Exhibit 2

IN THE UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

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IN RE PAXIL PRODUCTS :

LIABILITY LITIGATION : NO. CV 01-07937 MRP (CWx)

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Videotaped Deposition of ROBERT TEMPLE, M.D.

Washington, D.C.

Tuesday, December 7, 2004

10:16 a.m.

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Reported by: TRISTAN-JOSEPH, RPR

10:40:11 Q. Okay. And you recall that -- what was
10:40:13 it? Twelve days before the February 2nd hearing --
10:40:15 the ANCP submitted a position paper saying there
10:40:18 was not an issue regarding a suicide link between
10:40:20 antidepressants and the pediatric population?
10:40:25 MR. BROWN: I'll object to the form of
10:40:25 the question.
10:40:26 BY MR. MURGATROYD, III:
10:40:27 Q. You can answer.
10:40:28 A. Um, yes, I remember that.
10:40:29 Q. Okay. And it turns out they were not
10:40:32 right. Correct?
10:40:33 MR. BROWN: I'll object again.
10:40:34 THE WITNESS: We're eventually concluded
10:40:34 that was not correct.
10:40:38 BY MR. MURGATROYD, III:
10:40:38 Q. Okay.
10:40:37 A. Did you say suicide?
10:40:39 Q. Yes.
10:40:39 A. We've never concluded there's a
10:40:40 relationship to suicide --
10:40:41 Q. Suicidality.

10:40:42 A. -- suicide thinking.
10:40:45 Q. Correct.
10:40:45 A. Or suicidality, if you like.
10:40:45 Q. Okay.
10:40:46 A. Right.
10:40:46 Q. And I think that's now in -- I saw a,
10:40:47 um, letter on websites.
10:40:52 A. It will -- it will be in all labeling.
10:40:53 We're still negotiating the exact language but it
10:40:54 will be an all labeling for essentially all
10:40:58 antidepressants.
10:40:59 Q. Okay. Now when you say you're
10:41:00 negotiating the labeling, that's part of your job
10:41:03 responsibility. Right?
10:41:04 A. Yeah. We sent them what we thought it
10:41:08 should say and they're allowed to say we prefer
10:41:09 this or that.
10:41:10 Q. Okay.
10:41:10 A. And we -- we read it and make a
10:41:10 decision.
10:41:12 Q. Okay.
10:41:13 MR. MURGATROYD, III: Let me mark that

10:41:14 as the next exhibit, if I can find the exhibit
10:41:19 tabs.
10:41:19 (Temple Deposition Exhibit
10:41:19 No. 3 was marked for
10:41:19 Identification.)
10:41:19 BY MR. MURGATROYD, III:
10:41:31 Q. What I'm going to show you is the letter
10:41:33 from the department of the Health and Human
10:41:36 Services that were sent out to the various
10:41:37 antidepressant manufacturers in, I believe, October
10:41:42 of this year. October 15th is the date the letter
10:41:44 was created. And it's entitled Labeling Change
10:41:47 Request Letter for Antidepressant Medications.
10:41:59 Let me show that to you.
10:41:59 (Witness reviewed document.)
10:42:08 A. Okay.
10:42:09 Q. Did, um -- did you help participate in
10:42:11 drafting that letter?
10:42:12 A. Yes.
10:42:13 Q. Okay. And --
10:42:15 A. Although most of it was drafted by
10:42:17 Dr. Laughren and his colleagues.

10:42:19 Q. Okay. But you approved it. Correct?
10:42:21 A. Yeah. I should note that the really new
10:42:23 part of it is the box, is the parts related to
10:42:28 pediatrics.
10:42:28 Q. Okay.
10:42:28 A. The other material had been sent out in,
10:42:31 I think, March of that year to reflect the need,
10:42:33 the importance of watching patients but did not
10:42:37 reflect the conclusion that there was an increased
10:42:40 risk of suicidality, which we still don't believe
10:42:43 is documented for adults.
10:42:45 Q. Okay. I think you're looking into it
10:42:47 for adults; is that correct?
10:42:48 MR. BROWN: Object to the form of the
10:42:49 question.
10:42:49 THE WITNESS: Well, we've done a --
10:42:52 we've done a study that is almost complete of
10:42:56 actual suicides in adults based on the control
10:42:59 trials. And there's clearly no increase in
10:43:02 suicides within the limits of the study to be able
10:43:03 to show that.
10:43:05 We have been watching for suicidality in

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10:43:09 each application as it comes by and have not seen
10:43:12 anything. But the way suicidality is accessed, um,
10:43:18 we think is not optimal. And we believe we found
10:43:23 an optimal way to do that by having experts, in
10:43:25 this case, at Columbia review each of those
10:43:28 reports. The reports really weren't designed to
10:43:31 assess suicidality, but they were -- they've been
10:43:34 used that way. And we think they need to be read.
10:43:37 So we are -- we are in -- still in the
10:43:39 absence of any evidence of a problem in adults, we
10:43:45 are going to have those reports looked at by the
10:43:48 same experts, at least for sampling of drugs to see
10:43:50 whether there's anything there.
10:43:51 BY MR. MURGATROYD, III:
10:43:52 Q. Okay. And which drugs did you select
10:43:54 for sampling?
10:43:56 A. I don't think we've picked them yet.
10:43:57 Um, at the Advisory Committee meeting in September
10:44:00 actually there were data presented on Paxil in
10:44:04 adults that clearly at that level with that amount
10:44:06 of evaluation showed no suggestion of increased
10:44:11 suicidality in adults.

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10:44:12 Q. Okay.
10:44:12 A. Well, that was presented by Dr.
10:44:14 Mosholder and was in striking contrast to the data
10:44:17 in children where the very same analysis did show,
10:44:21 as you know, roughly a doubling of the risk of
10:44:23 suicidality.
10:44:26 Q. Right. Okay.
10:44:27 A. So we were -- we were deciding how to go
10:44:29 about looking at that.
10:44:31 Q. I saw that, um, I think Janet Woodcox,
10:44:32 she's with your CDR. Correct? Or she's with --
10:44:37 A. She's our actual director. She's now in
10:44:41 the Commissioner's office as an Acting Deputy
10:44:44 Director.
10:44:44 Q. Okay. I saw that she said something in
10:44:45 the newspaper. Again, I don't claim that
10:44:48 newspapers are that reliable. But said that you
10:44:50 were going to review -- "you," meaning the FDA --
10:44:52 was going to review -- what was it called? Tens of
10:44:56 thousands of experience reports --
10:44:59 MR. BROWN: I'll object to the form of
10:45:01 the question.

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10:45:02 Q. -- to look into the issue.
10:45:04 MR. BROWN: Object to the form of the
10:45:05 question.
10:45:05 THE WITNESS: Okay. Well, to some
10:45:05 extent, that's what I've been describing. Let
10:45:05 me -- let me be sure you know there are two
10:45:07 different things. One is we have control trials
10:45:10 involving tens of thousands of people in adults --
10:45:12 MR. MURGATROYD, III: Right.
10:45:12 THE WITNESS: -- in placebo-controlled
10:45:15 trials of antidepressants. We have looked at those
10:45:18 date and there is clearly no increase in suicides.
10:45:20 BY MR. MURGATROYD, III:
10:45:20 Q. Let me stop you right.
10:45:21 A. Not a --
10:45:21 Q. No --
10:45:21 A. Now the other question was suicidality,
10:45:22 okay.
10:45:23 Q. Let me just stop. When you say you
10:45:25 looked at those reports, what exactly -- did you
10:45:27 look at summaries? Did you look at the raw data?
10:45:31 A. Oh, no, no. We always looked at the

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10:45:31 actual cases.
10:45:32 Q. Okay.
10:45:32 A. Yeah. And we've put that as an
10:45:33 abstract. It's not final yet so -- but that's
10:45:36 what -- that's what it shows. I've seen
10:45:37 preliminary reports, but we really need to finish
10:45:40 that up. We all agree with that.
10:45:42 Q. Okay.
10:45:42 A. The other question is suicidality,
10:45:43 suicidal thinking, preparation for, you know, maybe
10:45:49 committing suicide. Those are the things that were
10:45:52 reviewed in the pediatric data.
10:45:55 Q. Right.
10:45:56 A. And while we have been looking at that
10:45:59 sort of thing with each application and having seen
10:46:00 anything, that's not the same as doing an overall
10:46:03 review with a rigorous attempt to look at the cases
10:46:06 and see what they mean, such as what we did -- such
10:46:09 as we did with the pediatric cases --
10:46:12 Q. Right.
10:46:12 A. -- and where you think there's reason to
10:46:14 do that because it's not always easy to tell

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10:46:16 whether someone was preparing for suicide or just
10:46:18 fooling around, you know. One is much more serious
10:46:21 than the other.
10:46:24 The only publicly available data on that
10:46:27 was the data on Paxil presented by Dr. Mosholder at
10:46:32 the -- I think it was in September Advisory
10:46:33 Committee meeting, which showed bar graphs that
10:46:37 showed absolutely no difference in suicidality in
10:46:41 the -- between adults -- in adults, between the
10:46:42 treated and the untreated patients. Why children
10:46:42 and adults should be different, is sort of
10:46:42 mysterious.
10:46:42 Um, but anyway, we are planning to look
10:46:51 or have the companies look more closely at those
10:46:54 data, including a careful review of the cases, such
10:46:57 as was done for the pediatric data.
10:47:00 Q. And --
10:47:00 A. And Dr. Woodcox referred to that review.
10:47:02 Q. Okay. The review of the actual cases?
10:47:04 A. Yes. It -- that's what's crucial, to
10:47:08 look at the actual reports to see what they were.
10:47:08 Q. Right. Because --

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10:47:09 A. Because that's what we found with
10:47:09 the Columbia. Some things that were called
10:47:11 suicidality didn't look persuasive. Some things
10:47:15 that weren't called suicidality did look like
10:47:16 suicidality. That's why we need to look at them.
10:47:18 Q. Okay. And I think you said you were
10:47:23 doing sampling of those reports or are you going to
10:47:25 look at all of those reports?
10:47:26 A. We're not fully decided yet.
10:47:28 Q. And, um, how long do you think something
10:47:28 like that process is going to take?
10:47:30 A. Hmm, too soon to say.
10:47:31 Q. Okay.
10:47:32 A. I don't know.
10:47:32 Q. Not months. I think it would be longer
10:47:33 than months.
10:47:35 A. Not months.
10:47:37 Q. Right.
10:47:36 A. And, again, that's in a context where
10:47:39 we're quite comfortable with the idea that in those
10:47:42 trials there's no increase in actual suicides. So
10:47:45 it's an interesting question to see if we'll see an

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10:47:46 increase in suicidality. We don't know.
10:47:52 Q. Okay. You understand, though, that drug
10:47:52 manufacturers, particularly in the SSRI business,
10:47:52 have bee known to miscode suicide events?
10:48:06 MR. BROWN: I'll object to the form of
10:48:06 the question.
10:48:06 THE WITNESS: No, I don't know that.
10:48:06 BY MR. MURGATROYD, III:
10:48:06 Q. Okay. Do you know what the --
10:48:06 A. I don't know what --
10:48:06 Q. -- code --
10:48:06 A. I don't know what miscode means.
10:48:06 Q. Okay.
10:48:06 A. What we know is that the -- well,
10:48:07 whenever you report adverse reactions, you have to
10:48:09 group them otherwise it doesn't make any sense.
10:48:12 Q. Right.
10:48:13 A. So you take the individual reports of
10:48:15 physicians and you call them something else in --
10:48:17 as everybody by now knows, suicidality was
10:48:22 incorporated into something called a emotional
10:48:25 lability, although it was very clear from reading

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10:48:27 the reports that some of them were suicidality.
10:48:29 That's why we were able to where -- where attempted
10:48:32 suicides or thinking about suicides. That's why we
10:48:36 were able to, um, to detect it. I wouldn't
10:48:38 characterized it as miscoding. I think it's a
10:48:40 consequence of having a coding dictionary.
10:48:42 Q. Well, does -- let's say, does Pfizer use
10:48:45 emotional lability to keep track of the suicides
10:48:48 and suicide attempts that occur during a clinical
10:48:49 trials for Zoloft?
10:48:52 A. Do they -- do they --
10:48:52 Q. Yeah, that's the question. Do they?
10:48:52 A. I don't know. I don't know that.
10:48:56 Q. Okay. So -- well, is there a -- if
10:48:59 Pfizer is using the word "suicide" --
10:49:02 A. Well, there are --
10:49:02 Q. -- and GSK is using emotional lability,
10:49:03 how do you --
10:49:05 MR. BROWN: I'll object to the --
10:49:06 Q. -- smoke that out --
10:49:06 MR. BROWN: -- form of the question and
10:49:06 on the basis of relevance. And it's clearly not

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11:44:01 more of those stickers. Thanks.
11:44:14 Ten?
11:44:14 MR. KELL: Yes.
11:44:14 (Temple Deposition Exhibit
11:44:14 Nos. 10 and 11 were marked for
11:44:14 Identification.)
11:44:18 BY MR. MURGATROYD, III:
11:44:19 Q. And I've marked this Code Section as
11:44:22 Exhibit 10, and "e" is on page 3. And I did a
11:44:28 little blowup, which I'll mark as 11, as to the
11:44:34 specific part I'm referring to.
11:44:38 MR. KELL: What section of the C.F.R.
11:44:39 are we looking at, at this point, please?
11:44:43 MR. MURGATROYD, III: 201.57 and it's
11:44:43 "e."
11:44:48 THE WITNESS: And it's "e."
11:44:48 MR. KELL: Which is warnings?
11:44:50 THE WITNESS: It's just warnings. It's
11:44:50 just got a warning names under the current
11:44:54 language.
11:44:54 MR. KELL: Right.
11:44:54 BY MR. MURGATROYD, III:

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11:44:55 Q. And do you see the part now that says,
11:44:55 The labeling shall be revised to include a warning
11:44:58 as soon as there is a reasonable evidence of an
11:45:02 association of a serious hazard with a drug; a
11:45:04 causal relationship need not be proved?
11:45:07 A. Yes --
11:45:08 Q. Okay.
11:45:08 A. -- I see that.
11:45:08 Q. And that's what I blew up on Exhibit 11.
11:45:12 Do you see that?
11:45:13 A. Right.
11:45:13 Q. Okay. Now --
11:45:14 MR. BROWN: Can I see that for just one
11:45:15 second, please.
11:45:17 MR. MURGATROYD, III: Sure.
11:45:17 MR. BROWN: Because what you read was
11:45:19 different than what was stated in the regulations,
11:45:21 but you -- this accurately captures it.
11:45:25 MR. MURGATROYD, III: Oh, okay. Maybe I
11:45:27 read it wrong. But Exhibit 11 is accurate.
11:45:31 Correct?
11:45:31 MR. BROWN: It is.

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11:45:33 MR. MURGATROYD, III: Okay, good.
11:45:33 BY MR. MURGATROYD, III:
11:45:34 Q. Now, so here we're talking about the --
11:45:39 this would be a drug manufacturer's responsibility
11:45:42 to revise a label under this code section.
11:45:47 Correct?
11:45:47 MR. BROWN: Object to the form of the
11:45:48 question.
11:45:52 MR. KELL: I'll object on foundation.
11:45:54 I'll let the Doctor answer if he feels
11:45:56 qualified to interpret legal standards.
11:46:02 Um, you have not established that.
11:46:04 MR. MURGATROYD, III: Okay.
11:46:07 THE WITNESS: They're supposed to do it.
11:46:08 We not uncommonly request such changes ourselves --
11:46:11 MR. MURGATROYD, III: Okay.
11:46:11 THE WITNESS: If we discover -- discover
11:46:12 something. But it's their job to keep the labeling
11:46:16 up to date, at least nominally the labeling is
11:46:18 owned by the company.
11:46:20 BY MR. MURGATROYD, III:
11:46:20 Q. Okay. All right. And then I'll show

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11:46:20 you the next code section that I've marked, um,
11:46:23 which is 3 --
11:46:24 A. Of course.
11:46:25 Q. -- 14.70.
11:46:27 A. Just to point out the -- based on the
11:46:29 standard for warning that you gave me, the
11:46:31 reasonable evidence of an association of a series
11:46:34 hazard is subject to interpretation.
11:46:39 Q. Correct. And we're going to get into
11:46:40 that.
11:46:40 A. Okay.
11:46:40 Q. Because I -- actually maybe we'll kind
11:46:42 of diverge here for a second and -- because I want
11:46:46 to make sure -- is there a difference between the
11:46:50 term "association" and "causation" in -- in the
11:46:53 eyes of the FDA?
11:46:58 A. Well, there is in my eyes. I -- I don't
11:47:02 think you should use the term association when you
11:47:05 think there's a causal relationship personally, but
11:47:08 it does -- it does show up in labeling. There's no
11:47:10 question about it. To me, it's something of a
11:47:13 lawful word. When you believe it's reasonable

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16:10:49 question I'm supposed to answer?
16:10:51 MR. KELL: Yeah, you can answer the last
16:10:52 question if --
16:10:54 THE WITNESS: Our source of data from
16:10:55 clinical trials was the results of the trials as
16:10:59 sent to the companies. We have some capacity to
16:11:02 inspect the actual trial sites to see if there's
16:11:04 anything missing, but there's no question there are
16:11:08 masses of data and we won't necessarily catch
16:11:11 everything.
16:11:12 BY MR. FARBER:
16:11:13 Q. And you don't have considerable
16:11:14 resources to go out and check every clinical trial
16:11:18 on the scene, do you?
16:11:18 A. Not --
16:11:21 MR. BROWN: Object to the form of the
16:11:22 question.
16:11:23 THE WITNESS: Of course, not. Um, we --
16:11:24 we -- you can expect a sample of them. Um, but
16:11:26 the -- the -- the data is the results of the
16:11:27 trials. They're carried by in many cases
16:11:30 independent people and they're not carried out by

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16:11:32 the companies. They're carried out for the
16:11:34 companies. The data generally comes to the
16:11:35 companies and they, uh, send it forward.
16:11:38 BY MR. FARBER:
16:11:40 Q. But the principal investigators are -- I
16:11:42 know you're not a lawyer but I'll ask you anyway.
16:11:42 The principal investigators are working for the
16:11:47 company in the execution of these clinical trials;
16:11:49 are they not?
16:11:51 A. Sure, they're paid by the companies --
16:11:55 Q. Okay.
16:11:55 A. -- to do it.
16:12:01 Q. If you go into the safety record,
16:12:02 please, Doctor, and go to page, uh --
16:12:09 A. I'm sorry. Which document now?
16:12:10 Q. The safety review -- Dr. Brecher's
16:12:12 Safety Review is Exhibit 29. It's the first
16:12:15 exhibit I handed out.
16:12:17 A. Okay. Did you state a page number?
16:12:28 Q. No, not yet. If you'll go to page 23.
16:12:46 We can save some time by basically asking you are
16:12:48 you aware of any of this suicide data prior to

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16:12:53 today on Dr. Brecher's report that you can -- that
16:12:57 you reviewed and are familiar with?
16:12:59 A. No. I'm sure I read it, but at the time
16:13:01 of the approval, a very long time ago, but I
16:13:03 haven't read it.
16:13:04 Q. Okay. If -- if Dr. Brecher's, uh, uh,
16:13:04 report had internal inconsistencies, would that be,
16:13:19 if it did, would that be something that the FDA
16:13:20 would be concerned about for presentation to the
16:13:20 advisory panel?
16:13:23 MR. KELL: Internal inconsistencies with
16:13:24 respect to what?
16:13:26 MR. FARBER: Well, let's -- let's --
16:13:26 let's go over some of them. The --
16:13:28 THE WITNESS: Well, we would -- we'd try
16:13:31 to, you know, each -- each, uh, review has a next
16:13:36 level review, and I might see it and we try to
16:13:39 catch inconsistencies.
16:13:39 BY MR. FARBER:
16:13:41 Q. Yeah, I -- I know you would. Uh, But
16:13:42 this was a very -- let's put it this way. This was
16:13:45 a very important document for the approval of Paxil

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16:13:50 initially in '92, wasn't it?
16:13:51 A. Was it the primary deal?
16:13:54 Q. Yes.
16:13:54 A. Sure.
16:13:54 Q. Now, uh, were you aware that there were
16:13:58 numerous discrepancies of suicide data in -- in
16:14:00 Dr. Brecher's report?
16:14:01 A. I don't know what you mean by
16:14:04 discrepancies.
16:14:04 Q. Okay. Well, if you go to page 23,
16:14:08 you'll see --
16:14:10 A. I'm on -- I'm on page 23, yes.
16:14:11 Q. -- you'll see up under the bold and
16:14:13 print death suicide.
16:14:13 A. Yes.
16:14:14 Q. Okay. And if you go down and you
16:14:16 indicate, uh, that, uh -- oh, yes. Here I found
16:14:29 it. The last sentence of that introductory
16:14:30 paragraph you'll -- do you see where it says two of
16:14:34 the five placebo suicides occurred during run in.
16:14:38 Do you see that?
16:14:39 A. Yeah. You shouldn't count those as part

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16:14:42 of the placebo rate.
16:14:42 Q. Right. Now, if you'll see the -- the
16:14:44 five -- and I won't ask you to sort through the
16:14:47 document because I already know -- you'll see the
16:14:50 bottom three on this page are placebo suicides.
16:14:56 And you'll see, uh, the third entry from the top is
16:15:02 a placebo suicide.
16:15:05 A. Sorry. The third entry from the top.
16:15:08 Q. The third patient from the top I should
16:15:10 say. Do you see that at a patient --
16:15:11 A. Volume 1 --
16:15:11 Q. -- do you see that?
16:15:12 A. -- .46 page 120?
16:15:15 Q. Yeah.
16:15:15 A. Okay. And then --
16:15:16 Q. And the bottom three --
16:15:18 A. Three or two?
16:15:21 Q. Three.
16:15:23 A. The 49 here --
16:15:23 Q. You see the patient is not identified
16:15:35 very well because it's deleted and apparently is a
16:15:35 FOIA document.

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16:15:35 A. Okay. That one doesn't say it was
16:15:35 during the placebo run in, but do you know that it
16:15:35 was?
16:15:37 Q. Uh, no. I'm -- I'm not -- I'm not
16:15:38 stating that one. I don't -- I can't tell by
16:15:41 looking at this and I guess --
16:15:43 A. But you did state -- you did state that
16:15:44 the bottom three were during the run-in period and
16:15:46 I'm just asking because it looks like two out of
16:15:50 the three were.
16:15:50 Q. Well, actually if I did that, it was a
16:15:52 mistake. And I was stating that two of the five
16:15:53 placebo suicides occurred during run-in. And
16:15:55 that's in that sentence up above. But let's --
16:15:57 A. All right.
16:15:57 Q. -- get to the -- let's get to the next
16:15:58 page at the top names, which is an 80-year-old man.
16:16:01 A. But before you do that, is there a
16:16:03 question? It seems true that two of the five
16:16:03 placebo occurred during run-in, the 49 year old and
16:16:06 the 43 year old.
16:16:09 Q. I just want to make sure we're tracking

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16:16:11 the same numbers here.
16:16:12 A. Okay.
16:16:13 Q. And we -- and you saw 4 on page -- on
16:16:16 page 23.
16:16:20 MR. BROWN: I'll object.
16:16:20 THE WITNESS: Four what?
16:16:20 MR. BROWN: I believe that
16:16:21 mischaracterizes his testimony.
16:16:25 MR. FARBER: Okay. Well, let's --
16:16:25 THE WITNESS: I'm sorry, where did I see
16:16:27 four?
16:16:27 BY MR. FARBER:
16:16:28 Q. Four placebo suicides on page 23. And I
16:16:31 pointed out the third patient from the top --
16:16:34 A. Yeah.
16:16:35 Q. -- and the bottom three patients.
16:16:41 A. That's correct.
16:16:41 Q. Okay.
16:16:42 A. Okay.
16:16:42 Q. That's four. Right?
16:16:44 A. Yeah.
16:16:44 Q. Okay. Now, let's go to the top of

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16:16:46 page 24 and we got the fifth one. Correct? The
16:16:51 80-year-old man?
16:16:57 A. Yes.
16:16:58 Q. Okay. Now, uh, let's go to the next
16:17:02 page, page 25 --
16:17:07 MR. KELL: Excuse me.
16:17:08 Q. -- where the x --
16:17:08 MR. KELL: Excuse me, Mr. Farber. I
16:17:09 don't mean to interrupt your question, and you need
16:17:13 not to answer this if you don't want to, but I'm
16:17:18 trying to follow where you could possibly be going
16:17:21 with this that has anything to do with the scope of
16:17:25 this deposition. If you would care to enlighten
16:17:30 me, you can. If not, I'll wait until you get to a
16:17:35 question.
16:17:35 MR. FARBER: Well, I -- I -- we already,
16:17:36 for the record, I -- I talked to you outside that
16:17:39 my initiative to tell you where I was going with
16:17:41 this on suicide. Do you remember that
16:17:43 conversation?
16:17:46 MR. KELL: All right. Then, um --
16:17:47 MR. FARBER: Well --

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18:33:39 adequate and well-controlled studies. Other kind
18:33:41 of information about effectiveness we know
18:33:44 represents more descriptive standards. I would
18:33:47 never allege that the exact choice of the dose is
18:33:49 always based on how well-controlled studies.
18:33:52 Um, advantages over other drugs, things
18:33:54 like that, they meet a very high standard. The
18:33:58 adverse reaction section of the labeling is largely
18:34:00 descriptive as adverse reaction date always are.
18:34:04 It may or may not come from well-controlled
18:34:07 studies. It may come from long-term extensions of
18:34:08 studies. It still has to be scientifically
18:34:11 credible in the evaluated persuasiveness.
18:34:13 Q. Well, let's --
18:34:14 A. It's a different standard.
18:34:16 Q. Let me focus on a couple of specific
18:34:17 sections on drug labeling --
18:34:18 A. Okay.
18:34:17 Q. -- then.
18:34:19 With respect to the warning section,
18:34:20 would you expect that this statement in the warning
18:34:25 section be supported by scientific evidence or

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18:34:27 having scientific basis?
18:34:31 A. Again, I -- I actually share some of the
18:34:32 objection to what exactly scientific means. We
18:34:35 didn't -- we would expect it to be pretty well
18:34:37 supported. As we point out in various labeling
18:34:40 points, it doesn't have to be proof positive if the
18:34:43 standard isn't always adequate in well-controlled
18:34:43 studies, but it has to be a reasonable
18:34:46 interpretation of the data. Um, not -- but well
18:34:52 short of proof positive and you -- you way to long
18:34:54 if you require that.
18:35:05 Q. Let me ask it -- let me ask it this way.
18:35:05 If a warning has no scientific basis, should it be
18:35:05 included in the labeling?
18:35:06 MR. FARBER: Object to the form.
18:35:07 THE WITNESS: No, no.
18:35:10 BY MR. BROWN:
18:35:11 Q. If --
18:35:11 A. The reasonable -- reasonably credible
18:35:12 evidence of causation and whatever the warning is
18:35:15 about.
18:35:16 Q. And if there were no scientific basis

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18:35:18 for a warning and it were included in the drug
18:35:22 labeling would that render the drug labeling false
18:35:26 or misleading?
18:35:28 MR. FARBER: Object. The witness isn't
18:35:29 qualified to make that --
18:35:33 THE WITNESS: Well, actually I think I
18:35:35 am. That would be a very unusual thing for us to
18:35:38 do. I mean, the fact is that the company strongly
18:35:41 wants labeling. Even if we think it's a little
18:35:44 flimsy, we would probably defer.
18:35:46 BY MR. BROWN:
18:35:47 Q. We're not talking about what a company
18:35:48 would want to do. If you saw drug labeling that
18:35:51 included a warning that had no scientific basis,
18:35:56 would you consider that drug labeling false or
18:35:58 misleading?
18:36:00 MR. FARBER: I'll just have a standing
18:36:01 objection against relatives on the word
18:36:01 "scientific." And go ahead on that basis, and I
18:36:02 won't interrupt anymore.
18:36:11 THE WITNESS: Well, that's a little
18:36:13 hard. I think the answer is generally, yes, but I

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18:36:16 cannot imagine. I don't believe I can recall ever
18:36:19 taking a regulatory action on that basis, but we
18:36:22 would not want a stupid warning. Let's put it that
18:36:26 way. It isn't supported by anything. And I can --
18:36:30 well you can imagine circumstances in which people
18:36:32 might want to make a warning to avoid a population
18:36:36 they're worried about and without a basis, so I --
18:36:36 I sort of talk myself into saying it would be false
18:36:41 and misleading, but we would have to be quite
18:36:42 persuaded to that it really was, uh, without merit.
18:36:47 BY MR. BROWN:
18:36:48 Q. Does the FDA require that there be
18:36:49 reliable data from controlled trials before the
18:36:52 sponsor is permitted to include incidence label --
18:36:56 I'm sorry -- incidence data in the labeling?
18:37:01 A. No. We sometimes make our best shot at
18:37:07 making an estimate from, uh, postmarketing reports.
18:37:12 There's -- if the events are relatively rare, you
18:37:14 won't have controlled-trial data. But we try to
18:37:18 convey the uncertainty about the estimate. Um, and
18:37:22 the problem usually is we don't know what the
18:37:25 reporting rate is. We don't know what fraction of

CERTIFICATE OF NOTARY PUBLIC & REPORTER

I, TRISTAN-JOSEPH, the officer before whom the foregoing deposition was taken, do hereby certify that the witness whose testimony appears in the foregoing deposition was duly sworn; that the testimony of said witness was taken in shorthand and thereafter reduced to typewriting by me or under my direction; that said deposition is a true record of the testimony given by said witness; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this deposition was taken; and, further that I am not a relative or employee of any attorney or counsel employed by the parties thereto, nor financially or otherwise interested in the outcome of this action.

Tristan-Joseph

Notary for the District of Columbia

My Commission Expires: NOVEMBER 30, 2008