16 your motion to strike. 17 BY MR. WISNER: Nowhere in this presentation does it 18 Ο. discuss the clinical efficacy of Celexa in treating 19 pediatric depression? 20 21 MS. THORNE: Objection. 22 THE WITNESS: Again, it shows what's 23 relevant to most clinicians, which is the 24 primary endpoint effect.

```
1
    BY MR. WISNER:
 2
            O. Doesn't discuss effect size?
 3
                   MS. THORNE: Objection.
 4
                   THE WITNESS:
                                 No.
 5
    BY MR. WISNER:
 6
                   Doesn't discuss number needed to treat?
            0.
 7
                   MS. THORNE: Objection.
                   THE WITNESS: No, nor does it for the
 8
 9
            other compounds that are included here.
    BY MR. WISNER:
10
11
            Q. I understand, but for citalogram it
12
    doesn't discuss that, correct?
13
                   MS. THORNE: Objection, asked and
14
            answered.
15
                   THE WITNESS: Sure, it does not discuss
16
            it.
17
    BY MR. WISNER:
            Q. And a second ago you said it only
18
19
    presents what's relevant for clinicians.
20
                   Is it your testimony or belief that the
21
    clinical efficacy of a compound is not something that's
22
    relevant to clinicians?
23
                   MS. THORNE: Objection. First of all,
24
            misstates the prior testimony, that's not what
```

he testified to. 1 Right. I said what is 2 THE WITNESS: 3 most relevant is the primary efficacy outcome, which is in the slides. 4 5 BY MR. WISNER: 6 And so then you would -- extrapolating 7 from that testimony then, it is less relevant, the 8 issue of clinical efficacy? 9 MS. THORNE: Objection. 10 THE WITNESS: My understanding is that 11 the FDA considers the outcome, primary efficacy 12 outcome the most important thing in the study. 13 BY MR. WISNER: 14 Ο. I'm sorry. My question to you was the 15 clinical efficacy of the results to you is less 16 important, in your opinion, to physicians than the results of the primary outcome? 17 18 Objection. At this point MS. THORNE: 19 we're going outside the scope of the 30(b)(6) 20 testimony. To the extent that Mr. Closter has 21 a personal opinion as to whether the clinical 22 results are less important to physicians than 23 the primary outcome, he can testify as to his 24 personal opinion.

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1
                    THE WITNESS: Yeah, I mean, I'm not a
            clinician, I don't treat patients. I believe
 2
 3
            the primary is the most important to
            clinicians, and there may be other parameters
 4
 5
            which are important but not as important.
    BY MR. WISNER:
 6
 7
            Q. And in those parameters would be
8
    clinical efficacy?
9
                    MS. THORNE: Objection, lack of
10
            foundation --
11
                    THE WITNESS: Again, I'm not --
12
                   MS. THORNE: -- assumes facts not in
13
            evidence.
14
                    THE WITNESS: The term clinical efficacy
            to me is a bit amorphous.
15
16
    BY MR. WISNER:
17
            Q. Okay. Let me ask you another silly
    question, but clinical efficacy isn't the second most
18
19
    important thing for physicians, right?
20
                   MS. THORNE: Objection. If we're going
21
            to keep using the term clinical efficacy, to
22
            make the record clear, I would urge you to
23
            define the term as you understand it because
            the record is unclear.
24
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1 MR. WISNER: Sure, I will do, will do, but before I do that, I want to finish this 2 document. 3 4 BY MR. WISNER: 5 Q. Nowhere in this presentation regarding citalopram does it disclose the results of Study 94404? 6 7 MS. THORNE: Objection. 8 THE WITNESS: It does not, nor does it 9 include the results of the other failed negative studies that exist in this class. 10 11 BY MR. WISNER: 12 0. Are you aware of any? 13 I'm pretty sure there's at least a dozen Α. 14 of them. 15 Are you aware of any right now? 0. 16 Α. I can do a lit search and find them for 17 you. Fair enough, but you're just shooting 18 Q. 19 from the hip here; you don't actually know --20 Α. Not really, no. I'm aware and I know 21 there's been commentary written in general when they 22 talk about studies on depression that there are more 23 failed and negative studies than there are positive 24 studies.

1 Q. I'm sorry, back up. 2 Are you talking about pediatric studies for Celexa? 3 4 Α. I'm saying on SSRIs. 5 Q. Oh, fair enough. I'm not talking about SSRIs. 6 7 talking about Celexa here. 8 That's fine. Α. 9 And for Celexa there's only been two Ο. 10 pediatric placebo-controlled clinical trials, right? 11 Α. That the sponsors have conducted, yes. 12 And at this point that this presentation Ο. was given, they were both completed? 13 14 Α. Yes. 15 One of them, the positive one was Ο. 16 presented? 17 Right, not the failed one. Α. The negative one was not, correct? 18 Q. 19 Α. Okay. 20 Ο. Correct? 21 You can call it negative. Α. 22 Q. You've called it negative, right? 23 Α. I have, and I've called failed too. 24 Okay. You would agree with me that this Q.

CME presentation, which was supported by an 1 unrestricted grant from Forest Pharmaceuticals, was 2 3 designed to promote the use of Celexa? 4 MS. THORNE: Objection. 5 THE WITNESS: Consistent with my many 6 previous answers on the topic, this is not 7 considered promotion. BY MR. WISNER: 8 9 Turn to the page 4 -- turn to the last page of the document. Unfortunately, it's not numbered 10 11 on the top. It would be -- it should be numbered 16, 12 the last page. 13 Yeah. Α. 14 The self-assessment questions. Q. 15 You see that? 16 Α. I do. 17 And it only has four questions, right? Q. 18 Α. Yes. 19 And the third question says, "Which of Ο. the following medication has been shown to be more 20 21 effective than placebo in the treatment of depression 22 in children and adolescents?" 23 You see that?

Α.

Yes.

And it lists out a bunch of 1 Q. antidepressants. 2 3 Do you see that? 4 MS. THORNE: Objection. 5 THE WITNESS: Yes. BY MR. WISNER: 6 7 0. The correct answer as noted just below 8 is C, citalopram, correct? 9 Α. Correct. 10 There's no discussion of Prozac? Q. 11 MS. THORNE: Objection. 12 THE WITNESS: It's not one of the 13 answers. 14 BY MR. WISNER: 15 0. They don't make an offer of sertraline? 16 Α. No. 17 They don't do -- the only answer that is Q. correct to the question of which of the following has 18 19 shown to be more effective than placebo in the treatment of depression in children and adolescents is 20 21 Celexa? 22 MS. THORNE: Objection. 23 THE WITNESS: Okay. 24 BY MR. WISNER:

It's your testimony to the jury that 1 0. 2 that's not promotion? 3 MS. THORNE: Objection. 4 This entire presentation THE WITNESS: 5 is not promotion. 6 BY MR. WISNER: 7 What about that question? Ο. 8 If you want to parse out individual Α. 9 parts of it, every part of it is not promotion. 10 Ο. So that question which guides physicians 11 to come to the conclusion that citalogram is safe and 12 effective for treating depression in children and adolescents is not a form of promotion? 13 14 MS. THORNE: Objection, misstates the 15 document, first of all. Second of all -- yeah, 16 misstates the document. 17 THE WITNESS: I mean, the question is "which of the following medications has been 18 19 shown to be more effective than placebo in the 20 treatment of depression in children and 21 adolescents" and doesn't mention safety. 22 BY MR. WISNER: 23 Ο. Mr. Closter, you can put that document 24 away for now. We're going to get into clinical

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efficacy definition in a second. I haven't forgotten
 1
    about that.
 2
 3
                   You stated -- we've discussed this
 4
    potential unblinding that occurred in Celexa Study 18,
 5
    correct?
 6
                Right, right.
            Α.
 7
                   Briefly, we didn't get into details, but
            O.
 8
    we discussed it briefly, right?
 9
            Α.
                   Yes.
10
            Q.
                   You understand that when those patients
11
    who were the subject of that dispensing error are
12
    removed from the primary efficacy results --
13
                   Right.
            A.
14
            Q.
                   -- the study is no longer statistically
15
    significant, correct?
16
                   MS. THORNE: Objection.
17
                   THE WITNESS: I'm aware of that.
18
    BY MR. WISNER:
19
            0.
                   Okay. So if, in fact, the patients had
20
    been removed from the study, the primary efficacy
21
    endpoint would have ultimately been negative, right?
22
                   MS. THORNE: Objection calls for
23
            speculation. That's outside the scope of the
24
            30(b)(6) notice. It calls for a hypothetical.
```

```
1
            To the extent that you have a personal opinion
2
            on that topic, you can feel free to answer.
3
            You're not answering on behalf of the company.
                   THE WITNESS: So the question is?
4
5
    BY MR. WISNER:
6
                   Well, Ms. Thorne is trying to instruct
            0.
7
    you that it's a hypothetical, but it's not a
8
    hypothetical, because they did conduct an analysis of
9
    the primary efficacy endpoint, excluding those nine
    patients that were subject to the dispensing error,
10
    correct?
11
12
                   MS. THORNE: Objection.
13
                   MS. KIEHN: You had said they were
14
            removed from the study.
15
                   MR. WISNER: Fair enough.
16
    BY MR. WISNER:
17
            Q.
                   Can you answer that question I just
18
    asked you?
19
                   If they were removed from the study, I
            A.
20
    understand that the result would have been negative.
21
                   Okay. And, in fact, when the dispensing
            0.
22
    error occurred, Forest sent a letter to the Food and
23
    Drug Administration; you're aware of that?
2.4
                   MS. THORNE: Objection, assumes facts
```

not in evidence. 1 2 THE WITNESS: Yeah, I would have to 3 see --MS. THORNE: Lacks foundation. 4 5 THE WITNESS: I would have to see the 6 letter. 7 BY MR. WISNER: 8 0. You haven't seen the letter that was 9 sent? 10 Α. I may have, but I would need to confirm. 11 MS. KIEHN: Why don't you describe it a 12 little bit more so he knows you're talking about the same thing. 13 14 BY MR. WISNER: 15 Ο. Isn't it true that in March of 2007, 16 Tracy Varner sent a letter to Dr. Katz at the FDA 17 indicating that there had been a dispensing error? 18 I believe that's true. Α. 19 And in that letter, Forest indicated O. 20 that they would exclude those patients who were the 21 subject of the dispensing error from the primary 22 efficacy analysis? 23 MS. THORNE: Objection, misstates the 24 letter, assumes facts not in evidence, lacks

```
foundation. If you're going to encourage
 1
 2
             Mr. Closter to speak to a document and if
 3
            you're going to characterize the document, I
 4
             would encourage you to put the document in
             front of him.
 5
 6
                    THE WITNESS: I'd like to see it, if I
 7
             can.
 8
                    MR. WISNER: Okay. Let's take a break.
 9
                    THE VIDEOGRAPHER: We are now off the
             record. The time is 4:22.
10
11
                    (Brief recess.)
12
                    THE VIDEOGRAPHER: We are now back on
13
            the record. The time is 4:40.
14
                    (Document marked for identification as
15
             ForestC Deposition Exhibit No. 20.)
16
    BY MR. WISNER:
17
             0.
                    I'm handing you a document that has been
    marked as Exhibit 20, so we're going back south again
18
19
     in the exhibit numbers.
20
                    Do you recognize this document,
21
    Mr. Closter?
22
            Α.
                   I do.
23
             O.
                    This is that letter that was sent to the
24
    FDA regarding the dispensing error?
```

- 1 A. Right.
- Q. Okay. And in this letter -- this is
- 3 dated March 21st, 20th or 21st, 2000?
- 4 A. March 20, 2000, yep.
- 5 Q. It looks like it was received on
- 6 March 21st; you see the stamp?
- 7 A. Yes.
- 8 Q. Okay. And if you read through the
- 9 letter, it says -- it mentions that there is a supply
- 10 packaging error.
- 11 And then the third paragraph reads, "For
- 12 reporting purposes, the primary efficacy analysis will
- 13 exclude the eight potentially unblinded patients, with
- 14 a secondary analysis including also to be conducted."
- 15 You see that?
- 16 A. I do.
- 17 Q. So in the initial -- this happened
- 18 contemporaneously or about the time that the unblinding
- 19 error was discovered?
- A. Right, the potential unblinding.
- MS. THORNE: Objection.
- 22 BY MR. WISNER:
- Q. And by "contemporaneously," I'm
- 24 referring to within a few weeks of.

1 Α. Okay. And according to this letter, Forest is 2 0. telling the FDA that it's going to, for its primary analysis, exclude those patients that were the subject 4 5 of a dispensing error, correct? 6 MS. THORNE: Objection, misstates the 7 document, lack of foundation, assumes facts not 8 in evidence. 9 THE WITNESS: That's what it says on the 10 paper. 11 BY MR. WISNER: 12 0. And, in fact, Forest states in this letter that as a secondary analysis including them will 13 14 also be conducted, correct? 15 MS. THORNE: Objection, assumes facts 16 not in evidence, lack of foundation, misstates 17 the document. 18 THE WITNESS: I mean, that's what the 19 author wrote, Tracy Varner wrote in the letter. 20 BY MR. WISNER: 21 Tracy Varner speaking on behalf of 0. 22 Forest? MS. THORNE: Objection, lack of 23

foundation, assumes facts not in evidence.

1 THE WITNESS: I mean, she works at 2 Forest. BY MR. WISNER: 3 4 Q. She was manager of regulatory affairs, 5 correct? 6 A. Right, one of the people in regulatory 7 affairs. 8 Q. And responsible for representing Forest 9 to the FDA? 10 MS. THORNE: Objection, lack of 11 foundation, assumes facts not in evidence. 12 THE WITNESS: Yeah, I'm not certain who 13 was copied on this communication. I don't know 14 who went into drafting it, other than Tracy, 15 whose name is here. 16 BY MR. WISNER: 17 Q. I'm sorry. That wasn't my question. 18 Α. Okay. 19 Ms. Varner was responsible -- Tracy is a 0. female, correct? Let's get that clarified. 20 21 Α. Yes. 22 Q. Ms. Varner was, in fact, responsible for 23 representing communications to the FDA on behalf of 24 Forest, correct?

1 MS. THORNE: Objection, assumes facts not in evidence, lack of foundation. 2 THE WITNESS: Yeah, I don't know her 3 exact responsibilities. 4 5 BY MR. WISNER: 6 Q. Well, she was a manager of regulatory 7 affairs, correct? 8 MS. THORNE: Objection, asked and 9 answered. 10 THE WITNESS: Correct. 11 BY MR. WISNER: 12 Q. And regulatory affairs is responsible for communicating to the FDA on behalf of Forest, 13 14 correct? 15 MS. THORNE: Objection, assumes facts 16 not in evidence, lack of foundation. 17 THE WITNESS: Yeah, I don't know if she was the sole person responsible or part of a 18 19 team that would have communicated with the FDA 20 through the regulatory affairs group. 21 BY MR. WISNER: 22 Q. Okay. And communicating a letter to 23 Dr. Katz at the FDA, she was communicating on behalf of 24 Forest, yes or no?

1 MS. THORNE: Objection. 2 THE WITNESS: Again, she is an employee at Forest communicating with the FDA. 3 4 BY MR. WISNER: 5 Q. So you can't state whether or not she is speaking for Forest or not in this letter? 6 7 MS. THORNE: Objection. 8 THE WITNESS: I can't. I wasn't in this 9 group at the time or ever. 10 BY MR. WISNER: Q. So you can't; that's your answer? 11 12 Α. Right. Okay. Do you know who within this group 13 Q. 14 Mrs. Varner would have coordinated with? 15 MS. THORNE: Objection. 16 THE WITNESS: At that time, I'm not sure 17 who was in the group at that time. BY MR. WISNER: 18 19 Okay. Now, in the final study report Ο. that was ultimately submitted to the FDA -- well, 20 21 strike that. 22 The final study report for Celexa Study 23 18 was ultimately submitted to the FDA, correct? 24 Α. Right.

```
And in that final study report, the
 1
             Ο.
    primary efficacy analysis included the data from the
 2
 3
    patients that were the subject of the dispensing error,
 4
     correct?
 5
                    MS. THORNE:
                                 Objection.
 6
                    THE WITNESS: Yeah, I think that was as
 7
             defined in the protocol that all the patients
 8
             in the ITT population would be included in the
 9
             efficacy analysis.
10
    BY MR. WISNER:
11
                    And, in fact, all the patients -- and,
12
     in fact, a secondary analysis excluding the patients
    was conducted in the final study report, correct?
13
14
                    MS. THORNE: Objection.
15
                    THE WITNESS: I believe that's true.
16
    BY MR. WISNER:
17
             Q.
                    So, in fact, the final study report did
     the exact opposite of what Mrs. Varner says they're
18
19
     going to do in the study as of March 20th, 2000?
20
                    MS. THORNE:
                                 Objection.
21
                    THE WITNESS: I believe so.
22
    BY MR. WISNER:
23
             Ο.
                    Okay. So back to my point that got us
```

here initially is I was just trying to establish that,

```
in fact, Forest had sent the letter in March of 2000
 1
     that indicated to the FDA that the patients that were
 2
 3
     the subject of the dispensing error would not be
     included in the primary efficacy analysis, correct?
 4
 5
                    MS. THORNE: Objection, lack of
 6
             foundation.
 7
                    THE WITNESS: That's what the letter
 8
             states.
 9
                    (Document marked for identification as
10
             ForestC Deposition Exhibit No. 31.)
11
    BY MR. WISNER:
12
             0.
                    Okay. All right. Handing you a
    document that's going to be marked as Exhibit 31 in
13
14
    response to your counsel's request that we help define
15
    the definition of clinical significance. This is a
16
    document that's titled "Navigating the Maze,
17
    Understanding Methods, Results and Risk in Psychiatric
18
    Research."
19
                    Do you see that, Mr. Closter?
20
             Α.
                    Yes.
21
                    And it looks like it's dated May 20th,
             Ο.
22
     2006?
23
             Α.
                    Yes.
24
                    And if you look down here, it is a
             Q.
```

- 1 program that was sponsored by the American Psychiatric
- 2 Association and supported by an educational grant from
- 3 Forest Pharmaceuticals.
- 4 You see that?
- 5 A. Yes, I do.
- Q. And if you turn the page, Page 2,
- 7 there's a table of contents.
- 8 Do you see that?
- 9 A. Yep.
- 10 Q. And in the second presentation it says,
- 11 "Assessing Statistical and Clinical Significance in
- 12 Medical Research."
- Do you see that?
- 14 A. Yes.
- Q. And it has a physician listed there
- 16 David Kupfer.
- Do you see that?
- 18 A. Yes.
- 19 Q. Do you know David Kupfer?
- 20 A. I do.
- Q. How do you know him?
- 22 A. I don't know him personally all that
- 23 well. I know that's someone that Forest would have
- worked with in an advisory capacity in the time frame

- that we're talking about. 1 Do you know what kind of physician he 2 Ο. is? 3 I believe he's a psychiatrist. 4 Α. 5 Q. Is he a pediatric psychiatrist or just a regular psychiatrist? 6 7 Α. I don't know. 8 Okay. Was Mr. Kupfer considered a key Q. 9 opinion leader within Forest? 10 MS. THORNE: Objection. 11 THE WITNESS: Dr. Kupfer was a key 12 opinion leader, yes. 13 BY MR. WISNER: 14 Q. Sorry, Dr. Kupfer. 15 Α. It's all right. 16 0. If you turn to Page 6 there is a "Conflict of Interest Disclosure Statement." 17 18 Do you see that? 19 Α. Yes. 20 And then down here we have David Kupfer 0.
 - 22 A. Yes.

listed?

- Q. And it states that he was an advisory
- 24 board member for Eli Lilly and Company, Forest

Laboratories, Inc., Pfizer Inc. and Solvay 1 Pharmaceuticals. 2 3 You see that? 4 Α. Yes. 5 Q. And that's the second there you said he worked in an advisory capacity for Forest 6 Pharmaceuticals. Was it your understanding that he was 7 8 an advisory board member? 9 Α. Yes. 10 Q. Okay. And also on this lineup of 11 physicians, we have Jeffrey Bostic. 12 Do you see that? 13 Α. Yes. 14 He was also a key opinion leader for Q. 15 Forest? 16 MS. THORNE: Objection. 17 THE WITNESS: He's a key opinion leader, 18 yes. 19 BY MR. WISNER: 20 Ο. He was a member of Forest speakers 21 bureau? 22 Α. Yes. 23 Ο. And he actually gave presentations

specifically on the treatment of pediatric depression?

1 MS. THORNE: Objection, assumes facts 2 not in evidence, lacks foundation. 3 THE WITNESS: He was part of the speakers bureau where he agreed to give 4 5 on-label presentations and was provided content in which to do that. 6 7 BY MR. WISNER: 8 And you said he was instructed to give 9 on-label content. He specifically would address adolescent and pediatric treatment of depression, 10 11 right? 12 MS. THORNE: Objection, lacks 13 foundation, assumes facts not in evidence. 14 THE WITNESS: My understanding is there 15 was, again, a handful of representatives that 16 would use him in that capacity. 17 BY MR. WISNER: O. Over the course of Dr. Bostic's 18 19 experience with Forest, he was paid over \$750,000 20 correct? 21 MS. THORNE: Objection. First of all, 22 that's outside the scope of the 30(b)(6) 23 deposition notice. 24 MR. WISNER: Are you instructing him not

```
1
            to answer?
 2
                    THE WITNESS: I mean, I can't confirm
 3
            that.
 4
                    MR. WISNER: Let's go off the record.
 5
                    THE VIDEOGRAPHER: We are now off the
 6
            record. The time is 4:50.
 7
                    (Discussion off the record.)
 8
                    THE VIDEOGRAPHER: We are now back on
 9
            the record. The time is 4:51.
10
    BY MR. WISNER:
11
                   It's your understanding that Dr. Bostic
    received payments in excess of $750,000 for his work
12
    consulting for Forest, correct?
13
14
            Α.
                   I can't confirm that amount.
15
            0.
                   You don't know offhand if that number is
16
    true?
17
            Α.
                   No.
                   And that's both in your representative
18
            Q.
19
    capacity on Forest, but also in your personal capacity?
20
                   That's right.
            Α.
21
                  Okay. Have you ever heard that he was
            0.
    paid $750,000?
22
23
            Α.
                   I was not.
24
                   Would you have any reason to dispute
            0.
```

```
that fact?
 1
 2
                    MS. THORNE: Objection.
 3
                    THE WITNESS: Again, I would have to see
             it.
 4
 5
    BY MR. WISNER:
 6
                    Okay. Still on this exhibit, let's turn
             Ο.
 7
    to page -- let's turn to Page 12. We're in the throes
 8
    of Dr. Kupfer's presentation.
 9
                    Do you see that?
10
             Α.
                    Yes.
11
                    All right. On the first slide here it
             Ο.
12
     says "Basic Criteria for Randomized Clinical Trial."
    The first bullet point is "Control group (placebo or
13
14
     active treatment). " The second, "Participants randomly
15
     assigned into the treatment or control groups," and the
16
    third one says, "Participants and researchers 'blinded'
    as to who was in which group." And then it has a
17
18
     subbullet point that says, "Most important, persons who
19
     evaluate the outcomes 'blinded' as to who is in which
     group."
20
21
                    Do you see that?
22
             Α.
                    Yes.
23
             Ο.
                    Now, you would agree that in a
    double-blind placebo-controlled trial, it's important
24
```

- 1 that both the participant in the clinical trial, as
- 2 well as the clinical investigator, be blinded as to
- whether or not they're in the placebo or treatment
- 4 group, correct?
- 5 MS. THORNE: Objection.
- 6 THE WITNESS: You know, again, not as an
- 7 expert, based on my understanding of trials,
- yes, that's true.
- 9 BY MR. WISNER:
- 10 Q. And, specifically in regards to
- 11 assessing the results of an antidepressant, since the
- 12 physician is making the assessment of the improvement
- over time of the patient, it would be very important
- 14 that the physician who is making that assessment or
- 15 clinician does not know whether or not the person
- 16 they're assessing is receiving placebo or citalogram or
- 17 Lexapro?
- MS. THORNE: Objection.
- 19 THE WITNESS: Yeah, I don't know if I
- 20 have the expertise to answer. I don't know if
- it's any different in -- as you mentioned, in
- 22 mood disorders, like a depression or other
- disease states.
- 24 BY MR. WISNER:

Okay. But you will agree, just 1 Ο. generally, with the principle that it's important for 2 the clinician and the patient to be blinded as to 3 whether or not they're in the placebo or treatment 4 5 group? 6 MS. THORNE: Objection. 7 THE WITNESS: Agree. 8 BY MR. WISNER: 9 Okay. So the next slide says "Limitations of Statistical Significance." It says, 10 11 "treatment is statistically significant better than 12 control is the same as our data indicate that something non-random differentiates treatment and control." 13 14 Do you see that? 15 Α. Yes. 16 Is that also your understanding of what Ο. statistical significance means? 17 18 Objection. That's outside MS. THORNE: 19 the scope of the deposition notice. I'm going 20 to instruct the witness not to answer on behalf 21 of your company. 22 Mr. Closter, to the extent that you have 23 individual understanding, you can answer. 24 THE WITNESS: Yeah, I mean, I'm not an

expert on this matter, so I'm not sure how I 1 would interpret that. 2 BY MR. WISNER: 3 4 Ο. So you don't know if that's what 5 statistical significance means on a personal level? 6 Α. No. 7 Okay. It goes on to read P values Ο. 8 indicate only how convincing the data are (i.e., the results are not a chance occurrence). Mainly 9 10 significant better treatments -- many "significantly 11 better" treatments offered no clinically significant 12 advantage. 13 Do you see that? 14 Α. Yes. 15 Do you understand the difference between 0. 16 clinically significant -- statistically significant improvement versus a clinically significant 17 18 improvement? 19 From the slide? Α. 20 Just as a general matter. Ο. 21 No, I don't. Α. 22 Q. Okay. Does this slide help you 23 understand that concept any better? 24 Α. No.

1 Ο. Do you understand that they are different, though, according to this slide? 2 3 Α. The slide says they're different. don't understand why. 4 5 Q. Okay. 6 MS. THORNE: I'm renewing my objection 7 to this line of questioning. 8 MR. BAUM: Just to be clear, are we 9 reserving discussions of this sort to Olanoff? 10 MS. KIEHN: We'll take it under 11 advisement. I mean, you know, again, you're 12 entitled to this territory of expert testimony 13 about clinical studies, as opposed to the 14 company's facts or opinions, so -- but Olanoff 15 certainly would be the more appropriate witness for this one. 16 17 MR. BAUM: So, also, I think we had discussed that Mr. Closter is prepared to talk 18 19 about the editorials; is that correct? 20 MS. KIEHN: The letters to the editor. 21 MR. BAUM: Yes, letters to editor. And 22 Forest's response? 23 MS. KIEHN: Yes, he's reviewed those 24 materials.

-		
	1	MR. BAUM: And the subject of clinical
	2	efficacy is pretty extensively discussed in
	3	those, and so I'm just wondering how is that
	4	beyond the scope and definitions of that beyond
	5	the scope? He has to know the difference in
	6	order to answer that section of our 30(b)(6).
	7	MS. KIEHN: I think maybe looking
	8	asking those questions in the context of the
	9	document you're interested in might be better
	10	than asking these kind of theoretical questions
	11	about this slide. I mean, you're asking about
	12	scientific principles.
	13	MR. BAUM: You're going to use the
	14	definitions
	15	MR. WISNER: Michael, can I just I'm
	16	running out of time.
	17	MR. BAUM: of the terms.
	18	MR. WISNER: Let's just go through this
	19	deposition.
	20	MS. KIEHN: He's telling you what he
	21	knows.
	22	MR. BAUM: So what I'd like to be clear
	23	is we're reserving then going over that with
	24	somebody who does.
- 1		

1 I understand. MS. KIEHN: 2 MS. THORNE: To the extent -- you can reserve it and we'll it under advisement, as 3 Mrs. Kiehn already stated. 4 5 BY MR. WISNER: 6 All right. I'm going to continue on Ο. 7 with the slide. 8 The next slide says "Medical Decision 9 Making Requires More." It reads, "Beyond statistical significance, need to know if the relationship is 10 11 meaningful, i.e. clinically significant. Providing 12 information about the strength of the relationship further informs clinical significance, i.e. the effect 13 14 size." 15 Do you see that? 16 Α. I do. 17 And throughout this deposition I've been Q. asking you questions about whether or not Dr. Wagner 18 19 was disclosing the effect size of the relationships 20 observed between citalogram treatment and depression --21 improvement of depression. 22 Based on the slide, do you see how 23 effect size could be related to clinical significance? 24 MS. THORNE: Objection. This is outside

1	the scope of the 30(b)(6) deposition notice.
2	To the extent Mr. Closter has an individual
3	understanding, he can testify, but he won't
4	testify on behalf of the company. If you would
5	like to ask about clinical significance in the
6	context of something on which Mr. Closter was
7	prepared to testify on behalf of the company,
8	we're not going to object on those grounds, but
9	asking these broad questions, that is outside
10	the scope of this notice.
11	MR. WISNER: Ms. Thorne, I do believe
12	you asked me to define clinical significance.
13	MS. THORNE: Yes, I asked you to define
14	for the witness what you mean when you say
15	clinical significance.
16	MS. KIEHN: And it was actually clinical
17	efficacy that you said not clinical
18	significance. That's adding to the confusion.
19	MS. THORNE: So that when you're using a
20	term, you and the witness are on the same page
21	and the record is clear. I was not asking you
22	to run through a document and have the witness
23	opine on your on whether your opinion of
24	clinical significance is accurate. I just want

you to explain to the witness what you mean 1 2 when you say it so that he can answer your 3 questions in a way that everyone is on the same 4 page. 5 MR. WISNER: Is your objection done? 6 MS. THORNE: First of all, that wasn't 7 an objection. You asked me a question and I 8 answered your question, so I was answering your 9 question. 10 MR. WISNER: Okay. Are you done? Because I'd like to actually continue with the 11 12 deposition. 13 MS. THORNE: Sure. I think I answered 14 your question hopefully to your satisfaction. 15 BY MR. WISNER: 16 Okay. So my question pending, I believe -- I don't remember the question, it's been a 17 while, but let me ask another question to see if we can 18 19 get going with this. 20 Α. Okay. 21 You understand that the effect size 22 observed in a relationship is indicative of clinical 23 significance, yes or no? 24 MS. THORNE: Objection, that's outside

the scope of the 30(b)(6) notice. I'm going to 1 renew my objection and instruct the witness to 2 answer in his personal capacity only to the 3 extent he is able. 4 5 THE WITNESS: The slide suggests that. 6 BY MR. WISNER: Dr. Kupfer is suggesting that, correct? 7 Ο. 8 Yes, he's the one presenting the slides. Α. 9 And he's one of Forest's members of the 0. 10 advisory board? Right. He also in his slides doesn't 11 12 literally define what clinically significance -- what clinically significant advantage means. 13 14 Mr. Closter, we'll get there. Ο. 15 Okay. Just so you're clear, in my mind Α. it does not define any of these things. 16 17 But he does suggest that the effect size Q. is one way of assessing clinical significance, correct? 18 19 MS. THORNE: Objection, renewing my 20 objection and the same instruction. 21 THE WITNESS: Yes, that's what he states 22 in his slide. 23 BY MR. WISNER:

Okay. And if we keep going here, on

O.

Page 13 there is a slide that says use of effect size. 1 2 Do you see that? 3 I'm sorry, the first slide. "Threshold 4 of Clinical Significance." 5 Α. Okay. 6 Ο. Do you see that? 7 Α. Yes, yes. 8 And he says, "Establishing it requires Q. 9 defining it." 10 Α. Okay. 11 Ο. Suggestion, the effect size would be -would motivate about half of well-informed clinicians 12 to use treatment rather than control in this 13 14 population. 15 Do you see that? 16 Α. Yes. 17 Have you ever seen that definition of Q. clinical significance before? 18 19 MS. THORNE: Objection, misstates the 20 document, and I'm renewing my same objection to 21 this being outside the scope and instructing 22 the witness to answer in his personal capacity 23 only. 24 THE WITNESS: Have I seen this before?

```
1
    BY MR. WISNER:
 2
            Q. Have you ever seen that definition for
    clinical significance?
 4
            Α.
                   Not that I can recall, no.
 5
                   MS. THORNE: Objection, misstates the
 6
            document.
 7
    BY MR. WISNER:
 8
                   I'm sorry. I couldn't hear the witness
            Q.
9
    testify.
10
                    What was your answer, sir?
                   Not that I'm aware of.
11
            Α.
12
            0.
                  Okay. Turn to the next page, on Page
    14, there's some slides there about effect size, I'm
13
14
    not going to belabor it, but here there's a middle
15
    slide that says "Some Risk Terminology."
16
                   Do you see that?
17
            Α.
                   Yes.
18
                   And the bottom one says "NNT: number
            Q.
19
    needed to treat."
20
                   Do you see that?
21
            Α.
                   Yes.
22
            Q.
                   It says, the number of subjects who need
23
    to be treated to expect one or more success than if all
```

had received control.

1 Do you see that? 2 Α. Yes. Is that your understanding of the 3 Ο. definition of number needed to treat? 4 5 Α. Yes. 6 MS. THORNE: I'm going to renew my 7 objection and the same instruction. 8 BY MR. WISNER: 9 Okay. And if you look down at the next 10 thing it says Interpretation of the Strength (Effect 11 Size) of a Positive Relationship. And then if you look down here, there's a chart that's created. 12 13 Do you see that? 14 I see the chart. Α. 15 Okay. And all the way on the right you Ο. 16 see it has "NNT"? 17 Α. Yes. And then it has a bunch of numbers. 18 Q. under "much larger than typical," it's NNT less than or 19 20 equal to 1.9. 21 Do you see that? 22 Α. Yes. 23 Ο. And all the way at the bottom it says

"small or smaller than typical," and then an NNT of

8.9. 1 2 Α. Yes. Okay. Now, if you look at the next 3 Ο. paragraph, on Page 15, the first slide has the "NNT: 4 Number Needed to Treat." 5 6 You see that? 7 Α. Yes. 8 And it says, "NNT: Number of subjects Q. 9 who need to be treated to expect to have one more success than if all had received control." It says, 10 11 "designed for success/failure outcomes," and then it has something about NNT equaling 1 over -- I think it's 12 13 an equation there. 14 Do you see that? 15 Α. I see the equation. 16 Ο. All right. And at the bottom it says "Highly recommended." 17 18 You see that? 19 Α. Yes. 20 In any of your interactions with Dr. --Ο. 21 the physician, Dr. --22 Α. Kupfer. 23 Ο. -- Kupfer, had you ever discussed 24 clinical significance?

```
1
                    MS. THORNE: Objection. Again, I'm
             objecting to this being outside the scope. I'm
 2
             renewing the same standing instruction to the
 3
 4
            witness.
 5
                    THE WITNESS: I'm not aware we've
 6
             discussed this or I've been in the presence of
             the discussion.
 7
 8
    BY MR. WISNER:
 9
               Okay. Isn't it true on behalf of Forest
    that the use of effect size in an NN treat number is a
10
11
    commonly used metric to assess clinical significance of
12
    a study result?
13
                    MS. THORNE: Objection, outside the
14
             scope, same instruction to the witness.
15
                    THE WITNESS: And the question is is it
16
             -- I'm sorry.
17
                    MS. KIEHN: That's okay. We'll reserve
             it for Dr. Olanoff.
18
19
                    MR. WISNER: I will withdraw the
20
            question, that's fine. I'll reserve it for
21
            Dr. Olanoff.
22
    BY MR. WISNER:
23
             O.
                    I'm going to hand you a document --
24
    well, actually, before I do that, are you familiar --
```

you can put the document away. 1 Are you familiar with the various 2 3 interactions that happened internally within Forest regarding the selection of which journal to have the 4 5 pediatric data from Study 18 published in? 6 I was not involved in the discussions. 7 Okay. Have you reviewed any of those O. correspondence, internal correspondence in preparation 8 9 for your testimony today? 10 Α. I think I've seen a couple of e-mails. 11 Q. Okay. (Document marked for identification as 12 ForestC Deposition Exhibit No. 40.) 13 14 BY MR. WISNER: 15 Ο. I'm handing you a document, Number 40. 16 Is this one of the e-mail correspondence 17 that you reviewed before? 18 Α. I feel like I've seen parts of it. I'm 19 happy to read through it, if you like. 20 I'll read through it with you. O. 21 Α. Okay. 22 Q. So if you look on Page 3. 23 Α. Okay.

You see this e-mail from John MacPhee?

Ο.

24

1 Α. Yes, we saw this earlier. 2 Ο. Exactly. This is the e-mail we saw 3 previously, correct? 4 Yes, it looks to be. Α. 5 Q. All right. Now, if you look in response to that e-mail, there is a response from Christina 6 7 Goetjen. 8 Do you see that? 9 Α. Yes. And it's to John MacPhee, Nefertiti 10 Q. 11 Greene and Jeffrey Lawrence. 12 Do you see that? 13 Α. Yes. 14 It says "FYI, we spoke with Karen Wagner Q. 15 today about the current state of affairs regarding the 16 pediatric data. We discussed Forest's decision to go with a publication other than JAMA as it fits our 17 corporate objectives." 18 19 Do you see that? 20 Α. Yes. 21 Do you understand why not publishing the Ο. 22 data in JAMA fit Forest's corporate objectives? 23 MS. THORNE: Objection.

THE WITNESS:

24

I mean, I can't say for

You know, if I was going to speculate 1 2 about it, you know, JAMA is highly selective. 3 They reject more than they accept, so in the efforts to, you know, get it published, they 4 5 would have selected another journal perhaps one 6 that is focused on psychiatry. 7 BY MR. WISNER: 8 Q. Okay. 9 But that's me speculating. Nefertiti Greene and John Mac -- what 10 Q. 11 was Nefertiti Greene's role at Forest? 12 Α. She was likely head of the Celexa brand team at the time. 13 14 The brand team? Q. 15 Marketing team. Α. 16 Okay. Q. 17 Α. She reported to John. 18 Q. Okay. So they both worked in marketing? 19 Α. Yes. 20 Ο. And Jeffrey Lawrence, who was he? 21 He worked on the marketing team as well. Α. 22 Q. So these are all three marketing people; 23 is that right? 24 Correct, including Christina. Α.

Okay. Including Christina. 1 Q. 2 She goes on to read, "She agreed with 3 the logic, yet reminded us that if we want to appeal to the PCP and pediatric audiences, we need to publish in 4 5 a place that provided the appropriate readership (something JAMA would've done). She also said that the 6 7 lack of data regarding the use of Celexa for pediatrics 8 is limiting it to the 'last choice' amongst physicians 9 - she just wanted to make sure we understood the 10 marketing advantages of the data. I assured her we got 11 it." 12 Did I read that correctly? 13 Α. Yes. 14 Okay. It appears here that Christina Q. 15 Goetjen -- Goetjen. 16 Goetjen. Α. 17 Q. Okay. Christina Goetjen is relaying a conversation she had with Dr. Wagner to other people 18 within the marketing group concerning Dr. Wagner's 19 20 concerns about the marketing advantages of publishing 21 the data in a sufficiently respectable journal; is that 22 right? 23 MS. THORNE: Objection, calls for 24 speculation, lack of foundation, assumes facts

not in evidence. 1 2 THE WITNESS: I mean, that's what she You know, the conversation that 3 Christina would have had with Dr. Wagner, we'll 4 5 never really know. BY MR. WISNER: 6 Okay. Well, the next paragraph says, 7 0. "She is excited about our Pediatric Regional CME series 8 9 and will be a fundamental part of speaker selection. She knows that she and Jeff will be working closely as 10 11 I will be on maternity leave." 12 Do you see that? 13 Α. Yes. 14 It goes to say, "She is extremely savvy Q. 15 about PR and is working well with GCI for surrounding 16 PR opportunities. We may want to give her a chance to familiarize herself with some media training." 17 18 Do you see that? 19 Α. Yes. 20 So it appears that a person from Ο. 21 marketing is having a conversation with the principal 22 investigator in a pediatric trial --23 Α. Right. 24 -- about the potential marketing 0.

advantages of how the pediatric data is disclosed to 1 the public? 2 3 MS. THORNE: Objection, calls for 4 speculation. 5 THE WITNESS: That's leaving out a fair 6 amount of details within this. You can 7 characterize the conversation any way you'd 8 like. 9 BY MR. WISNER: 10 Q. It appears that Dr. Wagner is concerned with reaching PCPs and pediatric audiences, correct? 11 MS. THORNE: Objection, calls for 12 13 speculation. 14 THE WITNESS: Yeah. Again, according to 15 this e-mail, absent hearing the conversation 16 that Christina would have had with Dr. Wagner. 17 BY MR. WISNER: Based on this e-mail it sure looks like 18 Dr. Wagner is thinking about the dissemination of the 19 pediatric data in the context of promotion? 20 21 MS. THORNE: Objection. 22 THE WITNESS: I wouldn't say any of this 23 is promotion. 24 BY MR. WISNER:

```
1
             Ο.
                    Discussing marketing advantages, getting
     an appropriate readership that gets the PCPs and
 2
    pediatric audiences, that's not promotion to you,
    Mr. Closter?
 4
 5
                    MS. THORNE:
                                 Objection.
 6
                    THE WITNESS: Yeah, it's not. I don't
 7
            know what -- again, the discussion of marketing
 8
             advantages, was that Dr. Wagner's words, were
 9
             those Christina's interpretation? Did they
10
             talk about claims data? We have no idea what
11
             the conversation was. So the fact that it says
12
            marketing advantages --
13
    BY MR. WISNER:
14
                    So it's your testi --
             0.
15
                    -- I can't put much weight to it.
             Α.
16
                    Sorry to interrupt you.
             Q.
17
                    So it's your testimony to this jury that
18
     it does not appear that Dr. Wagner was intending to use
     the pediatric data to promote the use of Celexa in
19
     children?
20
21
                                 Objection.
                    MS. THORNE:
22
                    THE WITNESS:
                                  No.
23
                    MR. WISNER: All right. Let's look at
24
             the next document.
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1 (Document marked for identification as ForestC Deposition Exhibit No. 41.) 2 BY MR. WISNER: 3 4 All right. I'm handing you a document which is marked as Exhibit 41. 5 6 Is this one of the e-mails that you may 7 have seen regarding the publication of the citalogram 8 pediatric manuscript? 9 I'm sorry, did you ask if I've seen 10 this? 11 Q. Yes. 12 Α. I don't think I've seen this one. 13 All right. This is an e-mail from Q. 14 William Heydorn. 15 You see that? 16 Α. Yes. 17 It's directed to Lawrence Olanoff and a Q. bunch of other individuals within Forest. 18 19 Do you see that? 20 Yes, and someone from Lundbeck. Α. 21 I was going to say and, in fact, there's 0. somebody there from Lundbeck as well? 22 23 Kerstin, I believe. Α. 24 And is that the same Kerstin --0.

1 Α. Kerstin Overo, who was on an earlier 2 e-mail that we saw. Okay. And subject of this is second 3 Ο. draft of citalopram pediatric manuscript, right? 4 5 Α. Right. 6 All right. And it reads, during our --Ο. 7 your review, please note the following: 1) the 8 publications committee discussed targeting -- discussed 9 target journals and recommended the paper be submitted to the American Journal of Psychiatry as a brief 10 11 report. The rationale for this was the following: 12 we'd like to see the paper published quickly and in a top tier journal; 2) Jack Gorman (editor) has seen the 13 14 results on the primary endpoint and was impressed; 3) 15 this is the third report of a positive effect of an 16 SSRI in young patients; and 4) as a brief report, we feel we can avoid mentioning the lack of statistically 17 significant positive effects at Week 8 or study 18 19 termination for secondary endpoints. 20 Do you see that? 21 Α. Yes. 22 According to this e-mail from Q. 23 Mr. Heydorn, the publications committee decided to

submit the original pediatric manuscript as a brief

24

report, so they could avoid mentioning the lack of 1 statistically significant positive effects at Week 8 or 2 study termination for secondary endpoints, correct? 3 4 MS. THORNE: Objection. That's the fourth bullet 5 THE WITNESS: 6 on the page. 7 BY MR. WISNER: 8 All right. Isn't it true that Ο. 9 deliberately trying to avoid the disclosure of the negative results of the secondary endpoints is 10 misleading? 11 12 MS. THORNE: Objection. 13 THE WITNESS: I mean, I think what's 14 more important is ultimately what was included 15 in the publication. 16 BY MR. WISNER: 17 Q. Mr. Closter, that wasn't my question. My question is deliberately trying to 18 19 avoid disclosing the lack of a statistically significant positive effect at Week 8 or study 20 21 termination for the secondary endpoints, that activity, 22 is that misleading? 23 MS. THORNE: Objection.

THE WITNESS:

24

I believe there's a lot of

1	information that could be included in a brief
2	report. You know, the discussion and the
3	decision of what to include, what not to
4	include, I don't believe is misleading.
5	BY MR. WISNER:
6	Q. Mr. Closter, they specifically are
7	deciding to use a brief report so they don't have to
8	disclose the negative outcomes of the secondary
9	endpoints, isn't that fundamentally dishonest?
10	MS. THORNE: Objection, misstates the
11	document, assumes facts not in evidence, lacks
12	foundation, calls for speculation.
13	THE WITNESS: I mean, I'd speculate, I
14	mean, because it's the fourth reason here, I
15	assume these are in some sort of proper you
16	know, priority order, but the choice of
17	choosing a brief report was, you know,
18	multifold, according to what I'm reading in
19	this. So it would include getting out quickly
20	in a top tier journal, the fact that the editor
21	was impressed by the results, you know, the
22	third study showing a positive effect in young
23	patients, which I think speaks to its
24	importance, the fact that there's not very many

1 in a population that used antidepressants at the time. 2 So I would need to know more context 3 4 whether or not this was misleading or not, and, 5 ultimately, it would have to -- I'd rather look 6 at the final paper and the other publications around this because there is not any one report 7 8 that shows the full impact of the study from 9 the publication to publications that may be related review articles, all the posters that 10 11 are presented as part of the data set. I think 12 you have to look at the body of evidence that was ultimately published and disseminated. 13 14 BY MR. WISNER: 15 Mr. Closter, is it your testimony that Ο. 16 you can't determine whether or not the desire or actually effort to avoid disclosing the lack of a 17 statistically significant positive effect at Week 8 or 18 at study termination for secondary endpoints was 19 20 misleading? 21 MS. THORNE: Objection, asked and 22 answered, renewing my prior objections to this 23 question. 2.4 THE WITNESS: Yeah, with just this

alone, I can't make that determination. 1 2 BY MR. WISNER: 3 0. If, in fact, the publication committee had elected to publish these results in a format that 4 5 would allow them to conceal the negative results, you 6 would agree that would be a miscarriage of science, 7 correct? 8 MS. THORNE: Objection. That calls for 9 speculation, is outside the scope of the 10 notice. 11 THE WITNESS: Again, I think you'd have 12 to look at the body of published data in its entirety over some period of time. 13 14 BY MR. WISNER: 15 And, to be clear, at this point in time Ο. 16 the body of published data as it relates to Celexa Study 18 only included the positive results from the 17 primary efficacy endpoint, correct? 18 19 MS. THORNE: Objection, lack of 20 foundation. 21 THE WITNESS: I mean, if you're 22 referring to the poster, it's not uncommon that 23 the first presentation of a dataset may include 24 only the primary variables.

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1
    BY MR. WISNER:
             Q. Mr. Closter, I'm not talking about the
 2
    poster. I'm talking about the poster, the
    presentation, the CME, the press release, none of that,
 4
    not a single one of them included any disclosure of the
 5
    negative outcomes in the secondary endpoints for Study
 6
 7
    18, right?
 8
                    MS. THORNE: Objection, asked and
 9
             answered.
10
                    THE WITNESS: Yeah, again, you'd have to
11
             look at the body of what came out post this
12
             time period. There's not a drug that all the
13
            data is released all at once. It doesn't
14
            happen.
15
    BY MR. WISNER:
16
                   Isn't it true, Mr. Closter, that if
    those results had been positive, they would have been
17
    included in all those different outlets?
18
19
                    MS. THORNE: Objection, calls for
20
             speculation.
21
                    THE WITNESS: Yeah, my speculation is
22
             that it doesn't mean that they would have been
             in there or not, regardless of outcome.
23
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BY MR. WISNER:

24

1 Ο. Isn't it true that the reason why they weren't in there is because Forest didn't want negative 2 data out there in the public domain that would reduce 3 or suppress the pediatric sales of Celexa? 4 5 MS. THORNE: Objection. 6 THE WITNESS: I mean, the pediatric 7 sales of Celexa were not a focus. There was no 8 promotional effort against it. I think it was 9 a matter of the forms that the data was 10 released in, the data that we had relative to 11 other products that may have been included in 12 those CME -- those CME events. 13 BY MR. WISNER: 14 So you do not believe, speaking on Ο. 15 behalf of Forest, that Forest did anything wrong in failing to disclose in the posters, the CME 16 17 presentations, the press releases, the ACNP presentation or any other publication prior to the 18 publication of the manuscript that all the secondary 19 20 negative outcomes were negative? 21 MS. THORNE: Objection. 22 THE WITNESS: So when you say negative 23 secondary outcomes, it's important to look at 24 even the data over time. So I think on the

```
balance of it, if you looked at those data
 1
             presentations by study visit, you'd probably
 2
 3
             find at least from even what I read today,
             there were more time points where there was a
 4
 5
             statistically significant difference on active
 6
             drug versus placebo than time points when they
 7
             weren't.
 8
    BY MR. WISNER:
 9
                    Mr. Closter, that wasn't the secondary
10
     endpoint, though, was it?
11
                    MS. THORNE: Objection.
12
                    THE WITNESS: You talked of secondary
             outcomes, which are different to me than a
13
14
             secondary endpoint. An endpoint is a point in
15
             time. Outcomes could be anything. You know,
16
             it could be over time, by visit, it could be
17
             responder analyses. I mean, there's a host
             of -- a broad range of topics, and the
18
19
             suggestion that if we wanted to provide the
20
             secondary outcomes, it's -- you know, it's a
21
             more positive picture than a negative one.
22
    BY MR. WISNER:
23
                    Mr. Closter, you previously testified
24
    numerous occasions that the secondary outcomes for
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Study 18 were all negative. 1 2 Are you changing your testimony now? 3 MS. THORNE: Objection. 4 MS. KIEHN: Endpoint. 5 THE WITNESS: I believe my testimony was 6 to the secondary endpoint. 7 MR. WISNER: Okay. 8 THE WITNESS: And if it wasn't, that is 9 my position. 10 BY MR. WISNER: 11 Ο. I think the record speaks for itself. 12 During your last break, did counsel instruct you to not use the word secondary outcomes? 13 14 MS. KIEHN: Don't answer that question. 15 He's not going to answer that question. 16 MR. WISNER: What's the grounds? 17 MS. KIEHN: He is not going to answer 18 it, attorney-client privilege. 19 MR. WISNER: Okay. It's privilege? 20 MS. KIEHN: Yes. 21 BY MR. WISNER: 22 Ο. Okay. Are you going to abide by your 23 counsel's instruction not to answer a question about 24 whether or not she might have obstructed a witness who

was in the process of being deposed? 1 I would take the advice of counsel. 2 Α. 3 Ο. Okay. So let me ask the question again then using the endpoint language that you now require. 4 Isn't it true that Forest acted 5 6 unethically or in a misleading way when it did not disclose that all of the secondary endpoints were 7 8 negative in the posters, ACNP presentations, CME and 9 initially in its efforts to get this published as a 10 brief report for the pediatric manuscript? 11 MS. THORNE: Objection. 12 THE WITNESS: My previous answer stands, it's not unethical, not misleading. 13 14 BY MR. WISNER: 15 Okay. To be clear, that's not unethical Ο. 16 or not misleading based on the standards employed at 17 Forest, correct? 18 MS. THORNE: Objection. 19 I don't understand the MS. KIEHN: 20 question. 21 BY MR. WISNER: 22 Ο. Mr. Closter, I asked you a question. 23 Α. Explain the question.

Do you not understand the question?

Q.

24

1 Α. No. 2 O. Because I heard her say that, I didn't 3 hear you say anything. 4 Yeah, I don't understand the question. 5 Q. So your opinion that what Forest did was not misleading or unethical is based on the standards 6 7 that are used and exercised at Forest, correct? 8 MS. THORNE: Objection. 9 THE WITNESS: Are you referring to 10 today, back in the time period that we should 11 be focused on? 12 BY MR. WISNER: Does it make a difference, Mr. Closter? 13 0. 14 MS. THORNE: Objection. 15 THE WITNESS: You tell me. 16 BY MR. WISNER: 17 Q. Does the ethics of what's right or wrong change between today or what happened in 2001? 18 19 MS. THORNE: Objection. 20 THE WITNESS: It's my understanding that 21 the focus was on a given time period of things 22 that have happened in the past. 23 BY MR. WISNER:

Q. Okay. So my question to you is the

Golkow Technologies, Inc.

24

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standard by which you have testified that Forest's
 1
    conduct was neither misleading or unethical is based on
 2
 3
     the standards used within Forest, correct?
 4
                    MS. THORNE: Objection.
 5
                    THE WITNESS: Yes.
 6
                    MS. KIEHN: Could we go off the record
 7
             for one second.
 8
                    MR. WISNER: Sure.
 9
                    THE VIDEOGRAPHER: We are now off the
10
             record. The time is 5:23.
11
                    (Brief recess.)
12
                    THE VIDEOGRAPHER: We are now back on
            the record. The time is 5:27.
13
14
    BY MR. WISNER:
15
                    Okay. Mr. Closter, isn't it true that
             Ο.
16
    Forest was in a rush to get the results of the
    pediatric trial Study 18 out to the public domain as
17
    fast as possible?
18
19
                    MS. THORNE: Objection.
20
                    THE WITNESS: Yeah, it was a, you know,
21
             study relevant to clinicians, so the goal was
22
             to disseminate it.
23
    BY MR. WISNER:
24
             0.
                    Why?
```

- 1 A. Well, it was topical. I mean, I think
- 2 the treatment of kids in depression, if you think about
- 3 the significance of depression in kids, it's, you know,
- 4 while beyond the age range of kids, but up to the age
- of 34 it's the second leading cause of death, suicide
- 6 is, so it's considered an underserved population.
- 7 There haven't been very many studies
- 8 that were positive. Either they were well done and had
- 9 a negative result or some of the studies were just not
- designed well, which I would argue that 94404 is not a
- 11 well designed study and probably never could have shown
- 12 that citalogram worked over placebo, just based on its
- 13 design.
- But the fact is it's an underserved
- 15 population. Clinicians use these products extensively,
- 16 meaning SSRIs and other antidepressants in that age
- 17 range, so there's certainly a need, so it was topical,
- and the company felt it was important to provide the
- 19 data to clinicians.
- Q. Mr. Closter, you just testified that you
- 21 thought Study 94404 was poorly designed; is that right?
- 22 A. From what I've read, expert opinion,
- even in the published paper it cites some of the
- 24 deficiencies in the design.

You've actually never looked at the 1 Ο. protocol for 94404, have you? 2 3 I've read the published paper. Α. 4 Q. That's not my question. 5 Have you actually read the study protocol for 94404? 6 7 Α. I don't recall. 8 Earlier when I asked you about the 9 primary efficacy result, you didn't know if that was a 10 checklist or not, did you? 11 MS. THORNE: Objection, misstates the 12 testimony. 13 THE WITNESS: You're talking about the 14 primary efficacy variables used in that trial? BY MR. WISNER: 15 16 0. That's correct. 17 I asked -- I mean, I don't even remember Α. what I asked about it, but we looked at the name of it 18 19 and the acronym. 20 0. And you had to actually look at the 21 protocol to understand -- or sorry, look at the study 22 report to understand what that checklist was, right? 23 MS. THORNE: Objection.

THE WITNESS: Yeah, I'm not familiar

2.4

with every efficacy, you know, measure that's 1 used in all the trials. 2 BY MR. WISNER: 3 4 Q. But you are able to testify under oath 5 before this jury that study 94404 was, in fact, 6 improperly designed; is that right? 7 MS. THORNE: Objection, misstates the 8 testimony. 9 THE WITNESS: Right. I can read the 10 published paper and other expert opinion just 11 like anyone else can. 12 BY MR. WISNER: 13 Why was it improperly designed? 0. 14 MS. KIEHN: Misstates the testimony. 15 MS. THORNE: Yeah, objection, misstates 16 the testimony. 17 BY MR. WISNER: 18 I'm sorry. I'll reask the question. 0. 19 Mr. Closter, you said it was so improperly designed that you don't think it ever could 20 21 have shown any efficacy. 22 Do you remember saying something to that 23 effect? 2.4 MS. THORNE: Objection, misstates the

testimony. 1 I believe there was some 2 THE WITNESS: 3 deficiencies in the study that made it 4 difficult to interpret the results. 5 BY MR. WISNER: What are those deficiencies? 6 Ο. 7 It would be helpful if I had the paper Α. out, but the trial was done over a very long period of 8 9 It was done in I believe seven countries. 10 know, I think given depression and there's, you know, 11 certainly cultural bias in even the recognition or 12 awareness of the depression as a medical condition, that that may introduce some bias, given that the study 13 14 was conducted across multiple countries. 15 I believe patients were allowed to be on 16 concomitant meds, other psychotropics. I believe there 17 were patients that were hospitalized in the trial and 18 some that weren't and even some that had previous 19 histories of suicidality. 20 So like with any clinical trial, you 21 know, the goal, my understanding is to test whether the 22 active drug works versus placebo, and the more 23 variables you introduce, the more difficult it is to 24 ascertain that and to assess whether the drug works or

- 1 not. So from my understanding and perhaps other
- 2 experts that have commented on the study, there was too
- 3 much variability introduced into the study over time,
- 4 which may have confounded the result.
- 5 Q. You mentioned one of the problems is
- 6 that it took place in a series of European countries;
- 7 is that right?
- A. Right, seven.
- 9 Q. Do you not believe that antidepressants
- 10 work with children in Europe?
- MS. THORNE: Objection.
- 12 THE WITNESS: I mean, my understanding
- is a properly designed study, well-controlled,
- controlling for a variety of factors will work
- across multiple countries. I think the point I
- 16 made about the countries is that you had that
- fact, plus many other variables that were
- introduced into the study, making it difficult
- 19 to assess the results.
- 20 BY MR. WISNER:
- Q. I'm just curious, how does the fact that
- 22 it was conducted in seven European countries have any
- impact whatsoever on whether or not citalogram would be
- 24 able to outperform placebo in treating adolescent

```
depression?
 1
 2
                   MS. THORNE: Objection.
 3
                    THE WITNESS: So as I explained, there
 4
            may be cultural bias in those countries that
 5
            may favor or disfavor the active drug versus
 6
            placebo.
 7
    BY MR. WISNER:
 8
            Q. Have you looked into the cultural
9
    proclivities of Astonia?
10
                    MS. THORNE: Objection.
11
                    THE WITNESS: No, but what I'm providing
12
            to is information that I've either read or
13
            heard of as it relates to that study.
14
    BY MR. WISNER:
15
            0.
                    This is information you read and heard
16
    of while you worked at Forest, correct?
17
                   MS. THORNE: Objection.
18
                    THE WITNESS: I've worked at Forest for
19
            17 years.
20
                   MR. WISNER: I'm sorry. That didn't
21
            answer my question.
22
    BY MR. WISNER:
23
            0.
                   This is information that you read and
24
    heard of while working at Forest, correct?
```

Of course. 1 Α. 2 Ο. So to be clear then, your understanding -- I'll move on. I'm handing you a document which is Exhibit 43. 4 (Document marked for identification as 5 ForestC Deposition Exhibit No. 43.) 6 7 BY MR. WISNER: 8 Do you recognize this document? Q. 9 Α. I do. 10 What is this document? 0. 11 Α. This looks to be the publication, the 12 initial publication of MD-18. 13 At the beginning of this document it Q. 14 lists all the authors. 15 Do you see that? 16 Α. Yes. 17 Q. And listed here is Dr. Wagner, Dr. Robb, Dr. Findling, Dr. Jin, Dr. Gutierrez and Dr. Heydorn. 18 19 Do you see that? 20 Α. Yes. 21 There is no mention of Natasha Mitchner, Ο. 22 is there? 23 Α. No. 24 There is no mention of Mary Prescott? 0.

1 Α. No. There is no mention of any role that 2 Ο. BSMG or Weber Shandwick may have played in helping draft or create this manuscript, correct? 4 5 Α. That's correct. 6 And you agree that that's something 0. 7 called ghostwriting? 8 MS. THORNE: Objection. 9 THE WITNESS: I mean, I don't. I mean, 10 what's your definition of ghostwriting? BY MR. WISNER: 11 12 O. You're not familiar with the term ghostwriting? 13 14 I am. What's your definition of it? Α. 15 Just so I'm clear and when you're asking me it's 16 qhostwriting --17 Q. Let me ask you ---- I'm using your definition. 18 Α. 19 0. Sure. Let's use yours. What is your definition of qhostwriting? 20 21 Someone who puts their name on something Α. 22 that had absolutely nothing to do with the publication

Q. Okay. And when you say "absolutely

at any stage.

23

24

nothing to do, " does that mean they didn't put their 1 name on it at the end? 2 3 No, they put their name on it, but they 4 didn't do anything to provide any of the either 5 editing, fact checking, the discussion section, you 6 know, commentary. They literally had no involvement in 7 the paper. 8 Okay. And what would you call not Q. 9 disclosing somebody who did play a substantial role in 10 creating the manuscript; what would you call that 11 activity? 12 MS. THORNE: Objection. 13 THE WITNESS: I'd call that customary. 14 I mean, when you look at papers such as this, 15 and I'm not a publication expert, so let's just 16 be clear on that, it was not common to put the 17 vendor that you used to help you put the paper 18 together, you know, the vendor which you gave 19 them the tables and the graphs and many of the 20 sections and they literally format it and took 21 the data from you. I don't think it's common 22 that you would include the agency or the person

who happened to be working for you in doing

that.

23

24

```
1
                    Just like I don't believe if Dr. Wagner
             decided to publish an academic paper at her
 2
             institution, you know, she may, in fact, have
 3
             fellows, students, residents that may have
 4
 5
             worked on her behalf to put a paper together,
 6
             supported, you know, putting the paper
 7
             together, they may not be mentioned either.
 8
                    So the failure to disclose an author who
             Ο.
 9
    had a primary role in drafting a manuscript is, in your
10
    words, a customary thing?
                    MS. THORNE: Objection, misstates the
11
12
             testimony, lack of foundation, assumes facts
13
             not in evidence. There's been no testimony
14
             that an author of this paper was not disclosed.
15
                                  Right. I would not
                    THE WITNESS:
16
             consider the person or the agency you're
17
             referring to as an author.
18
    BY MR. WISNER:
19
             Ο.
                    Okay. That wasn't my question.
20
                    Sure it was.
             Α.
21
                    When I asked you what would you call it,
             Ο.
22
    the word you said is I'd call it customary; that's what
    you said, correct?
23
24
                    MS. THORNE: Objection.
```

```
1
                    MS. KIEHN: Objection.
 2
                    THE WITNESS: You're going to need to be
 3
            more clear in what you're asking me.
 4
    BY MR. WISNER:
 5
             Q.
                    Okay. Let's go back and read the
     question and answer, at least the first part.
 6
 7
                    MS. KIEHN: Which question and answer?
 8
                    MR. WISNER: The question that's
 9
            pending.
10
                    MS. THORNE: There are like --
11
                    MS. KIEHN: That's the one that doesn't
12
            make sense.
13
                    MS. THORNE: The question pending
14
             doesn't make sense. If you want to go back to
15
             the one I think you guys are arguing about,
16
             it's several questions back. So you really
17
             will need to specify for the court reporter the
             question and answer you're looking for. We're
18
19
            not trying to be difficult here.
20
                    MR. WISNER: Then please stop, and we'll
21
             do it. Can go back up a couple questions where
22
            he said customary.
23
                    MS. THORNE: And the question that
24
            preceded that answer.
```

```
1
                    (The court reporter read back the record
 2
             as requested.)
    BY MR. WISNER:
 3
 4
                    So a second ago when I asked you what
 5
    you would call the activity of not disclosing an author
    who had a primary role in developing --
 6
 7
                    MS. THORNE: Objection, misstates.
 8
                    MR. WISNER: I need to finish my
 9
             question, please. That is outrageous.
10
                    MS. KIEHN: You're misquoting yourself.
11
                    MR. WISNER: I'm asking a new question.
12
                    MS. KIEHN: Then don't characterize
13
            yourself as saying when I asked "X," which was
14
             something different.
15
                    MR. WISNER: Okay. Please stop
16
             interrupting. At this point you clearly are
17
             well -- can one of you pick the objections at
             this point because this is becoming a tag team
18
19
             and inappropriate.
20
                    MS. THORNE: First of all, no one is
21
             tag-teaming you. Kristin still doesn't have a
22
             voice, for the record. The audio will reflect
23
             that. Don't do that. That's not right and you
24
             know it.
```

1 Second of all, we're not tag-teaming. 2 MR. WISNER: Are you kidding me? 3 literally tags your arm and interrupts you with objections. 4 5 MS. KIEHN: Just keep going. What is the question? 6 7 BY MR. WISNER: 8 Mr. Closter, earlier I asked you what Ο. 9 would you call the practice of not disclosing an author 10 who had a primary role in --11 MS. THORNE: Objection. 12 BY MR. WISNER: 13 -- drafting the manuscript --Ο. 14 MR. WISNER: Please let me ask my 15 question. This is becoming harassment. Can 16 you please let me ask my question, Danielle. 17 Thank you. 18 BY MR. WISNER: 19 Ο. So let me see if I can get my question 20 out before she interrupts me. 21 Mr. Closter, earlier when I asked you 22 what would you call the practice of not disclosing a 23 primary author who had a primary role in drafting the 24 manuscript in the final publication, what would you

- 1 call that, let's just ask you that now, what would you
- 2 call that?
- MS. THORNE: Objection. Misstates the
- 4 prior question. To the extent you're asking a
- new question, the witness can answer.
- 6 THE WITNESS: All right. Before you
- 7 didn't say author. You said someone who had
- 8 some role in putting the paper together, right,
- 9 that was the question.
- 10 BY MR. WISNER:
- 11 Q. Fair enough. So let's get the question.
- 12 What do you understand the question to be?
- 13 A. All right. So there is no author that
- isn't listed here. If you're referring to the med
- 15 agency as an author, that is incorrect. They're not
- 16 considered authors.
- 17 Q. Mr. Closter, Natasha Mitchner wrote
- 18 almost all of the words in this initial draft, didn't
- 19 she?
- MS. THORNE: Objection, lack of
- foundation, assumes facts not in evidence.
- THE WITNESS: I couldn't possibly verify
- that.
- 24 BY MR. WISNER:

1	Q. So your testimony to this jury is you
2	don't know if Natasha Mitchner drafted the first draft
3	with almost all of the words on this manuscript
4	initially; is that your testimony?
5	MS. THORNE: Objection, misstates the
6	testimony. That wasn't the initial question,
7	assumes facts not in evidence, lacks
8	foundation.
9	THE WITNESS: Yeah, I can't verify the
10	work she did, the work Dr. Heydorn did,
11	Dr. Gutierrez did, Dr. Jin did and the other
12	outside authors that are listed on the paper.
13	I know that they were investigators, and,
14	certainly, Dr. Wagner would have had
15	substantive review of this paper, writing it
16	herself, editing it or formatting it.
17	The role of Natasha Mitchner or whomever
18	else would have been working at I guess it
19	was Weber Shandwick I guess was the name of the
20	company that Mary Prescott was helping manage,
21	they would have had some involvement in
22	literally formatting, putting together and
23	perhaps writing some of the drafts of the
24	content that's in here, but without seeing all

of the documentation, the back and forth, you 1 wouldn't know. 2 And even after all of that 3 4 investigation, she still wouldn't qualify as an 5 author on this paper. BY MR. WISNER: 6 7 Mr. Closter, I don't mean to fight with 0. you, but I asked a very simple question, and now I'll 8 9 just ask an open-ended question, do you know what role 10 Natasha Mitchner played in putting together this 11 manuscript? 12 Α. No, I don't have any direct knowledge of how -- what was her role was in the paper. 13 14 So how could you know one way or the Ο. 15 other whether or not she did not draft the first draft 16 of this manuscript? 17 MS. THORNE: Objection, misstates the 18 testimony, misstates the question. That was 19 not the initial question. The witness can 20 answer. 21 MS. KIEHN: That's not what he 22 testified. 23 THE WITNESS: Yeah, I'm speaking to you 24 as someone who has, you know, been in this line

- of work for some time and understanding the
- 2 roles of a publication support group.
- 3 BY MR. WISNER:
- 4 Q. You actually don't know what role
- 5 Natasha Mitchner played putting together this
- 6 manuscript, do you?
- 7 A. She could have done very, very little.
- 8 She could have done a little more than that.
- 9 Q. Is it possible that she could have
- 10 written the whole thing?
- 11 A. I doubt it.
- MS. THORNE: Objection.
- 13 BY MR. WISNER:
- 14 O. You doubt it?
- 15 A. This information here she wouldn't even
- 16 have had access to. Some of the documents are
- 17 handed -- most of the documents are handed to her from
- 18 Forest, and then, obviously, Karen Wagner has quite a
- 19 bit of input to it, so she'd be incapable of writing it
- 20 on her own.
- Q. I'm going to hand you a document, it's a
- 22 bit out of sequence, Exhibit 46.
- MS. THORNE: For the record, the topic
- that Mr. Closter was prepared for was to

```
testify to the general -- the general process
 1
             by which defendants engaged third parties to
 2
             assist with manuscript development for Celexa
 3
             and Lexapro prior to 2013.
 4
                    MR. WISNER: And he has testified to his
 5
 6
             representations on behalf of the company that
 7
             Natasha Mitchner could not possibly have
 8
             written the primary first draft of this
 9
             article.
10
    BY MR. WISNER:
11
                    I'm handing you a document --
             O.
12
             Α.
                    I didn't say that.
13
                    MS. KIEHN: No, no, the topic --
14
                    MR. WISNER: The record speaks for
15
             itself. We don't need to talk over.
16
                    MS. KIEHN: The topic speaks for itself.
                    (Document marked for identification as
17
18
             ForestC Deposition Exhibit No. 46.)
19
    BY MR. WISNER:
20
                    I'm handing you a document that is
             Ο.
21
    Exhibit 46 to your deposition.
22
                    Have you ever seen this document before?
23
             Α.
                    I have.
24
                    This is an editor's note that was
             0.
```

- 1 published in August of 2009, correct?
- 2 A. That's what it says in the paper.
- Q. And this was an editor's note published
- 4 by the American --
- 5 A. Journal of Psychiatry.
- 6 Q. Let's try to get it right. The American
- 7 Journal of Psychiatry, right?
- A. Apparently, it's a page number and
- 9 there's a citation to a website.
- 10 Q. It says on the bottom right American
- 11 Journal of Psychiatry, right?
- 12 A. Right, and then there's a URL address to
- 13 the left of it.
- Q. So this was published in the American
- 15 Journal of Psychiatry, right?
- 16 A. Or published online.
- MS. THORNE: Objection, asked and
- answered.
- 19 BY MR. WISNER:
- Q. Okay. All right. Turn to the second
- 21 page. Second to last paragraph it says, we are
- 22 satisfied that the named contributors of this study --
- of this article satisfy the criteria for authorship as
- 24 set forth in the "Uniform Requirements for Manuscripts

- 1 Submitted to Biomedical Journals from International
- 2 Committee of Medical Journal Editors. However, the
- 3 Journal's instructions to authors in 2004 and our
- 4 policy today do not allow contributions by unnamed
- 5 writers to the preparation of a paper. Thus, the
- 6 editorial contributions of Prescott Medical
- 7 Communications Group should have been acknowledged in
- 8 the published article as required at the time the
- 9 article was published.
- 10 Do you see that?
- 11 A. So just to be clear, this is being
- 12 published in 2009 on an article that was published in
- 13 2004.
- Q. Did I read that correctly, Mr. Closter?
- 15 A. Yeah I'm just making sure it's put into
- 16 context.
- 17 Q. And I appreciate you bringing the
- 18 context that this journal felt compelled to make this
- 19 disclosure five years after it had been published,
- 20 didn't they?
- MS. THORNE: Objection, calls for
- 22 speculation.
- THE WITNESS: Yeah, I can't speak to the
- journal's intent.

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1 BY MR. WISNER:
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- Q. And the journal says specifically that
- 3 the failure to disclose Prescott Medical Communications
- 4 as an author violated its policies as they existed in
- 5 2004; isn't that true?
- 6 MS. THORNE: Objection, misstates the
- 7 document.
- 8 THE WITNESS: Whatever is written in
- 9 this document.
- 10 BY MR. WISNER:
- 11 Q. So, Mr. Closter, a second ago when you
- 12 testified that you don't think Natasha Mitchner
- 13 qualified as an author, the journal that published the
- 14 article doesn't agree with you, does it?
- MS. THORNE: Objection, misstates the
- document, calls for speculation.
- 17 THE WITNESS: I can't speak on behalf of
- the journal.
- 19 BY MR. WISNER:
- 20 Q. Natasha Mitchner, to your understanding,
- 21 worked with Mary Prescott at Prescott Medical
- 22 Communications Group, right?
- MS. THORNE: Objection, assumes facts
- not in evidence, lacks foundation.

1 THE WITNESS: I don't know what the name 2 of the company was back then or the time period they're -- you know, you're referring to. 3 4 BY MR. WISNER: 5 Q. But you know that she worked with Mary 6 Prescott? 7 MS. THORNE: Objection. 8 THE WITNESS: Back at the correspondence 9 we've reviewed earlier. 10 BY MR. WISNER: 11 All right. Now, it says up here also in 12 this editorial if you go up to the top of the page, there's a sentence that says Drs. Wagner. 13 14 Do you see that? 15 Α. Yes. 16 It says, "Drs. Wagner, Robb and Findling Ο. 17 report that they contributed with Dr. Heydorn to the resubmission and that they were not aware that 18 19 Dr. Heydorn was working with a commercial writer." 20 Do you see that? 21 Α. Yes. 22 Q. Now, we had seen several e-mails 23 indicating that, in fact, Dr. Wagner had direct 24 communications with both Natasha Mitchner and Mary

```
Prescott; isn't that true?
 1
 2
                    MS. THORNE: Objection.
 3
                    THE WITNESS: I don't think we saw
 4
            direct -- I mean, I don't believe we saw
 5
            e-mails between the parties.
    BY MR. WISNER:
 6
 7
            0.
                    Okay. In all of your reviewing of the
 8
    various documents preparing for your testimony today,
 9
    have you not seen any direct communications between
10
    either Mary Prescott or Natasha Mitchner with Karen
11
    Wagner?
12
                    MS. THORNE: Objection.
                    THE WITNESS: I haven't seen any.
13
14
    BY MR. WISNER:
15
            0.
                   I'm sorry. What?
16
            Α.
                    I have not seen any.
17
                   Okay. Fair enough. Took it out of the
            Q.
    exhibits.
18
19
                    Mr. Closter, if, in fact, there had been
    direct communications between Karen Wagner and Mary
20
21
    Prescott or Natasha Mitchner in the context of
22
    preparing this manuscript, that representation to the
23
    journal article would have been false, correct?
24
                    MS. THORNE: Objection, calls for
```

speculation. That's also outside the scope of 1 2 the 30(b)(6) notice. 3 THE WITNESS: Can you ask the question 4 again. 5 BY MR. WISNER: 6 If, in fact, Dr. Wagner had direct 7 communications with Mary Prescott and/or Natasha 8 Mitchner in drafting this manuscript, that would make 9 the statements that were made to this journal as 10 reflected in Exhibit 46 false? 11 MS. THORNE: Objection, calls for 12 speculation, falls outside the scope of the 13 30(b)(6) notice. 14 THE WITNESS: Yeah, I don't know the 15 answer. 16 BY MR. WISNER: Q. 17 Okay. Well, it says right here that "Drs. Wagner, Robb and Findling report that they 18 19 contributed with Dr. Heydorn to the resubmission and that they were not aware that Dr. Heydorn was working 20 21 with a commercial writer. 22 Do you see that? 23 Α. I see that. 24 If, in fact, there is evidence that Q.

Dr. Wagner was working directly with a commercial 1 writer, that would indicate that Dr. Wagner's 2 representations to the journal were false, correct? 3 4 MS. THORNE: Objection. 5 THE WITNESS: I'm sorry. When you say "representations" of what? 6 7 BY MR. WISNER: 8 I'm sorry, what? Q. 9 What is she representing to the journal? 10 You referred to representations to the journal would be false, so what representations are you talking about? 11 12 Ο. It says right here, it says, "Drs. Wagner, Robb and Findling report that they 13 14 contributed with Dr. Heydorn to the resubmission and that they were not aware that Dr. Heydorn was working 15 16 with a commercial writer." 17 Do you see that? 18 Α. So you're saying Dr. Wagner would be 19 false if she had had communications with --20 A commercial writer. Ο. 21 Α. Okay. 22 Q. Yes? 23 Α. Sure.

MS. THORNE: Objection.

24

```
BY MR. WISNER:
 1
 2
            Q. All right. Turning your attention back
    to Exhibit 43. This is the publication. You got the
 4
    exhibit?
 5
            Α.
                  Yep.
 6
            Q. Let me draw your attention back to
    Exhibit 35.
7
 8
                   MS. KIEHN: Michael, can I have my
            exhibits back?
9
                   MR. BAUM: These are mine.
10
11
                   MS. KIEHN: Well, we need them to follow
12
            along with the question.
13
                   MS. THORNE: We at least need 35.
14
                   MR. BAUM: You have it.
15
                   MS. THORNE: All of them were in one --
16
                   MR. BAUM: We gave you two.
17
                   MS. KIEHN: That's our official stack.
18
            Sorry.
19
                   MR. BAUM: You can have these back.
20
            Give me the unofficial stack. Can I have the
21
            unofficial stack back.
22
                   MS. KIEHN: They're in order.
23
    BY MR. WISNER:
            O. Mr. Closter.
24
```

1 Α. Yes. 2 You're back on Exhibit 35? Ο. Yes. 3 Α. 4 Q. Okay. I believe this first paragraph 5 here it says, "Attached please find the final slides 6 submitted to ACNP on behalf of Dr. Wagner." 7 Do you see that? 8 Α. Yes. 9 We discussed the slides earlier; do you Ο. recall? 10 11 Α. Yes. 12 Ο. And then it goes, "Working with Dr. Wagner and Charlie Flicker, we finalized the slides 13 14 yesterday." 15 Do you see that? 16 Α. Yes. 17 And that was an e-mail from Natasha Q. Mitchner? 18 19 Α. Yes. 20 And so she's indicating that she's Ο. 21 working with Dr. Wagner, isn't she? 22 MS. THORNE: Objection. 23 THE WITNESS: It reads what it says, we 24 finalized the slides yesterday in reference to

- 1 working with Dr. Wagner and Charlie Flicker.
- 2 BY MR. WISNER:
- Q. Okay, great. Let's turn to Exhibit 43.
- 4 Sorry I keep making you jump around the exhibits like
- 5 this.
- 6 A. That's all right. I have them in order
- 7 now, okay.
- Q. Okay. If you turn to Page 2 in the
- 9 study report -- I'm sorry, the manuscript.
- 10 A. Yeah.
- 11 Q. And there's a section that says "Study
- 12 Design."
- Do you see that?
- 14 A. Yes.
- 15 Q. All right. It goes, "Following an
- initial screening visit in a 1-week, single-blind
- 17 placebo lead-in period, patients returned for a
- 18 baseline visit to determine whether they remained
- 19 eligible to participate. Eligible patients were then
- 20 randomly assigned in double-blind fashion to 8 weeks of
- 21 citalopram or placebo treatment."
- Do you see that?
- 23 A. Yes.
- Q. Nowhere in the remainder of that

- 1 paragraph or anywhere in the study design does it
- 2 mention that there was a potential unblinding issue
- 3 with at least eight or nine of the patients who were
- 4 participating in Study 18?
- 5 A. Okay.
- 6 MS. THORNE: Objection.
- 7 BY MR. WISNER:
- 8 Q. That's correct, right?
- 9 A. Correct.
- 10 Q. In fact, this issue about potential
- 11 unblinding is not disclosed in any capacity anywhere in
- 12 this publication, correct?
- MS. THORNE: Objection.
- 14 THE WITNESS: No.
- 15 BY MR. WISNER:
- 16 Q. Okay. Now, if you turn to Page 3, we're
- 17 here now in the "Results" section of the paper.
- Do you see that?
- 19 A. Yep.
- Q. Okay. And there's a paragraph, it's the
- 21 first full paragraph in the second column, it starts
- 22 off with citalogram treatment.
- You see that?
- 24 A. Yes.

1 Ο. It says that citalogram treatment showed statistically significant improvement compared with 2 3 placebo on the Children's Depression Rating Scale -Revised as early as week 1, which persisted throughout 4 5 the study (Figure 1). 6 Do you see that? 7 Α. Yes. 8 At Week 8, the effect size on the Q. 9 primary outcome measure, Children's Depression Rating 10 Scale - Revised was 2.9. 11 Do you see that? 12 Α. Yes. 13 Do you know what that means, 2.9? Q. 14 I mean, it may be referring to the Α. 15 difference between citalogram and placebo, but that's 16 just an educated guess. 17 Okay. Would Dr. Olanoff be someone who Q. 18 would probably be better able to answer a question like 19 that? 20 Α. Yes. 21 Okay. And then keep going, skip the 22 next sentence, it says -- the next sentence reads, the 23 portion of patients.

Do you see that?

24

1 MS. THORNE: It says proportion. 2 BY MR. WISNER: 3 Ο. Sorry, the proportion of patients. 4 Do you see that, with a CGI improvement 5 rating? 6 Α. Yes, the proportion of patients. 7 With a CGI improvement rating --Ο. 8 Α. Yes. 9 Ο. -- less than or equal to 2 at Week 8 was 48% for the citalogram group and 45% for the placebo 10 group, last option carried forward values. 11 12 Do you see that? 13 Α. Yes. 14 So it's actually reporting the Q. 15 percentage of values for that secondary endpoint from 16 the study, right? 17 Α. Right. But it doesn't actually disclose what 18 Q. 19 the P value is, does it? 20 No, it does not. Α. 21 So it actually doesn't indicate that 22 that difference was not statistically significant? 23 Α. No, it just provides the values. 24 Okay. And then for the next secondary Q.

- 1 outpoint for this CGI severity rating, baseline values
- were 4.4 for the citalogram group and 4.3 for the
- 3 placebo group and endpoint values (last observation
- 4 carried forward) were 3.1 for citalogram group and 3.3
- 5 for the placebo group.
- 6 Do you see that?
- 7 A. Yes.
- Q. Again, it does not provide a P value
- 9 there, does it?
- 10 A. There's no P value on the paper.
- 11 Q. With regards to that endpoint, correct?
- 12 A. Yes.
- Q. Okay. And so reading that, how would a
- 14 physician know that those, in fact, were not
- 15 statistically significant differences?
- MS. THORNE: Objection, calls for
- 17 speculation.
- THE WITNESS: I mean, you have to ask
- 19 physicians how they would interpret that.
- 20 BY MR. WISNER:
- Q. Okay. Now, interestingly enough, in
- reporting the primary outcome, which according to the
- 23 final study report was positive, they do report the P
- value, don't they?

- 1 A. Yes.
- MS. THORNE: Objection.
- 3 BY MR. WISNER:
- 4 Q. But when it comes to these two secondary
- 5 negative -- secondary negative endpoints, they do not
- 6 report the P value, do they?
- 7 MS. THORNE: Objection.
- 8 THE WITNESS: No, because the most
- 9 relevant one is the primary. That's why it's
- 10 called the primary.
- 11 BY MR. WISNER:
- 12 Q. So the reason why they didn't report the
- 13 P value for the negative outcomes is because it wasn't
- 14 as relevant?
- 15 A. I don't know the reason. You'd have to
- 16 talk to the study authors or those who were more
- involved in the publication to understand why they
- 18 included what they did.
- 19 Q. Okay. So you do not know then why the
- 20 authors of this manuscript did not disclose the P value
- 21 for the secondary outcomes?
- 22 A. I do not know.
- Q. Do you know if they were instructed by
- 24 Forest to hide the negative secondary outcomes?

```
1
                    MS. THORNE: Objection.
 2
                    THE WITNESS: I'm fairly certain they
 3
             were not.
 4
    BY MR. WISNER:
 5
             Q.
                    Well, we do know that when this
 6
    manuscript was originally submitted, it was submitted
 7
    as a brief report, correct?
 8
                    MS. THORNE: Objection.
 9
                    THE WITNESS:
                                  There was some language in
10
             a e-mail that we saw that suggested it might
11
             have been, but I don't know if it was or not.
12
    BY MR. WISNER:
13
             Ο.
                    So you don't know whether or not this
14
    manuscript was originally submitted as a brief report
15
     to the American Journal of Psychiatry?
16
                    No, nor do I know if it was submitted to
     any other journal prior to this publication.
17
                    And do you know whether or not the
18
             Ο.
19
    American Journal of Psychiatry actually rejected the
    manuscript as a brief report?
20
21
                    MS. THORNE: Objection, misstate -- lack
22
             of foundation, assumes facts not in evidence.
23
                                  I can't say for sure.
                    THE WITNESS:
24
    BY MR. WISNER:
```

1 Q. So you don't know that one way or the other? 2 I don't. 3 Α. Okay. Now, in the publication it does 4 Q. 5 mention the effect size, correct? 6 I believe in a section we just read, it references the effect size. 7 8 And do you know whether or not that Ο. 9 effect size represents clinical efficacy? 10 I don't know. Α. 11 Q. Okay. 12 Α. It's not defined in the paper. Now, at this point in 2004, the data 13 Q. 14 from Study 94404 had been available to Forest for 15 nearly three years, correct? 16 MS. THORNE: Objection. 17 THE WITNESS: Yeah, the time point would have been some point in 2001 to now 2004. 18 19 BY MR. WISNER: 20 Ο. So it's approximately three years? 21 Α. Yes. 22 Q. And, in fact, the final study report had 23 been completed for over two years at this point,

correct?

24

1 MS. THORNE: Objection. 2 THE WITNESS: Yeah, I don't know the 3 date when the final study report was published. BY MR. WISNER: 4 5 Q. Okay. Nowhere in this journal article does it reference the results of Study 94404, does it? 6 7 Α. No. 8 On here are listed author William 9 Heydorn, do you see that? William Heydorn was an 10 author on this manuscript? 11 Α. Yes. 12 0. And he sure knew about the results from Study 94404, correct? 13 14 MS. THORNE: Objection. 15 THE WITNESS: He would have known about 16 them. 17 BY MR. WISNER: And isn't it true that Forest publicized 18 Ο. 19 and promoted the results from the positive Forest study, while at the same time Forest did not publicize 20 21 or disclose the results of the negative study to 22 persons outside of the FDA or the Danish company which 23 sponsored the negative study? 24

Α.

That's true.

At this point Forest had actually 1 0. applied for a pediatric indication for Celexa, correct? 2 I believe we made a submission as upon 3 Α. FDA request to get a pediatric exclusivity of a period 4 of six months and the guidance from FDA was to submit 5 for the indication, and that's how they would review 6 7 the data on whether or not to give us the six months of 8 exclusivity. 9 To be clear, Forest did submit an 10 application to the FDA requesting a pediatric 11 indication for Celexa, correct? That would have been the submission, 12 Α. 13 yes. 14 And that application was rejected, Q. 15 correct? 16 MS. THORNE: Objection. 17 The six months of THE WITNESS: exclusivity was granted. The indication was 18 19 not included in the label. 20 BY MR. WISNER: 21 So the FDA determined that it was 22 inappropriate to allow for a pediatric indication for 23 Celexa, correct? 24 MS. THORNE: Objection.

1 THE WITNESS: It's my understanding they would have required a second positive study. 2 BY MR. WISNER: 3 4 Q. At this point all you had was Study 18, 5 correct? 6 MS. THORNE: Objection. 7 THE WITNESS: I'm sorry. What time 8 period is this? 9 BY MR. WISNER: 10 Q. Well, the next study would be Study 15, 11 but that wasn't positive either? 12 Α. Right, so I'm just making sure. So the only positive study you had at 13 Q. 14 this point was Study 18? 15 Α. That's right. 16 And by positive you mean only the primary efficacy endpoint was positive and all the 17 secondary outcomes -- secondary endpoints were 18 19 negative, correct? 20 MS. THORNE: Objection. 21 THE WITNESS: I believe FDA's 22 interpretation would be positive based on the 23 primary because that's the most important 24 parameter they're looking at.

```
1
    BY MR. WISNER:
 2
             0.
                   And you'd agree that that was only
    positive because it included patients from the
    potentially unblinded cohort that had been subject to
 4
 5
    the dispensing error?
 6
                    MS. THORNE: Objection.
 7
                    THE WITNESS: I mean, I believe it was
 8
            positive because it included all the patients
 9
             in the ITT population that was defined in the
10
            protocol.
11
    BY MR. WISNER:
12
             0.
                    I'm sorry, wait. Didn't the protocol
    say that any patient that was unblinded was
13
14
     automatically excluded from any efficacy analysis?
15
                                 Objection, misstates the
                    MS. THORNE:
16
             document, assumes facts not in evidence, lacks
             foundation.
17
18
                    THE WITNESS: Yeah, I'd have to see the
19
            document.
20
    BY MR. WISNER:
21
                   You want to take a look at the protocol?
             0.
22
             Α.
                    Sure, if you'd like to.
23
             Ο.
                    All right. Let's turn to Exhibit 15.
24
             Α.
                    Okay.
```

Page 6. 1 Q. You said 15? 2 Α. 3 Ο. Yes. 4 Α. Okay. 5 Q. Page 6. Fourth paragraph, it's in italics, but not bolded. 6 7 Do you see that? 8 Α. Yes. It reads, "Any patient for whom the 9 Ο. blind has been broken will immediately be discontinued 10 11 from the study and no further efficacy evaluations will be performed." 12 13 Do you see that? 14 Α. Yes. 15 Okay. All right. Let's go back to the Ο. 16 clinical trial we're at -- I'm sorry, the publications, 17 Exhibit 43. Sorry I keep making you jump between 18 documents. I can do it. 19 Α. 20 Starting to look like my desk. O. 21 Okay. Mr. Closter, we were talking 22 about the FDA's denial of a pediatric indication for 23 Celexa. 24 Do you recall that?

1 Α. Yes. Nowhere in this publication does it 2 O. indicate that the FDA had denied Forest's application for a pediatric indication? 4 5 Α. I'm not sure why it would. 6 Ο. That's not in there, right? 7 It's not in there. Α. 8 And it's not something then -- you don't Q. 9 think that the fact that the FDA had rejected an 10 application for a pediatric indication is not relevant in a clinical trial purporting to support the efficacy 11 of citalogram in children? 12 13 MS. THORNE: Objection. 14 THE WITNESS: They're describing the 15 results of the study. 16 BY MR. WISNER: 17 Isn't it true when you publish a result, Q. you're supposed to discuss data that you know about? 18 19 MS. THORNE: Objection. 20 THE WITNESS: I mean, it's up to the 21 study authors to include what they like. 22 BY MR. WISNER:

Let's go back to Exhibit 46. Don't put

Golkow Technologies, Inc.

O.

away the study. We'll come back to it.

23

24

1 Α. Okay. 2 Ο. Again, on second page, the second to 3 last paragraph, that's not signatures it says "furthermore." 4 5 Do you see that? 6 Α. Yes. 7 Furthermore, "Forest Laboratories failed Ο. 8 to disclose to the Journal that it was aware of data 9 from a study by Lundbeck that showed increased suicidality in children and adolescents who were 10 11 treated with citalogram. Authors and sponsors are 12 expected to disclose the existence of all data that affects the interpretation of their study. This note 13 14 will appear in Medline and other databases as a Comment 15 on the paper." 16 Did I read that well? 17 Α. Yes. 18 So, in fact, it was expected at the Q. 19 journal for authors to disclose all known data that could bear upon interpretation of the study results, 20 21 correct? 22 MS. THORNE: Objection. 23 Yeah, that's what the THE WITNESS: 24 journal is stating in their article.

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1 BY MR. WISNER:
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- Q. And the fact that the FDA had rejected a
- 3 pediatric indication, that would constitute known data
- 4 that would affect a doctor's interpretation and reading
- 5 of this journal article, correct?
- 6 MS. THORNE: Objection.
- 7 THE WITNESS: Yeah, I wouldn't know
- 8 that. You'd have to ask clinicians what they
- 9 think.
- 10 BY MR. WISNER:
- 11 Q. Well, you'd agree, at the very least,
- 12 referencing or discussing Study 94404 would have been
- 13 appropriate to disclose in the manuscript, correct?
- MS. THORNE: Objection.
- THE WITNESS: The journal has their
- opinion.
- 17 BY MR. WISNER:
- 18 Q. I'm asking about Forest's opinion.
- MS. THORNE: Forest's opinion on what?
- 20 BY MR. WISNER:
- Q. Whether it was appropriate to not
- include 94404 in the manuscript for Study 18?
- A. Again, it was not our study, granted it
- 24 was a compound that we sold in the United States, but,

- 1 ultimately, it's Lundbeck's decision, and you've got to
- 2 take their guidance into account as to what they wanted
- 3 to do with the study.
- 4 Q. Are you aware of Lundbeck telling Forest
- 5 not to mention the 94404 study in their publication of
- 6 Study 18?
- 7 MS. THORNE: Objection, assumes facts
- 8 not in evidence, lacks foundation.
- 9 THE WITNESS: I'm not suggesting they
- 10 did that. I'm saying they had their own plan
- on their own study.
- 12 BY MR. WISNER:
- Q. Okay. So you're not aware of any
- 14 communications that were sent to Forest telling Forest
- 15 not to include a reference 94404 in the manuscript for
- 16 Study 18 by Lundbeck?
- 17 A. No, I'm not aware of any information.
- 18 Q. Okay. Now, in the publication for Study
- 19 94404, it does reference Study 18, though, doesn't it?
- 20 A. I believe it does. I think, in part,
- 21 because I believe it was published after this was
- 22 published.
- Q. And it was published after this was
- 24 published because Forest deliberately wanted to avoid

negative data being in the public domain about the 1 pediatric efficacy of Celexa, correct? 2 3 MS. THORNE: Objection, asked and 4 answered. 5 THE WITNESS: Yeah, I can't agree with 6 the statement. 7 BY MR. WISNER: 8 All right. Q. 9 We can put this paper away now? 10 Q. No, keep the paper out. 11 MS. THORNE: Brent, when you get to a 12 convenient stopping point, we'd like to take a 13 break. 14 MR. WISNER: Okay. 15 MS. THORNE: Preferably in the not 16 terribly distant future. MR. WISNER: I'm almost done. I really 17 am almost done. 18 19 BY MR. WISNER: 20 You are aware that there is a black box 0. 21 warning for both citalopram and escitalopram related to 22 risks associated with pediatric suicidality? 23 MS. THORNE: Objection. 24 THE WITNESS: Yes, class labeling that's

```
applied to all antidepressants, including
 1
             Celexa and Lexapro.
 2
    BY MR. WISNER:
 3
 4
             Ο.
                   But there is a black box warning on both
 5
    citalopram and escitalopram, correct?
 6
                    MS. THORNE: Objection, asked and
 7
             answered.
 8
                    THE WITNESS: And every other
 9
             antidepressant.
10
    BY MR. WISNER:
11
                    Sorry, that's a yes, right?
             Ο.
12
             Α.
                    Yes.
13
                    Okay. I hadn't heard a yes. I heard
             Q.
14
    and every other antidepressant, I hadn't heard a yes.
15
             Α.
                    Well, the first time I answered yes. I
16
     said on every antidepressant, including Celexa and
    Lexapro, so if you want to ask me questions, twice feel
17
     free, I'll answer the same way.
18
19
                    Okay. So there is, in fact, a black box
             Ο.
     -- I'm just kidding.
20
21
                    MR. WISNER: Take a break.
22
                    THE VIDEOGRAPHER: We are now off the
23
             record. The time is 6:10.
24
                    (Brief recess.)
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1 THE VIDEOGRAPHER: We are now back on the record. The time is 6:33. 2 BY MR. WISNER: 3 4 Q. All right, Mr. Closter, earlier I asked 5 you and I'll just clarify it again, Forest did 6 publicize and promote the results from the positive 7 study, correct? 8 Α. Yes. 9 I'm handing you a document -- well, before I do that, isn't it also true that through that 10 11 publicity and promotion, Forest saw a market increase in the sales of Celexa for patients under the age of 12 13 20? 14 MS. THORNE: Objection, lacks 15 foundation, assumes facts not in evidence. 16 THE WITNESS: Yeah, I don't believe I 17 can confirm that. (Document marked for identification as 18 19 ForestC Deposition Exhibit No. 47.) 20 BY MR. WISNER: 21 Q. Okay. Handing you a document that's 22 marked as Exhibit 47 to your deposition. 23 Α. These are all connected, right, just the 24 staple is a little --

1 Q. I think you're missing one. There's a 2 Page 23. 3 Yeah, this looks like it's on the back. Α. Sorry about that. 4 Q. 5 Α. That's all right. 6 MS. THORNE: Since they're all in color, 7 would you like to swap one of the nondamaged 8 goods. 9 MR. WISNER: That's a good idea. 10 BY MR. WISNER: 11 O. All right. You have now in front of you Exhibit 47, correct? 12 13 Α. Yes. 14 All right. You recognize this document? Q. 15 The e-mail on top or the document Α. 16 attached to it? 17 Q. Fair enough. Do you recognize the document attached to the e-mail beginning with Lexapro 18 19 FYI -- fiscal year 2004 dated December 3rd, 2002? 20 Α. It looks like a strategy presentation. 21 Did you specifically review this Ο. 22 document in preparation for your testimony today? 23 Α. I did not see this one specifically, no. 24 Q. Okay.

1 MS. THORNE: Brent, just for the record, 2 is this excerpted at all. MR. WISNER: Yes, it is. I had taken --3 it's like a 200-page document, so I just took 4 5 excerpts, that's correct. 6 MS. THORNE: Okay. So, to be clear, the 7 page numbers are numbers that you applied to 8 the document for clarity in getting through the deposition? 9 10 MR. WISNER: Yes, just like all the 11 other exhibits, that's correct. 12 MS. THORNE: Okay. 13 THE WITNESS: Just a question, are these 14 in any given order? Was it just -- meaning, 15 did these flow in order in the document you 16 took from? 17 BY MR. WISNER: Q. Yes, that's correct. I did not take 18 19 them out of sequence. 20 Α. They're continuous. Right, so they're 21 in sequence from whatever slide one to whenever it is. 22 Q. Precisely, but pages are missing between 23 slides. 24 Α. They are, so it's not continuous?

There's pages missing between slides, 1 Q. but they're in the order of the slides. Does that make 2 sense? 3 4 Α. All right. So if there's, what, 23 here, there's, I don't know -- you said it was a 5 6 200-page deck? 7 Q. It's a fairly large deck. I don't know 8 the exact number. 9 All right. So it's missing a lot of whatever is in between these slides, potentially. 10 11 Q. That's correct. 12 Α. All right. So on the front page here, there is --13 Q. 14 it's from Nikhil Nayak. 15 Do you see that? 16 Α. Yes, Nikhil Nayak. 17 Do you know who that is? Q. 18 Α. Yes. 19 Is that a he? Ο. 20 Α. He. 21 Who is he? Ο. 22 Α. He was on the marketing team. 23 O. Okay. Did you work with him?

Α.

I did.

24

- 1 Q. And, in fact, there's a bunch of
- 2 recipients here, including yourself, Steven Closter.
- 3 Do you see that?
- 4 A. Yes.
- 5 Q. All right. Do you recall receiving this
- 6 deck at any point?
- 7 A. I mean, obviously, I was copied on it,
- 8 so I would have seen it at some point, yes.
- 9 Q. Okay. And the e-mail is dated
- 10 December 20th, 2002.
- 11 Do you see that?
- 12 A. Yes.
- Q. And if you turn -- this document was --
- 14 these types of presentations and slide decks, they're
- 15 sort of documents created in the regular course of
- 16 business at Forest, correct?
- MS. THORNE: Objection, calls for a
- 18 legal conclusion.
- THE WITNESS: What do you mean by the
- "regular course of business"? That's not a
- 21 term I'm familiar with.
- 22 BY MR. WISNER:
- Q. You regularly would see or there was
- 24 created tactical presentations?

```
MS. THORNE: Objection.
 1
                   THE WITNESS: Yeah, there would have
 2
 3
            been, as in this document, a strategic options
            type of presentation, which is what looks like
 4
 5
            this is. There may be then a follow-on
 6
            tactical presentation, and then, ultimately,
 7
            there may be a written -- a written brand plan.
    BY MR. WISNER:
 8
 9
            O. Okay. And the creation of those various
10
    documents, that was regularly done at Forest, correct?
11
                   MS. THORNE: Objection. What do you
12
            mean by "regularly"? To the extent that calls
            for a legal conclusion, I object.
13
14
                   THE WITNESS: You're asking how often
15
            these were done?
16
    BY MR. WISNER:
17
            Q. My question is they were regularly
    created at Forest, correct?
18
19
                   MS. THORNE: Objection to the extent it
20
            calls for a legal conclusion.
21
                   THE WITNESS: All right. We would
22
            produce these once a year, essentially.
23
    BY MR. WISNER:
24
            Q. So it's regularly created once a year?
```

1 MS. THORNE: Objection, calls for a 2 legal conclusion. 3 THE WITNESS: If you want to use the 4 word "regularly," you can. You know, there 5 were some years that we didn't do this kind of stuff, but in this time period, we did these 6 7 annually. 8 BY MR. WISNER: 9 And these documents were produced in the 10 context of your business at Forest, correct? 11 MS. THORNE: Objection. When you say 12 "your," because you were asking him in his 13 personal capacity about the document a little 14 while ago, are you now asking him in his 15 capacity as a 30(b)(6)? MR. WISNER: I'm asking him in both. 16 17 BY MR. WISNER: This document was created in the regular 18 0. 19 course of Forest business, correct? 20 MS. THORNE: Objection, calls for a 21 legal conclusion. 22 THE WITNESS: Yes, whether it was 23 Lexapro or other brands, we would produce these 24 on an annual basis.

- 1 BY MR. WISNER:
- Q. Thank you. It says here, "As a
- 3 reminder, the tactical presentation with Elaine and
- 4 Howard is scheduled for February 6, 2003."
- 5 Do you see that?
- 6 A. Yes.
- 7 Q. Is a tactical presentation different
- 8 than -- I'll read the next sentence. Therefore, please
- 9 review the Lexapro fiscal year 2004 strategies with
- 10 your appropriate agencies (see first attachment below
- 11 for final fiscal year 2004 strategic operations
- 12 presentation).
- Do you see that?
- 14 A. Yes.
- 15 Q. So these strategic operations
- 16 presentations, are they different than tactical
- 17 presentations?
- 18 A. Yeah, there would be, you know, few to
- 19 no tactics in this planning document.
- Q. So I'll ask my question, what is the
- 21 difference between a strategic operations presentation
- versus a tactical presentation?
- A. I mean, a strategic operations
- 24 presentation, you know, would be higher level, you

- 1 know, overall strategies, you know, how do we look at
- 2 the usage of our product. You know, you break down the
- 3 market in a variety of different ways, where is
- 4 utilization, what are some things that we're going to
- 5 want to focus on. They could be relevant to the next
- 6 planning year or well beyond that, perhaps lifecycle
- 7 strategies, formulations, new indications things like
- 8 that.
- 9 The tactical presentation tended to be
- 10 focused on the next year's activities, and, you know,
- 11 you would lay out tactics that you would execute, you
- 12 know, against the brand. You know, note that these
- were done at one point in time, obviously, things
- 14 change during the year and, you know, what you even saw
- in the tactical presentation doesn't mean that tactic
- 16 was actually executed. It was merely a planning
- 17 document to guide some of our activities.
- 18 Q. Okay. I think you turn to the page
- 19 numbered at the top right Number 9.
- 20 A. Okay.
- Q. Are you there?
- 22 A. Yes.
- Q. Okay. And it says -- a title says
- 24 "Market Segments."

1 Do you see that? 2 Α. Yes. 3 O. What is a market segment, based on your 4 experience at Forest? 5 Α. It's just breaking down the market into, you know, different types of categories based on what 6 7 you see here, disorders, right, because these drugs are 8 used for a variety of mood disorders, depression, all 9 sorts of anxiety disorders, PTSD, you name it. Provider, you know, you know it's likely to be 10 11 specialist versus let's say primary care physician and 12 then patient age. Your drug is used across the age population. So you can look at different segments that 13 14 the drug may be used in within using patient age as a 15 divider. 16 And it reflects here AD market. 0. referring to antidepressant market? 17 18 Α. Yes. 19 Okay. And was it your understanding in Ο. approximately 2002 that the antidepressant market was 20 21 over \$2 billion? 22 Α. It says 12 billion. 23 I'm sorry, \$12 billion. Ο.

Yeah, that's likely what the value of

Golkow Technologies, Inc.

Α.

- 1 the market was at that point in time.
- Q. And that's obviously not the sales by
- 3 Forest; that's the overall antidepressant market,
- 4 right?
- 5 A. It would be dollarizing all of the
- 6 antidepressant use, yes.
- 7 Q. All right. If you turn to the next
- 8 page.
- 9 A. Yeah.
- 10 Q. This is a section that's titled "SRI
- 11 Usage by Age."
- Do you see that?
- 13 A. I do.
- Q. And there is a section specifically
- 15 reflecting patients under 20.
- Do you see that?
- 17 A. I do.
- Q. And that represents 8% of the -- what
- 19 appears to be the antidepressant market.
- 20 Do you see that?
- 21 A. Yeah, SRI usage is 8% is in that age
- 22 group.
- Q. Okay. And this is based, according to
- the bottom part here, on an IMS National Disease &

Therapeutic Index. 1 2 Do you see that? 3 Α. Yes. Are you familiar with IMS data? 4 Q. 5 Α. I am. What is IMS data? 6 Ο. 7 It's a third party that collects data at Α. typically the pharmacy level, wholesaler level, and 8 9 they sell that data to pharmaceutical companies. And Forest regularly -- if you have a 10 Q. 11 problem with that word, let me know -- but regularly used IMS data in its operations, correct? 12 13 We did. Α. 14 Now, if you turn to Page 11, this is a Q. 15 document that says percentage share under 20. 16 Do you see that? 17 Α. Yes. And the various color lines here 18 Q. 19 represent the market share for those various drugs. 20 Do you see that? 21 Α. Yes. 22 Q. And one of the lines is a green line, and according to this key, that represents Celexa. 23 24 Do you see that?

1 Α. Yes. 2 Ο. It's green with a triangle? 3 Α. Yes. 4 Okay. And then right there showing in Q. the second quarter of 2002, third quarter of 2002, 5 there's an increase in market share for Celexa. 6 7 Do you see that? 8 Α. Well, it's increase in the share of the 9 utilization in that age group. 10 Yes. So there's an increase in market Q. share of Celexa use in patients under 20? 11 12 Just want to make sure this data is an Α. accurate reflection of market share. Percent share. 13 14 (Witness reviews document.) Thirty, 60, 75. 15 Okay. 16 Ο. Is that right? 17 Α. Yes. Okay. Now, in this presentation, this 18 Q. upward increase in the second quarter 2002 moving into 19 the third quarter of 2002 is circled in a white circle. 20 21 Do you see that? 22 Α. Yes. 23 Ο. And there's a box that extends from it. 24 Do you see that?

- 1 A. Yes.
- Q. And it says "Celexa began to Increase -
- 3 (Wagner data)."
- 4 Do you see that?
- 5 A. Yes.
- 6 Q. This is referring to the publication or,
- 7 sorry, the distribution of the data by Karen Wagner of
- 8 the pediatric data for Celexa Study 18, correct?
- 9 MS. THORNE: Objection.
- 10 THE WITNESS: I mean, I don't know
- exactly what it's referring to. It's simply
- 12 saying Wagner data.
- 13 BY MR. WISNER:
- Q. Well, it's talking about the percentage
- share for patients under 20, right?
- 16 A. I don't know. I mean, when you look at
- 17 the line, I mean, there's been previous periods where
- 18 there was the same type of share increase in the
- 19 absence of any data, so, I mean, I'm not aware of any,
- 20 you know, intense market research analysis, aware of
- 21 seeing any or anything that directly related to the
- 22 Wagner data, however you want to characterize it,
- whether it was the poster, I guess the publication was
- 24 after this, but I note it's on the slide, but I don't

- 1 know why it would have been included there, and I don't
- 2 know to the extent you can assert that that increase
- 3 was due to the data when you saw a previous increase of
- 4 a similar magnitude and there was no data at that time.
- 5 Q. Well, that's not entirely true,
- 6 Mr. Closter. I mean, when did Karen Wagner begin
- 7 presenting data regarding the pediatric trial MD-18?
- MS. THORNE: Objection.
- 9 THE WITNESS: I guess the first time
- would have been in the very end of 2001.
- 11 BY MR. WISNER:
- 12 Q. And what quarter would that put it in?
- 13 A. Well, it would put it at the very end of
- 14 Q4, but if you're alleging that that would have -- that
- 15 the increase you see in shares is well before that data
- 16 would have been presented at that meeting.
- 17 Q. So you do not know why or, sorry, you
- 18 cannot explain to me why this increase in market share
- 19 circled in white here states Celexa began to increase
- 20 Wagner data; is that right?
- 21 A. Yeah, I don't know who put it on there
- 22 and what analysis would ever have been done to show
- 23 that. Just like there's, you know, Paxil goes down
- 24 quite dramatically in prior quarters, and I don't know

```
what would have contributed to that either.
 1
 2
                    This is in the context of a strategic
             Ο.
    plan, right?
 3
 4
             Α.
                   Yes.
 5
             Q.
                    Is it a fair inference that whoever put
    together this plan is suggesting that the introduction
 6
    and promotion of the Wagner data helped increase
 7
 8
    Celexa's market share?
 9
                    MS. THORNE: Objection calls for
10
             speculation.
11
                    THE WITNESS: Yeah it's difficult to
12
             speculate why someone would have put there it
13
            and what the motivation was behind it.
14
    BY MR. WISNER:
15
                   Mr. Closter, you got this document,
             Ο.
16
    didn't you?
17
                    MS. THORNE: Objection.
18
                    THE WITNESS: Right. I was sent this 14
19
            years ago.
20
    BY MR. WISNER:
21
                    Sure. I understand. And you obviously
             0.
22
    don't have any independent recollection of this
23
    document, right?
```

Α.

No.

But reading this circling of this 1 Ο. increased market share, and it reads "Celexa began to 2 3 Increase - (Wagner data), " that suggests that whoever 4 is presenting this strategy is suggesting that the 5 Wagner data caused an increase in Celexa market share, 6 correct? 7 MS. THORNE: Objection, asked and 8 answered, calls for speculation. This is also 9 outside the scope of the 30(b)(6) at this 10 point. 11 THE WITNESS: Yeah, again, I don't know 12 what the motivation was behind the person who created this slide, put the comments on the 13 14 page and possibly presented it. 15 BY MR. WISNER: 16 So you just look at the slide and you have no idea why they're referencing the Wagner data or 17 Celexa began to increase in circles and increase in 18 19 market share for Celexa; is that right? 20 MS. THORNE: Objection, argumentative. 21 At this point this has been asked and answered 22 numerous times. You're just arguing with the 23 witness at this point. The witness has 24 answered the question.

1 THE WITNESS: My answer stands. 2 BY MR. WISNER: I'm sorry. I don't believe you've 3 0. answered my question. 4 5 Can you please answer my question, Mr. Closter? 6 7 MS. THORNE: Objection, asked and 8 answered. 9 BY MR. WISNER: 10 Q. It's your testimony to this jury that you don't understand what this slide says? 11 12 Α. I'm telling you --13 MS. THORNE: Objection, asked and 14 answered, argumentative. At this point, Brent, you're really just 15 16 arquing with the witness. 17 THE WITNESS: Yeah, like I said several times now, I don't know what the motivation was 18 19 behind the person who indicated this. 20 BY MR. WISNER: 21 Q. Mr. Closter, I didn't ask you about 22 motivation, I'm sorry. It's not an answered question. 23 My question to you is is it your

testimony to this jury that you don't understand what

this reference to the Wagner data is? 1 2 MS. THORNE: Objection, misstates the 3 testimony, argumentative, calls for speculation. 4 5 THE WITNESS: Yeah, I don't specifically 6 know. 7 BY MR. WISNER: 8 Q. Okay. Thank you. 9 Turn to the next page, Page 12. Page 10 12? 11 Α. The only thing I'll say is that it would 12 have been helpful to see the entire document in its entirety, because even this could be taken out of 13 14 context. I don't know what came before this. Were 15 there other age groups that were evaluated? So it 16 would have helped my interpretation had I seen those 17 things, just saying. Okay. So you would have preferred to 18 Q. 19 have seen the 200-page document? 20 Absolutely. Α. 21 Okay. Slide 12, do you see that? Ο. 22 Α. Yes. MS. THORNE: Objection for the record. 23 24 That's not necessarily slide 12. It is Page 12

of the document, as you numbered for this 1 deposition, but referring to it as slide 12 is 2 misleading. 3 BY MR. WISNER: 4 5 Q. Referring your attention to the document that has the number 12 on it in the right-hand corner, 6 7 do you see that, Mr. Closter? I do. 8 Α. 9 Ο. Okay. This says here, "Close the data gap for both Geriatrics and Pediatrics." 10 11 Do you see that? 12 Α. Yes. And keep going down, it says "Improve 13 Q. 14 labeling." 15 Do you see that? 16 Α. Yes. 17 Q. And the next one says, "Launch oral liquid" (January 2003). 18 19 Do you see that? 20 Α. Yes. 21 Do you understand that Forest created Ο. 22 programs to promote the oral liquid suspension fluid --23 strike that. 2.4 Do you understand that Forest created

- 1 programs to promote for pediatric use the
- 2 peppermint-flavored oral solution that was created for
- 3 Lexapro and Celexa?
- 4 MS. THORNE: Objection, assumes facts
- 5 not in evidence, lack of foundation. Assumes
- facts not in evidence and lack of foundation.
- 7 THE WITNESS: I'm not aware of any
- 8 promotional programs to promote the oral liquid
- 9 to that population.
- 10 BY MR. WISNER:
- 11 Q. Isn't it true that Forest specifically
- 12 contracted with CME, Inc. to create those programs?
- MS. THORNE: Objection, lack of
- foundation, assumes facts not in evidence.
- THE WITNESS: Yeah, as I've stated in
- earlier testimony, I don't believe those are
- 17 promotional activities.
- 18 BY MR. WISNER:
- 19 Q. Okay. So you are aware that Forest
- 20 created CME programs in conjunction with CME, Inc. to
- 21 suggest the use of the oral liquid solution for use in
- 22 children?
- MS. THORNE: Objection, misstates the
- document, assumes facts not in evidence, lack

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of foundation.
 1
 2
                    THE WITNESS: Yeah, I mean I need to see
 3
             the materials. I don't think it's fair to say
             Forest created. We funded and worked as an
 4
 5
             organization with the faculty and those
 6
             involved in presenting at those programs.
             That's the extent of our involvement.
 7
    BY MR. WISNER:
 8
 9
                    Okay. I was just asking if you knew
10
    whether or not Forest created CME programs with CME,
11
     Inc. designed to discuss the use of the oral solution
12
     in pediatric populations?
13
                    MS. THORNE: Objection, lack of
14
             foundation, assumes facts not in evidence.
15
                                  Right, and, as I stated,
                    THE WITNESS:
16
             we were involved to the extent we funded those
17
             programs, and our internal staff worked with
             the faculty that ran those programs that
18
19
             ultimately created the content for those
20
             programs.
21
    BY MR. WISNER:
22
             Ο.
                    Fair enough. I guess I'm just trying to
    make sure we're talking about the same thing here.
23
24
                    I'm saying are you aware one way or
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another whether or not Forest specifically contracted 1 with CME, Inc. to develop CME programs to stress the 2 use of the oral solution for use in children, that's 3 4 whether or not you know that is my question? 5 MS. THORNE: Is your question did the 6 company work with CME, Inc. to design a CME 7 program specifically designed to discuss the 8 use of oral solution in pediatric populations? 9 MR. WISNER: Yes. 10 MS. THORNE: So you want to know did the 11 company engage with CME, Inc. to design a CME 12 program that was specifically intended to 13 discuss the use of the oral liquid; that's your 14 question? 15 MR. WISNER: In children, yes. 16 MS. THORNE: Okay, just to make sure the 17 record is clear because everybody seems to be talking past each other, and I didn't 18 19 understand your question. 20 THE WITNESS: From what I am aware of, 21 that was not the sole focus of those programs. 22 BY MR. WISNER: 23 0. So you're not aware -- okay. 24 If you turn to Page 14. This is

- 1 reflecting SRI detailing doctors, do you see that?
- 2 A. Detailing dollars.
- Q. Detailing dollars, thank you. That's
- 4 what it says, right?
- 5 A. Yes.
- Q. Thank you.
- 7 And it shows different amount of
- 8 expenditures being spent on detailing dollars in
- 9 thousands, correct?
- 10 A. Yes.
- 11 Q. And then there's a line for Celexa.
- Do you see that?
- 13 A. Yes.
- Q. And there's also a line at the very end
- 15 for Lexapro.
- Do you see that?
- 17 A. For Celexa -- I see both, yes, Celexa
- 18 and Lexapro.
- 19 Q. Okay. Now, Lexapro doesn't begin until
- 20 July of 2002, right?
- 21 A. Right. Well, it's probably zero in 2000
- in July, but by August there's some evidence.
- Q. And that's because the drug has just
- 24 been approved, right?

1 Α. Yes. 2 0. And then as you see as the increase in Lexapro dollars goes up for detailing, the dollars go 4 down for Celexa, correct? 5 Α. That's right. 6 And it was, in fact, a strategy within Ο. 7 Forest to recommit the money that was spent on 8 detailing for Celexa to Lexapro as it came on to 9 market, correct? 10 MS. THORNE: Objection. 11 THE WITNESS: Yeah, I mean, the thought 12 is you had two antidepressants. We believe 13 Lexapro was the better drug, so why would we 14 continue to promote the drug we didn't think 15 was as good. 16 BY MR. WISNER: 17 So Forest did, in fact, shift detailing Q. budgets away from Celexa and to Lexapro, correct? 18 19 Α. Correct. 20 And Celexa was shortly going to come off 0. 21 of exclusivity, correct? 22 MS. THORNE: Objection, assumes facts 23 not in evidence.

THE WITNESS: Yeah, I don't think

shortly. There was some time left on that 1 2 patent in years. BY MR. WISNER: 3 4 Ο. Do you know when the patent expired? 5 Α. I can't say for sure, but I believe it extended at least, I believe, two years beyond this. 6 7 Okay. Ο. 8 Maybe even three. Α. 9 So turn to Page 15, does this slide say Ο. "Maintaining SOV during expansion"? Do you know what 10 SOV refers to? 11 12 Share of voice. Α. 13 What is share of voice? Q. 14 Just either the level of promotional Α. 15 effort you have against a product relative to your, you 16 know, other branded competitors in the marketplace. 17 And it lists out "Strategies," right? Q. 18 Α. Yes. 19 Maintain current level of details, Ο. right; that's the first bullet point? 20 21 Α. Yes, yes. 22 Q. The next bullet point says "Augment with 23 non-personal promotion, "right?

Α.

Right.

And the first thing listed there is "Med 1 Ο. Ed (CME)," correct? 2 Α. 3 Yes. 4 0. So this document is, in fact, reflecting 5 that it was Forest's strategy of non-personal promotion 6 to sponsor continuing medical education programs? 7 MS. THORNE: Objection, assumes facts 8 not in evidence, lack of foundation, misstates 9 the document. 10 THE WITNESS: Yeah, it says this on the 11 slide, but I can't speak to who created it and 12 why they would characterize it this way. 13 BY MR. WISNER: 14 According to the e-mail on the front, Ο. 15 this is in fact the final fiscal year 2004 strategic 16 operations presentation, correct? 17 Α. Yes. And in the final fiscal year 2004 18 strategic operations presentation it states as a 19 20 strategy for promotion augmenting CME programs, doesn't 21 it? 22 MS. THORNE: Objection, misstates the 23 documents, also assumes facts not in evidence, 24 also lacks foundation, also asked and answered.

1 THE WITNESS: Also, it's difficult to look at this one slide when I have to believe 2 3 there were many other slides around strategies and other areas of focus. 4 5 BY MR. WISNER: 6 Ο. This slide has as a strategy for 7 nonpersonal promotion augmenting continuing medical 8 education programs, doesn't it, Mr. Closter? 9 MS. THORNE: Objection, misstates the 10 document. That just misquotes the document. 11 THE WITNESS: Yeah, again, I'd have to 12 see more of the document to have a better conclusion. 13 14 BY MR. WISNER: 15 Ο. It also lists "public relations," 16 doesn't it? 17 That is also included on the slide. Α. "Data dissemination," correct? 18 Q. 19 That's also on the slide. Α. 20 And on this slide, all of those things, O. 21 CME, public relations, data dissemination are all 22 listed as types of non-personal promotion, aren't they? 23 According to the slide, whoever crafted 24 the slide included it as such.

1 And the slide happens to be one from the 0. final fiscal year 2004 strategic operations 2 presentation, correct? 3 4 MS. THORNE: Objection. THE WITNESS: Yeah, it is one slide of 5 what you've said roughly 200 slides. 6 7 BY MR. WISNER: 8 Do you consider sampling part of 0. Forest's promotional efforts? 9 10 Yes, I would. Α. 11 Ο. If you turn to Page 22, the page that 12 has the number 22 listed on the top right. 13 Α. Yes. 14 Q. It has right here fiscal year 15 expenses/investments. 16 Do you see that? 17 Α. Yes. And it lists a whole bunch of different 18 Q. 19 programs. It has "Samples." 20 You see that? 21 Α. Yes. 22 Q. "Tokens"? 23 Α. I see that. 24 O. What's a token?

Usually a low value giveaway, a pen, 1 Α. magnet, things like that. 2 3 0. And those are designed to encourage physicians to prescribe the product with the logo on 4 5 it, correct? 6 MS. THORNE: Objection, assumes facts 7 not in evidence, lacks foundation. 8 THE WITNESS: Yeah, the use of tokens is 9 really just awareness, get the name of the drug 10 out. 11 BY MR. WISNER: 12 Ο. And by increasing awareness, you hopefully will increase sales, right? 13 14 If you would like to make that link, you Α. 15 can do that. 16 I'm not making that link, Mr. Closter. That's the link that Forest has made in deciding to 17 spend \$12 million on making tokens, correct? 18 19 MS. THORNE: Objection, lack of 20 foundation, misstates the document, assumes 21 facts not in evidence and at this point is also 22 outside the scope of the 30(b)(6). So if

Mr. Closter can answer based on his own

personal experience, he may do that.

Golkow Technologies, Inc.

23

1 THE WITNESS: We do them for brand 2 awareness. BY MR. WISNER: 3 4 Q. And brand awareness, from my understanding, still can increase sales, right? 5 6 So people think of our drug when if 7 there's -- you know, for an appropriate patient, sure. 8 Q. Okay. We also have under here targeted 9 program. 10 Do you see that? 11 Α. I do. 12 Ο. Do you know what that is referring to? 13 I don't. Α. 14 Q. We have CME programs. 15 Do you see that? 16 Α. Yes. 17 And it looks as though they've budgeted Q. approximately \$12 million for those? 18 19 Α. Right. 20 Ο. Lunch and learn programs. 21 Do you see that? 22 Α. Yes. 23 And there's \$19.5 million set aside for O. 24 that?

1 Α. Right. 2 Ο. What is a lunch and learn program? 3 Α. It's essentially for us to see target 4 customers. The expectation is that we provide a meal 5 for them to have a discussion on a product. 6 And is the purpose of these lunch and Ο. 7 learn programs to encourage the participants to raise 8 their brand awareness of the product? 9 No, it's to give us time to talk to Α. 10 them. 11 Q. And to promote to them, correct? 12 Α. Correct. "Teleconferences/Peer." 13 Q. 14 Do you see that? 15 Α. T do. 16 Do you know what that's referring to? Ο. 17 These were likely promotional programs Α. where we would have trained speakers that would engage 18 an audience of other clinicians who wanted to learn 19 20 about our products. So teleconferences would be a 21 phone conference. Peer was likely reference to a round 22 table discussion, perhaps over at a restaurant. 23 Ο. Now, if you turn to the second page,

this is a continuation of the list.

- 1 A. Okay.2 Q. It says speaker programs.
 - 3 Do you see that?
 - 4 A. Yes.
 - 5 Q. Is that different than the peer?
 - 6 A. The only difference there, it was the
 - 7 same concept, is that speaker programs these were rep
 - 8 initiated. They were able to select and approve
 - 9 speaker and then arrange for that speaker to attend a
- dinner meeting, could have been a lunch program, where
- 11 they would then invite interested clinicians to attend
- 12 those events.
- Q. And it says here for speaker programs,
- 14 there's \$42 million; is that right?
- 15 A. That's right.
- 16 Q. Keep going down here it says
- 17 professional relations; do you know what that's
- 18 referring to? That's on Page 22.
- 19 A. I think I would understand, you know,
- 20 this was probably funds to support a variety of
- 21 advocacy groups. So these would be physician groups,
- 22 professional groups or patient advocacy groups, and we
- 23 would allot grant monies to organizations to support
- 24 what they did, which tends to be around disease

- 1 awareness, awareness of the condition, things likes
- 2 that.
- Q. What is a "preceptorships"?
- 4 A. Preceptorships were really training
- 5 initiatives for representatives to work closely with a
- 6 practitioner, and they would spend perhaps a day
- 7 together, and the representative would learn, you know,
- 8 what is it like for a clinician to see patients, treat
- 9 patients.
- 10 Q. Okay. On the next page, Page 23, it has
- 11 "Journals" listed.
- Do you see that?
- 13 A. Yes.
- Q. Does that refer to journal advertising?
- 15 A. Yes, it does.
- Okay. And, finally, the last one says
- 17 "Managed Care."
- Do you see that?
- 19 A. Yes.
- 20 O. What is managed care referring to?
- 21 A. These would likely be funds that we
- 22 would use to support materials that we may partner with
- a managed care plan, where maybe Lexapro was preferred
- on formulary, and we would, you know, generate a sales

- 1 piece that included the brand's name, and we would, you
- 2 know, use those as sales materials.
- Q. All right. Want to switch topics here,
- 4 you can put that document away.
- Isn't it true that prior to the entry of
- 6 Forest's criminal plea in 2010, Forest did not make a
- 7 public representation in any capacity indicating that
- 8 Forest was engaged in the illegal off-label promotion
- 9 of Celexa or Lexapro for pediatric use?
- MS. THORNE: Objection.
- 11 THE WITNESS: Sorry. Could you repeat
- 12 the question.
- 13 BY MR. WISNER:
- 14 Q. Sure. Isn't it true that prior to the
- entry of Forest's criminal plea in 2010, Forest did not
- 16 make a public representation in any capacity indicating
- that Forest was engaged in the illegal off-label
- 18 promotion of Celexa or Lexapro for pediatric use?
- MS. THORNE: Objection. I'm going to
- object to this as being outside of the scope.
- I think this veers outside of the topics. If
- 22 you think I'm incorrect, we can --
- MR. WISNER: Let's go off the record.
- 24 THE VIDEOGRAPHER: We are now off the

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record. The time is 7:07.
 1
 2
                    (Discussion off the record.)
 3
                    THE VIDEOGRAPHER: We are now back on
             the record. The time is 7:08.
 4
 5
    BY MR. WISNER:
 6
                    Mr. Closter, I'm going to ask the
             Ο.
 7
     question again, okay?
 8
             Α.
                    Yes.
 9
                    Isn't it true that prior to the entry of
    Forest's criminal plea in 2010, Forest did not make a
10
11
    public representation in any capacity indicating that
12
    Forest was engaged in the illegal, off-label promotion
    of Celexa or Lexapro for pediatric use?
13
14
                    MS. THORNE: Objection.
15
                    THE WITNESS: I don't believe we did.
16
    BY MR. WISNER:
17
             Ο.
                    In fact, isn't it true that prior to
     2010, Forest made multiple affirmative representations
18
     that it was not engaged in the illegal off-label
19
    promotion of Celexa and Lexapro for use in pediatric
20
21
    populations?
22
                    MS. THORNE: Objection, lack of
23
             foundation, assumes facts not in evidence.
24
                    THE WITNESS:
                                  Yeah, I'd have to see some
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of the declarations, the multiple declarations 1 that you're referring to. 2 3 MR. WISNER: Okay. (Document marked for identification as 4 5 ForestC Deposition Exhibit No. 58.) BY MR. WISNER: 6 7 All right. I'm handing you a document 0. 8 that's been marked as Exhibit 58 to your deposition. 9 Do you recognize this document, sir? I have seen this document. 10 Α. 11 What is this document? O. 12 Α. I believe this is a -- I quess an oral testimony as well as a written statement from Dr. Larry 13 14 Olanoff to the committee on energy and commerce in the 15 House of Representatives. 16 I know this is a silly question, but by Larry Olanoff, you're referring to Lawrence S. Olanoff? 17 18 Α. Yes. 19 O. Okay. If you turn to Page 5. 20 Α. Okay. 21 Go down five paragraphs, you see that, 0. 22 starts with a paragraph saying, "I want to emphasize"? 23 Α. Yes. 24 Q. All right. It reads, "I want to

- 1 emphasize that, because the FDA has not approved
- 2 pediatric labeling for our products, Forest has always
- 3 been scrupulous about not promoting the pediatric use
- 4 of our antidepressant drugs, Celexa and Lexapro. That
- 5 is the law, and we follow it."
- Did I read that well?
- 7 A. You read that well.
- Q. Okay. And this was testimony that was
- 9 proffered in September 2004, correct?
- 10 A. Yes.
- 11 Q. So, in fact, Mr. Olanoff is speaking to
- 12 Congress -- sorry -- is testifying to Congress that
- 13 Forest has not engaged in the off-label promotion of
- 14 pediatric use for Celexa and Lexapro, correct?
- MS. THORNE: Objection, mischaracterize
- 16 -- misstates the document, mischaracterizes the
- 17 testimony of Mr. Olanoff, assumes facts not in
- 18 evidence, lack of foundation.
- 19 THE WITNESS: I mean, I would go with
- what the document says. Forest has always been
- scrupulous about not promoting the pediatric
- use of our antidepressant drugs.
- 23 BY MR. WISNER:
- Q. And specifically states Celexa and

```
1
    Lexapro, correct?
 2
             Α.
                    Yes.
 3
             0.
                    So, in fact, Mr. Olanoff has now
    represented in a public hearing or public proceeding --
 4
 5
             Α.
                    Right.
 6
                    -- that Forest has always been
             Ο.
 7
     scrupulous about not promoting the pediatric use of our
 8
     antidepressant drug Celexa and Lexapro?
 9
             Α.
                    That's right.
                    Now, to be clear, we know that that
10
             Q.
11
     statement by Mr. Olanoff is not correct, right?
12
                    MS. THORNE: Objection, lack of
13
             foundation, assumes facts not in evidence.
14
                    THE WITNESS: I mean, I believe we know
15
             now, but at that time he wouldn't have known.
16
    BY MR. WISNER:
17
             0.
                    Mr. Weinstein admitted that Forest
    promoted the pediatric use of Celexa, correct?
18
19
                    MS. THORNE: Objection, misstates the
20
             plea.
21
                    THE WITNESS: Yeah, but that was in
22
             what, 2010?
23
    BY MR. WISNER:
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Let me clarify the question.

0.

1 Α. Sure. 2 Mr. Weinstein stated, admitted that Ο. Forest promoted the pediatric use of Celexa between 3 1998 and December of 2002, correct? 4 5 Α. Right. 6 And a little about two years later, Ο. 7 Dr. Olanoff testifies before Congress that Forest has 8 always been scrupulous about not promoting the 9 pediatric use of our antidepressant drug Celexa and 10 Lexapro, correct? 11 Yes, that's what he believed to be true 12 at that time. 13 Have you talked to him? Q. 14 I'm reading what he said -- what it Α. No. 15 says here. 16 Okay. Is it possible that he could have O. 17 been lying? 18 You'd have to ask him. Α. 19 Okay. So you don't know what he Ο. 20 believed? 21 No. Α. 22 Q. All right. But we know that this 23 testimony that he provided was not accurate, correct?

MS. THORNE: Objection, lack of

foundation. 1 BY MR. WISNER: 2 3 Q. Let me rephrase that. We know that this testimony he provided was incorrect, as we know today, 4 5 correct? MS. THORNE: Objection, lack of 6 7 foundation, assumes facts not in evidence, not 8 established on the record. 9 THE WITNESS: As we know today. 10 BY MR. WISNER: Okay. All right. Let's -- I'm handing 11 you a document that has been labeled as Exhibit 45 to 12 your deposition. 13 14 (Document marked for identification as 15 ForestC Deposition Exhibit No. 45.) 16 MR. WISNER: I think I might have handed 17 you two, if you could hand one to Ms. Thorne, that would be great. 18 19 BY MR. WISNER: 20 Q. You recognize this document, 21 Mr. Closter? 22 Α. I've seen this before. 23 0. This is a press release that was issued

24

in June of 2004?

- 1 Α. Right. And this was issued by Forest 2 Ο. Laboratories, correct? 3 4 Α. Yes. 5 Q. And the title of the press release is "Forest Discusses Disclosure of Citalogram Clinical 6 Trial Data in Children and Adolescents, "correct? 7 8 Α. Yes. 9 And this press release was issued partly in response to The New York Times article that came out 10 11 criticizing Forest for not disclosing the results of 94404 earlier? 12 13 MS. THORNE: Objection. 14 THE WITNESS: I believe that's true. 15 BY MR. WISNER: 16 Okay. If we read here in the first 17 paragraph, the second sentence says, "Citalopram is not approved for use in children or adolescents and has not 18 19 been promoted by Forest for use in these populations." 20 Do you see that? 21 Α. Yes.
 - Q. So it would be fair to say that Forest
 - is making a representation in a publicly released press
 - 24 release stating that it was not engaged in the

- 1 off-label promotion of Celexa for use in children or
- 2 adolescents?
- MS. THORNE: Objection.
- 4 THE WITNESS: That's what it appears to
- say.
- 6 BY MR. WISNER:
- 7 Q. So back to my first question that led to
- 8 these two documents being presented to you, would it be
- 9 fair to say, then, that prior to 2010, there were at
- 10 least two instances in which Forest or Forest employees
- 11 made public representations indicating that Forest was
- 12 not off-label promoting the pediatric use of Celexa?
- MS. THORNE: Objection, misstates the
- documents, assumes facts not in evidence, lack
- of foundation.
- 16 THE WITNESS: Yeah, that was the belief
- 17 at that time.
- 18 BY MR. WISNER:
- 19 Q. I'm sorry. That wasn't my question
- 20 about what they believed. Maybe that was a poorly
- 21 worded question. Let me try it one more time.
- Isn't it true that prior to 2010, there
- had been public representations made by Forest and by
- 24 Dr. Olanoff stating that Forest was not engaged in the

off-label promotion of Celexa for pediatric use; is 1 2 that correct? MS. THORNE: Objection, that misstates 3 4 Dr. Olanoff's testimony, assumes facts not in evidence, lacks foundation. 5 BY MR. WISNER: 6 7 Answer the question, please. 0. 8 Α. You've shown me two documents that 9 suggest that. 10 Okay. And it would, in fact, have been 0. 11 reasonable for either a physician or a consumer to rely upon the representations made by Forest in its press 12 release in 2004, correct? 13 14 MS. THORNE: Objection, calls for a 15 legal -- to the extent it calls for a legal 16 conclusion. 17 THE WITNESS: So you're asking if these 18 statements had impact on clinicians and 19 patients? 20 BY MR. WISNER: 21 No, I asked if it would have been 22 reasonable to rely upon these statements made by Forest 23 in this press release dated June 24th, 2004? 2.4 MS. THORNE: Objection, calls for a

legal conclusion. 1 2 THE WITNESS: To the extent they read these documents, sure, and they heard it. 3 4 BY MR. WISNER: 5 Q. In fact, a physician who read this press release would have no indication whatsoever that Forest 6 7 was, in fact -- sorry, let me strike that. 8 A physician reading this press release would not know or -- let me strike that. 9 10 A physician reading this press release 11 would not reasonably conclude that Forest was, in fact, engaged in the off-label pediatric promotion for Celexa 12 or Lexapro, correct? 13 14 MS. THORNE: Objection, calls for 15 speculation. This is now outside the scope of 16 the 30(b)(6) notice. To the extent Mr. Closter 17 wants to answer the question in his personal 18 capacity, he may. 19 THE WITNESS: You're going to have to 20 just repeat the question, the same question you 21 asked. I'm sorry. 22 BY MR. WISNER: 23 Ο. I understand. It's getting late.

just rephrase it again and see if it becomes clear and

24

- she'll make the same objections.

 A. I'm just forgetting the question. It's not a matter of not understanding.
- 4 Q. All right. Let me try it again.
- 5 Do you believe in your personal capacity
- 6 that it would have been reasonable for a physician to
- 7 see this press release and think that Forest was
- 8 engaged in the off-label pediatric promotion of Celexa
- 9 or Lexapro?
- 10 MS. THORNE: Objection calls for
- 11 speculation.
- 12 THE WITNESS: Right. I'd speculate they
- 13 wouldn't -- they wouldn't believe that we
- were -- that there was a off-label promotion in
- that population.
- 16 BY MR. WISNER:
- Q. And you say that because the press
- 18 release says that Forest is not doing that, right?
- MS. THORNE: Objection.
- THE WITNESS: No, sure.
- MR. WISNER: Can we go off the record
- for a few minutes, so we can wrap this up.
- MS. THORNE: Yep.
- 24 THE VIDEOGRAPHER: We are now off the

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record. The time is 7:19.
 1
 2
                    (Brief recess.)
 3
                    THE VIDEOGRAPHER: We are now back on
             the record. The time is 7:22.
 4
 5
    BY MR. WISNER:
                   All right. I'm going to return back to
 6
             Ο.
    the peppermint formulation of Celexa and Lexapro.
 7
 8
                    Forest manufactured and marketed an oral
 9
    suspension formulation of Celexa and Lexapro, correct?
10
                    MS. THORNE: Objection, assumes facts
11
            not in evidence, lacks foundation.
12
                    THE WITNESS: Correct.
13
                    MS. KIEHN: You missed describing one of
14
            the oral formulations, leave out the intro and
15
             ask the question.
16
    BY MR. WISNER:
17
                   These formulas were peppermint-flavored,
             Q.
18
    correct?
19
                   MS. THORNE: Objection.
20
                    THE WITNESS: I believe Celexa, I think,
21
            was peppermint. I'd have to check the package.
22
             I don't know the exact flavoring.
23
    BY MR. WISNER:
24
             Q. Okay. You know that Celexa was
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peppermint flavored?
 1
 2
             Α.
                    I believe that's true.
 3
             Ο.
                    Do you know if Lexapro was peppermint
 4
     flavored?
 5
             Α.
                    I don't know.
 6
                    This is not something that you looked
             Ο.
 7
     into prior to testifying today?
 8
                    No, I just don't remember.
             Α.
 9
             Ο.
                    Okay. Isn't it true that Forest used
10
     the peppermint-flavored liquid formula to promote the
11
    use of Celexa and Lexapro in children and adolescents?
12
                    MS. THORNE: Objection, lacks
13
             foundation, assumes facts not in evidence.
14
                    THE WITNESS: It's not true.
15
                    MR. WISNER: Well, I'm going to hand you
             a document that's labeled Exhibit 59.
16
17
                    (Document marked for identification as
             ForestC Deposition Exhibit No. 59.)
18
19
                    MS. THORNE: Again, before we begin, for
20
             the record, I'd like to clarify the number of
21
22
                    MR. WISNER: Please let me create the
23
             record, it's fine. I'm going to do that.
24
    BY MR. WISNER:
```

Mr. Closter, I've handed you a document 1 Ο. that has at the front "Celexa Citalogram HBr." 2 3 Do you see that? 4 Α. Yes. 5 Q. And it has -- it spans a series of numbers from 1 through 200 -- sorry -- to 25 at the top 6 7 right. 8 Do you see? 9 Α. Yes. 10 Q. You see at the bottom it ends on Page 11 211. 12 Do you see that? 13 Α. Yes. 14 So, again, the top right numbers here, Q. 15 this is an excerpt of slides from this presentation. 16 You understand that? 17 Α. Right. So there were at least 211, maybe more. You've included, I don't know, however 18 19 many are here, 25 --20 Twenty-five, right? 0. 21 Twenty-five, right. Α. 22 MS. THORNE: I'm going to object, not 23 going to stop you from using it, but I'm going 24 to state an objection for the record that using

1	the excerpted document is misleading. It
2	really would be more appropriate to show the
3	entire document.
4	MR. WISNER: Let's go off the record.
5	THE VIDEOGRAPHER: We are now off the
6	record. The time is 7:25.
7	(Discussion off the record.)
8	THE VIDEOGRAPHER: We're now back on the
9	record. The time is 7:29.
10	MR. WISNER: Can you please state your
11	record again, Ms. Thorne. I want to make sure
12	that's fully documented.
13	MS. THORNE: I mean, is there a question
14	pending?
15	MR. WISNER: I actually hadn't asked a
16	question. I handed him a document, you issued
17	objection. I'd like you to place your
18	objection.
19	MS. THORNE: Right. For the record, on
20	the document which is now Exhibit I'm sorry,
21	what are we on?
22	MR. BAUM: Fifty-nine.
23	MS. THORNE: On Exhibit 59, for the
24	record, I'm going to object to the use of the

document because it includes excerpts and is 1 misleading on that basis because it does not 2 provide the full context of the full marketing 3 plan to the witness. However, I'm not going to 4 5 prevent the witness from answering questions. 6 He may proceed to answer any questions that you 7 pose, assuming they are not otherwise 8 objectionable. MR. WISNER: I just want to point out 9 10 the irony that you are claiming that this 11 document is misleading because it doesn't 12 contain information. BY MR. WISNER: 13 14 All right. Let's continue with my Ο. 15 questioning. 16 Have you seen this document before, Mr. Closter? 17 I believe I have. 18 Α. 19 Okay. And you saw this document in Ο. preparation for your testimony today? 20 21 Likely did. Α. 22 Ο. This is the fiscal year 2001 marketing plan, and it says it's a tactical presentation, 23 24 correct?

1 Α. That's what it says. 2 Presented February 10th, 2000? O. 3 Α. That's what the document says. 4 Q. Okay. Turn to the second page. It says "Today's Agenda," and it has a bunch of different 5 bullet points. 6 7 You see that? 8 Α. I do. 9 Okay. If you turn to Page 21. Ο. 10 Α. Sorry, so it's the top right corner I'm 11 looking at, right? 12 Ο. That's right. 13 Α. Okay. Twenty-one. 14 This is a slide that has the word Q. 15 "Tactics" and it says "Patient Segments." 16 Do you see that? 17 Α. Yes. 18 And then there's an arrow pointing Q. 19 downward that says "Elderly Pediatric." 20 Do you see that? 21 Α. Yes. 22 Q. And then it goes down and up and it 23 leads to language that says "Oral Liquid 10 mg Tablet." 24 Do you see that?

I do. 1 Α. 2 0. Okay. We're going to come back to this document in a minute. I want to move on to another 3 4 document. (Document marked for identification as 5 ForestC Deposition Exhibit No. 60.) 6 7 BY MR. WISNER: 8 Handing you a document which has been 0. 9 labeled as Exhibit 60 to your deposition. 10 Have you seen this document before, 11 Mr. Closter? 12 Α. I don't believe I've seen this. 13 This is an e-mail exchange, do you see Q. 14 that, from Rich Caracio? 15 Do you see that? 16 Α. Rich Caracio. 17 Rich Caracio. Do you know Rich? Q. 18 Α. Yes. 19 How do you know Rich? 0. 20 When he worked at CME and I think even Α. 21 after he left there a number of years ago, but it's 22 been some time since I've seen them.

And he worked at CME?

That's right, he did.

Golkow Technologies, Inc.

0.

Α.

23

24

1 Q. This is to Peggy Palamar; is that right? 2 Α. Yes. At Forest? 3 Ο. 4 Α. Yes. And Delta? 5 Q. 6 Schonhoft. Α. 7 Schonhoft. Ο. 8 Going to help you when it's --Α. 9 Ο. I appreciate that. 10 This is dated -- appears to be 11 December 3rd, 2001, right? 12 Α. Right. 13 Who is Peggy Palamar? Q. 14 She was on the brand team. Α. 15 Okay. And Delta -- I can't say that Ο. 16 name. 17 Α. Schonhoft, yes, she was also on the brand team. 18 19 Okay. So they were all -- these two Ο. were in marketing; is that right? 20 21 Α. Correct. 22 Q. All right. If you look at this e-mail, 23 you can see that it's from Rich. 24 Do you see that?

1 Α. Yes, to Peggy. 2 Ο. All right. And if you look at the second to last paragraph, it says, "Finally, we are proud to now be pursuing 2 new internal programs to 4 5 Forest. We are developing pediatric based programs for Celexa in liquid formulation, as well as pursuing the 6 7 launch of escitalopram." 8 Do you see that? 9 Α. I do. Do you -- are you aware of what the 10 Q. pediatric-based programs for Celexa in liquid 11 formulation refers to? 12 13 MS. THORNE: Objection. 14 THE WITNESS: I don't. 15 BY MR. WISNER: 16 Are you aware of whether or not Mr. Caracio was charged with developing a 17 pediatric-based program for Celexa in liquid 18 formulation? 19 20 MS. THORNE: Objection, assumes facts 21 not in evidence, lacks foundation. 22 THE WITNESS: Yeah, I'm not aware. (Document marked for identification as 23 24 ForestC Deposition Exhibit No. 61.)

BY MR. WISNER: 1 2 I'm handing you a document which has 0. been marked as Exhibit 61 to your deposition. 3 4 This is a selection of call notes, 5 correct? 6 They look to be, yes. Α. 7 Okay. I'm going to ask you some general O. 8 questions about these various fields, so I can understand what they refer to, all right? 9 10 Α. Okay. Do you know what "Event_ID" is referring 11 0. 12 to? I don't. I can speculate that it's 13 Α. 14 perhaps the number of that specific call note. 15 Ο. Okay. It says "Region." 16 Do you see that? 17 Α. Yes. 18 What's that referring to? Q. 19 Probably the region that the Α. representative resides in. 20 21 And then you have a territory number. Ο. 22 Do you see that? 23 Α. Yes. 24 And then a rep number. Q.

1 Do you see that? 2 Α. Yes. Is that a unique ID number for every 3 O. single sales rep? 4 5 Α. I mean, I don't know. I would believe I mean, if you've talked to anybody from the sales 6 administration group, they would probably be able to 7 8 give you more detail on it. 9 Ο. Okay. Then it has doctor_first, M and 10 last. 11 Do you see that? 12 Α. Yes. 13 I assume that refers to the physician's Q. 14 first middle initial and last name? 15 Α. That's probably true. 16 Ο. All right. And then it has a product detail. 17 18 Do you see that? 19 Α. Yes. 20 It refers to what product is being 0. 21 detailed at that time? 22 Α. Right. 23 O. And then you have the call date, there's 24 a date?

1 Right. Α. 2 Ο. So August 22nd, 2000 is the first one 3 listed here, right? 4 Α. Yes. 5 Q. Okay. Look at the second call note. Do you see that? 6 7 Α. Yes. 8 And this was in April 20th, 2000. Q. 9 Do you see that? That's when the call date was logged, 10 Α. 11 yes. 12 Yes. And it says -- the note says, Ο. "begged for any new starts and did mention that the 13 14 oral suspension was available for her younger 15 patients." 16 Do you see that? 17 Α. Yes. Sales representatives promoting the use 18 Q. of the oral suspension formula to physicians would 19 constitute off-label pediatric promotion, correct? 20 21 MS. THORNE: Objection, calls for 22 speculation. This is outside the scope of the 23 30(b)(6) notice, so to the extent that 24 Mr. Closter can speak to this in his individual

capacity, he may do so. 1 2 THE WITNESS: I think you said the 3 promotion of the oral suspension would qualify 4 as off-label use, that's not true. 5 BY MR. WISNER: 6 No, I said the promotion of the oral 7 suspension for use in pediatric patients would 8 constitute off-label promotion, correct? 9 MS. THORNE: Objection, calls for speculation, assumes facts not in evidence, 10 11 lack of foundation and is also outside the 12 scope. 13 MR. BAUM: It's not outside the scope. 14 MS. THORNE: I'll withdraw the part 15 about it being outside the scope. 16 MR. BAUM: He should be able to answer 17 this. 18 THE WITNESS: I would answer, yes, that 19 would qualify as off-label promotion. 20 BY MR. WISNER: 21 Q. Okay. Let's turn to Page 4, second call 22 note from the top. This is a call note dated 23 February 28th, 2002. 2.4 Do you see that?

1 Α. February -- yes. 2 Ο. It says invited to the globe trotter program on March 12th, 2002. 4 Do you see that? 5 Α. I do. Just offhand, do you know what the globe 6 Ο. 7 trotter program is? 8 MS. THORNE: Objection. At this point 9 I'll object that this is outside the scope of 10 the 30(b)(6) notice. To the extent that 11 Mr. Closter can testify to this in his 12 individual capacity, he may do so, but he is 13 not testifying on behalf of the company, as to 14 the meaning of the substance of the text of 15 these call notes. 16 MR. WISNER: Respectfully, Ms. Thorne, 17 to the extent that the globe trotter program 18 constitutes a promotional program, that would 19 be within the scope, but I just don't know what 20 it is, so I'm asking if he happens to know what 21 a globe trotter program is. 22 MS. THORNE: Again, it's outside the 23 I'll renew my objection, but he can 24 answer the question.

```
1
    BY MR. WISNER:
 2
             Ο.
                    Do you know what it is?
 3
             Α.
                    No.
                    Okay. Continues reading, brief mention
 4
             Q.
 5
    of Celexa and oral suspension for easier dosing with
    kids and compliance.
 6
 7
                    Do you see that?
 8
             Α.
                    Yes.
 9
                    Recommending the use of Celexa in oral
             Ο.
     suspension for dosing with kids, that would constitute
10
11
     off-label promotion, correct?
12
                    MS. THORNE: Objection, assumes facts
13
             not in evidence, lacks foundation, calls for
14
             speculation.
15
                    THE WITNESS: Yeah, I mean, it doesn't
16
             say recommending. It says brief mention, but,
17
             you know, we don't really know what happened on
             the call, and we really don't know what the
18
19
             writing about whether these are things the
20
             physician said, the rep said, when they were
21
             said, how they were said, the rest of the
22
             conversation.
23
    BY MR. WISNER:
24
                    My question for you, Mr. Closter, was
             O.
```

- 1 simply a sales representative recommending the use of
- 2 the oral suspension medication for Celexa for dosing
- 3 with kids would be off-label promotion, correct?
- 4 MS. THORNE: Objection, calls for
- 5 speculation, assumes facts not in evidence,
- 6 lacks foundation, improper hypothetical.
- 7 THE WITNESS: It would.
- 8 BY MR. WISNER:
- 9 Q. Look at Page 5 -- oh, sorry, I meant to
- 10 do this. For the last call note that we saw the rep
- 11 number was 20242.
- Do you see that?
- 13 A. 20242, yes.
- Q. And in the first call note that we
- looked at which was the first one, that was rep number
- 16 2410, right?
- 17 A. Yes.
- 18 Q. So it appears to be different sales
- 19 reps?
- 20 A. It would appear that way.
- Q. And, also, the region on the first one
- 22 says Region 12 and the region on the one we just looked
- 23 at said Region 35.
- 24 Do you see that?

- 1 A. Yes.
- Q. All right. So it's a different region
- 3 as well?
- 4 A. It is.
- 5 Q. Okay. If you look at Page 5, the first
- 6 call note listed on Page 5, again -- well, it starts on
- 7 Page 4, actually, but moves on. There it has a rep
- 8 number of 21470.
- 9 Do you see that?
- 10 A. Yes.
- 11 Q. Again, that's a different rep number
- than the ones we've seen already?
- 13 A. Yes.
- Q. Okay. And it also has Region 64, again,
- 15 different region, right?
- 16 A. Yes.
- 17 Q. Okay. And it reads, doc was finishing
- 18 up for the day. We went on a car ride to pick up some
- 19 food, and we went over everything that was new with
- 20 Lexapro, including anxiety data, 5-milligram tablets,
- 21 syrup form for pediatric and elderly population, et
- 22 cetera.
- Let me stop right there.
- The syrup form, was that for pediatric

```
populations?
 1
 2
                    MS. THORNE: Objection, and just to
            clarify the record, when you read where you
 3
 4
             said Lexapro, the call note says LX. I'm not
 5
            disputing it. I'm just making sure the record
             is clear.
 6
 7
                   MS. KIEHN: The questions about the
 8
            Lexapro oral liquid are outside the scope, so
 9
            he can answer in his personal capacity. We
10
            agreed to talk about the Celexa oral liquid.
11
                    MR. WISNER: Are you kidding me?
12
                    MS. KIEHN: Umm-umm. If he knows, he
13
            can answer. What's the question?
14
                    THE WITNESS: No, so the syrup was for
15
            anybody who couldn't take a tablet. That's the
16
            purpose of the syrup.
17
    BY MR. WISNER:
                   And it wasn't specifically indicated for
18
            0.
    pediatric populations?
19
20
                   MS. THORNE: Renewing Ms. Kiehn's
21
            objection.
22
                    THE WITNESS: Yeah, I think it's just --
23
                                          I mean, I don't --
            it's alternate formulation.
24
             I don't know if it's indicated for anything per
```

It is another form of Celexa that was 1 se. available, just like the tablets were. 2 BY MR. WISNER: 3 4 Q. We're actually talking about Lexapro here, though, right, for this call note? 5 6 Α. Sorry. 7 Ο. I know, it's fine. 8 Same thing holds. Same thing holds. Α. 9 Ο. And Lexapro as of -- this is dated 10 January 1st, 2003. 11 You see that? 12 Α. Right. 13 As of January 1st, 2003 Lexapro was not Q. 14 approved for any pediatric indications, correct? 15 Α. No. 16 Okay. Through the next one, this is a 17 call note dated March 11th, 2003. 18 Do you see that? 19 Α. Yes. 20 0. It also relates to Lexapro, right? 21 Α. Yes. 22 Q. And it has a rep number of 21446, which is a different rep number than the other ones, correct? 23 24 Α. Yes.

It also has a region of 42 now. 1 Q. 2 Do you see that? 3 Α. Yes. 4 Ο. And this looks like it appeared to have occurred in Illinois? 5 Yes, Benton, Illinois. 6 7 Okay. It says, "Dr. B said she has been Ο. very impressed with lx." I'll stop right there. 8 9 refers to Lexapro, correct? 10 MS. THORNE: Objection. Interpreting 11 any of these call notes is outside the scope of 12 the 30(b)(6) notice, so Mr. Closter can testify 13 to the extent that he knows in his individual 14 capacity. He is not testifying on behalf of 15 the company to the extent that you're asking 16 him to interpret call notes. This or any other 17 call note that you decide to ask about after this, I'll make a standing objection, so I 18 19 don't have to take up time with each one. 20 THE WITNESS: LX refers to Lexapro, I 21 believe. 22 BY MR. WISNER: 23 0. Thank you. 24 She is very glad that it was on public

- 1 aid and -- I'll continue reading. She was very glad
- 2 that it was on public aid and she was completely out of
- 3 samples. She asked about pediatric indications. I
- 4 discussed the 18 year old age limit but all the success
- 5 psychs and other f.p.s, appears to say have but it's
- 6 misspelled, have in children.
- 7 Do you see that?
- A. I see that.
- 9 Q. Do you know what an FP refers to?
- 10 MS. THORNE: I'm going to renew the same
- 11 standing objection and give the same
- instruction to the witness.
- THE WITNESS: Probably family
- 14 practitioner.
- 15 BY MR. WISNER:
- 16 O. Okay. I informed her of the oral
- 17 solution. She was very impressed with that since no
- 18 other SSRI is in an oral form. I'll stop right there.
- 19 Having a sales rep tell a physician that
- 20 other family practitioners have had success using
- 21 Lexapro in children would qualify as a form of
- 22 off-label promotion, correct?
- MS. THORNE: Objection, lacks
- foundation, assumes facts not in evidence. To

1 the extent you are asking Mr. Closter to interpret this call note or answer your 2 3 question in the context of interpreting this call note, he is answering only in his 4 5 individual capacity and not on behalf of the 6 company because it's outside the scope. THE WITNESS: 7 I mean, with the 8 limitations of the call note, not knowing 9 exactly what the discussion was back and forth 10 between the clinician and the representative, 11 you know, had they made reference to, you know, 12 the use or the success one physician had had in 13 an off-label population I believe would qualify 14 as off-label promotion. 15 BY MR. WISNER: 16 And if I turn your attention to the 17 second to last call note on the page, it's actually the next one, this is dated March 21st, 2003. 18 19 Do you see that? 20 Α. Yes. 21 All right. Has the region of 34. Ο. 22 Do you see that? 23 Α. Region of 34, yes. 24 Q. And then that's not any other region

```
we've seen so far?
 1
                    I don't believe so.
 2
             Α.
 3
             Ο.
                    And this is in Gainesville, Florida,
 4
    right?
 5
             Α.
                    Yes.
 6
             Ο.
                    And it's about Lexapro, right?
 7
                    Looks as though it was a Lexapro call,
             Α.
 8
    yes.
 9
             Ο.
                    All right. Call note says coming
    around, like liquid option for kids.
10
11
                    Do you see that?
12
             Α.
                    Yes.
13
                    Was the liquid option of Lexapro
             Q.
14
     specifically created for kids?
15
                    MS. THORNE: Objection. Again, that's
16
             outside the scope of the 30(b)(6) notice, but
17
             to the extent that Mr. Closter is aware, he can
18
             answer in his individual capacity.
19
                    THE WITNESS: Yeah, I mean, the liquid
20
             option was provided just for ease of use for
21
             patients who preferred a liquid as opposed to
22
             tablets, that's it.
23
    BY MR. WISNER:
24
                    Fair enough.
             0.
```

1 So it's not specifically indicated for kids, right? 2 3 It wasn't developed specifically for 4 That was your question. 5 Q. So why then did Forest pick a peppermint flavor, if it wasn't meant for children? 6 7 MS. THORNE: Objection. 8 THE WITNESS: Because it wasn't meant 9 for children. I mean, I don't know why we 10 picked mint. 11 BY MR. WISNER: 12 0. It tastes best, right? 13 MS. THORNE: Objection. 14 THE WITNESS: Yes, you want something 15 that people can tolerate, that's it. 16 BY MR. WISNER: 17 And if, in fact, a sales representative 0. were to tell a physician in 2003 that the liquid option 18 was specifically for kids, that would be off-label 19 promotion? 20 21 MS. THORNE: Objection, calls for 22 speculation, improper hypothetical, assumes 23 facts not in evidence, lacks foundation. 24 the extent that you are asking Mr. Closter to

interpret this call note or answer in the 1 context of this call note, that is outside the 2 scope of the 30(b)(6) notice, and he will 3 answer only in his individual capacity. 4 5 THE WITNESS: I've already said several 6 times that the oral liquid was developed for 7 people that preferred an oral -- a liquid 8 formulation as opposed to tablets. If A 9 representative was to suggest that the drug was 10 approved for use in children, yes, it would be considered off-label promotion at that time. 11 12 BY MR. WISNER: 13 Ο. All right. Let's just do one more. 14 All right. Let's turn to Page 8, second 15 one from the top, one dated May 12th, 2003. 16 Do you see that? 17 May 12, 2003, yes. Α. 18 All right. This is in Nashville, Q. 19 Tennessee, right? 20 Α. Yes. 21 Region 32, right? 0. 22 Α. Region 32. 23 Ο. A completely different region than all the others ones we've seen so -- that we've read so 24

```
1
    far?
                    I believe so.
 2
             Α.
 3
             Ο.
                    It appears to be a different rep number
    at 3895, right?
 4
 5
             Α.
                    Yes.
 6
                    All right. The note reads, "talked
             Ο.
 7
    about how LX comes in oral liquid and how this might
 8
    make it easy for her to dose for children. Need to
     schedule dinner with her."
 9
                    Did I read that right?
10
11
             Α.
                    Yes.
12
                    Recommending to a physician that Lexapro
             O.
    comes in an oral liquid and how that might be easy to
13
    dose children would be a form of off-label promotion,
14
15
    correct?
16
                    MS. THORNE: Objection, lack of
17
             foundation, assumes facts not in evidence,
             calls for speculation. To the extent that you
18
19
             are asking Mr. Closter to testify with respect
20
             to this particular call note or in connection
21
             with it or in the context with it -- context of
22
             it, it is outside the scope of the 30(b)(6)
23
             notice, and he will answer in his individual
24
             capacity only.
```

```
1
                    THE WITNESS: Again, if the
             representative was suggesting that the drug was
 2
             approved for use in children, it would be
 3
             considered off-label.
 4
 5
    BY MR. WISNER:
 6
                    In fact, if the representative were to
    be recommending that they use the liquid formulation to
 7
 8
    dose children, that also would be off-label promotion?
 9
                    MS. THORNE:
                                 Objection. I'm renewing my
10
            prior objections to the previous questions and
             the same instruction to the witness.
11
12
                    THE WITNESS:
                                  Right. It depends on how
13
             they said it. I can't suggest that this
14
             actually happened or even know that it actually
15
            happened or how it happened or the context of
            how it was discussed.
16
17
    BY MR. WISNER:
                    Seeing that sales note, you would agree
18
    with me that this exemplifies a sales representative
19
     engaging in the off-label promotion of Lexapro for use
20
21
     in children, correct?
22
                    MS. THORNE: Objection, lack of
23
             foundation, assumes facts not in evidence.
24
                    THE WITNESS:
                                  Yeah, I can't interpret
```

```
this.
 1
 2
    BY MR. WISNER:
 3
             O.
                    So it's your testimony to the jury that
     that call note doesn't suggest that there's off-label
 4
 5
    promotion occurring?
 6
                    MS. THORNE: Objection, renewing the
 7
             same objections.
 8
                                  Again, without, you know,
                    THE WITNESS:
 9
             mandatory use of call notes, how they are
10
             formatted, how they're collected, the kind of
11
             information that they conveyed in the call note
12
             based on the actual call itself, there's not a
13
             lot you can gather from any of these call
14
             notes.
    BY MR. WISNER:
15
16
                    Now, earlier you testified that there
    was only just a handful of sales representatives, to
17
    your knowledge, that actually engaged in the off-label
18
19
    promotion of pediatric use for Celexa; is that correct?
20
             Α.
                    That's correct.
21
                    I just showed you five separate call
22
    notes in regions spanning across the United States at
23
    different times for different products.
24
                    Isn't it true that these call notes
```

```
reveal a consistent pattern and deliberate effort by
 1
    Forest to promote the use of Celexa and Lexapro for use
 2
     in children?
 3
 4
                    MS. THORNE: Objection, misstates the
 5
             record, misstates the document, misstates the
 6
             testimony, misstates the prior questions, lack
 7
             of foundation, assumes facts not in evidence.
 8
                    THE WITNESS: No, this doesn't show a
 9
            pattern.
10
    BY MR. WISNER:
11
                   Have you or anyone at Forest ever
12
     engaged in a audit of the sales note database to
13
    determine how many sales representatives were making
14
    what appear to be inappropriate references to off-label
15
    pediatric promotion?
16
                    MS. THORNE: Objection. It's outside
17
             the scope of the 30(b)(6) notice. To the
             extent that Mr. Closter is aware, he can answer
18
19
             in his individual capacity.
20
                    THE WITNESS: Yeah, I haven't been
21
             involved in an audit.
22
    BY MR. WISNER:
23
             0.
                    Do you know of one that has occurred?
24
                    MS. THORNE: Same objection, same
```

```
instruction to the witness.
 1
 2
                   THE WITNESS: I don't know, but you'd
 3
            have to ask someone in compliance on their
            history on the topic.
 4
 5
                   MR. WISNER: All right. Let's take
 6
            another short break.
 7
                   THE VIDEOGRAPHER: We're now off the
 8
            record. The time is 7:53.
9
                    (Brief recess.)
10
                   THE VIDEOGRAPHER: We are now back on
            the record. The time is 8:05.
11
12
    BY MR. WISNER:
13
            Q. Mr. Closter, could you go back to
14
    Exhibit 59.
15
            A. Okay.
16
                   If you could turn to the page that's on
17
    the top right numbered 10?
18
            A.
                   Ten, yes.
19
                   And just for reference, this is the
            0.
    tactical presentation dated February 10th, 2000,
20
21
    correct?
22
            Α.
                   Right, of the slides you've provided.
23
            O.
                   And this relates specifically to Celexa,
24
    right?
```

```
1
             Α.
                    Yes.
 2
                    MS. THORNE: Reiterating the objection I
 3
             stated earlier with respect to the use of this
 4
             document.
 5
    BY MR. WISNER:
 6
                    It says "Communication Objectives," the
 7
     first bullet point says "Disseminate data that supports
 8
     Celexa's broader scientific profile."
 9
                    Do you see that?
10
             Α.
                    Yes.
11
                    And then the next bullet point says,
             Ο.
12
     "Leverage Washington Legal Foundation to disseminate
     off-label data."
13
14
                    Do you see that?
15
             Α.
                    Yes.
                    And there's a bunch of bullet points,
16
             Ο.
     one of the bullet points is pediatric?
17
18
             Α.
                    Yes.
19
                    What is Washington Legal Foundation?
             O.
20
                    MS. THORNE:
                                 Objection.
21
                    THE WITNESS: I believe it was a group
22
             that provided a pathway for pharmaceutical
23
             companies to disseminate information of an
24
             off-label fashion. The Court ruling, I don't
```

remember exactly. 1 BY MR. WISNER: 2 If you go down to "Other Objectives," 3 0. it's the next page, Page 11. 5 Α. Okay. It has "Other Objectives" listed on top. 6 0. 7 Do you see that? 8 Α. Yes. 9 Q. And it has a bullet point for "Patient Populations." 10 11 Do you see that? 12 Α. Yes. 13 And below that it says achieve 11.6 Q. 14 new -- NRx share by end of quarter 4, Q4 in pediatrics 15 0319. 16 Do you see that? 17 Α. Yes. 18 I want to get some nomenclature Q. 19 established here. 20 NRx, refers to new prescriptions, right? 21 New prescriptions. Α. 22 Q. And by end of Q4 refers to the fourth 23 quarter? 24 End of Q -- right. Α.

```
Isn't it true that at this time period
 1
             Ο.
     in 2000, Forest had an objective to increase its market
 2
     share of new pediatric prescriptions specifically with
     regards to Celexa?
 4
 5
                    MS. THORNE: Objection, lack of
             foundation, assumes facts not in evidence,
 6
 7
            misstates the document.
 8
                    THE WITNESS: Again, it's an other
 9
             objective in a slide of over 200 slides in a
10
            presentation. I'm not sure if it was final.
11
    BY MR. WISNER:
12
             0.
                   Putting aside the slide for a second, it
    was, in fact, Forest's objective to increase its market
13
14
     share of new prescriptions for Celexa in the pediatric
15
    population, correct?
16
                    MS. THORNE: Objection, lack of
17
             foundation, misstates the testimony, assumes
             facts not in evidence, and this question is
18
19
             outside the scope of the 30(b)(6) notice. So
20
             to the extent that Mr. Closter can answer, he
21
             can answer in his individual capacity.
22
                    THE WITNESS:
                                  Yeah, I think it's a
23
             stretch to say it's Forest's objective.
24
             think it is what it is. It's indicated on a
```

slide in a tactical presentation. 1 BY MR. WISNER: 2 I understand, but you speak -- putting 3 Ο. this document aside for one second, it was Forest's 4 5 objective to increase its market share for the pediatric population of new prescriptions for Celexa in 6 2000, correct? 7 8 MS. THORNE: Objection, asked and 9 answered, renewing my prior objections to this 10 identical question. 11 THE WITNESS: Yeah, my answer stays the It's noted on one slide within a much 12 same. larger deck, that's it. 13 14 BY MR. WISNER: 15 I'm sorry, Mr. Closter, I'm not asking about the slide. 16 17 I'm asking you if it was Forests's --All we can look at is the slide. That 18 Α. is where the evidence is, right, that's what I'm 19 20 looking at. 21 Q. I understand. I'm asking you, put the 22 slide down for a second. 23 A. Sure.

24

O. Put it aside.

```
1
             Α.
                    Yep.
 2
             Ο.
                    Wasn't it Forest's objective in 2000 to
 3
     increase its pediatric share of new prescriptions for
 4
     Celexa, yes or no?
 5
                    MS. THORNE:
                                 Objection, asked and
 6
             answered like several times already and also
 7
             outside the scope. So, again, to the extent
 8
             that Mr. Closter is answering this question, he
 9
             is doing so in his individual capacity.
10
                    THE WITNESS:
                                  Yeah, I'm not aware.
11
             There's not enough documentation for me to
12
             believe that.
13
    BY MR. WISNER:
14
                    Well, Mr. Weinstein admitted that Forest
             Ο.
    was promoting the use of Celexa for use in pediatric
15
16
    population at his arraignment in 2010, correct?
17
                    MS. THORNE: Objection.
                                              That
18
             drastically misstates the plea to the extent
19
             that you are suggesting that Mr. Weinstein
20
             admitted that it was the company's objective.
21
                    MR. WISNER: I'm sorry, misstates the
22
             testimony is your objection. Can you please
23
             just stop with the speaking objection. I only
             have ten minutes left. You're wasting my time.
24
```

I'm trying to get us out of here. She has a 1 2 train to catch. Your objection is noted. BY MR. WISNER: 3 4 Ο. Mr. Closter, can you answer my question, 5 please. 6 You're saying did Herschel Weinstein, on Α. 7 behalf of the company, admit that there was off-label 8 promotion of Celexa? 9 Ο. Yes. 10 Α. Yes. 11 Q. Okay. Now, if you go back to the slide 12 presentation that we were just looking at, if you turn to Page 12 on the top right. 13 14 Α. Okay. 15 It says "Direct Impact of Details on New Ο. Prescriptions." 16 17 Do you see that? 18 Α. Direct impact, yes. 19 And it has what appears to be a chart. Q. 20 Do you see that? 21 Α. Yes. 22 Q. And it's plotting new prescriptions 23 against calls. 24 Do you see that?

1 Α. Yes. 2 Ο. And if you look to the right it says, "Number of details are highly correlated with the number of prescriptions." 4 5 Α. Right. 6 Ο. Isn't it true that in 2000 Forest was, 7 in fact, calling upon pediatricians and pediatric 8 psychiatrists? 9 MS. THORNE: Objection. 10 THE WITNESS: I mean, there were 11 physicians on the call panel that IMS had 12 designated as child psychiatrists and 13 pediatricians, yes. 14 BY MR. WISNER: 15 And isn't it, in fact, true that there Ο. 16 is a direct correlation between the number of details that a company does for a particular product and the 17 number of new prescriptions? 18 19 MS. THORNE: Objection. 20 THE WITNESS: I'm not familiar enough 21 with this analysis. I mean, there's one slide 22 on a page. I don't know if this is -- I assume 23 it's speaking generally to called on 24 physicians, that would include all the call

- panel physicians, with a general correlation of
- 2 more calls results in more new prescriptions.
- 3 BY MR. WISNER:
- 4 Q. When Forest was creating a budget for
- 5 its sales force, did it segregate the budgets that it
- 6 had for calls on pediatric specialists versus calls on
- 7 adolescent -- sorry on adult specialists?
- MS. THORNE: Objection.
- 9 THE WITNESS: So you're saying budgeted
- sales calls, where did we devote those calls
- 11 to?
- 12 BY MR. WISNER:
- 13 Q. Sure.
- 14 A. So you're asking more about how we
- 15 created the call plan --
- Q. Exactly.
- 17 A. -- and then how we prioritize those
- 18 physicians?
- 19 Q. Let me back up a little bit. I don't
- 20 want to go down that road of the deciles and all that
- 21 thing.
- 22 What I want to get -- what I want to
- 23 just establish is whether or not Forest created a
- 24 separate budget for the promotion to pediatric

specialists. 1 2 Did it have such a budget? 3 Α. No. 4 Q. Okay. So to the extent that pediatric 5 specialists or pediatric psychiatrists were called on, 6 that was done as part of Forest's regular promotional 7 activity, correct? 8 MS. THORNE: Objection. THE WITNESS: Yes, and we took the call 9 10 panel, you know, prioritized based on their 11 volume of SSRI prescribing to include all the 12 drugs in the market, and then we would devote 13 calls, sales calls to those physicians. 14 BY MR. WISNER: 15 And at least in this time period in 2000 Ο. 16 and 2003 time period, that was regardless of whether or not that physician was a pediatric specialist or some 17 other type of physician? 18 19 MS. THORNE: Objection. 20 Yes, we treated all THE WITNESS: 21 physicians the same. IMS would designate what 22 the specialty was based probably on their AMA 23 designation, so that's how they were identified 24 in the system.

```
1
    BY MR. WISNER:
 2
             Ο.
                    And, in fact, when Forest spent money on
     its promotional activity, specifically through
    detailing, it didn't distinguish between pediatric
 4
 5
     specialists or regular physicians, did it?
 6
                    MS. THORNE: Objection.
 7
                    THE WITNESS: It didn't distinguish in
             terms of sales effort, no.
 8
 9
    BY MR. WISNER:
10
             Ο.
                    So every dollar spent on promotion for
11
    pediatricians, a same dollar was spent on promotion to
12
     other physicians; is that fair to say?
13
                    MS. THORNE: Objection, calls for
14
             speculation, misstates the prior testimony,
15
             assumes facts not in evidence, lacks foundation
16
             and is also outside the scope of the 30(b)(6)
17
             notice. So to the extent that Mr. Closter is
18
             going to answer the question, he can do so in
19
             his individual capacity.
20
                    THE WITNESS: You know, you'd be better
21
             off speaking to someone who's expert on the
22
             subject, which would be those in sales
23
             administration, but generally how it worked was
24
             those physicians, regardless of specialty, that
```

generated the most prescriptions got the most 1 sales effort. 2 BY MR. WISNER: 3 4 Ο. Now, I want to be clear, Forest never 5 maintained an off-label promotion budget, right? 6 There was no such thing as an off-label Α. 7 promotion budget. 8 So any off-label promotion that may or 9 may not have occurred would have occurred in the 10 context of Forest's regular promotional budget? 11 MS. THORNE: Objection. 12 THE WITNESS: You're going to have to restate the question. 13 14 BY MR. WISNER: 15 Ο. All right. We've established that and 16 Mr. Weinstein admitted and you have several times that Forest engaged in the off-label promotion of Celexa, 17 right? 18 19 MS. THORNE: Objection. 20 THE WITNESS: Yes. 21 MS. THORNE: Misstates the prior 22 testimony. 23 BY MR. WISNER: 24 Q. Okay. The budget that was set aside

that paid for that form of off-label promotion was not 1 a different budget than the budget that Forest set 2 3 aside to pay for all of its promotion, correct? 4 MS. THORNE: Objection, lack of 5 foundation, vague, misstates the prior 6 testimony, assumes facts not in evidence. 7 There was no off-label THE WITNESS: budget. There was one budget. 8 9 BY MR. WISNER: 10 Q. And, to be clear, you said I should talk to someone in sales administration, right? 11 12 Α. If you want to get very detailed questions on this topic. 13 14 Are you familiar with Mr. Stevic? Q. 15 Α. Stasic. 16 Ο. Stasic? 17 Α. Yes. Are you familiar with Mr. Stasic? 18 Q. 19 Α. Yes. 20 And would he be somebody who would have 0. 21 a sort of greater understanding of how budgets were 22 assigned with regards to detailing? 23 MS. THORNE: Objection, misstates the 24 prior testimony. For the record, I really

don't think it is clear what Mr. Closter was 1 referring to when he said it would be better to 2 speak to sales admin but... 3 MR. WISNER: That's why I asked him the 4 5 question, Danielle. BY MR. WISNER: 6 7 So let me just ask the question again. 0. 8 Would Mr. Stasic be somebody that would 9 have sort of a more detailed understanding of the sales administration than yourself? 10 MS. THORNE: Objection. 11 12 THE WITNESS: Depends on your levels of 13 questions. If I haven't answered your 14 questions to your satisfaction or you wanted 15 more detail, someone who was expert in the 16 creation of call panels may be suitable to 17 speak with, if you haven't already done so. BY MR. WISNER: 18 19 Fair enough. I'm trying to ask, Ο. 20 Mr. Stasic is one of those people, right? 21 He was in sales administration at the Α. 22 time, I believe. 23 THE VIDEOGRAPHER: Just so you know, 24 we're at seven hours.

- 1 MR. WISNER: Okay. Just going to finish
 - this document. I just want to see if I have
 - any questions. I probably don't. Just give me
 - 4 one second.
 - 5 Thank you, Mr. Closter. I appreciate
 - 6 your patience and time in testifying today. I
 - 7 turn the witness over.
 - MS. KIEHN: Go back and clarify a couple
 - 9 points of testimony.
- 10 BY MS. THORNE:
- 11 Q. Mr. Closter, you were asked earlier
- whether Dr. Olanoff could have been lying, and you
- 13 responded -- lying in his Congressional testimony, and
- 14 you responded that Mr. Wisner would have to ask
- 15 Dr. Olanoff.
- I'd like to clarify and ask you for
- 17 Forest's position on whether Dr. Olanoff was lying in
- 18 his Congressional testimony?
- 19 A. You know, on behalf of the company, we
- 20 do not believe he was lying. You know, the statements
- 21 he made were true and accurate, to the extent of the
- 22 knowledge that he had at that time.
- Q. I'd like to just further clarify the
- 24 company's position on Dr. Olanoff's testimony.

- 1 You indicated earlier that Dr. Olanoff's
- 2 testimony was accurate to the best of his knowledge at
- 3 the time but acknowledged that it may not or stated
- 4 that it may not be accurate today.
- 5 What is the company's position on
- 6 whether the specific language used in Dr. Olanoff's
- 7 testimony remains accurate?
- 8 A. You know, I think Dr. Olanoff referenced
- 9 being scrupulous about the prevention of off-label
- 10 promotion. You know, and he's referencing, you know,
- 11 the structures that were in place, the policies that
- were in place preventing off-label promotion, making it
- 13 clear to the field sales team that off-label promotion
- 14 was not prohibited, and the policies that were in place
- 15 at the time were sound. The training was very good.
- 16 It was extensive, and it was repeated over time at
- 17 sales meetings and other opportunities, and the plan
- 18 and the program we had in place at the time we felt was
- 19 excellent, at least up to industry standard.
- MS. THORNE: Okay. We have no further
- 21 questions.
- 22 BY MR. WISNER:
- 0. One quick follow-up.
- Have you ever spoken to Mr. Olanoff

about whether or not he was lying in his testimony 1 2 before Congress? 3 MS. KIEHN: He's here -- that's not a 4 relevant question. He's given you the 5 company's position. He has been prepared to 6 testify to the company's position. End of 7 story. 8 MR. WISNER: I appreciate your 9 objection. Can you please answer my question. 10 MS. KIEHN: He's not answering. 11 MS. THORNE: We're instructing the 12 witness not to answer. 13 MS. KIEHN: Plus, he already answered 14 the question, actually. You asked him that 15 earlier. 16 MR. WISNER: Mr. Closter, I will ask you 17 the question again. You can just object and we 18 can keep a clear record, because that was a 19 very long rambling objection. 20 BY MR. WISNER: 21 Mr. Closter, did you ever talk to 22 Mr. Olanoff about whether or not he misrepresented the 23 facts in his testimony before Congress? 24 MS. KIEHN: Objection.

1 MS. THORNE: Going to object and 2 instruct the witness not to answer the 3 question. 4 MS. KIEHN: He already answered the 5 question earlier, I mean, asked and answered. He said he hadn't talked to him. 6 7 MR. WISNER: I'm sorry. This is the tag 8 team situation I was talking about. What's the 9 objection, and are you instructing him not to 10 answer or not? 11 MS. KIEHN: He can answer the question 12 again, as he already answered it. MR. WISNER: Okay. So let me ask the 13 14 question again, do your objection, and he'll 15 give me an answer, okay. Let's try this one 16 more time. 17 BY MR. WISNER: 18 Mr. Closter, have you ever spoken to Mr. Olanoff about whether or not he misrepresented the 19 facts in his testimony before Congress? 20 21 I don't believe he misrepresented his 22 comments before Congress, nor lied. 23 I appreciate your answer. Listen to my 24 question. I wasn't asking about whether or not you

think did he lie or not lie. 1 My question is have you ever personally 2 spoken with Dr. Olanoff about whether or not he misrepresented the facts that he gave to Congress? 4 5 Α. I'm not going to answer the question. 6 Ο. I'm sorry, what? 7 MS. KIEHN: I think he asked you that 8 earlier. I mean, how he prepared is 9 irrelevant, so I don't know why the question --10 and you've already asked him and he's already 11 answered, so I don't know why you keep pressing 12 the point. I don't know why it's relevant. 13 He's here to testify about the company. He has 14 just given you the company's testimony. 15 BY MR. WISNER: 16 Mr. Closter, I asked you a straightforward question, and is it your position that 17 you refuse to answer my question? 18 19 I mean, am I speaking on behalf of Α. 20 myself? 21 He already asked you, and MS. KIEHN: 22 you already answered, so I think just answer 23 again the way you did before. 24 MS. THORNE: If you want to speak on

```
1
            behalf of yourself as to whether you've ever
 2
             spoken to Dr. Olanoff.
 3
                    MS. KIEHN: Right, if that's the
 4
            confusion, right, yes, you personally.
 5
                    THE WITNESS: I personally have not
 6
            spoken to him.
 7
    BY MR. WISNER:
 8
            Q. Fair enough. Let me ask the question
    again so it's clear, and we can stop monkeying around
 9
10
    here.
11
                   Mr. Closter, have you ever personally
    spoken with Dr. Olanoff about whether or not he
12
    misrepresented the facts in his testimony before
13
14
    Congress?
15
            Α.
                    I have not spoken to him.
16
                    MR. WISNER: Thank you. No further
17
            questions.
18
                    MS. KIEHN: You asked it already.
19
                    THE VIDEOGRAPHER: This concludes
20
            today's deposition. The time is 8:22, and we
21
            are now off the record.
22
                    (Witness excused.)
23
24
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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	
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ACKNOWLEDGMENT OF DEPONENT		
I, STEVEN L. CLOSTER, do hereby certify		
that I have read the foregoing pages, and that		
the same is a correct transcription of the		
answers given by me to the questions therein		
propounded, except for the corrections or		
changes in form or substance, if any, noted in		
the attached Errata Sheet.		
STEVEN L. CLOSTER DATE		
Subscribed and sworn to before me this		
day of, 2016.		
My commission expires:		
Notary Public		