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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Deposition of ROBERT TEMPLE, M.D.
Washington, D.C.
Tuesday, December 7, 2004
10:16 a.m.

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Deposition of ROBERT TEMPLE, M.D., held at the offices of:

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Pursuant to agreement, before Tristan-Joseph, Registered Professional Reporter and Notary Public of the District of Columbia.

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C O N T E N T S

E X H I B I T S

(Attached to the Transcript)

CERTIFIED QUESTIONS

P R O C E E D I N G S

THE VIDEOGRAPHER: Good morning. I'm Don Berger, the videographer, and I represent Accurate Vision in Granada Hills, California. I'm not financially interested in this action, and I'm not related to any employee of any attorney or of any of the companies.

Today's date is December 7, 2004. The time is approximately 10:16 a.m. The location is 1250 24th Street, Northwest, Washington, D.C. There is -- this case is entitled In Re Paxil Products Liability Litigation. The deponent today is Dr. Robert Temple. Our court reporter is Tristan-Joseph.

Will counsel please introduce themselves for the record.

MR. MURGATROYD, III: My name is Skip Murgatroyd and I represent the Plaintiffs in this action.

MR. FARBER: Don Farber. And I'm also representing the Plaintiffs.

MR. BROWN: This is Mark Brown. I'm

with King & Spaulding here on behalf of Glaxo SmithKline. And with me are Andy Bayman and Nikki Reeves also from King & Spaulding, and Bob Glanville from Phillips Lytle, also here on behalf of Glaxo SmithKlein.

MR. KELL: Geral Kell from the Department of Justice representing Dr. Temple. And accompanying me is Marci Norton from the FDA' Office of Chief Counsel.

MR. MURGATROYD, III: You get a special instruction.

MR. KELL: Oh, good.

(Witness sworn.)

MR. BROWN: I'd like to get a couple of things on the record before we begin if that's okay with you, Skip.

MR. MURGATROYD, III: Go ahead.

MR. BROWN: I'd just like to note that Dr. Temple's deposition has been requested by the Plaintiffs because Dr. Temple submitted a declaration concerning the GSK promotional statement that Paxil is nonhabit forming. GSK

objects to questions about on drug or dose increase adverse events such as suicidality. These events are not the basis of Plaintiffs' claims, have nothing to do with Dr. Temple's declaration and are irrelevant to the issues and the allegations made by the Plaintiffs.

Because of this, GSK is not prepared to address these issues. If you grant me a standing objection on this so that I don't have to make it every time the issue is raised, it will speed up the questioning.

MR. MURGATROYD, III: That's fine. We will be going into those issues, so your standing objection will be noted.

MR. BROWN: Okay, I appreciate that.

The second thing I'd like to note for the record is that prior to the time deposition Plaintiffs' counsel has represented to us that they intend to use seven hours of their time for Dr. Temple's questioning.

We believe that we have a right to also ask Dr. Temple questions with respect to issues

associated with his declaration directly or indirectly. We've asked for time to provide us with an opportunity to ask those questions. It's unclear to us exactly how long your questioning will go. We do know that the scope of the deposition has been defined with respect to Dr. Tempel's deposition according to the stipulation entered into between the government and the Plaintiffs' counsel as limited to the scope of Dr. Temple's declaration given in this case.

MR. MURGATROYD, III: Well, let me stop you right there. There was not stipulation. It's a court-ordered deposition.

MR. BROWN: The order was entered pursuant to the joint stipulation. I'll let Mr. Kell raise objections to the extent that he has questions as to scope.

But the point I want to make is that if the deposition questioning is limited to the scope of his declaration, we think -- feel that that questioning both the plaintiffs and the questions that we would like to ask Dr. Temple should take

substantially less than seven hours.
MR. MURGATROYD, III: Well, I --
MR. BROWN: So I just want to note that for the record.
MR. MURGATROYD, III: That's fine. And I think -- I'll let you know right now that the -- we're here as a matter of a court-ordered deposition. It was not -- there was no stipulation. That was a joint motion that's required by Federal Rules to be filed when there's a discovery dispute.
The issue -- the issue that's before the court is how much weight, if any, to give the brief that was submitted by the United States Government in this case, which was wholly supported by Dr. Temple's decklaration. So we have in our moving papers and in conversations we've had with the court, alleged FDA bias which we intend to explore and another -- another of other issues, which we think is perfectly relevant to whether or not the intervention by the U.S. is proper and whether or not the court, either a judge or a jury, should pay

any attention to either the moving papers of the United States Government or Dr. Temple's declaration.

So we have a lot to cover today. I have no doubt that we will be here for the seven hours that we're entitled to under the law. I have over 23 pages of questions that I intend to ask. I understand, the court understands, that -- and I don't know if you were at the last status conference -- but the court acknowledges that there are going to be disputes on what's going to happen today. We have the magistrate standing by, obviously on L.A. time. So we can only use her when that's appropriate.

So we expect there will be disputes. That's fine. The magistrate judge is ready to handle them as they come up, and we'll take breaks as necessary. I probably won't break every time Gerald instructs Dr. Temple not to answer a question. I'll probably have the court reporter mark those. And we'll do them in blocks. We'll have to decide on how big the blocks will be and

how much we want to hit the magistrate with at one time. But I have the magistrate's number. She's already been informed by my office to be on standby, which was with the approval of --

MR. FARBER: Judge Fowser.

MR. MURGATROYD, III: -- Judge Foswer.

So with that in mind, I'd like to proceed. In terms of your questioning, when we're finished, I think you are entitled to ask the number of questions you want. And I don't have any objection to that whatsoever. When you ask them, I may object to the questions. But the ^,)in fact, you want to ask questions, fine.

In terms of our questioning, I intend to go probably six to six and a half hours and reserve the last half an hour for Mr. Farber. And, um, if we finish in five hours or four hours or five and half hours, and Mr. Farber finishes his half an hour, which is what he expects, then you will certainly have the floor.

MR. BROWN: We appreciate your recognition of our right to ask Dr. Temple

questions in connection with this deposition. I don't intend to speak for the government. They have company counsel here to represent their views.

Based on the order that Judge Fowser er entered authorizing this deposition, though, it's clear that that order was entered pursuant to the joint stipulation of the parties, and I'll let that stipulation speak for itself.

MR. MURGATROYD, III: Ready to go? Great.

Whereupon,

ROBERT TEMPLE, M.D.

was called as a witness and, having first been duly sworn, was examined and testified as follows:

EXAMINATION BY COUNSEL FOR THE PLAINTIFFS

BY MR. MURGATROYD, III:

Q. All right. Doctor, can you please state your full name and spell it for the record.

A. My name is Robert Temple. Robert, as usual; Temple, T-E-M-P-L-E.

Q. Okay. And what is your current address?

A. 3325 Rowand, R-O-W-A-N-D, Place,

Northwest. That's in Washington --
Q. Okay.
A. -- 20008.
Q. And have you ever had your deposition taken before?
A. I've given depositions.
Q. Okay. How many times.
A. I don't remember. Several.
Q. Okay. More than 10.
A. No, not more than 10.
Q. Okay. More than five?
A. Several.
Q. Okay.
A. I don't think so.
Q. All right. So you're familiar -- somewhat familiar with the process. Correct?
A. Yes.
Q. Okay. You understand you're under oath?
A. Yes.
Q. Okay. And that's the same oath as if you were sitting in a court before a judge and jury?

A. Right.
Q. Okay. Now is there any reason why you can't give your best testimony today?
A. My best testimony?
Q. Are you under the influence of any drugs or anything like that?
A. No.
Q. Okay. So are you prepared to testify today?
A. Yes.
Q. Okay. One of the things that's going to be important for the court reporter during the course of this deposition is that you wait for me to completely ask the question before you answer it, and I in kind, will wait for you to completely answer the question before I ask the next question. Is that okay?
A. Yes.
Q. Okay. And then the last thing is it's important that your answers are spoken, because the court reporter can't take down nods or shrugs. It would make the record confusing. Okay?

A. Okay.
Q. And if during the course of the deposition you have any questions, you obviously are free to consult with your counsel. Okay?
A. Yes.
Q. Great. Now, I've already stated on the record that this court-ordered deposition and it's regarding the In Re Paxil Litigation. And I take it you are familiar with that litigation to some degree.
A. Only to a small degree.
Q. Okay.
A. I'm mostly familiar with the depo -- the statement I provided.
Q. Okay. Have you read the complaint in that action?
A. No.
Q. Okay. Are you aware of the allegations?
A. Not in -- not in a way I'd care to characterize it. I don't really know what they are.
Q. Okay. Do you know how many people are

involved in the litigation?
A. No.
Q. Okay. You haven't heard that it's thousands of people?
A. I probably heard that, but I don't know that.
Q. Okay.
A. I don't know the details of the case, no. I've read the complaint or anything like that.
Q. Okay.
THE COURT REPORTER: I need you to speak up.
THE WITNESS: Sorry.
Yeah, I haven't read the complaint. I don't really know the details of what's being asked.
BY MR. MURGATROYD, III:
Q. Okay. Did you review any documents in preparing for this deposition today?
A. I read the two letters approving changes in labeling in 2001.
Q. Okay. There was a reference in your

declaration. Correct?
A. Yes.
Q. Okay. Any other documents?
A. No. Although, I found a couple of news reports on the British action on antidepressants yesterday of some interest.
Q. Okay.
A. So I looked at those.
Q. Okay. That's the NHRA?
A. Yes.
Q. Okay. Anything else?
A. I just recently glanced at my original statement.
Q. Okay.
A. That's it.
Q. All right, fine. Now, I guess I'd like to start with your -- your background. You are a doctor. Correct?
A. Yes.
Q. And where did you go to medical school?
A. Uh, New York University.
Q. Okay. When did you graduate?

A. 1967.
Q. Okay. And did you have any specialty?
A. I had training in internal medicine at Columbia. And I have boards in clinical pharmocology, which was sort of unofficial boards that clinical pharmocologists believed that no one else pays attention to.
Q. Okay.
A. All right.
Q. Did you go into private practice after graduating from or after completing your medical training?
A. No.
Q. Okay. Did you -- what did you do after you finished your medical training?
A. Uh, my -- I went to Columbia for two years to do training in internal medicine, and I went to NIH to the clinical endocrinology branch it was then called the National Institute of Metabolism and Digestive Diseases, or something like that. Uh, I did that until 1972 and then I went to the Food and Drug Administration.

Q. Okay. So you have been with the Food and Drug Administration now for 32 years. Correct?
A. Correct.
Q. Okay. Now, I looked at some charts that I pulled off the Internet to try to understand the structure of the FDA.
A. Okay.
Q. And I'm not real interested in what you did in the past. I'm more interested in what your current position is. And it's my understanding that you hold two distinct positions; is that correct?
A. Yes. One of them as acting because you're not allowed to hold two positions.
Q. Okay, great. Let me just --
MR. MURGATROYD, III: Can I have some stickers to mark exhibits with, please. I need the court reporter --
MR. BROWN: Do you have copies for us?
MR. MURGATROYD, III: You know, you know, I came all the way and I don't. You're going to have to kind of stand behind the deponent or --

BY MR. MURGATROYD, III:

Q. Let me show you what I'm going to mark as --

MR. FARBER: I have two, two.

(Temple Deposition Exhibit No. 1 was marked for Identification.)

BY MR. MURGATROYD, III:

Q. This is a chart that I retreived from the Internet that has a title The Department of Health and Human Services. And if you would, could you take a look at that, please.

(Witness reviewed document.)

A. Okay. I'm in the Center For drug Evaluation and Research.

Q. Okay. And that's at the bottom left. Correct?

A. Yes.

Q. The second -- second from the left?

A. That's right.

Q. Okay. And that -- the director is Dr. Galson who is acting --

A. Yes.
Q. -- acting director?
A. Yes.
Q. Okay. Then let me show you the next chart that I found.
A. Do you want it back?
Q. Just put it -- we'll put it here on the table.

(Temple Deposition Exhibit No. 2 was marked for Identification.)

BY MR. MURGATROYD, III:
Q. The next chart is entitled the Center For Drug Evaluation And Research which is where you work. Correct?
A. Yes.
Q. Okay. Take a look at that.
A. Sure.
Q. Am I correct in stating that this is -- this shows you holding two different positions?
A. Uh, should I circle one or something?
Q. Yeah, that would be great.

A. Okay. Yes, I'm Acting Director of the Office of Drug Evaluation 1. And -- sorry. Let me find it. Oh.

Q. I think it's the upper left.

A. And I'm Director of the Office of Medical Policy, which has sort of general responsibilities but also contains the division of Scientific Investigations and the Division of Drug Marketing, Advertising and Communication.

Q. Okay. And the Division of Drug Marketing, Advertising, and Communications known as DDMAC; is that correct?

A. That's correct.

Q. So if I use that term today, you'll understand what I'm talking about.

A. Yeah, I can understand that.

Q. Okay. Because we're going to have some questions regarding that.

Now -- now taking the Office of Drug Evaluation, is that Roman numeral one? Is that -- or just one is that what you call it?

A. Either is fine.

Q. Okay. What are your responsibilities as acting director of that office?

A. The office contains three review division. The review divisions are the basic way FDA deals with both the development of drugs under an IND and the approval of drugs from marketing in response to a new drug application or marketing application.

So the three divisions that are in there are Division of Oncology Drug Products, the Division of Neuropharmacologic (sic) Drugs Products, which also includes psychiatric type drugs, and the Division of Cardo-Renal Drug Products.

They have considerable independence and operate, but certain major actions come to the office for -- for -- for -- to be dealt with. For example, any new molecular entity. Do you know what that is?

Q. Uh-hmm.

A. Okay. Any new molecular entity has to be signed off as a yes or no at the office level.

Q. Okay.
A. Other kinds of actions can be signed off legally at the division level and only if there's a problem or something of particular interest where it would come to the office.
I attend large numbers of *ENDO *Phase *II meetings, along with the division itself. My own personal interest are study design and how to approve things, so I find the development process particularly interesting.
Q. Okay.
A. And any controversies are likely to come to the office level and perhaps higher.
Q. Okay. And of those three, they're considered three divisions, the three drug divisions?
A. Yes.
Q. Okay. How many drugs are you responsible for?
A. Um, I don't know how to answer that question. Um, the number of say new drugs that would get -- pulling new drugs, new molecular

entities that would be approved in any given year might be something in the neighborhood of six.

Q. Okay.

A. And they'll be a few that don't get approved, so the actions related to those. Then the divisions themselves have responsibilities and take care of them mostly without direct office input, although that varies for new dosage forms, like control of release product and new claims.

Just as an illustration, the two documents referred to in my, uh, in my statement refer to two new uses Paxil. Those typically are done at the division level, sometimes with discussions, sometimes without, on how novel they are and how difficult they are.

Q. Okay.

A. The total number of drugs that are approved and that we help monitor are certainly in the many hundreds, probably in the thousands.

Q. Okay. And that was my next question. You do monitor -- after the drugs has been approved, that, um -- well, is it, I guess,

offices, that's the word that you used, that office is responsible for monitoring safety?

A. Well, there's a joint responsibility. This has been --

Q. Right.

A. -- very much in the news, so you've probably been reading about it. We have an Office of Drug Safety --

Q. Right.

A. -- that is responsible for looking at the adverse reaction reports that come in. They actually also come to the -- to the offices -- within the Office of New Drugs. And together we look to see how the labeling needs to be modified to account for new information. And that's a continuing responsibility and it's to some extent shared, although the review divisions and the offices have responsibility for maintaining the labeling and being sure it's accurate and so on.

Q. Okay. So that's not the drug -- that's -- you're not the Office of Drug Safety. That's your -- that's your office that's

responsible --
A. Well --
Q. -- for drug --
A. -- yeah --
Q. -- labeling?
A. -- one -- we -- we negotiate when there's a disagreement. But one of the things being discussed is who should have more responsibility and so on. But at the present time responsibility for the labeling --
Q. Right.
A. -- is -- belongs in the three divisions.
Q. Okay. So if there's a labeling change, that goes to your division?
A. Right.
Q. Okay. But, again, so it's clear, and I think you know this. I just want to make it clear for the record. The only division obviously is the Neuropharmacologi?
A. Yes.
Q. Okay. And Paxil falls within that. Correct?

A. It does.
Q. Okay, good. So the other two divisions I have not interest in.
So when it comes to the labeling of Paxil, that's something that would go through your office. Correct?
A. Yes.
Q. Okay, great. Now, in terms of -- well, let me -- I'll come back to that in a minute.
Let's move to -- well, before I got too much further, in your Office of Drug Evaluation I, you have two subordinates by the name of Dr. *Laughren and Dr. Katz; is that correct?
A. Well, they -- Dr. Katz is the director of the division of Neuruopharmacologic drug products.
Q. Okay.
A. Okay. And Dr. Laughren is a team leader within that division --
Q. Okay.
A. -- for psychiatric drugs. There are actually now two team leaders for psychiatric

drugs.
Q. Okay. But they are subject to your orders? They --
A. Yes.
Q. -- report to you. Correct?
A. Yes.
Q. Okay, good. And that's true also for Drs. *Leber and *Brecker, who are no longer with the FDA?
A. Leber was the former director of that division.
Q. Okay.
A. And Brecker was a reviewing medical officer --
Q. Okay.
A. A reviewer.
Q. I've had the opportunity to meet a reviewing medical officer recently by the name of Richard *Cappett. Do you recall who he is?
A. I do.
Q. Okay. And did he and Dr. Brecker, would that be considered on the same -- have the same job

responsibilities?
A. They would have when they were in those positions, yeah.
Q. Okay. And they would have reported to Dr. Leber when he was there?
A. Yes.
Q. Okay. Now, do the PDACs, the PsychOpharmacological Drug Advisory Committees, do they fall within that division?
A. Well, normally the advisory committees all work for the commissioner, but their day-to-day interactions are with the division -- with the review division.
Q. And who has final authority in selecting committee numbers?
A. Ooh. It's beyond us. It's the Commissioner's Office that does.
Q. Okay. It's not something you participate in?
A. No, I wouldn't say that. I might participate it. But, in.
^,)in fact,, the choice of these people is much

more -- is much better known to the people within the division, doctors, for example, Laughren and Kats would know those people better than I do.

Q. Okay.

A. I mean they're in the neurologic and psychiatric business. I'm not.

Q. Okay. Well, maybe -- maybe I can get -- maybe if I -- there was a PDAC recently on suicidality in February and September --

A. Sure.

Q. -- of this year. Correct?

A. Right.

Q. Who was responsible for putting that panel together?

A. Well, one of the panels, maybe both, but I don't remember, had representatives from the pediatrics community also. And I don't remember or know how the members from the pediatric committee that joined in were chosen, but the members of the committee were the standing members of the committee.

Q. Okay.

A. Those were the regular members. They're chosen for four-year terms.
Q. Okay.
A. And unless they're barred from a meeting, for one reason or another, those are the people who come unless they are unavailable.
Q. Okay.
A. And we have fairly rigorous conflict of interest rules so that it's not uncommon for someone who is on the committe not to be able to participate, or not to be able to vote in a particular action if they've been involved with the -- with the drug.
At the February meeting and the subsequent meeting in September, um, a couple of -- a couple of people who were on the committee were not allowed to participate because they joined in the statement from the American College of Neuropharmacology, uh, serving -- the drugs were free of problems, and that seemed, uh, inappropriate for someone who was about to consider that question. So they weren't allowed to

participate or some of them were.
Q. Okay. And that included Dr. Andrew Leon?
A. I think he actually participated in the first meeting because it wasn't a decisional meeting and not in the second.
Q. Okay. And his --
A. But I'm not positive of that.
Q. Okay. And his participation would have been precluded because he was part of the ANCP -- AN -- ANCP?
A. Yeah, yeah. My -- my recollection -- I'm not certain of this -- is that he was the only available person with the relevant skills. I guess he's a viro -- he's a viro statistician.
Q. Right.
A. And he was, uh, allowed to participate in the first meeting, which was not a decisional meeting, but not the second. He was thought to -- there was no -- no substitute thought to be available for the first. So I think he participated in the first.

Q. Okay. And you recall that -- what was it? Twelve days before the February 2nd hearing -- the ANCP submitted a position paper saying there was not an issue regarding a suicide link between antidepressants and the pediatric population?

MR. BROWN: I'll object to the form of the question.

BY MR. MURGATROYD, III:

Q. You can answer.

A. Um, yes, I remember that.

Q. Okay. And it turns out they were not right. Correct?

MR. BROWN: I'll object again.

THE WITNESS: We're eventually concluded that was not correct.

BY MR. MURGATROYD, III:

Q. Okay.

A. Did you say suicide?

Q. Yes.

A. We've never concluded there's a relationship to suicide --

Q. Suicidality.

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

as as the next exhibit, if I can find the exhibit tabs.

(Temple Deposition Exhibit No. 3 was marked for Identification.)

BY MR. MURGATROYD, III:

Q. What I'm going to show you is the letter from the department of the Health and Human Services that were sent out to the various antidepressant manufacturers in, I believe, October of this year. October 15th is the date the letter was created. And it's entitled Labeling Change Request Letter for Antidepressant Medications.

Let me show that to you.

(Witness reviewed document.)

A. Okay.

Q. Did, um -- did you help participate in drafting that letter?

A. Yes.

Q. Okay. And --

A. Although most of it was drafted by Dr. Laughren and his colleagues.

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

each application as it comes by and have not seen anything. But the way suicidality is accessed, um, we think is not optimal. And we believe we found an optimal way to do that by having experts, in this case, at Columbia review each of those reports. The reports really weren't designed to assess suicidality, but they were -- they've been used that way. And we think they need to be read.

So we are -- we are in -- still in the absence of any evidence of a problem in adults, we are going to have those reports looked at by the same experts, at least for sampling of drugs to see whether there's anything there.

BY MR. MURGATROYD, III:

Q. Okay. And which drugs did you select for sampling?

A. I don't think we've picked them yet. Um, at the Advisory Committee meeting in September actually there were data presented on Paxil in adults that clearly at that level with that amount of evaluation showed no suggestion of increased suicidality in adults.

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

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

actual cases.
Q. Okay.
A. Yeah. And we've put that as an abstract. It's not final yet so -- but that's what -- that's what it shows. I've seen prelimary reports, but we really need to finish that up. We all agree with that.
Q. Okay.
A. The other question is suicidality, suicidal thinking, preparation for, you know, maybe committing suicide. Those are the things that were reviewed in the pediatric data.
Q. Right.
A. And while we have been looking at that sort of thing with each application and having seen anything, that's not the same as doing an overall review with a rigorous attempt to look at the cases and see what they mean, such as what we did -- such as we did with the pediatric cases --
Q. Right.
A. -- and where you think there's reason to do that because it's not always easy to tell

whether someone was preparing for suicide or just fooling around, you know. One is much more serious than the other.

The only publicly available data on that was the data on Paxil presented by Dr. Mosholder at the -- I think it was in September Advisory Committee meeting, which showed bar graphs that showed absolutely no difference in suicidality in the -- between adults -- in adults, between the treated and the untreated patients. Why children and adults should be different, is sort of mysterious.

Um, but anway, we are planning to look or have the companies look more closely at those data, including a careful review of the cases, such as was done for the pediatic data.

Q. And --

A. And Dr. *Woodcock referred to that review.

Q. Okay. The review of the actual cases?

A. Yes. It -- that's what's crucial, to look at the actual reports to see what they were.

Q. Right. Because --
A. Because that's what we found with the Columbia. Some things that were called suicidality didn't look persuasive. Some things that weren't called suicidality did look like suicidality. That's why we need to look at them.
Q. Okay. And I think you said you were doing sampling of those reports or are you going to look at all of those reports?
A. We're not fully decided yet.
Q. And, um, how long do you think something like that process is going to take?
A. Hmm, too soon to say.
Q. Okay.
A. I don't know.
Q. Not months. I think it would be longer than months.
A. Not months.
Q. Right.
A. And, again, that's in a context where we're quite comfortable with the idea that in those trials there's no increase in actual suicides. So

it's an interesting question to see if we'll see an increase in suicideality. We don't know.

Q. Okay. You understand, though, that drug manufacturers, particularly in the SSRI business, have bee known to miscode suicide events?

MR. BROWN: I'll object to the form of the question.

THE WITNESS: No, I don't know that.

BY MR. MURGATROYD, III:

Q. Okay. Do you know what the --

A. I don't know what --

Q. -- code --

A. I don't know what miscode means.

Q. Okay.

A. What we know is that the -- well, whenever you report adverse reactions, you have to group them otherwise it doesn't make any sense.

Q. Right.

A. So you take the individual reports of physicians and you call them something else in -- as everybody by now knows, suicidality was incorporated into something called a emotional

lability, although it was very clear from reading the reports that some of them were suicidality. That's why we were able to where -- where attempted suicides or thinking about suicides. That's why we were able to, um, to detect it. I wouldn't characterized it as miscoding. I think it's a consequence of having a coding dictionary.

Q. Well, does -- let's say, does Pfizer use emotional lability to keep track of the suicides and suicide attempts that occur during a clincial trials for Zoloft?

A. Do they -- do they --

Q. Yeah, that's the question. Do they?

A. I don't know. I don't know that.

Q. Okay. So -- well, is there a -- if Pfizer is using the word "suicide" --

A. Well, there are --

Q. -- and GSK is using emotional lability, how do you --

MR. BROWN: I'll object to the --

Q. -- smoke that out --

MR. BROWN: -- form of the question and

on the basis of relevance. And it's clearly not addmissible in this action.

THE WITNESS: There are multiple coding dictionaries. The one that's currently coming into vogue is called *Medra. It's better than the previous ones. But one of the reasons we, uh, get both the actual physician report and the coded report is that you need to look in any coded report, uh, at the actual cases. There are many examples of this.

I don't have any basis for believing that anybody is manipulating it. It -- you have to -- you have to combine events into a single code, otherwise what you have is a thousand individual reports, which isn't helpful. So you have to group them somehow.

BY MR. MURGATROYD, III: Okay.

THE WITNESS: Whether they were optimally grouped or not, youknow, could be debated.

Now I think now that we're aware of the suicidality issue, if they now appeared under the

heading of emotion *liability, that would be unsatisfactory.

BY MR. MURGATROYD, III:

Q. Okay. What -- what is a term that they should be coded under now?

A. Well, you know, I'm -- I'm not -- it may have been on this, but I would think something that had SUI word in it.

Q. Okay. So the emotional lability term is not -- no longer acceptable to --

A. That would not be appropriate anymore.

Q. Okay. Now I take it that if a drug company says that the average reaction is nausea, but if you go into the internal documents and see that the reason the person discontinued from the trial was because they wanted to kill themselves and other people, that would be a miscoding --

MR. BROWN: I'll --

Q. -- miscoding.

MR. BROWN: I'll object to the form of the question.

BY MR. MURGATROYD, III:

Q. Would you agree that's miscoding?
A. Well, you're asking two different things. The person may have been nauseated and may have been suicidal.
Q. Right. But the report to the FDA was strictly nausea. But if you looked at the --
A. And the other was left out.
Q. Yes, yes.
A. No, it shouldn't be left out.
Q. Okay. They would be -- so that's what I'm talking about, a miscoding, have an example of miscoding. Correct?
A. Right.
Q. But it --
A. No. That all depends on what the people knew. If they knew that the person tried to kill themselves and didn't tell us, that would be not miscoding. That would be omitting something that's critical.
Q. Okay.
A. But, you know, I -- I don't -- you haven't defined the circumstance well enough.

Q. No, I haven't shown you the documents either but --
A. Right.
Q. -- maybe if somebody --
A. If somebody missed something, we -- we are realist. We know people miss something sometimes.
Q. Okay. What is a penalty for reporting a incident where somebody wants to kill other people on an SSRI, but it gets reported to the FDA as nausea?
MR. KELL: Objection.
BY MR. MURGATROYD, III:
Q. Is there a --
MR. KELL: Objection.
Mr. Murgatroyd, I'm trying to let the witness be as forthcoming as possible so you can get a general background since, but I think we're going pretty far field.
MR. MURGATROYD, III: Gerald, I agree. Let me just finish that one question and --
MR. KELL: I will allow you --

MR. MURGATROYD, III: -- I'll be done in that category. How about that?
MR. KELL: I will let the witness answer that question.
MR. MURGATROYD, III: Okay.
BY MR. MURGATROYD, III:
Q. Do you remember the question?
A. Well, there are penalties for lying to the government. I'm not an expert and knows there are other people here that know better. So if one concludes that there's a deliberate misrepresentation, there are variously -- and those are -- those are what I've learned to call Title 18 violations. So that's no good.
Q. Okay.
A. Being poorly competent could also raised questions whether they are doing it right. And there's a variety of threats, like, we're not going to listen to your data and things like that. But there's not a lot of experience with those things. We haven't caught too many people lying.
Q. Okay.

A. So I can't tell you any more than that.
Q. Okay. Now going to your other -- I think we've covered Office of Drug Evaluation. Correct? Your responsibilities there, which are basically, if I had to summarize them, it would be -- well, for my purposes -- with two key would be labeling and safety.
A. Oh, no. Efficacy is very important.
Q. No, I understand but okay. Okay, great.
A. Yeah.
Q. Labeling --
A. Right.
Q. -- efficacy?
A. Right. One of the things we worry about is whether the drug has been shown to work. We spend a lot of time worry about that. And then we spend a lot of time worrying about whether safety has been appropriately characterized, enough people you can study, what the data show, all of that.
Q. Okay, great --
A. And --
Q. Now --

A. Right. And then getting into labeling.
Q. Great. Let's go to your other job or your other position and that is where you are Director of the Office of Medical Policy. Correct?
A. Yes.
Q. And I take -- it is that considered a more senior position, if that's --
A. It -- it --
Q. -- a appropriate?
A. Sort of. It reports more directly to the, uh, to the center director. That's why that's my permanent job.
Q. Okay.
A. Because it's normally higher.
Q. And in that -- in that position --
A. You can debate -- you can debat that, but --
Q. Oay.
A. -- anyway, that's right.
Q. Okay. But in that position you -- your report directly to Dr. Galson. Correct?
A. Yes.

Q. Okay. Where in your other position --
A. I report to Dr. Jenkins.
Q. Dr. Jenkins, Office of New Drugs?
A. That's right.
Q. Okay. Who then reports to Dr. Glason?
A. Right.
Q. Okay. Now, as director of the office of medical policy, what are your responsibilities there?
A. Well, they're both specific and general. The division of scientific investigations are the people who go out and see how studies are carried out. And the division -- and DDMAC, which we've agreed to call it, is responsible for our monitoring of advertising and sending letters when we don't think they're doing it correct, writing guidance on how to do a properly balanced ad, and all of those things.
So a lot of what they do is send, um, letters to people whose promotion they consider violative.
Q. Okay.

A. And, um, although this didn't -- it used to be true. They used to send the letters out. Starting about three or four years ago, all of these letters now are seen by the Office of Chief Counsel, so, naturally, we, and my office, have to look at them first.

So we've, uh, have a new policy. So I now see all the letters before they go out --

Q. Okay.

A. -- or my -- or my deputy does it.

Q. And how do you divide up which you see in which --

A. Whosever around.

Q. Okay. And so it'd go from the person in your division in the Office of Medical Policy a drafted letter. Does it have --

A. The draft letter is seen by their boss, Tom Abrams, and then either Rachel Berman or I look at them. And then they're all seen by the Office of Chief Counsel and eventually by the Director of Chief Counsel, whatever the right title is.

Q. Okay. And that's -- that -- Dan Troy

introduced that. Right?
A. Yes.
Q. Okay. Now he's gone. Correct?
A. Yes.
Q. Okay.
A. We're still doing it.
Q. You're still doing it, okay. Is his predecessor is required to, to your knowledge?
A. No, they did not.
Q. Okay. You're just doing it as a matter of habit?
A. Sorry.
MR. BROWN: Object to the form of the question.
THE WITNESS: You mean is successor?
BY MR. MURGATROYD, III:
Q. Successor. I'm sorry. Successor.
A. I don't know the details. We haven't changed the process.
Q. Okay. There's some criticism about that process. Correct?
MR. BROWN: I'll object to the form of

the question.
BY MR. MURGATROYD, III:
Q. The fact that by the time the letters get out, the ads have stopped running. You've heard that, I take it.
A. I have.
(Temple Deposition Exhibit No. 4 was marked for Identification.)
BY MR. MURGATROYD, III:
Q. Okay. Now, in looking at the charts for the FDA, I came across, um, another document that I want to show you. I think this is Exhibit 4. And it's entitled Improving Public Health: Promoting Safe and Effective Drug Use.
MR. BROWN: Can I see that as well?
MR. MURGATROYD, III: Yeah.
(Witness reviewed document.)
MR. BROWN: Do you have a lot of questions around this particular document?
MR. MURGATROYD, III: Yes, I do.
MR. BROWN: Well, I don't have a copy.

MR. MURGATROYD, III: I know. You don't have a copy of any of them. I may have one for you in this instance.

THE WITNESS: Okay.

BY MR. MURGATROYD, III:

Q. Okay. Do you remember that document?

A. No.

Q. Okay. Do you see that it lists five strategic areas for the -- for CDER. Right?

A. Yes.

Q. Okay. And do you -- can you tell me what those five strategic areas are?

MR. KELL: Are you just asking him to read what's on the document?

MR. MURGATROYD, III: Yeah. I'm going to ask him --

MR. KELL: He said he's not familiar with it.

MR. MURGATROYD, III: Yeah, I just want to see if he's familiar with them.

THE WITNESS: Well, the first one is strong FDA that the people, efficient risk

management which goes to, uh -- it's always easy to tell what these are saying. The efficient risk management points out that, um, uh, there have been very few truly new drugs recent. So we're interested in, um, removing barriers to innovation. That probably is a foreshadowing that's been called the critical path initiative.

Um, and also reflected a desire to modernize manufacturing. We're working on making the drug safety program, um, as good as possible, including watching over them after they're approved to see how they're being used. Um, took note of the possibility of special safety restrictions on certain drugs. And we -- this isn't the first time we were trying to communicate better with, um, with consumers. We tend to talk mostly to other physicians.

Q. Okay. That was -- that was one of my questions.

A. When there's a counter-terrorism thing, too.

Q. Okay. The -- the one I was more

concerned is talking with consumers. Is that -- does -- does the consumer have access to FDA personnel to talk to if they have a concern about a drug they're taking?

A. Oh, you mean like call up and say, Should I be on this drug?

Q. Well, no. Just say I'm on this drug and I'm having this problem. Is that -- is that a line that exists within the --

A. We have --

Q. -- organization?

A. We have an Office of, uh, Consumer Affairs in the Commissioner's office, which tends to fill those questions, and we'll get help as appropriate. There's a limit to -- you know, we can't be the local physician.

Q. Okay.

A. So we don't try to do that.

Q. Okay.

A. But they -- they answer lots of questions. Um --

Q. Okay.

A. -- and that's where they mostly go.
Q. Would a citizen, such as myself, if I had a concern about a drug that I had quite a bit of experience with, would I have access to anybody in your office?
MR. BROWN: Object to the form of the question.
THE WITNESS: Yeah, I'm not sure what you mean. You mean to report it? To send us a --
MR. MURGATROYD, III: Yeah.
THE WITNESS: -- a letter or --
BY MR. MURGATROYD, III:
Q. No. To come in and discuss it.
A. Conceiveably but not as an ordinary routine matter. There's just not enough of us to do that. But this Office of Consumers Affairs, I probably have the title slightly wrong. Um, receives a lot of -- a lot of comments of that kind. And if there's detailed information, um, they might facilitate getting it. And, of course people, do petition us --
Q. Okay.

A. -- sometimes with information. And then we have to respond to the petition.
Q. And I think that happens, doesn't it, with --
A. It does happen.
Q. With Prozac it happened. There was a petition. Do you remember that back in --
A. I don't remember. There are petitions. There are a lots --
Q. Okay.
A. -- of petitions.
Q. Okay. And just so I understand the process. When the petition is denied, then, if you want to -- if the consumer or whoever filed the petition is unhappy, they then take that into a court of law. Is the procedure?
A. You're -- you're past what I know.
Q. Okay, that's fine. In terms of that document in front of you, there's nothing in there that talks about CDER's role in protective drug companies. Right? That's not a role --
A. Protecting drug companies?

Q. Yeah, protecting drug companies' interest?
A. Like from what.
Q. From lawsuits.
A. Oh, no. Nothing in there about that.
Q. Do you feel that that's any part of your responsibilities as, uh, as an employee of the FDA, Doctor?
A. Project drug companies against lawsuits?
Q. Yeah.
A. No.
Q. Okay. Now, um, you -- I take it you realized that there are allegations currently that, um, there -- it is perceived that the FDA has what I can quote it, Far too cozy of a relationship with drug companies. You're aware of that. Right?
MR. BROWN: I'll object to the form of the question, Jim.
MR. KELL: Objection. What are you quoting if you're going to read a quote to the witness?
MR. MURGATROYD, III: Well, I'll showed

him the documents. It's Senator Grasswood before --

MR. FARBER: Grassley.

MR. MURGATROYD, III: Grassley in front of Jim Lehrer's news hour.

THE WITNESS: Yeah, you can't print and I can't say what I think of those allegations. I think they're wrong, misunderstand the situation. And I totally disagree with them.

BY MR. MURGATROYD, III:

Q. Okay. But you're aware that there are at least one continuing congressional investigation and I think Representative Hinchey Adam earlier congressional investigation into the allegations that the FDA is too cozy with the drug companies.

MR. BROWN: Again, object --

MR. MURGATROYD, III: Yeah.

MR. BROWN: -- to the form of the question.

THE WITNESS: Right.

MR. BROWN: Dr. Temple, if I may just git my objection --

THE WITNESS: Please, go ahead. Go ahead.
MR. BROWN: -- on the record before you answer.
THE WITNESS: That's fine.
MR. BROWN: I'll just object to the form of the question.
I'm sorry. You may -- you may answer.
MR. MURGATROYD, III: Okay. Well, the reason I'm asking him why it's relevant to why we're sitting here today is that representative *Hinch's investigation encompassed this case, discussed this case.
BY MR. MURGATROYD, III:
Q. Do you -- are you aware of that?
MR. BROWN: Objection.
MR. KELL: Objection.
THE WITNESS: I don't know anything about that.
MR. KELL: Objection. No foundation.
MR. BROWN: I'll object --
MR. MURGATROYD, III: Okay.

MR. BROWN: -- to the form --
MR. MURGATROYD, III: All right, that's fine.
MR. BROWN: -- of the question as well.
MR. MURGATROYD, III: I'll put the foundation in there.
THE COURT REPORTER: Excuse me one moment. When you guys are objecting, he's mumbling and it's not going to be on the record. So he needs to wait for the objections, so that the record is clear.
THE WITNESS: Fine. I'll wait. Okay.
MR. MURGATROYD, III: And we'll all agree they're the same. Right?
MR. BROWN: Correct.
MR. MURGATROYD, III: Good.
MR. BROWN: And you'll allow him to finish the answer to his questions. Right?
MR. MURGATROYD, III: Absolutely.
BY MR. MURGATROYD, III:
Q. I think the last exhibit in front of you is No. 4; is that correct?

A. How would I know that?
Q. It would at the bottom -- a little sticker.
MR. KELL: It's No. 4.
THE WITNESS: Oh, yeah. It is No. 4.
(Temple Deposition Exhibit No 5 was marked for Identification.)
BY MR. MURGATROYD, III:
Q. Okay. Let me show you what I've marked as Exhibit 5. And it is a document entitled FDA Misleads House Subcommitte that was prepared by the office of Representaive Maurice D. Hincey. And your absolutely free to look through the whole document, but the part of the document that references the case that we're here today for is on the second page.
MR. BROWN: Do you have another copy of that one?
MR. MURGATROYD, III: Mark, you know I do.
MR. BROWN: Thank you.

MR. MURGATROYD, III: I need that back, though, so I can ask questions.
THE WITNESS: Yeah, I have --
MR. KELL: No.
THE WITNESS: Oh, no. Okay, fine.
MR. KELL: There's no question pending, Doctor.
THE WITNESS: Okay, fine.
MR. KELL: Wait for a question
THE WITNESS: Good.
MR. KELL: And wait for any objections.
THE WITNESS: Fine.
MR. BROWN: Let me just get an objection on the record, because based on the copy that I'm reviewing, it's not clear whose document this was.
MR. MURGATROYD, III: Well, I think it says it on the front. It's the title.
MR. BROWN: Prepared by the office of Representative Maurice D. Hinchey.
MR. MURGATROYD, III: Right. You can take it right off his website. It's sitting right there. That's where I got it.

MR. BROWN: Okay.
MR. MURGATROYD, III: All right.
BY MR. MURGATROYD, III:
Q. And, Doctor, I just want to reference the paragraph 5 of this document. First -- first of all, um, the brief that was submitted, to which your declaration was attached, which you said you -- you reviewed today. Correct?
A. Just my attachment. Yeah, okay.
Q. You didn't look at the brief itself?
A. Nope.
Q. Okay. Are you aware that that brief was unsolocited by any court?
MR. BROWN: I'll object to the form of the question.
THE WITNESS: Am I supposed to answer?
BY MR. MURGATROYD, III:
Q. Yes.
MR. KELL: You can answer.
THE WITNESS: Okay.
Um --
MR. KELL: The question is --

THE WITNESS: I would --
MR. KELL: -- are you aware?
THE WITNESS: I would not have been aware of those circumstances particularly.
BY MR. MURGATROYD, III:
Q. What are you aware of?
A. I don't know that.
Q. Okay. Do you know that a court didn't ask for that brief?
A. No, I don't.
Q. Okay. I'm the first one to tell you that?
A. Yeah, I -- I -- I don't know what I knew about it. I don't remember the circumstances of the case at all. I wasn't particularly part of it.
Q. Okay.
A. I just responded to a request for a particular matter.
Q. Okay.
Q. Well ,are you aware that your participation in the In Re Paxil case resulted in this investigation that was done by Representative

Hinchey?

MR. KELL: I object. Leading.

THE WITNESS: I'm not aware that my participation did. I think -- I mean, I can see where our participation did. My -- my memo was on a very small point I thought. But, no, I was not aware of it.

(Temple Deposition Exhibit No. 6 was marked for Identification.)

BY MR. MURGATROYD, III:

Q. Okay. Well, let me -- let me just -- hold on for a second. I'm going to mark the next exhibit just so I can follow-up on this with, um -- these should be read so I can see them. They blend in with the documents. We're at 7? Can you turn that page over and tell me what exhibit number that is.

A. This is five.

Q. That's 5, okay.

A. This is No. 5.

Q. Okay. Let me show you another document

which is entitled Representative Maurice D. Hinche Press Conference on FDA Failures. It's Prepared Remarks July 30 (sic) 2004. And, again, the case for which we're sitting here today is mentioned on page 6.

Let me just show that to you. Ask you're perfectly free to read the entire document, but that -- that one page is the one I want to refer to.

(Witness reviewed document.)

A. Okay, I've read that part.

Q. Okay. You seen that it says the "In re Paxil is a fourth case." Right.

A. Yes.

Q. Okay. And you see the next sentence where it says, "What these few cases describe are massive conflicts of interest and a pattern of collusion between the federal agency and the industry it is supposed to regulate."

Do you see that?

A. I see it.

* Q. Do you have any reason to believe that

that statement is incorrect?
MR. KELL: Objection.
Don't answer the question, Doctor.
MR. MURGATROYD, III: So you're instructing him not to answer the question?
MR. KELL: I'm instructing him not to get into this whole issue of bias. It is not --
MR. MURGATROYD, III: Well, that's why we're here.
MR. KELL: It is not -- well, that may be why you're here but it's not the subject of this deposition. You can spend the whole day asking those questions, if you wan to. And I will spend the whole day instructing the witness not to answer. He may well have opinions on that. That is not the purpose of this deposition.
MR. MURGATROYD, III: Okay. Well, we'll disagree on that.
Let's mark that as the first question to take before the magistrate.
And, again, we'll continue and let these build as they may and address the court when we

need to.
BY MR. MURGATROYD, III:
Q. Now, um, did you see the, uh, the, uh, recent ABC news local affiliate did a little piece on, uh, this topic, the conflict of interest between the FDA and, uh, and drug companies? The conflict of interest representing or helping drug companies in civil litigation?
MR. BROWN: I'll object to the form of the question.
THE WITNESS: Okay. I did not see it, no.
BY MR. MURGATROYD, III:
Q. Okay. Um, were you aware that Representative Hinche was on TV and -- and said that, uh, um, the FDA coming in on behalf of drug companies in civil litigation, uh -- here's his quote:
The health and safety of the American people has been put in jeopardy as the result of the corrupt practices within the Food and Drug Administration.

Have you ever heard that quote before?
A. No.
Q. Okay. Um, are you -- have you heard those allegations being made about the former chief counsel DAn Trowy?
MR. KELL: You're simply asking if he's heard --
MR. MURGATROYD, III: Yes.
MR. KELL: -- such allegation?
THE WITNESS: There -- there have --
MR. KELL: You can answer yes or no --
THE WITNESS: Yeah --
MR. KELL: -- Doctor.
THE WITNESS: -- yeah.
I've -- I've heard criticism of our participation in the -- in these matters. Or I -- I don't know that I've heard the corruption allegation or the conflict of interest or any of those things. There's been some question about whether we should be doing that. That's -- that's all I know about it.
BY MR. MURGATROYD, III:

Q. Okay.
A. I don't know any more -- more details.
Q. Well, let me ask you this: Have you ever personally submitted a declaration on behalf of a drug company in a civil case?
A. Other than the one --
Q. Yeah, other than that one.
A. -- here now?
Q. Yes.
A. No.
Q. Okay. Have you ever been been asked to do something like that before?
A. There are request periodically, yes. We generally are asked not -- we would be -- we would spend all of our days doing them if we joined in, so we generally don't.
Q. Okay. And -- well, we're going to get into the -- why you didn't in this specific case in a few minutes. But, um, were you aware that by entering into this case, In Re Paxil -- or actually are you aware that the FDA has entered into in the -- into four cases in the last few years?

MR. BROWN: Object to the form of the question.
MR. KELL: Object. The question is to form. And the question is so vague it can't possibly be answers.
MR. MURGATROYD, III: All right.
BY MR. MURGATROYD, III:
Q. Well, let's go back to the exhibit that's in front of you. And it discusses, um, four cases in which the FDA has intervened.
A. Can --
Q. And I'm just going to ask --
A. Can I just tell you what I do know?
MR. KELL: Doctor, there's no question pending. No, you may not.
THE WITNESS: Okay, okay.
BY MR. MURGATROYD, III:
Q. We're going to find out what you know. Don't worry.
MR. KELL: You're going to find out what the doctor knows on matters relevant --
THE WITNESS: That's fine.

MR. KELL: -- to the subject of this --
THE WITNESS: Okay.
MR. KELL: -- deposition.
MR. MURGATROYD, III: Correct.
BY MR. MURGATROYD, III:
Q. Okay. I just want to know whether or not -- when you were asked to participate in, uh, the *Motis case in which the government intervened.
MR. KELL: Objection.
Don't answer the question, Doctor.
Let's talk about this case Mr. Murgatroyd.
MR. MURGATROYD, III: Okay. I -- I --
MR. KELL: Or let's go home.
BY MR. MURGATROYD, III:
Q. No. I just want to understand the extent of the FDA involvement in the four cases that are represented in this document --
MR. KELL: Well, your --
Q. -- one of which is In Re Paxil.
MR. KELL: We -- we needn't argue or brief this, but you see what my instructions are

going to be when we get beyond this case.
MR. MURGATROYD, III: Okay. And, again, what I'm trying to show, so the record is clear, is that there was a pattern of collusion, a pattern of corruption, as it's been described, within the FDA to improperly intervene into civil litigation, in which the FDA did it on multiple occasions under the auspices of a gentleman by the name of Dan Troy who fortunately I believe for the consumers in this country is no longer in his office.
MR. KELL: Thanks --
MR. MURGATROYD, III: I want to --
MR. KELL: -- for the speech, Mr. Murgatroyd.
MR. MURGATROYD, III: Yeah. I will --
MR. KELL: But if that -- if that's the purpose of the deposition, then we needn't stay here.
MR. BROWN: I'll put an objection on the record too as to the speech.
MR. MURGATROYD, III: Okay. Duly noted.
Let's go off the record just for a

minute.
MR. KELL: No, let's stay on the record.
MR. FARBER: No. Let's go off the record.
MR. MURGATROYD, III: We'll go off the record.
MR. FARBER: He's paying -- he's paying the clerk. We can go off the record.
MR. KELL: I am representing the witness and I want everything said in this deposition on the record.
MR. FARBER: Fine. May I ask a question, sir, do you have an objection if I ask you a question?
MR. KELL: You can ask me whatever you like.
MR. FARBER: Have you attended all of the hearings in which Judge Fowser indicated FDA bias may be an issue on this lawsuit, yes or no?
MR. KELL: I've said you could ask me a question. If you want to use up the transcript, I'm not answering your questions. I'm not the

deponent.
MR. FARBER: All right. Well, I'm advising you on the record that FDA bias is an issue. It was in our papers. The judge has acknowledged it. And if you instruct the witness not to answer on FDA bias issues outside of this case, then you're on notice that I'm telling you the court has noted that.
MR. KELL: I will instruct --
MR. FARBER: And that's the --
MR. KELL: -- the witness --
MR. FARBER: -- end of my current speech, sir.
MR. KELL: I will instruct the witness as to particular questions.
MR. FARBER: Thank you.
BY MR. MURGATROYD, III:
Q. Okay. Now, so in terms of your participation, the only case that you're aware of that the four that are listed in Exhibit 6 is the In Re Paxil case; is that correct?
MR. BROWN: I'll object to the form of

the question.
MR. KELL: You can answer the question.
THE WITNESS: And I'm aware of that case only to the extent that my, um, statement was pertinent to -- I don't know the details of the whole case at all.
BY MR. MURGATROYD, III:
Q. Okay. And you're not familiar with the FDA's intervention in the other case that represent that are referenced in Exhibit 6?
MR. KELL: Object to the form.
You can answer.
THE WITNESS: I'm aware there are other cases in which that happened. I don't know any of the details or anything about the, uh, the statements that were made or any of those things.
BY MR. MURGATROYD, III:
Q. Okay. You weren't consulted in those cases as you --
A. No. As near as I can remember, I was not.
Q. Okay. That's all I wanted to know.

Thank you.

Now, the quote, so the record is clear, the quote that I made earlier that Gerald had asked that I supply the document for -- I hate to keep track of these exhibits. That was six, right, and seven?

MR. KELL: This is No. 6 that's before the witness.

(Temple Deposition Exhibit No. 7 was marked for Identification.)

BY MR. MURGATROYD, III:

Q. Okay. Let me show you seven which is a transcript of a broadcast of the Jim Lehrer news hour dated November 23rd, 2004. If you look at the second sentence, I think you'll see where I got that quote from.

A. The second sentence?

Q. Yes.

MR. KELL: There is not a question pending, Doctor. You needn't say anything.

MR. MURGATROYD, III: 2004.

THE WITNESS: Okay.
BY MR. MURGATROYD, III:
Q. Do you see that sentence where it quotes Senator Grassley?
MR. KELL: Object to the form.
You can answer whether you see the sentence.
THE WITNESS: I do see it.
BY MR. MURGATROYD, III:
Q. Okay. And it states, "One of my concerns is that the FDA has a relationship with drug companies that is far too cozy."
Do you see that?
MR. BROWN: Object to the form of the question.
THE WITNESS: I see it.
MR. MURGATROYD, III: I'm just establishing for the record where I got the quote. That's the purpose of that.
BY MR. MURGATROYD, III:
Q. Now, this interview also included a, um, a guess by the name of Dr. David Graham. You know

Dr. Graham. Correct?
A. Yes.
Q. Okay. And in this, uh, news hour report he's quoted as saying that the CDER as regards to safety is a broken organization. Did you see that?
MR. BROWN: I'll object to the form of the question and the relevance of the question.
MR. KELL: I'll join in that objection.
And you can answer whether you see such as representation --
MR. MURGATROYD, III: It's the --
MR. KELL: -- in the transcript.
MR. MURGATROYD, III: -- the bottom of the first page, top of the second page.
THE WITNESS: I see it.
BY MR. MURGATROYD, III:
Q. Okay. Would you agree with his statement?
MR. KELL: Objection.
Don't answer the question.
MR. MURGATROYD, III: Okay.
BY MR. MURGATROYD, III:

Q. Well, you -- you testified before one of the, um --
A. SSRIs?
Q. No. But before -- one of these congressional investigations was Senator Grassley's investigation?
A. No, it was not.
Q. Which one was that?
A. It was Representative Barton.
Q. Okay. That was the Barton. The Barton, um, --
A. Was the one on SSRISs.
Q. Right. And who was the -- who was the representative who was supposed to participate in it originally and then went to work for the drug company?
MR. BROWN: Object to the form of the question.
MR. FARBER: Greenwood.
MR. MURGATROYD, III: Oh, Greenwood.
BY MR. MURGATROYD, III:
Q. Were you aware that Greenwood was going

to have the investigation and then went to work for a drug company?

MR. BROWN: Object to the form --

MR. KELL: Objection.

MR. BROWN: -- of the question.

MR. KELL: Relevance.

I'll let you answer the --

THE WITNESS: I was aware of --

MR. KELL: -- question if you're

THE WITNESS: I was aware of that.

BY MR. MURGATROYD, III:

Q. Okay. Um, so -- but you gave a written statement -- you prepared a written statement that was given before that congressional hearing --

MR. KELL: Objection.

Q. -- correct.

MR. KELL: What -- what hearing? What statement?

MR. MURGATROYD, III: The one we were just talking about, Barton.

MR. KELL: Well, if you'd ask your question so that I can understand it, maybe the

witness can understand it as well. I just want a question so we know what we're answering.

MR. MURGATROYD, III: Okay.

THE WITNESS: I prepared a written statement for the Barton hearing.

BY MR. MURGATROYD, III:

Q. Okay. And what was Barton looking into them?

A. The suicidality in children's and adolescents' question in whether we handled it correctly.

* Q. Okay. And, um, actually I have a copy of that statement. We'll get into that a little bit later.

Um, and whether or not you handled that issue of suicidality in kids who take SSRIs on -- was it your decision not to let Dr. *Masholder testify --

MR. KELL: Objection.

Q. -- on February 2nd --

MR. KELL: Don't answer the question, Doctor.

MR. BROWN: Object to the form of the question also.

MR. MURGATROYD, III: I guess we'll have to mark that one down.

Um, is there any reason why you're not letting him answer that? I was just asking: Was it his decision? I'm not asking --

MR. KELL: It is beyond --

MR. MURGATROYD, III: -- process --

MR. KELL: -- the scope of the deposition.

MR. MURGATROYD, III: Well, it gets into --

MR. KELL: I understand what you want to get into, Mr. Murgatrody. You should understand that we are not going to get into that, absent some court order on specific questions.

MR. MURGATROYD, III: Okay. Would you --

MR. KELL: So, I mean, you can put your questions and probably should put your questions on the record.

MR. MURGATROYD, III: No, I am --
MR. KELL: I will instruct the witness not to answer that I think -- those that I think are inappropriate.
MR. MURGATROYD, III: Okay. Just so -- you may be missing something. I'm just going to fill you in and you can either -- you do with it as you please. But the allegations in this lawsuit, um, include suicidality upon withdraw of Paxil. And we have hundreds and hundreds of people who are Plaintiffs in the case who experienced those type of adverse reactions. So that's why. And some of them are children, um, under the age of 20.
So that's why these questions I believe are relevant, and I'll present it to the court obviously to get the -- the, uh, the court's ruling on whether or not Dr. Temple should answer the question. I just want to make sure -- I don't know if you knew that that was -- those are allegations made in the lawsuit. Those are existing living Plaintiffs who are making those claims, which I believe is relevant to Dr. Temple's deposition here

today. You don't have to respond. I just want to make sure that that's noted.

MR. BROWN: Let me -- let me put on the record, then, that, um -- and make clear that Dr. Temple's deposition was provided in connection with the In Re Paxil discontinuation litigation --

MR. MURGATROYD, III: Right.

MR. BROWN: -- in which there are no suicide-related allegations.

MR. MURGATROYD, III: No. That's --

MR. BROWN: And that's why we believe that it's beyond the scope of what this deposition ought to extent to. I just want to put that on the record.

MR. MURGATROYD, III: Okay. Well, you know from deposing one of the five exemplar Plaintiffs; that one of them became suicidal upon withdrawing Paxil.

MR. BROWN: You've heard my objection.

MR. MURGATROYD, III: Right.

MR. BROWN: We can move on. Thank you.

BY MR. MURGATROYD, III:

Q. Um, okay. Uh, I think we've -- at this point we've established that your responsibilities, including drug labeling, drug advertising, and drug safety. And I know efficacy is a fourth one. I want to take up drug labeling.

Um, what is -- what is the purpose of drug labeling?

A. It's, uh, to provide adequate directions for the safe and effective use of the drugs.

Q. Okay. And --

A. So it combines a mixture of information to advise the user on what's known about the drug and a wide range of, uh, questionary information about what to watch out for, what not to do, depending on the particular drug.

Q. Okay. And is that information that's provided to both the patient who's taking the drug as well as the doctor who's prescribing it?

A. Not necessarily. All labeling has a section called "information for patients" which advises the physician on what to tell -- what the physician should notify the patient about and then

some labeling but not a -- not all has a section called a "patient package insert" or nowadays Med-Guide, which is intended to go to patients and would tell them what they need to know and what they need to do.

Q. Okay.

A. But that's a minority of labeling has that.

Q. Okay. Well, if I were to go out and get a prescription for Paxil to day and I get a -- I went to my pharmacist, okay.

A. I want to add one thing.

Q. Okay.

A. Some years ago there was, uh, an attempt by us to put patient labeling on all drugs that was stopped. And, instead, private organizations now provided at least some labeling or supposed to provide at least some labeling for almost all drugs that are given to people. They're attached to the package that you get.

Q. And --

A. But we -- we don't in any -- we don't

regulate those. We don't control the content. It's suppose to be derived from the physician labeling.

Q. And are those prepared by the drug companies or by somebody else.

A. No. There are several third parties who do it.

Q. And then is that -- is that authorized by the FDA?

A. Yes.

Q. Okay. And --

A. It's part of an attempt to see if that mechanism would work before we went further and actually wrote them all ourselves. We -- we at one point were proposing to write them all ourselves, which would have been a lot of work --

Q. Right.

A. -- but we were proposing it.

Q. And --

A. So -- and we are obliged to evaluate the progress of this periodically. I can't remember when the next evaluation is, uh, coming, but we

have done that. We've used outside consultants to assess the quality of the information.

Q. And who pays that third party to prepare the package inserts for the patients, if you know?

A. I don't know.

Q. And --

A. They're available at the pharmacy. Sometimes they're printed off, uh, some kind of web based thing.

Q. I know that --

A. I don't know that -- you get -- you've gotten them undoubtedly.

Q. Yeah, I think I had a box of antibiotics once and it had a sheet in it folded up.

A. No, that's different. That's probably the actual package insert. Some -- some -- this is variable. But some dosage forms actually contain the physician's package insert.

Q. Okay.

A. Uh, that's not required to be given out but sometimes they do. How useful patients find those is probably debatable. There are some cases

where we require unit of use packaging that will contain the patient package insert. And we think that's a very good way to make sure that it actually is delivered. As you probably know, we've concluded that all antidepressants are going to have both a Med-Guide and unit of use packaging. It takes --

Q. Right.

A. -- a little while to convert the unit of use packaging. That's so -- it will definitely be given out. If you require the pharmacist to do it, sometimes it's given out, sometimes not, this will assure that everybody will get it.

Q. Okay. And, um -- and that's important, I take it, because it's important for both prescribing doctors and consumers to know what side effects to look at when they're taking a drug like an SSRI.

MR. BROWN: Object to the form --

MR. KELL: Object to the form.

MR. BROWN: -- of the question.

MR. KELL: Okay. You can answer.

THE WITNESS: Especially the important ones, right.

BY MR. MURGATROYD, III:

Q. Okay. Now, am I correct in stating -- and, again, I'm limiting this to SSRIs and Paxil, in particular, that in the normal course of the approval process the drug company drafts the label -- makes a first draft of the label they submitted to the the FDA and then -- then there's a negotiation process as to what the final label will look like?

MR. KELL: Object to the use of the word "negotiation."

You can answer the question, Doctor.

THE WITNESS: Yeah, that's what I was going to say. We tell them what we think about it. And we have a fair capacity to get our way. We listen to intelligent objections, of course.

BY MR. MURGATROYD, III:

Q. Okay.

A. Well, I don't -- I don't actually think of it. I mean, it -- it's a negotiation in the

sense that they're allowed to argue for what they want, but we really fell we have control over the contents of the labeling.

Q. Okay. But am I correct in saying that normally the drug companies, such as GSK in this case, would prepare the first label?

A. That is true.

Q. Okay.

A. That is true.

Q. Okay. Now, there's various sections of a label. Correct? There is the --

A. Sorry. Yes.

Q. Okay. Thank you. Self-correcting, very good.

Um, and I have a Paxil label. Let me see me if I have one handy. We can take that as an example. Um, well, let me see. Let me go through without it just one being -- there's a warning section, correct, of a label if warnings are being necessary?

A. Yes.

Q. Okay. And is that -- is that considered

the important information for a doctor to have who's prescribing the drug?

A. Yes, it is.

Q. Okay. And then after that I believe there's a caution section.

A. Yes, there is. There's some ambiguity between what's a warning and what's a precaution. In a recent proposal, we proposed combining them.

Q. I was going to ask you that, what the difference was but --

A. The warnings are bigger.

Q. Okay. And then the strongest warning that's I've seen --

A. I'm sorry. I have to tell you one other thing. Precautions also came -- became the place where you throw everything. So drug-drug interactions got put in precautions. Pediatric use got put into precautions. It became a catch-all place to put everything. So we were hoping to improve that.

Q. Okay. By eliminating the procaution section?

A. By combining warnings and precautions in one section and having specific sections for drug-drug interactions and so on.
Q. Okay. And the strongest warning that a drug company can get that is my understanding is what's called the black box warning?
MR. BROWN: Objection. Object to the form the question and use of the term "strongest."
MR. MURGATROYD, III: Well, I'm asking him. That's the question.
BY MR. MURGATROYD, III:
Q. Is that -- is there a stronger warning than a black box warning in label?
A. Well --
Q. Just in a label.
A. -- ironically there's something called a contraindication.
Q. Okay.
A. Historically, those were not put in boxes necessarily. And a contraindication means un no circumstances should you use it in particular people. We don't think there's ever any reason to

use it in particular people. In some ways, that's the strongest. But the most prominent warning you would write we put in the box either because of the extreme severity and actually often because there's something you can do about it by avoiding certain people. Anyway. But, yes, it's -- boxing it is the most prominent way to get people's attention.

Q. Okay. Then the next section labeled -- and I'm trying to get this from memory -- is usually the adverse event tables and statements about adverse events; is that correct?

A. Um, I'm just thinking. I'm sorry. I'm just thinking about official sections. There's a lot of other stuff in precautions.

Q. Right.

A. I guess the next separate section is adverse reactions.

Q. Okay. And that is where -- would -- there's guidelines on what goes into that section --

A. Yeah.

Q. -- in terms of frequency related to

placebo. Is it always based on relation to placebo? Is that --

A. Well, there's guidance on this. Um, the -- the -- for the more common adverse reactions, the best way to learn what the drug does versus what just happens, uh, without a drug is to compare the rate in the drug and placebo groups.

So for drugs that are developed with placebo-controlled trials, you'll see a table showing the rate on drug and the rate on placebo. Sometimes for some drugs you don't have placebo-controlled trials. You don't have placebo-controlled trials with antibiotics, or many cancer drugs.

So you put in the comparison with the other drug which is less sure about what the drug did versus what just happened because of the disease, but you do the best you can.

Q. Okay. And is there a difference between the adverse events that are contained in the label and what I, as a layperson, would know as a side effect?

MR. BROWN: Object to the form of the question.

THE WITNESS: I think they mean the same thing to most people.

BY MR. MURGATROYD, III:

Q. Okay. Then going down in terms of moving further down into the label, then you have what are called post-marketing events. Correct?

A. Yes. It's also true, though, that if a post-marketing event becomes important, prominent, and believable, it may move to some other part of the label like precautions or warnings or get a prominent part of the adverse reaction section. One -- one of the -- I don't know how much you want to hear about this. But --

Q. No. Go ahead on. I'm just --

A. -- adverse reactions are presented in this table, but the table just names them.

Q. Right.

A. And not every adverse reaction is clear from the name. So one of the things we've talked about in our proposed revision is to have a section

that make its clear what's going on here.
Q. Right.
A. So if, you know, if the report is, um, hypotension -- means falling blood pressure -- we provide some details about when it occurs in the course of therapy, how how bad it is. Do people pass out?
So they'll be little sections on the more prominent adverse reactions, and that could make you post-marketing data or pre-marketing data, depending on what you have.
Q. Okay.
A. But there's typically a list of things that have been reported after marketing and usually a statement about how we -- we're not sure whether this is due to the drug or not.
Q. Right. I think, uh Dr. Laughren referred that to as the more obscure part of the label. Would that be a correct assessment?
A. It's a --
MR. BROWN: I'll object to the form of the question.

THE WITNESS: It's at the end or it was at the end under the current format, right.
BY MR. MURGATROYD, III:
Q. Okay. Now, um, let me see if I actually .... let me show you -- let me show you what exactly he did say to see if you agree on this or not.
MR. MURGATROYD, III: Gerald, are we up to eight?
MR. KELL: Seven is the last one I see.
MR. MURGATROYD, III: Okay.
(Temple Deposition Exhibit No. 8 was marked for Identification.)
MR. BROWN: What's that, Skip?
MR. MURGATROYD, III: This is a copy of the transcript of a psychopharmalogical drug advisory committee dated, uh, September, 20th, 1991. And there is a section -- I'm going to highlight Dr. Laughren testifying.
And then he goes on to state what I've marked with a box regarding this part of the label.

I just want to see if you concur with what he says.
MR. BROWN: Can you identify the page number --
MR. MURGATROYD, III: Yes.
MR. BROWN: -- from the transcript, please?
MR. MURGATROYD, III: I can indeed. It is --
THE WITNESS: Am I supposed to be looking.
MR. MURGATROYD, III: Gerald, what page is that?
MR. KELL: I see page 137 with a bracket. Is that where you --
MR. MURGATROYD, III: Yes, that's it, yes.
BY MR. MURGATROYD, III:
Q. And I'll just -- all I'm doing is putting your attention what Dr. Laughren testified to and see it that's your understanding also.
Can you read that into the record, please, sir.

A. The section you asked about says:
"Again, to be clear, putting these terms in that somewhat obscure location of labeling reflects our lack of confidence in a causal link between the taking of the drug and those behaviors."
Q. Okay. Is that -- would you agree with that statement?
A. Yes, I do. And when you become more confident, you move it somewhere else.
Q. Right. That's when it starts getting pushed earlier into the label.
A. And -- or it becomes a precaution or something like that.
Q. Okay. Now, um -- now, would you agree with the fact that the FDA can't or does not catch all the problems with the drug during the NDA process that they can show up later in the postmarketing period?
MR. BROWN: Object to the form of the question and lack of foundation.
MR. KELL: You can answer.

THE WITNESS: Um, sure. That is well-known. We try to say it as often as possible.

BY MR. MURGATROYD, III:

Q. Okay. And would you -- I actually had pulled another document off the web -- a web browser that you can tell. This one I actually took off a while back. I don't know if it's still on there or not.

MR. MURGATROYD, III: I'll mark it as exhibit nine.

(Temple Deposition Exhibit No. 9 was marked for Identification.)

BY MR. MURGATROYD, III:

Q. And, uh, it's just a blowup. And I'll hand to you. But it says, "When a drug goes to market, we know everything about its safety. Wrong."

And then it gives the number for the FDA, which, I guess, is that would be a MedWatch number or something.

A. Probably for MedWatch encouraging people

to repor to us.
Q. Right.
MR. BROWN: Mr. Murgatoyd?
MR. MURGATROYD, III: Yeah.
MR. BROWN: If I can see that for one second, please.
(Counsel reviews document.)
MR. MURGATROYD, III: Yeah.
BY MR. MURGATROYD, III:
Q. Okay. Would you agree that, in fact, the FDA does not know everything about a safety once it's put on the market?
MR. BROWN: Object to the form of the question.
MR. KELL: Are you asking -- the question is so broad I'm having trouble figuring --
MR. MURGATROYD, III: All right.
MR. KELL: -- it out.
MR. MURGATROYD, III: Let me narrow it down.
BY MR. MURGATROYD, III:
Q. Let's take Paxil for instance. Paxil

was approved for the market. Correct?
A. Sure, it was. Yes, it was.
Q. Do you agree that, um, more information has come out about Paxil and its side effects since it's hit the markets?
MR. KELL: Go ahead and --
THE WITNESS: Yes.
MR. KELL: -- answer.
THE WITNESS: Yes.
BY MR. MURGATROYD, III:
Q. Okay.
A. That -- that is invariably true.
Q. Okay. And would you agree that GSK -- I'm just going to be specific with regard to Paxil -- knows more about that drug than the FDA does because of its personal experience and clinical trials and everything else it knows about the drug.
MR. KELL: Objection.
BY MR. MURGATROYD, III:
Q. Would you agree they have more knowledge than the FDA about that drug.

MR. KELL: Object to the form.
MR. BROWN: Object.
MR. KELL: You can answer if you have any notion of what GSK knows or doesn't know.
MR. MURGATROYD, III: Well --
MR. BROWN: I'll also object on the basis of the form of the question.
THE WITNESS: I don't, um -- I don't actually know that that's true. The -- but some aspects of it might be true. Um, they have obligations to report to us any new safety information.
So if they are, indeed, reporting all of that, we should know what they know.
BY MR. MURGATROYD, III:
Q. Correct.
A. Um, there are undoubtedly clinical trials that are ongoing or that haven't been submitted to use on a new use or something that we may not know about yet. It may have been reported in an annual report. We may or may not know much about them.

Um, I guess I do want to make the observatoin about post-marketing reports of adverse affects that there is an inherent problem with all of those. They don't arise from a controled trial and it's not easy to tell, and it may be impossible to tell whether something happened because the person took the drug or just happens spontaneously. That's the fundamental difficult with all post-marketing reports.

And it's clearly signaled by such things as suicidal thinking. This has been part of all of the discussions. The very first time this arose was, uh -- the most prominent time it arose was in 1991 related to Prozac where *Martin Tischer reported a bunch of people who seemed to do much worse when they were put on Prozac. And this went before an advisory committee.

The consensus was you couldn't tell whether those poor people who were suicidal because that was the nature of their disease, or whether the drug provoked it even though it happened after they took the drug. That is the hard part of all

post-marketing reporting, because it's not from controlled trials. It isn't even usually from an epidemiologic studies, which to a small degree solve that problem, although they're still hard to interpret.

So that's -- that -- I just thought it was important to mention that. It's part of the whole deal.

Q. Okay.

A. It's very hard to know.

Q. I understand. And the MedWatch program has its -- has a purpose. I mean, I'm going to get into this a little bit later. But it basically looks for signals. So it may be a possible --

A. Exactly.

Q. -- signal generator?

A. That's exactly right. You get a report and you look at other reports. You compare those reports with what you get for other drugs. You do your best to deal with the system that does not represent controlled observations.

Q. Correct.

A. All kinds --
Q. There were --
A. -- of problems. The patient is getting one drug may be different from the patients getting another drug. Uh, *post Hace air -- thought *Proptohac is a logical error or not a kind of evidence, you know, things like that.
Q. Right. And I think the -- the MedWatch reports are -- will be considered anecdotal?
A. Yeah. Anecdotal is an insulting way to describe them. I prefer to think of them as signals.
Q. Okay.
A. Not really firm evidence. Except in some cases there are certain kinds of adverse events, adverse reactions that simply don't occur in the absence of a drug, massive hepatic injury, liver injury.
Q. Right.
A. And those frequently are interpreted, if there's a few of them anyway, as being strong evidence that a drug caused thme. But when you're

talking about, you know, anxiety after a drug, anxiety is common in the population, very hard to do it. We've been having a lot of talk about Vioxx and heart attacks. Heart attacks are extremely common in the population. So if someone has a heart attack after taking a drug, you don't really know what that means until you do an epidemiologic study, do a controlled trial and so on. It's the nature of the beast.

Q. Okay. So I'm clear, information that's gotten from a spontaneous report is different than information the FDA gets from a report of arising from a clinical trial in terms of the quality of the information; is that correct?

MR. BROWN: Object to the form of the question, and it's vague.

THE WITNESS: I don't think it's so much the quality. It's the interruptibility. One arises from a controlled comparison where you look at the rate and one group in the rate in another group. The other is the report of what happened. It's not that you doubt that it happened. What you

don't know is why it happened, whether it was the person's underlying disease. Sometimes some other drug they were taking or is it really due to the drug.

BY MR. MURGATROYD, III:

Q. Okay.

A. And sometimes it's easier to reach a conclusion than other timees.

Q. Okay. And it's easier to reach a conclusion, I take it, with a clinical trial report than a spontaneous MedWatch type report.

MR. BROWN: Object to the form of the question.

THE WITNESS: Um, but, yes, because you have a control group.

BY MR. MURGATROYD, III:

Q. Right.

A. So, I mean, that's what -- even in, for example, the suicidality discussin in children, the rate of suicidality was 2 percent in the placebo group. So those events happened but they obviously weren't due to the drug. They were due to the

underlying disease.

So if there were more of them in the people getting the drug, and that's what is important, but the events themselves were seen in both groups. So if all you had was the reports of the events, you just wouldn't know it.

Q. Right. It didn't have that comparison?

A. Well, in those cases we did.

Q. Right, correct.

A. Right.

Q. Okay. Now, um, I think it was, um, Dr. Leber in his deposition stated that the, um, the label was like a science moving forward in that as new things are being learned, the label changes to reflect the new information that is -- is, uh, known; is that correct?

MR. KELL: Object to the form of the question, and compound.

THE WITNESS: The label is an evolving document. It's supposed to reflect what we know and that changes --

MR. MURGATROYD, III: Okay.

THE WITNESS: -- over time.
BY MR. MURGATROYD, III:
Q. Okay. And, in fact, um, drug companies are under an -- a legal obligation to make label changes once they become aware of a serious risk; is that correct?
MR. BROWN: Object to the form of the question.
BY MR. MURGATROYD, III:
Q. Are you familiar with that code section of the, um, C.F.R.s?
A. Yes. Well, they're really supposed to tell us about them, and they are allowed to put in changes even at the same time as they tell about them if they're about serious things.
Q. Okay. I pulled it up, um, two code sections that I thought was important to your department in terms of labeling.
Um, one is what's called C.F.R. 201.57(e). And I'll -- it's kind of a long statute, so I'll try to find it for you. Here it is right here.

MR. MURGATROYD, III: And can I have more of those stickers. Thanks.

Ten?

MR. KELL: Yes.

(Temple Deposition Exhibit Nos. 10 and 11 were marked for Identification.)

BY MR. MURGATROYD, III:

Q. And I've marked this Code Section as Exhibit 10, and "e" is on page 3. And I did a little blowup, which I'll mark as 11, as to the specific part I'm referring to.

MR. KELL: What section of the C.F.R. are we looking at, at this point, please?

MR. MURGATROYD, III: 201.57 and it's "e."

THE WITNESS: And it i's E.

MR. KELL: Which is warnings?

THE WITNESS: It's just warnings. It's just got a warning names under the current language.

MR. KELL: Right.

BY MR. MURGATROYD, III:

Q. And do you see the part now that says, The labeling shall be revised to include a warning as soon as there is a reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not be proved?

A. Yes --

Q. Okay.

A. -- I see that.

Q. And that's what I blew up on Exhibit 11. Do you see that?

A. Right.

Q. Okay. Now --

MR. BROWN: Can I see that for just one second, please.

MR. MURGATROYD, III: Sure.

MR. BROWN: Because what you read was different than what was stated in the regulations, but you -- this accurately captures it.

MR. MURGATROYD, III: Oh, okay. Maybe I read it wrong. But Exhibit 11 is accurate. Correct?

MR. BROWN: It is.
MR. MURGATROYD, III: Okay, good.
BY MR. MURGATROYD, III:
Q. Now, so here we're talking about the -- this would be a drug manufacturer's responsibility to revise a label under this code section. Correct?
MR. BROWN: Object to the form of the question.
MR. KELL: I'll object on foundation.
I'll let the Doctor answer if he feels qualified to interpret legal standards.
Um, you have not established that.
MR. MURGATROYD, III: Okay.
THE WITNESS: They're supposed to do it. We not uncommonly request such changes ourselves --
MR. MURGATROYD, III: Okay.
THE WITNESS: If we discover -- discover something. But it's their job to keep the labeling up to date, at least nominally the labeling is owned by the company.
BY MR. MURGATROYD, III:

Q. Okay. All right. And then I'll show you the next code section that I've marked, um, which is 3 --
A. Of course.
Q. -- 14.70.
A. Just to point out the -- based on the standard for warning that you gave me, the reasonable evidence of an association of a series hazard is subject to interpretation.
Q. Correct. And we're going to get into that.
A. Okay.
Q. Because I -- actually maybe we'll kind of diverge here for a second and -- because I want to make sure -- is there a difference between the term "association" and "causation" in -- in the eyes of the FDA?
A. Well, there is in my eyes. I -- I don't think you should use the term association when you think there's a causal relationship personally, but it does -- it does show up in labeling. There's no question about it. To me, it's something of a

lawful word. When you believe it's reasonable likely that it's causally, you're supposed to convey that.

So association is not uncommonly used and it's not only the industry of people that use it. Um, and this is a good example of it. Reasonable evidence and association of a serious hazard with a drug in some sense doesn't really capture it. What there needs to be is reasonable evidence that the drug caused it. That's what you really -- and that's -- I believe that's the standard we impose.

Q. Okay. Even though it says a causal --

A. We --

Q. -- association need not be assigned?

A. Yeah. I mean -- right. No, no, no. A -- it is correct to say that a causal relationship need to have been proved -- proof. Proof is a very high standard. We commonly would write warning language based on a lesser standard than that.

Q. Okay.

A.

A. Reasonable likelihood, whatever the term is. But the thing we're looking for is reasonably likelihood that the drug actually did it.

Q. Right.

A. So an associate to me is something of a waffle word. I don't like it but I can't say I'm removed it from everything either. Um, and a lot of people don't make the distinction I'm making anyway.

Q. Okay.

A. But you put it in when it's reasonably -- when you're reasonably satisfied that the drug probably did it.

Q. Okay.

A. That's the standard I would say we use.

Q. Okay, good. Now, am -- am I correct in stating that, um, the, um, drug companies, in this case, GSK, which is the drug company in question, they actually under the law can make a lable change without the FDA's prior approval.

MR. BROWN: I'll object to the form of

the question.
THE WITNESS: They can't -- they're called changes being effected. We, um, try to look at those very rapidly and see if we think what's said captures the fax properly and can object and, uh, make them subject to our prior approval. But, yes, they are allowed to do that and encouraged to do that.
BY MR. MURGATROYD, III:
Q. Okay. And I think that's 21 C.F.R. 314.70 and it goes on pretty far. It's C(6) litte 3(a). And you would -- can I show you -- should I show you that or do -- you understand that somehow --
A. No. It's the --
Q. -- right?
A. -- CVE part.
Q. Right. Okay, good. Now, I think, uh this --
MR. BROWN: Let me --
Q. -- comes to --
MR. BROWN: Let me note for the record

that I'll raise an objection because I don't believe you accurately characterized the specific C.F.R. section. But we can move on.

MR. MURGATROYD, III: All right.

BY MR. MURGATROYD, III:

Q. Well, it says changes in the labeling to accomplish any of the follow, a, to add or strengthen the contraindication, warning precaution or adverse reaction. That's what you understand it to be. Correct?

A. Yeah, yeah. We -- often enough we look at what they've done and conclude and even that doesn't quite do it. But they are allowed to do that and put them in place.

Q. Okay. And --

A. And encouraged to in.

^,)in fact,, right.

Q. Okay. Now -- and, in fact, uh, with regard to the suicid issue, I noticed in your statement that you gave, um, before the Barton committee that you referenced it, um, one particulary drug company Wyeth actually used this

section and changed their label regarding suicide -- suicidality and the pediatric population.

Let me show you what I'll mark as Exhibit 12 so you can see what you said there. I hope this upside down and that's right. Well, I'm just going to do it this way.

Then I've high -- I've marked on the, um -- I put a tab on page 6 where you actually talk about Effexor Lableing Change. And before I get to -- what -- what is the industry term for change?

A. CBE, change being effected.

Q. Okay. CBE, all right. I'm going to show you what I've marked as Exhibit 12.

(Temple Deposition Exhibit No. 12 was marked for Identification.)

MR. BROWN: Do you have an extra copy of that or can I just see the cover sheet again, please?

MR. MURGATROYD, III: Yeah. It is -- and I'll identify it for the record it is entitled

Antidepressant Use Among Children - Dr. Robert Temple. It's a statement of Dr. Robert Temple, Director of Office of Medical Policy, Committee on House Energy and Commerce Subcommittee on Oversight and Investigations. And it is page --

MR. BROWN: Dated?

MR. MURGATROYD, III: -- 6.

Uh, 23 September, 2004.

MR. BROWN: Okay. Is there a section that you're reading from because I have a different pagination of --

MR. MURGATROYD, III: Uh, yes. It's, uh, the section --

BY MR. MURGATROYD, III:

Q. Am I correct, Doctor, it's the "August 2003 Effexor Labeling Change and FDA's Response? " Do you -- do you see that section of your statement, Doctor?

A. Uh-hmm. Yes --

Q. Okay.

A. -- I do. Right.

Q. And in this you're referencing a label

change that was done by Wyeth who manufactures, um, the SSLI Effexor. Correct?

A. Yes.

Q. And, in fact, they changed their label to address the issue of suicidality and hostility in the pediatric -- pediatric population that were taking the drug. Correct??

A. They did.

Q. And that was perfectly acceptable. Correct?

MR. BROWN: I'll object to the form of the question and -- and as to relevance, this whole line of questioning.

MR. MURGATROYD, III: Yeah.

BY MR. MURGATROYD, III:

Q. At the time that was -- they were allowed to do that under the law and they chose to do it. Correct?

MR. BROWN: Again, object to the form of the question.

MR. KELL: You can answer.

THE WITNESS: Uh, yes, they did that.

BY MR. MURGATROYD, III:
Q. Okay. Now, if, um -- and I take it this is a -- what's considered for the consumer to be a -- a good procedure that drug companies can do this because it gets information to the treating physicians or in prescribing physicians quickly. Correct?
MR. BROWN: Object, again, to the form of the question.
MR. KELL: You can answer. Doctor, you can answer anytime that Mr. Brown objects --
THE WITNESS: Okay.
MR. KELL: -- unless I also object.
THE WITNESS: Okay. Well, I was looking over to see if you objected.
Um, it's generally a good thing. One of my anxieties is that companies put stuff in there just to defend themselves. Then it may not be true but, in general, it's a good thing.
BY MR. MURGATROYD, III:
Q. Right. And --
A. But you like to think it's reasonable.

Q. Okay. When -- and the idea here is they were actually strengthening their label, is that correct, with the Effexor, um, change? They're providing more information --
A. Yeah.
Q. -- about this --
A. Right.
Q. -- to make sure --
A. Well, I have no idea is what -- I don't know what their motives are. I mean, I don't think the company's care that much about pediatric use. So maybe they'd like to avoid trouble. But in this case, they apparent thought they had enough evidence from the Effexor trials. And, in fact, when we looked at all the trials, the Effexor was one of the more prominent ones. Whether that was random or true, uh, I don't think we know. And they put it in labeling. And we did not object them, although we did object later.
Q. Right, I understand.
A. When we --
Q. -- and they had --

A. When we had a more general statement that applied to all of them.
Q. Correct. You wanted them to confirm technically.
A. For a year or so or more they had that statement in there.
Q. Correct. Now, um, now, with regard to -- let me just put this -- have you ever, um -- if a, uh, drug company wants to strengthen its label, as Wyett did in this example, um -- well, strike that. I'm not going to ask that question. Let's just go to the next one.
Um, now, the issue that we're here today for is -- involves Paxil and what are known as withdraw symptoms that occur when the patient either misses a dose or thought it discontinues or reduces the dosage. Do you understand that?
MR. BROWN: Object to the form of the question.
THE WITNESS: Okay. I sort of understand it. I didn't testify on any -- I mean, I did -- my -- my statement didn't address anything

except what that should be called.
BY MR. MURGATROYD, III:
Q. Right.
A. So --
Q. We're getting --
A. -- I guess I had some hope that it would be about that but --
Q. Yeah.
A. -- obviously -- obviously I'm disappointed.
Q. We're going to get to that.
A. Right, okay.
Q. I guarantee you we'll get to that.
A. That's good. Okay.
Q. Before I do get to it, let's, uh, let's just take a -- well, how long have we been going? About an hour and half now?
MR. FARBER: An hour and 40 minutes.
MR. MURGATROYD, III: Let's just take a -- well, let's go off the record. Lead us off the record. Gerald, I'm just going to talk about lunch and supper.

MR. KELL: That's right.
THE VIDEOGRAPHER: Going off the record at 11:56.
(A brief recess was taken.)
THE VIDEOGRAPHER: We are back on the record in order to actually end the videotape. This is the end of Videotape No. 1. The time is 11:58 a.m. We are going off.
(Whereupon, at 11:58 a.m., a recess was taken, and the proceedings resumed at 12:09 p.m., this same day.)
THE VIDEOGRAPHER: This the beginning of Videotape No. 2. We are back on the record at 12:09 p.m.
BY MR. MURGATROYD, III:
Q. Okay. Doctor, just to follow up on my last question. When Wyeth made that label change that was referenced in your statement before Congress, am I correct in saying that it's your job to determine whether or not a strengthening label is false or misleading? That falls in one of your responsibilities?

A. Me personally --
Q. No. Your --
A. -- no.
Q. -- division.
A. The review division would exam that question.
Q. Okay. Now, with regard to, uh -- and we're kind of going back, uh, the statute on the warning when there's a serious risk of injury. Have you made an inquiry into when Glaxo SmithKlein actually knew that Paxil was causing severe or serious, as that term is defined by the FDA, withdraw and reactions?
MR. BROWN: Object to the form of the question, please.
MR. KELL: Same objection.
BY MR. MURGATROYD, III:
Q. You can answer it.
MR. KELL: You can answer.
THE WITNESS: No, I haven't. I don't know if we've, uh, if we've looked or if we think the reports were delayed, or I don't know anything

about that.
BY MR. MURGATROYD, III:
Q. Okay. Let me just show you a document that -- it's -- it's a big document but I've tabbed the parts that I think that I want to ask you questions about that -- to make it speedier, I did not want this to be a long process. And I'll mark it as Exhibit 13.
(Temple Deposition Exhibit No. 13 was marked for Identification.)
BY MR. MURGATROYD, III:
Q. And it's a SmithKlein Beecham Pharmaceuticals document dated 24 September 1997. And it's Safety Review of Discontinuation Symptoms. And, uh, I'd just like to show that to you.
MR. MURGATROYD, III: Do you have -- dod you need a copy?
MR. BROWN: If you have an extra one, that would be great. The other thing I guess I'd like to raise at this point is testimony relating to GSK documents submitted to the IND or the MDA

are designated as confidential. And the testimony around it, uh, is designated as confidential. We can work that out later.

MR. MURGATROYD, III: Yeah.

MR. BROWN: There are parts of it that we declassified, but I -- I want to have sort of a standing objection with respect to submissions that are going to be shown to Dr. Temple during the course of the deposition that -- that there is a confidential designation with respect to the document and the testimony around it.

MR. MURGATROYD, III: That's absolutely acceptable.

MR. BROWN: Okay, thank you.

MR. MURGATROYD, III: This is my -- I'm going to ask for that back, but you're more than welcome to look at it.

THE WITNESS: Okay. What are you --

BY MR. MURGATROYD, III:

Q. If you would just turn your attention to those tabbed parts, just -- and they're highlighted.

A. There's a lot --
Q. I tried to make it as quick as --
A. There's a lot of tabbed parts. An particular tabe?
Q. No. All the -- we're going to do one at a time. I was just -- again, there's no rush. We can go off the record if -- I went to by highlighted, tabbed it, to help speed up the process for you.
MR. KELL: Now if you'd --
THE WITNESS: Sorry. I'm just --
MR. KELL: -- required to --
THE WITNESS: -- look at tabs or at highlighted parts.
MR. MURGATROYD, III: Highlighted parts.
MR. KELL: And if you'd refer to a page number or a Bates number or something, please, counsel, so we know where we're looking.
THE WITNESS: Yeah. I mean, you've highlighted the titles so --
MR. MURGATROYD, III: Yes.
THE WITNESS: -- tell me where to go.

BY MR. MURGATROYD, III:
Q. To go to the first yellow stab. It'll have a little sticky and it'll have a --
A. A little sticky --
Q. -- highlighted part.
A. -- tab.
Q. Right. And then there's a highlighted part. That's a part. And the same three throughout the document, just to speed up the whole process for you, but if you want to read any more, absolutely you're free to do that.
(Witness reviewed document.)
THE WITNESS: Okay. I'm looking at the first one. What's the question?
BY MR. MURGATROYD, III:
Q. Uh, my question, if you -- let me just follow along with you. What page is that that you're on at the bottom?
MR. KELL: Mr. Murgatroyd --
MR. MURGATROYD, III: It might be 13.
MR. KELL: -- we're going to be here all day.

MR. MURGATROYD, III: It might be 1331.
BY MR. MURGATROYD, III:
Q. Okay, that's fine. We can do that quickly.
A. Okay, great.
Q. Now, you see the Study 095. Correct?
A. Yes.
Q. And do you see the percentage of patients who experience withdraw reactions, uh, after coming off of paroxetine?
A. Uh, right. You can't tell that they're withdraw reactions. They occurred during the cessation period.
Q. Okay. So it's at least one cessation-emergent AE was reported by 27/64?
A. Right.
Q. -- 42 percent of the paroxetine patients. Correct?
A. Yeah. I'd have to see what they are, but some -- that you just know that the adverse reaction occurred during the cessation period.
Q. Okay. Um -- well, it says right above

it, The incidence of discontinuation effects. So this is the drug manufacturer saying this.

A. Right. But they still can't really know that.

Q. Okay. Do you --

A. It all depends.

MR. KELL: And, Mr. Murgatroyd, I suggest you ask the drug manufacturer about this. I don't see that this is in any way within the scope of Dr. Temple's declaration submitted in this case or the purpose for which he has provided for this deposition, or as you would characterize it for the purpose for which he was ordered to attend this deposition.

So I'm going to object and instruct the witness not to answer any further questions regarding these tabs or these highlights.

MR. MURGATROYD, III: Okay. Well, I think maybe I can shortcut the question. And I -- your objection is duly noted and, if necessary, we'll take it up with the magistrate judge.

BY MR. MURGATROYD, III:

Q. Were you aware of the extent or the numbers, either in percentages or whole numbers, of people who are affected by withdraw reactions caused by Paxil?

MR. BROWN: Object to the form of the question.

MR. KELL: Object to the form.

THE WITNESS: Answer?

MR. KELL: You can answer --

THE WITNESS: Um --

MR. KELL: -- if you can understand the question.

THE WITNESS: No. And I still don't know what the right number of people who were affected, yes.

BY MR. MURGATROYD, III:

Q. Okay. Are you aware that in the U.K, uh, GSK puts in information given to patients that it affects 25 percent of the people who take the drug?

MR. BROWN: Object to the form of the question, and it lacks foundation.

MR. KELL: You can answer.
THE WITNESS: But, no, I'm not aware of that.
BY MR. MURGATROYD, III:
Q. Okay. Are you aware that GSK has acknowledged that withdraw reactions include such reactions as suicidality?
MR. BROWN: Same objection.
THE WITNESS: I am not aware of that. And I don't -- I mean, I have to see the study. I don't know how you'd know that.
BY MR. MURGATROYD, III:
Q. Okay. Well, let's talke look at a -- at a letter that, um, GSK sent to healthcare professionals in the U.K. before -- well, let's just take a look at this. What is that number in -- I'm sorry -- that document that you have? Is that --
A. This one?
Q. Yeah. The front page is, uh --
A. Thirteen.
Q. Thirteen, okay. Let's go to No. 14.

And actually the important part of that document is at the very last paragraph on the second page.

MR. BROWN: Mr. Murgatroyd, do you have another copy, please?

MR. MURGATROYD, III: Uh, I don't.

MR. BAYMAN: Can you identify the document, please, sir?

MR. MURGATROYD, III: Yeah, I will. Yeah, I had some ....

(Temple Deposition Exhibit No. 14 was marked for Identification.)

BY MR. MURGATROYD, III:

Q. The document is entitled Dear Healthcare Professional, Re: Seroxat (paroxetine hydrochloride contraindication in children under 18 for treatment of major depressive disorder. And what I'm talking about is, uh, Section 4.8. And the second page, and it's the very last sentence. It says, in studies.

MR. BROWN: Is there a date on the document?

MR. MURGATROYD, III: No, there's not a date on this document. I was surpised but it's not. Oh, well, there at the bottom it says June 2003.

BY MR. MURGATROYD, III:

Q. Again, Doctor, I'm just referring to this very last sentence on the second page. It says, "In studies that used tapered withdrawal regimen."

A. Yeah. See, what I can't tell from this is the nature of the study. Um, did they withdrawal --

MR. KELL: Doctor, there's really not a question --

THE WITNESS: Yeah.

MR. KELL: -- pending.

THE WITNESS: Okay.

MR. KELL: Let Mr. Murgatroyd ask the question if he --

THE WITNESS: Okay.

MR. KELL: -- has one.

BY MR. MURGATROYD, III:

Q. The question I have -- and is GSK has made a statement in this document. And it says, for the record, in studies that use a tapered withdrawal regimen, symptoms reported during the taper phase or discontinuation of paroxetine at a frequency of at least 2 percent of patients that occurred at a rate at least twice that of placebo were: Nervousness, dizzyness, nausea, emotional lability -- which then has a parenthesis -- including crying, mood fluctuations, self-harm, suicidal thoughts and attempted suicide -- end parenthesis -- and abdominal pain.

Do you see that section, Doctor?

A. I see it, yeah.

Q. Okay. Now if, uh, GSK believes that this is true, do you have any reason to disagree with it?

MR. BROWN: Object to the form of the question.

THE WITNESS: Yeah, I don't know what they belive is true and I don't know what the nature of the study is. For example, um, they

compare it to placebo, but I don't know what the placebo group is. Um, uh, it may be that they stopped the drug in some people and left the other -- I mean, I can't tell what they did. They -- I don't know what the comparison to placebo is. If you took people who finished the study, typically the people who are on placebo and still manage to finish the study are doing well without a drug. So they may not be dependent on the drug to do well, but that would be a, uh, only a fraction of the people who entered the study. It wouldn't be surprising if they did better than the people who were benefitting from the drug. When you take the drug away, some of the consequences were being depressed and come back. So I just need to know way more about the study to form any sensible conclusion.

Q. No, I just want -- I want -- if GSK believes this is true, do you -- do you object with that statement?

A. I don't know what --

MR. BROWN: The same objection.

THE WITNESS: I don't know what they believe. I just know what they wrote here. I -- I haven't probed them or asked anything about it.

(Co-counsel confers with counsel.)

MR. MURGATROYD, III: Okay.

BY MR. MURGATROYD, III:

Q. Um, do you believe that the FDA United States has the same information that the regulators in the U.K. were provided?

A. Well, I think we generally do. I can't speak to a particular piece of information --

Q. Okay.

A. -- or ....

Q. Okay. Now, in a, um, -- well, let me show you what, um ... what I've marked as the next exhibit, which is 15.

(Temple Deposition Exhibit No. 15 was marked for Identification.)

BY MR. MURGATROYD, III:

Q. And it is an e-mail dated, um, October 29, 1996, on Paroxetine -- discontinuation

symptoms. And I've highlighted the relevant part for you.

MR. BROWN: From whom to whom?

MR. MURGATROYD, III: I'll tell you in a second.

MR. BROWN: Okay.

MR. MURGATROYD, III: From Noel -- and the last name -- I'm sorry. From Tamara Gidgrift -- Pedgrift, P-E-D-G-R-I-F-T, in central clinical saftey, to Noel. And the last name is K-R-I-T-Z-I-N-G-E-R.

MR. BROWN: Can I take a look at it, please?

MR. MURGATROYD, III: Yeah.

Yes. Looking for the next page, me too (laughter.)

THE WITNESS: Yes, this doesn't say much.

BY MR. MURGATROYD, III:

Q. No, it doesn't. It just tells you something, though, doesn't it?

A. No.

Q. Well, it tells you that in 1996 GSK had looked into the issue of withdrawal reactions related to Paroxetine. Correct?

MR. KELL: Object to the form.

MR. BROWN: I'm going to object. And I'm going to ask for an opportunity to read the two paragraphs in the document.

MR. MURGATROYD, III: Okay.

MR. BROWN: If you'll just wait for one second, please.

MR. MURGATROYD, III: Okay.

(Counsel reviews document.)

MR. KELL: Okay.

MR. MURGATROYD, III: Thanks.

BY MR. MURGATROYD, III:

Q. Okay. Now, this document you'll see that, um, it talks about, um, a report on the subject of discontinuation symptoms of Paroxetine. And we don't have that report, though. Correct? And it says that, uh, "Please note that this information is for in-house use only and is not to be passed to regulatory authorities, external

investigators and other clinicians."
Do you see that part?
A. Yes.
Q. Okay. Do you know whether or not, uh, GSQ was providing you with, uh, reports, meaning you, the FDA person involved in their drug, with reports that set forth the number, um, or percentages of people who are experiencing, uh, withdraw symptoms from Paroxetine?
MR. KELL: Object to the form. Vague as to time.
MR. MURGATROYD, III: It does take away this time period.
BY MR. MURGATROYD, III:
Q. Were you aware that GSK considered this an issue in 1996?
MR. BROWN: Object to the form of the question.
THE WITNESS: I'm not aware of when concern about this arose. I think there's been concern about withdraw symptoms for a long time however.

BY MR. MURGATROYD, III:
Q. Okay.
A. I don't know where this fits into that.
Q. Are you ware that one of the executives of GSK has testified under oath that it was their, uh, belief that 10 percent of those people who experienced withdrawal symptoms of -- were of such magnitude or such severity that they were rendered disabled?
MR. BROWN: Object to the form of the question.
THE WITNESS: No, never heard that.
BY MR. MURGATROYD, III:
Q. Okay. Uh, are you aware that -- well assume -- you don't have any idea how many people have taken Paxil in this country?
A. No, not really. Many millions I'm sure.
Q. Okay. And if the GSK number of that they use in the U.K. that 25 percent of the people experience withdrawal reactions from Paroxetine and say -- just use the number of million people have taken it, how many people would be affected with

withdrawal reactions?
MR. BROWN: Object to the form of the question.
MR. KELL: Object to the form. And the Doctor is not here to do your math for your, Mr. Murgatroyd, or to answer such hypothetical questions.
You needn't answer that question, Doctor.
MR. MURGATROYD, III: Okay. Well, you know, I want to get -- you know the Doctor entered into this lawsuit, and I want to get an idea --
MR. KELL: The Doctor did not enter into this lawsuit.
MR. MURGATROYD, III: He certainly did.
MR. KELL: If you have questions --
MR. MURGATROYD, III: He submitted a declaration.
MR. KELL: -- you may ask them. And I will object to them.
BY MR. MURGATROYD, III:
Q. Well, I want to know what the Doctor --

the extent of the Doctor's knowledge when he signed that declaration. Was he aware that hundreds of thousands of American citizens were being render disabled by Paxil withdrawal symptoms at the very time you signed that declaration.

A. Well --

MR. KELL: Object to the --

MR. BROWN: Objection.

MR. KELL: Go ahead.

MR. BROWN: Object to the form of the question and assumes facts not in evidence.

MR. KELL: I have the same objection. And, therefore, I instruct the witness not to answer since any answer would be formulated based on facts that are not before him but rather on conclusions stated by counsel.

You need not answer that question, Doctor.

MR. MURGATROYD, III: Well, then -- well, then I'm going to take the time to establish that foundation. If you want to bill time into this deposition, that's fine.

MR. KELL: It's your --
BY MR. MURGATROYD, III:
Q. The percentage --
MR. KELL: -- deposition, counsel.
Q. -- of Paxil's investigation -- I mean GSK's investigation into the number of or the percentage of the patients who were affected with withdrawal symptoms is contained in that document that has the many tabs that I tried to avoid going through.

Now, if you want me to go through that, we'll establish that. But you will see by going through that document that the numbers in the healthy volunteers was 62 percent of the people experienced with withdrawal reactions. And many, many other trials that was in the 30s, 40s, or 50 percent. It's not some minor percentage. It's not 5 or 10 percent, all of them. Every single one of them exceeded 25 to 30 percent.

My question to you is if, in fact, 25 or 35 percent of the people were experiencing withdrawal reactions and 10 percent they're of such

severity the people were disabled is that not a hazard with this drug?

MR. BROWN: Object to the form of the question, the speech given in advance of the question, the vague nature of the question, the lack of foundation associated with the question.

MR. MURGATROYD, III: Okay.

MR. KELL: And I object on the basis that it is a hypothetical question. It calls for expert opinion. The doctor is not here to provide expert opinion for any party in this case.

MR. MURGATROYD, III: I'm not asking for expert --

MR. KELL: Don't answer the question --

MR. MURGATROYD, III: -- opinion.

MR. KELL: -- Doctor.

BY MR. MURGATROYD, III:

Q. All right. Then we will go through this the more tedious way. Let's go back to that Exhibit 13. You'll see that there was one study there where GSK --

MR. KELL: Mr. Murgatroyd, I've already

told you and I've already instructed the Doctor not to answer any questions about this document as a whole or in any particular tabs or highlighted portiions of it. My objection is on the record. My instructions are on the record. You need not ask any more questions about the document.

MR. MURGATROYD, III: All right. Well, then, I'm going to ask a couple of questions.

MR. KELL: Let --

BY MR. MURGATROYD, III:

Q. And the question is: Doctor, have you or any member of your staff at the FDA, to your knowledge, seen the document that has been marked as Exhibit 13?

A. I haven't -- I have no idea.

Q. Okay.

A. I have not.

Q. Okay, good. And, again, what is the date of that document?

A. 24 September 1997.

Q. Okay. Now, we agreed earlier that if a drug company is aware of a hazard it has a duty to

change its warning; is that correct?
MR. BROWN: I'll object to the form of the question. And I think it mischaracterizes his testimony.
MR. KELL: Same objections.
If you understand the question, and have an answer, you can provide it.
THE WITNESS: Yeah, I wouldn't have said that. I believe they have an obligation to tell us about it and see what -- whether a warning should be rendered.
BY MR. MURGATROYD, III:
Q. Okay.
A. It depends.
Q. Okay. Have you ever required -- has the FDA ever required a report such at that in your hand, Exhibit 13, from GSK regarding withdrawal symptoms?
A. I don't know.
Q. Okay.
A. Somebody else might know.
Q. But your -- your division did require

GSK to change their label in --
A. Yes.
Q. -- in 2001. Correct?
MR. BROWN: Object to the form of the question as to --
MR. MURGATROYD, III: Okay.
MR. BROWN: -- the vague nature of the question. What change?
BY MR. MURGATROYD, III:
Q. The change to make a precaution on regarding withdrawal symptoms. Do you recall that?
A. Yes.
Q. Okay. And that was something that the FDA instituted not GSK. Correct.
MR. BROWN: Object to the form of the question.
THE WITNESS: Um, I don't know that.
BY MR. MURGATROYD, III:
Q. Okay, we'll get into the --
A. I don't know where that came from.
Q. Okay. We'll get into the document that shows that.

Now -- well, actually it'll be -- it's the next, uh, exhibit. Which I believe we're up to 15 -- uh, no. I think we're 16, correct, Gerald?

MR. KELL: I see one numbered 15 here in front --

MR. MURGATROYD, III: All right.

MR. KELL: -- of us.

MR. MURGATROYD, III: Then we'll make this this one 16.

(Temple Deposition Exhibit No. 16 was marked for Identification.)

BY MR. MURGATROYD, III:

Q And obviously this is -- this is a long document. But to shorten it, it is a e-mail dated 9/27/2001 written by Thomas F. Kline who is the regulatory part of GSK. And it discusses the proposed labeling by you -- by the FDA and the proposed label is attached.

A. Okay. Say the date again.

Q. September 27th, 2001.

A. 2001, okay.

Q. Okay. And the FDA give its reason for changing the precaution with this highlighted tab, as well as the whole label is attached, the proposed change of label. But I want you -- it would be helpful if you read the memo. It's very quick. And then just look at that one section.

A. It went to plenty people.

Q. It went to lots of people. You caused some problems over there.

A. Is there some particular part you want me to --

Q. Yeah, just that --

A. The first one.

Q. -- page.

MR. BROWN: Can I take a look at that for a minute?

MR. MURGATROYD, III: Yeah.

(Witness reviewed document.)

MR. MURGATROYD, III: Thanks.

THE WITNESS: Okay. I've read the first page.

BY MR. MURGATROYD, III:

Q. Okay. And do you see that, um, the first sentence says, Attached below is FDA's proposal labeling?
A. Yes.
Q. Okay. And then if you go to that labeling that's marked with a red tag, you see the part where it says, "We?"
A. Yes.
Q. Can you read that into the record, please.
A. Yeah. This is typical format for neuropharm letters. It's a little explanatory statement. It says, "We have decided that the withdrawal symptoms observed upon discontinuation of paroxetine are of sufficient importance to justify mention of these findings in this section. The information pertinent to withdrawal symptoms from Postmarketing reports has also been moved to this section, given the increasing evidence that is a drug-related risk."
Q. Okay. Do you have any reason to disagree with that statement?

A. No.
Q. Okay. Do you agree that there are withdrawal reactions that some people experiend that are drug-related to Paxil?
A. Oh, yes.
Q. Good. Now, let me give you the next exhibit. And it's just one section. And, again, I'm trying to move through this quickly.
(Temple Deposition Exhibit No. 17 was marked for Identification.)
BY MR. MURGATROYD, III:
Q. And the only part that I'm interested in -- this is, for the record, another e-mail from Thomas Kline, and it's regarding the FDA conversation having to do with the draft Paxil labeling. And it has -- it's a -- it's a, um, basically describes a conversation that Mr. Kline had with Dr. Loughran of the FDA. And the GSK Question No. 3 is the question I'd like to show the, Doctor.
MR. BROWN: The date of the e-mail,

please?
MR. MURGATROYD, III: It is 12/7/01.
THE WITNESS: Well, maybe 12/5/01. It's hard to tell.
BY MR. MURGATROYD, III:
Q. It's hard to tell. It's 12 -- 12/7 or 12/5.
A. Okay. And Question No. 3?
Q. Yes, Question No. 3. Can you read that, please?
MR. KELL: Do you want him to read it out loud or just review it for himself?
MR. MURGATROYD, III: He can just -- he can review it for himself.
(Witness reviewed document.)
MR. MURGATROYD, III:
Q. Okay. And do you see that GSK is asking the FDA to not use the word "witdrawal symptoms?"
MR. BROWN: Object to the form of the question.
THE WITNESS: Uh, yes, I do see that.
BY MR. MURGATROYD, III:

Q. Okay. Now, um, I'm going to get to that later. I just want to make sure that document came into the record at this point.

Now, I'm going to show you what has now been the changes label. This was approved and is not being -- it was being used after the FDA requested it. And I have a question -- actually, let me just highlight that part for you to save some time.

A. Okay. I know where it is.

Q. Okay. Just -- yeah, the precaution section.

MR. BROWN: What's the PX number on that label?

MR. MURGATROYD, III: Twenty-two.

THE WITNESS: Okay. It generally uses the term discontinuation.

BY MR. MURGATROYD, III:

Q. Okay.

A. Is that your point?

Q. Yeah. Withdrawal -- withdrawal symptoms gone. Right?

A. Yeah. I think it's correct that we consider those terms equivalent.
Q. Okay. Well, we're going to get it done in a minute.
Do you agree that drug companies used their labels, and, particularly, GSK as a marketing device?
MR. BROWN: Object to the form of the question.
THE WITNESS: Can you tell me more about what you're asking.
BY MR. MURGATROYD, III:
Q. Okay. Do you agree that it's important for drug companies, such as GSK, to try to keep things out of the labels that a competitor would be able to use to differente the products?
MR. BROWN: Object to the form of the question.
THE WITNESS: Can I answer?
MR. KELL: You can answer.
THE WITNESS: I think companies worry a lot about how exactly everything is said and they

are always conscious of how similar drugs say it. So if -- they would be unhappy with something that said the same thing in a worse way.

Now, if it's a worse problem for their drug, they don't have much of a case. If as far as we know the drugs are similar and theirs looks worse, they probably do have some case. Whether we change both or, you know, we have to decide. But, yes, they don't like to be disadvantaged by language.

Q. Okay.

A. Um, and that's understandable. Keeping something important out is not understandable. We would have very little sympathy for that.

Q. Okay. Now, are you aware that when the FDA requested GSK to change the label with regard to withdrawal symptoms that they try to get a classwide labeling change?

MR. BROWN: Object to the form of the question.

THE WITNESS: I was not aware.

BY MR. MURGATROYD, III:

Q. Okay. Now, are you aware of the -- of how much money GSK thought a discontinuation label could cost them?

MR. BROWN: Object to the form of the question?

THE WITNESS: No, I have no idea.

BY MR. MURGATROYD, III:

Q. Let me show you the next document.

A. I don't -- I also don't understand the question. You even mentioning a discontinuation syndrome?

Q. Yeah. Have it in the label.

A. Okay.

Q. Correct.

A. No, I have no idea what they about --

Q. Let me show you the next document which is Minutes of Discontinuation Meeting dated 7/11/1997. This label change was in 2001. Correct?

A. Yes.

Q. Okay. This is 1997, July 11th. And let's see. Hold on. I'll show the one document

that I think you may find of interest.
(Temple Deposition Exhibit No. 18 was marked for Identification.)
MR. BROWN: Can I see that, please? Can you give him an opportunity to look at it before you ask questions?
MR. MURGATROYD, III: Sure.
MR. BROWN: Thanks.
(Witness reviewed document.)
THE WITNESS: This is them. Right.
BY MR. MURGATROYD, III:
Q. Okay. Just that top part?
A. I've looked -- oh. Like deliverables?
Q. No, the next page. I think it's the next page.
A. Well, sorry. Right, you are. Okay.
Q. Okay. Do you see that page by the tab that says, Discontinuation? Do you see that? It says why this is an issue.
A. Yes.
Q. Okay. And -- well, why is it an issue

to GSK?
MR. BROWN: I'll object.
MR. KELL: Objection.
Are you asking the Doctor to read the page? Because I'll let you waste your time and have him read it. If you're going to ask him anything substantive --
MR. MURGATROYD, III: Okay.
MR. KELL: -- about it, but I'm not going to allow him to --
MR. MURGATROYD, III: Well --
MR. KELL: -- answer it.
BY MR. MURGATROYD, III:
Q. Were you aware Doctor that GSK was afraid that this discontinuation of withdrawal issue would cost its billion-dollar-plus sales of Paxil?
MR. BROWN: I'll object to the form of the question. Lacks foundation. Mischaracterizes the document.
MR. KELL: Object to the form.
Answer the question. The question is --

THE WITNESS: Okay.
MR. KELL: -- are you aware?
THE WITNESS: I was not aware of any discussion. I don't think it says that they're worried about losing a billion dollars. That's what their total sales are. So, obviously, they're concerned about losing some of them.
BY MR. MURGATROYD, III:
Q. Okay. Thank you. Now, after you --
A. And my guess is what their concerned about is being fingered as worse than the other drugs in this respect.
Q. Right. And they are. Correct?
A. Um, I don't know --
MR. BROWN: Object to the form --
A. -- that I know that.
MR. BROWN: -- of the question.
THE WITNESS: I'm sure there was some --
BY MR. MURGATROYD, III:
Q. Okay. Are you aware that the reporting in the mid-nineties was 100 fold for Paroxetine over Prozac?

MR. BROWN: Object to the form of the question.
BY MR. MURGATROYD, III:
Q. But I could show you the document. I'm only saying --
A. No, I believe that.
MR. BROWN: Can I get my objection on the record --
THE WITNESS: Yes --
MR. BROWN: -- please?
THE WITNESS: I'm sorry.
MR. BROWN: Object to the form of the question and lacks foundation.
BY MR. MURGATROYD, III:
Q. Go ahead.
MR. KELL: Objection.
Don't answer, Doctor.
We're just -- we're getting --
MR. MURGATROYD, III: Okay.
MR. KELL: -- so far field. I think I'll just --
MR. MURGATROYD, III: Okay.

MR. KELL: -- cut it off here.
MR. MURGATROYD, III: Yeah, that's fine.
BY MR. MURGATROYD, III:
Q. Let me show you the next exhibit. When the FDA deemed the withdrawal issue to be such that it require a procaution, obviously, because we had this label change. Correct?
MR. BROWN: Object to the form of the question again.
THE WITNESS: Yes, it was a precaution.
BY MR. MURGATROYD, III:
Q. Okay. And then did you ever -- when they, um, sent letters out, uh, announcing the label changes, is part of them a general letter to doctors, is that something that gets reviewed by your office?
A. Um, my office, no. But by the division -- except rarely. By the division, yes, usually.
(Temple Deposition Exhibit No. 19 was marked for Identification.)

BY MR. MURGATROYD, III:
Q. Okay. Let me show you the letter that was sent out I've marked as Exhibit 19. And it's stated Paxil PTS (sic) Indication Mailings. And --
MR. BROWN: PTSD?
MR. MURGATROYD, III: PTSD, that's correct.
BY MR. MURGATROYD, III:
Q. And --
A. Well, I have to say that I'm not sure that we see all of them.
Q. Okay.
A. We see many of them. And I don't think there's a clear requirement but I'm not sure.
Q. Okay. Well I'd like you to look through that and see if you can, um, find in there where the -- where GSK is telling doctors that the FDA has required it to change its label to include a precaution of withdrawal symptoms.
MR. KELL: Objection.
If -- Mr. Morgatroyd, if you can give me some enlightenment as to where you are trying to go

within the proper scope of this deposition, I may allow the Doctor to anwere these kinds of questions, but if you can't, and you need not --

MR. MURGATROYD, III: No, I don't --

THE WITNESS: -- it's up to you, then, uh, then I'm going to instruct him not to answer this question.

MR. MURGATROYD, III: What -- what time is it now?

MR. FARBER: It is, uh --

THE WITNESS: Twelve -- 12:42.

MR. FARBER: -- 20 to one.

MR. MURGATROYD, III: At lunch I'll be glad to discuss it with you.

MR. KELL: Okay.

MR. MURGATROYD, III: Is that fair enough?

MR. KELL: Okay. Can I have the question.

MR. MURGATROYD, III: We're going to be at lunch in 18 minutes.

MR. KELL: Can I have the question read

back so I can decide whether -- what I'm instructing the witness.

MR. FARBER: While he's looking for the question, let me make a technical correction for the record.

MR. KELL: Well, he can't take it for the record because he's looking for the question.

MR. FARBER: No. But I want to make just a technical correction. And that is on Exhibit 17 which refers to Mr. Kline's e-mail of 12/17/01. He actually -- the actual attached phone conversation and the options 1, 2, 3 and 4 so far are taken from, uh, on the date October 4th, 2001. This is your document. So I think you --

MR. MURGATROYD, III: That's mine.

MR. FARBER: Well, I mean --

MR. MURGATROYD, III: Well --

MR. FARBER: -- she has -- document. So we're talking about a conversation that occurred on October 4th, 2001, just for the record.

MR. BROWN: We have a sticker on page 2, not 1. I'm not sure why that is.

MR. MURGATROYD, III: That's a question - that was the question being --
MR. BROWN: I think you're attaching the whole exhibit, the whole document as an exhibit.
MR. MURGATROYD, III: Yeah. We're going to come back to this exhibit.
MR. FARBER: Okay. But it was -- okay.
MR. MURGATROYD, III: It is --
MR. FARBER: Thank you.
MR. MURGATROYD, III: -- it is October though the e-mail is dated later.
THE WITNESS: Okay.
BY MR. MURGATROYD, III:
Q. Okay. In that -- in the letter --
MR. BROWN: What's the question?
THE WITNESS: Tell Jerry what the question is.
MR. MURGATROYD, III: Maybe I'll rephrase it. I'll give it again.
MR. KELL: Okay.
BY MR. MURGATROYD, III:
* Q. In the letter, does it reference the fact

that the FDA required GSK to change its label to include a precaution or withdrawal symptoms?

MR. KELL: Objection. The letter speaks for itself, if it speaks to anything. It certainly doesn't speak to the subject of this deposition.

Don't answer the question, Doctor.

MR. MURGATROYD, III: So you're instructing him not to answer?

MR. KELL: I'm instructing him not to answer.

MR. MURGATROYD, III: Okay.

So we'll mark that one down, please.

MR. MURGATROYD, III: All right. Fair enough. The -- I'm going to get to a subject that's more -- more to your like Gerald.

BY MR. MURGATROYD, III:

Q. And that's --

MR. KELL: Go ahead.

Q. -- advertising because that's what we're hear with regard to Dr. Temple's declaration in this matter was an advertising issue. Correct?

A. A very narrowed particular advertising

issue, yes.
Q. That's correct, okay.
Now, I -- we established you do have responsibilities with regard to advertising as director of medical policy.
A. Yes.
Q. Because DDMAC falls underneath your --
A. Yes.
Q. Yeah. Okay. Good.
How many people work in that department?
A. No wise guy, answer it like 50 percent.
Q. Okay.
(Laughter.)
A. Um, the advertising group is about in the neighborhood of 40.
Q. Okay. And how many people actually review ads, drug ads?
A. Uh, mostly those people --
Q. Okay.
A. -- divide it into the direct consumer and other things, but that's what most of them do.
Q. Now are these for drug --

A. Probably -- probably 30.
Q. Okay, 30. I'm sorry, 30.
MR. BROWN: Go ahead. Close the door.
MR. MURGATROYD, III: You want to close -- yeah, let's close it.
MR. BROWN: Can you go back and reread the answer to the question about how many people are in the --
MR. MURGATROYD, III: 40.
MR. BROWN: At DDMAC?
MR. MURGATROYD, III: DDMAC, 40.
THE WITNESS: DDMAC is about 40.
BY MR. MURGATROYD, III:
Q. And I ask of those how many actualy review ads and the answer was?
A. Most. They have supervisors also and they participate at a next, you know, at the -- down the line, but that's -- that what their entire business is.
Q. Okay. And how many in -- in are they reviewing ads for new drugs? Existing drugs? All drugs? How does it -- what comes through DDMAC?

A. They review -- well, all the above. They review promotion -- initial campaigns, um, because companies want to not have problems with their initial campaigns. So they come in for advisory opinions. And we also watch the ads that are, uh, um, put out into various forms. And promotional material that goes in -- indirect mailers. We go to various meetings and see what people are saying at booths. But there's 40 of us in there. It's a lot more.

Q. That's what I was going to say. How many drugs, I mean, if you have to count the drugs?

A. Well, drugs that are off patent are largely unpromoted.

Q. Right.

A. They also don't appear in the PDR anymore. If you -- you can't fin --

Q. Yeah, I noticed that.

A. You can't find the Prozac --

Q. I don't understand that.

A. -- labeling -- label in the PDR. Well, I do. It's private, uh,

enterprise. They don't find any interest in that. Um, so it's mostly more recent drugs that, um, that are actively promoted.

Q. Okay. Is that in the hundreds? As today, would there be hundreds of drugs?

A. I'm sure there's hundreds of drugs that have some degree of promotion, but I have no specific number in mind.

Q. Okay. And -- and as you said, there's all kinds of ads. There's print ads. There's radio ads, TV ads. I mean, there's all kinds of ads. Right?

A. Correct. And there's direct consumer and there's professional ads too.

Q. Right. And the ads, if I'm correct in -- I think I -- Dr. Loughran said this and I don't want to attribute to it, if he didn't. But the ads are supposed to be consistent with the drugs label. Correct?

A. Yes.

Q. Okay. Now, when the reviewers are reviewing an ad, say, for the drug Paxil, which

we're for, would they have the Paxil label in front of them so that they can compare --
A. Yes.
Q. -- the two to make sure they're --
A. They -- they will, right.
Q. Okay. Try to make sure they're -- they're proper, not misleading.
MR. BROWN: Object to the form of the question.
MR. MURGATROYD, III: Okay.
BY MR. MURGATROYD, III:
Q. But do drug companies have to preapprove their ads or is that voluntary?
A. Uh, they usually do not preapprove their ads. They have to send us an ad -- I forget the name of the form -- that they do this on -- they'll send us an ad when they start to use it, but they do not have to get preclearance. That's quite explicit in the law.
Q. Okay. But some companies do get preclearance?
A. Yes. That's relatively uncommon once

you leave the launch. The only required sumbission for a so-called subpart h ad. That's where the drug's been approved, um, on the basis of a surrogate endpoint. We don't need to get into that. Those have to be cleared for a period of, uh -- those have to be cleared, um, really until it states its changes.

Uh, others do not, absolutely do not have to be clear unless there are, quote, special circumstances, rarely, uh, rarely applied.

Q. Okay. Are there any other departments within the FDA who review ads other than DDMAC?

A. We work closely with the review divisions to get their help on whether something is violative or misleading or not.

Q. New to light. I mean, is there another whole department that -- I mean, is it just --

A. No.

Q. -- one ad review department within the whole FDA?

A. No. There are units for devices and things like that, but this is the only drug place.

Q. Okay. For drugs --
A. Right.
Q. -- you're it?
A. Yeah.
Q. Okay. The buck stops with you?
A. Yeah.
Q. Okay, good. Now --
A. With -- with help from general counsel.
Q. Yeah, good. I was reading a book by, um, Marcia Angell.
A. Correct.
Q. Have you heard of that drug -- I mean, that book?
A. Yes.
Q. It's called The Truth by Drug Companies?
A. Yes.
Q. And how is -- how is it -- have you read the book?
A. No. The peer reviews are good.
Q. Okay. And it -- and it talks about the daunting tasks that your division has in reviewing ads. And she throws out the number of 34,000 ads a

year?
MR. BROWN: Objection.
BY MR. MURGATROYD, III:
Q. Does that seem like the right number to you?
MR. BROWN: Objection to the form of the question. Lacks a foundation.
THE WITNESS: In any event, I don't know how many ads there are.
BY MR. MURGATROYD, III:
Q. Do you -- do you understand it's thousands?
A. I'm sure it's thousands.
Q. Okay. And, um, would you agree that the FDA is not really properly staffed to look at every single ad --
MR. BROWN: Object.
Q. -- that's put out by a drug company?
MR. BROWN: Object to the form of the question.
THE WITNESS: We do not undertake to look at every other ad. We don't say that we do

and we couldn't.
BY MR. MURGATROYD, III:
Q. Okay. It's physically impossible?
A. Right. But we do notice all the ones on TV because they're very conspicuous. We notice the ones that appear in journals, in -- in patient directed, um, magazines, because they're very conspicuous. And we notice the more prominent ones in regular journals, but we in no sense get to all of them.
Q. Okay. I was looking at the numbers. It would be just, you know, 34,000 ads and there's 40 people.
A. Right.
Q. I mean, you just -- you couldn't do it. You couldn't do it.
A. I know if there's --
MR. BROWN: Again --
A. -- 34,000 --
MR. BROWN: -- object to the form of the question. Lacks foundation with respect to the number of ads that are submitted to FDA. Dr.

Temple testified that he has not read Marcia Angell's book.

MR. MURGATROYD, III: Okay.

BY MR. MURGATROYD, III:

Q. That's fine. Um --

A. We actually rely heavily on complaints from --

Q. Yeah.

A. -- aggrieved other companies.

Q. Right.

A. And from individuals that we would be happy to review any of Dr. Angell's complaints, but I don't believe she's sent any.

Q. Okay. Thought that's -- I don't think she was critical of the FDA. She just said that you're under -- overworked and undermanned, which I think you probably might not disagree with it. I'm not going to ask you to answer that because it may get you in trouble.

A. That's fine.

MR. BROWN: Well, I enter an objection.

(Laughter.)

MR. MURGATROYD, III: It wasn't a question. You don't have to object.

All right. We're going to break for lunch. Um, let's, uh -- I think half an hour is unrealistic. I think 45 minutes is probably closer to reality. But let's shoot for half an hour. If everybody gets back here in half an hour, let's start and be done. We're moving along very quickly. I'm glad to say I don't think I would be more than another hour and a half to two hours, and I'll be done. And hopefully get Dr. Temple out of here lot earlier than we thought.

MR. FARBER: We'll be done --

MR. BROWN: Can we go off the record?

MR. MURGATROYD, III: Only if Gerald allows it.

MR. KELL: We're off the record.

THE VIDEOGRAPHER: Going off the record at 12:54.

(Whereupon, at 12:54 p.m., a recess was taken, and the proceedings resumed at 1:53 p.m., this same day.)

AFTERNOON PROCEEDINGS

[1:54 p.m.]

THE VIDEOGRAPHER: We are back on the record at 1:54 p.m.

Whereupon,

ROBERT TEMPLE, M.D

Resumed as a witness and, having previously been duly sworn, was examined and testified as follows:

EXAMINATION BY THE PLAINTIFFS (Continued)

BY MR. MURGATROYD, III:

Q. Ready? Okay, great.

Actually, Doctor, I just want to jump back to one -- an earlier, um, exhibit we went over, which was three, which was the letter that the FDA sent out regarding the Black Box Warning on suicidality in the pediatric population.

A. Okay.

Q. Do you recal that?

A. Uh-hmm.

Q. And there's a sentence in there that says, um, It caused a wall for antidepressants in inducing suicidality has been established from

pediatric patients.
What's an age cut off for that? Is is it 18? 19? 20?
A. They start at 15.
Q. Fifteen. Would it apply to 19 years-old too?
A. Nobody can answer that question. The studies included adolescents, whatever -- however they were defined
Q. Okay. So --
A. Well, there's -- there's no precise meaning. The British have just put out something that looked at, uh, their experience with, uh, 18 to 30 years olds and they don't find any problem. But they say, Well, people develop at different ages. There's -- there's no way to refine it better.
Q. Okay, Thanks.
A. All right.
Q. Um, now, we talked about -- we touched on briefly, it was in an earlier exhibit, the -- the difference between the terms withdrawal

symptoms and discontinuation symptoms. Correct?
MR. BROWN: Object to the form of the question.
BY MR. MURGATROYD, III:
Q. I was asking -- do you remember we looked at that earlier? Dr. Loughran made a comment in it in one of the documents you saw earlier.
A. Yeah, saying he thought they meant roughly the same thing.
Q. Okay. Are you -- are you -- or have you ever seen the word "discontinuation symptoms" in any medical dictionary?
A. I don't read medical dictionaries for that purpose.
Q. Okay. But have you ever see it defined in -- in a medical dictionary?
A. No.
Q. Okay. Is it a medical term, that's a formal medical term to your knowledge?
A. I have no knowledge whether that's used in the people who talk about these things.

Q. Okay.
A. Certainly have been in labeling. It's an easily understood term.
Q. Is it a term that -- that was used by drug companies that try to differentiate, say, SSRIs from benzodiazepines?
A. I don't know.
Q. Okay. Um, would you agree that benzodiazepines cause physical dependence?
A. Yes.
Q. Okay. Um, would you agree that benzodiazepines are habit-forming?
A. Yes.
Q. Okay. Um, when they were first approved by the FDA, meaning benzodiazepines, were they believed to be habit-forming at that time?
A. I don't know. It's a long time ago.
Q. Okay. Were you aware that it it took over 10 years for there to be a warning in the -- in the label for either Xanax or, um, Valium about it's --
A. Review?

Q. -- habit -- yeah.
A. Xanax --
Q. But --
A. Xanax -- I mean Xanas is later.
Q. Yeah, right. Librium and Valium.
A. Librium and Valium.
Q. Yeah. It took 10 years to get --
A. I was not aware of it. It wouldn't surprise me.
Q. Okay. Um, are you aware what the withdrawal symptoms are for benzodiazepines?
A. Not in any intimate way.
Q. Okay.
A. Excitability and things like that.
Q. Okay. Are you aware of the --
A. But I don't know in detail.
Q. Are you aware if -- do you know if there's any difference between withdrawal symptoms suffered by Paxil users as opposed to withdrawal symptoms suffered by, um, Valium users?
MR. BROWN: Object to the form of the question.

THE WITNESS: I don't know enough of the details of those to make a, uh, sensible statement.
BY MR. MURGATROYD, III:
Q. Okay. Well, let me just show you something real quickly.
Oh, let me go back on the record. I.
Um, I notice in going through the exhibits during lunch that we have two 18s, so I'm going to change the Paxil label which is PX:L22 to 18-A. And then there's a 19. This would be Exhibit 20.
MR. BROWN: Before we go on, can you identify the other document with the 18 number --
MR. MURGATROYD, III: Yeah.
MR. BROWN: -- so that the record is clear.
MR. MURGATROYD, III: Okay. Eighteen is the Minutes of Discontinuation Meeting 7/11/97.
So now we're up to 20.
MR. BROWN: Thank you.
(Temple Deposition Exhibit No. 20 was marked for

Identification.)
BY MR. MURGATROYD, III:
Q. Okay. Let me just so you this chart. And I have one -- I actually spent my lunch copying this just for you so you'd have a copy.
Doctor, what I'm showing is a chart that compares the Paxil withdrawal symptoms to the withdrawal symptoms of Xanax and Valium.
(Witness reviewed document.)
MR. BROWN: I'll object. Lack of foundation. It's not clear what this document represents, where it's from, and date.
MR. KELL: Is there a question pending?
MR. MURGATROYD, III: No. I'm sorry. I thought he was reviewing the document.
THE WITNESS: Yeah.
BY MR. MURGATROYD, III:
Q. Okay. In looking at this chart, uh, can you differentiate between the withdrawal sypmtoms caused by Paxil as those from Xanax or Valium?
MR. BROWN: And again --
MR. KELL: Object. Uh, no foundation.

Um, if --
MR. MURGATROYD, III: Well, here. Do you want to see the buying label?
MR. KELL: I'll -- I'll let him -- if you want him to assume that your --
MR. MURGATROYD, III: That these are correct.
MR. KELL: That these are correct. And you want to ask him some limited questions about them, I won't cut him off at this point, but it's based on the assumption that these -- that document is correct.
MR. MURGATROYD, III: That's fine.
MR. BROWN: And -- and I'll restate my objection --
MR. MURGATROYD, III: I got it.
MR. BROWN: -- as well.
MR. MURGATROYD, III: You don't have to. I got it the first time.
THE WITNESS: They overlap considerably.
BY MR. MURGATROYD, III:
Q. Okay. Now, what, um -- how do you

define physical dependence?
A. Well, physical dependence has, um, pharmacologic definitions where you assume some receptor has increased in the amount or things like that. But I think basically it means that when you try to stop the drug, there was some kind of withdrawal syndrome. That's what physical dependence means.
Q. Okay. And are you aware that, um -- I mean have you reviewed any of the MedWatch reports regarding serious or severe withdrawal reactions of people experiencing coming off of Paxil?
MR. BROWN: I will object to the form of the question.
THE WITNESS: I haven't reviewed the specific MedWatch reports. I have no doubt there were some reports of serious reaction.
BY MR. MURGATROYD, III:
Q. Okay. Are you aware of the ones where people discussed, um, moving refrigerators to try to find the pill that they thought they dropped behind it because they were experiencing such

severe withdrawal reactions --
A. No.
Q. -- they just want --
A. No, I would not be aware of those.
Q. Okay. Or the ones where the people going on vacation and forget their Paxil and go begging to a pharmacist?
A. No. I've told you I haven't read any of the reports.
Q. Okay. Now, do you know, as you sit here today, how many people in the United States are actually hooked on Paxil and can't get off no matter how hard they try?
MR. BROWN: Object to --
MR. KELL: Object to the form.
MR. BROWN: -- the form of the question.
MR. KELL: Same objection. My objection is specifically to the word "hooked."
MR. MURGATROYD, III: Okay.
BY MR. MURGATROYD, III:
Q. You can answer.
A. Yeah. Yeah, I -- what I can't tell is

what the basis for that is. And I find it implausible that people can't get off of it. As far as -- as far as I understand it, if you taper sufficiently you can get off of it. Uh, maybe there's evidence to the contrary but that's my impression.

Q. Well, have you seen the evidence that's to the contrary of the actual label for Paxil?

A. What label would that be?

Q. Well, let's take a look at that.

(Counsel briefly confers with co-counsel.)

BY MR. MURGATROYD, III:

Q. Well, let me strike that. I'll come back to that.

So you're not aware that there are people in this country today who -- and children included, that no matter how hard they try and how conscientously theirs doctors are in weaning them that they cannot get off Paxil without excruciating and debilitating withdrawal reactions?

MR. BROWN: Object to the form of the

question and the speech provided.
THE WITNESS: Yeah, I would not be aware of that. But I don't know whether I would believe it it until I saw the cases, what attempts they made to get off of it, how they went about it and so on. I mean, the usual idea with withdrawal reactions from, you know, Beta Blockers, Clonidine, and other things because they cause, uh, withdrawal reactions or discontinuation reactions, whatever you call them, is that if you taper it carefully enough usually you can get off of it. That's even true for benzodiazepines, as far as I know.
If there are exceptions to that, I don't know about it. I'd have to see the details.
Q. Is that something important for the FDA to know?
A. If there's literally people who couldn't get off of it, that would be of interest.
Q. Okay. How would you like that presented to you in forms of -- how would -- how would you like that information presented to you? Affidavits? Um, doctors' testimony? What would

be --
A. Well, you --
Q. -- the most --
A. You need -- -- you need detailed reports.
Q. Correct.
A. Describe it probably it would be best to have the physician who tried to manage it say what he or she saw and so on. You need details of the case in how it was tried.
Q. And how many -- how many of those would you want before you would consider it a problem?
A. I don't know. I got to see it.
Q. Okay. Would -- would --
A. I don't know the nature of the reports yet --
Q. Okay. Perhaps --
A. -- or what the --
Q. Woult it be --
A. Or why it --
Q. -- a hundred?
A. -- why it is they wouldn't get off or

what it was.
Q. Okay. Well, would a hundred reports --
A. Well --
Q. -- tell you anything? I just want to get an idea --
A. No --
Q. -- of the magnitude.
A. You -- you can't answer that. I need to see the reports and see how strong they are. And you need to see the circumstances under which they were developed. Uh, I can't tell you how many. But you can feel free to send them our MedWatch or in a copy me to and I'll get them to the right place.
Q. Okay. Have you -- have you prior to submitting your declaration in the In Re Paxil case, did you go into the MedWatch reports to see how many reports there were of Paxil discontinuation and withdrawal?
A. No, of course, not. I wasn't addressing the question of Paxil withdrawal.
Q. Okay.

A. We all agree that there's a withdrawal syndrome.
Q. Okay. Um, as you sit here today, are you aware of how prevalent a problem that is?
MR. BROWN: Object to the form of the question.
THE WITNESS: No, I'm not. I haven't heard from the data to tell me.
BY MR. MURGATROYD, III:
Q. Okay. And, um, what kind data would help you to understand that? Internal studies by Glaxo SmithKline?
A. Well, what I really rather see is the results of controlled trials that show people trying to discontinue and see what fraction of them really can't. Um, that's the best kind of data, individual reports. You have to know a lot about the circumstances, and they're hard to interpret.
Q. Okay. I'm just trying figure out how -- what kind of information they give to you.
A. Um, right. You understand we don't -- we don't doubt that there's a -- call it what you

want -- a withdrawal or discontinuation syndrome for Paxil and probably many of the other anitdepressants, and that's not a doubt.

Q. Okay. I -- I -- I just don't know if you're aware of the severity of the problem. I just want to know if you're aware -- the extent or the severity --

A. Well, it isn't the awareness. I haven't seen data on how severe it is. That's of a nature that's considerable that I can consider. It hasn't be presented to me. Maybe it has been to others.

Q. Okay.

A. But, no, I have not seen that.

Q. Well, that's why I asked you if you had seen earlier the internal studies that Glaxo did on the probelem, whethor or not it had come to your attention.

A. Well, the --

MR. BROWN: Object to the form of the question.

THE WITNESS: The little bits you've showed don't communicate how severe 0.

MR. MURGATROYD, III: Okay.
THE WITNESS: -- it is.
BY MR. MURGATROYD, III:
Q. No, I understand.
A. Maybe I didn't read all of them but --
Q. No, you didn't. That was -- remember, that's the document that had about 30 tabs on it and --
A. Yeah. One of them said the rate of discontinuation syndrome was the same as the Tricyclic, so I don't know how helpful that was.
Q. Okay, that's fine. And, again, I'm just trying to see what kind of information is helpful to the FDA. Um --
A. In -- in -- in those also it's not easy, although there may be other data that go to this to tell whether it's the person's underlying condition coming back or something new that represents withdrawal. Certainly, excitability sounds like it's something new. Becoming depressed again, it's hard to know.
Q. How about electrical zaps?

A. That sounds new.
Q. Okay.
A. Those things sound new.
Q. Okay. Um, do you know how the -- how -- how a doctor who is presented with a patient who is going through Paxil withdrawal can differentiate whether it's relapse or a withdrawal?
A. Well, I think he'd bring the same kind of thinking to it that I just asked you about. If what the person is experiencing is renewal of the symptoms that got him on the drug in the first place, he would have trouble knowing which it was. So he might try another drug. I mean, you know, I don't know. I don't deal with patients very much.
If it was excitability and things like that, probably they'd go back and start the drug again with a lower dose and try to retaper. But for some kinds of things, you won't be able to know.
Q. But are you aware that in foreign labels, for instance, GSK tells doctors how to differentiate between relapse and withdrawal

effects?
A. No.
MR. BROWN: I'll object to the form of the question. And lacks a foundation.
THE WITNESS: In any case, I'm not aware of that.
BY MR. MURGATROYD, III:
Q. Okay. Let me, uh, let me see if I....
MR. MURGATROYD, III: Let me show you what I'll mark as the next exhibit.
What are we up to, 21?
I'm not going to ask you Gerald to help me out.
(Laughter.)
BY MR. MURGATROYD, III: What I'm going to show you is the, uh, Paxil label for Switzerland. In Switzerland they call it Seroxat or Deroxat. Deroxat, D-E-R-O-X-A-T.
(Temple Deposition Exhibit No. 21 was marked for Identification.)
MR. MURGATROYD, III: Mark --

MR. BROWN: What's this from.
MR. MURGATROYD, III: -- here you go.
MR. BROWN: Yeah, okay.
THE WITNESS: Okay. Um, I don't know the basis for that. It may be true.
BY MR. MURGATROYD, III:
Q. Okay. Do you have any reason to disagree with this statement that -- that GSK has made from its label for Switzerland?
A. I just -- no, I wouldn't say I would have a basis for disagreeing. I don't know the basis for that statement. It does seem likely that renewed depression would take a little longer to return but --
Q. Okay.
A. -- I don't know that.
Q. And --
A. And if I understood what some people have said in their reports, depression was something that returned very early --
Q. Okay. Well, this --
A. -- so --

Q. The section I'm referring to is the symptoms, meaning withdrawal symptoms usually start abruptly within a few days of discontinuation and can be distinguished from relapse symptoms, which are occur later and build up gradually.

A. I know. I guess I'm referring to some descriptions of the cases that you described earlier where people became very badly depressed right away after stopping the drug.

Q. No, no. They weren't depressed. They were drug craving it. That's what I was trying to -- well, people who --

A. I mean, they had these symptoms.

Q. Yes, correct.

A. Yeah. Okay. I -- this is not implausible. I don't know. I can't -- now true -- whether it's true or not, I just don't know the data.

Q. Okay. Did -- when you formulate the -- or work with the labels for, in this case, Paxil, do you ever look at what the drug companies, such as GSK, is doing with its label in other countries?

A. Yeah. They're supposed to tell us actually if there are important changes in other countries. Whether what they do -- is this -- is this Gustan, Switzerland or --

Q. This language comes from the Swiss label. They've been -- they've been worried about discontinuation for many, many years.

A. Yeah, I don't know that we would usually look at the Swiss labeling,, but we would be aware of changes of, uh, you know, changes that the EMEA made, and things like that.

Q. How about the Italian authorities?

A. No, that would be more unusual.

Q. Okay. So -- I'm sorry. Look to the European regulatory?

A. Well, -- I mean, as you probably know uh, some drugs are pretty much still country by country. If they --

Q. Right --

A. -- were developed a while ago. And many of the newer ones are -- have a common language and it's supposed to be translated appropriately but

similarly in all the -- we'd be more likely to know what they say especially if there's a major change.

Q. And which country would you defer to or look at?

A. Well, it isn't the country. It's the whole European Union.

Q. Okay, okay. The European Union.

A. We're more likely to know about those. You know, we are -- we are -- there's been something in the paper about changes in Great Britain on the labeling for a number of antidepressants, just this morning.

Q. Right. Okay.

A. So we've become -- we've become aware of those. We might become aware of others, but it's, uh, catch as catch can.

Q. Okay. Now, would you agree that the people who can't get off Paxil without experiencing severe withdrawal sypmtoms or to that degree dependent upon the drug to get through a day?

MR. BROWN: Object.

MR. KELL: Object to the form.

MR. BROWN: Object to the form of the question also.
MR. KELL: You can answer, if you can -- if you can answer.
THE WITNESS: Well, I have to tell you I don't know that there are such people.
BY MR. MURGATROYD, III:
Q. That -- that's --
A. I've heard --
Q. -- what shocks me because, you know, I have in my office --
A. Yeah.
Q. -- in excess --
A. But it doesn't mean --
Q. -- of 10,000 reports.
A. It's -- well, okay. Right. There -- I mean --
Q. I mean in excess and they are unsolicited. I didn't want them.
A. Yeah. Um --
MR. BROWN: Is this question, Mr. Murgatroyd?

THE WITNESS: It's at odds with everything one knows about all other, quote, dependency situations. There's always thought to be a way you can get people off.

Now, you know, I'm -- that's -- that's not my business so I don't know that in a hands-on way. But the whole idea is that you can taper it and eventually the receptor goes back or whatever it is. Whether it's narcotics, which are obviously highly addicting and, you know, create tremendous dependcy or whatever it is. So it would surprise me that there's somebody who has, in a sense, a permanent change, uh, from having taken the drug. That would be at odds with everything one knows. It doesn't mean it's not true.

BY MR. MURGATROYD, III:

Q. Okay.

A. But it's very surprising.

Q. Would you find it more likely with a child or an adult if that's -- if that condition --

A. I have --

Q. -- occurs?

A. -- I have no opinion on that.
Q. Okay. Now, if a person is on -- assuming there are people out there who cannot get off of Paxil, just assuming that --
A. Okay.
Q. -- would you agree that they have developed a physical dependence upon the drug?
MR. BROWN: I'll object again for the --
MR. KELL: Objection. Calls for an expert conclusion. It's not what he's for.
MR. MURGATROYD, III: Well, it's getting whether he has --
MR. KELL: If he has --
MR. BROWN: Objection.
MR. KELL: -- if he has any opinion that he wants to give, I won't instruct him not to give it.
MR. BROWN: Will also object on the basis of the form of the question.
BY MR. MURGATROYD, III:
Q. After all that you still got to --
A. Well, I would call those things physical

dependency.
Q. Okay.
A. That's what a continuation syndrome is.
Q. Okay.
A. It's because there's a physical dependency.
Q. And --
A. And -- those are things I don't know about. As I -- for reasons I just gave you, the idea that it becomes permanent is very hard to swallow based on all other experience. It couldn't be true.
Q. Okay.
A. That would be surprising.
Q. All right. Well, I hope to surprise you.
Um, would you agree that the term physical dependence and habit-forming are comparable terms?
A. No.
Q. Okay. What would -- what would be the difference between those?

A. Again, habit-forming doesn't have a precise definition. People I'm sure use it differntly. But what I said in my, uh, in my document is that it unusually refers to, um, a drug that people feel good about taking. It gives them elation. It makes them feel happy. And the models -- the models are narcotics, which give you an appropriate buzz.

And benzodiazepines, um, most people don't think of, uh, any of the antidepressants as having those properties. And there are other drugs where nobody would be believe for a second that there's any pleasure in taking the Beta Blockers, and things like that. They plainly have a withdrawal syndrome. So I don't think of them has habit-forming. It doesn't mean there are consequences to the dependents. You can have a heart attack, uh, if you stop your Beta Blocker to quickly, so it doesn't mean it's trivial. But I don't count that aas habit-forming.

Q. Okay.

A. So a lot depends on the sensations you

get when you -- when you take the drug. And that's -- uh, that's all I attempted to say and that's what I still think. Uh, I note that in their announcement about antidepressants. Uh, that's more or less what the, uh, British have said --

Q. Well --

A. -- yesterday.

Q. Okay. Well, let's -- actually, let's, um -- let's get to your declaration, which we'll mark as Exhibit 20 --

MR. FARBER: Two.

MR. MURGATROYD, III: Two, thank you.

(Temple Deposition Exhibit No. 22 was marked for Identification.)

BY MR. MURGATROYD, III:

Q. I'll show that to you, Doctor. Okay. Okay. You've reviewed it. Right?

A. Um, yeah.

Q. Okay.

A. Not necessarily in the detail that will

prove necessary but we'll see.
Q. Okay. Um, you signed that declaration; is that correct?
A. Yes.
Q. Oka. And that's -- that's your signature?
A. It looked like it when I saw it before. Sorry, I'll have to get to the document. Yes.
Q. Okay. Um, you didn't write this declaration, though, did you?
A. I wrote parts of it. I got help in describing my job and stuff.
Q. Okay. Well, I mean, did you sit down and type this?
A. No.
Q. Okay. Who -- did somebody --
A. I don't --
Q. -- give you --
A. I don't --
Q. -- this you for --
A. I don't type.
Q. Okay.

A. I, um, I saw and contributed it to drafts and, uh, satisfied myself that I believe what it said.
Q. Who prepared the first draft?
A. I don't remember.
Q. It wasn't you?
A. I'm sure -- probably not.
Q. Okay. I mean, I know your a busy man, so I don't --
A. Probably not.
Q. -- think this is the kind of thing that you're going to sit down and --
A. Well, you can see it comes to many different, uh, parts of it. The parts on what habit-formings means, I certainly, uh, wrote most of it, but I didn't, for example, do the parts about what the Ninth Circuit noted.
Q. Okay. Well, let -- let -- why don't we kind of go through it and see which parts -- was there -- was there any part that you -- you originally drafted or was it all drafted on your --
A. I --

Q. -- behalf?
A. -- I don't remember that.
Q. Okay. You don't recall writing any of this. Correct?
A. Well, no, I don't -- I didn't say that. Um, I'm sure I wrote or contributed to or helped people get ready to write what my various jobs were. I don't think that's the part you care about particulary.
Q. Okay.
A. Um .... and I believe I had the most major input into parts five and six.
Q. Okay. Would you believe the other parts were drafted for you?
MR. BROWN: I'll object to the form of the question. I think it's been asked and answered.
MR. MURGATROYD, III: No, I'm just asking him if he can narrow it down, Mark.
THE WITNESS: I'm sure I had more help on those.
BY MR. MURGATROYD, III:

Q. Okay. Now, we'll get into -- into those parts, but, um -- well, actually before -- let me just go back to one thing. We're talking -- we're talking about the Doctor's ability to differentiate between relapse and withdrawal effects. Right?
A. For some of them, for some parts of it.
Q. Right. Did, um -- do you have any idea of the amount money that has been wasted in this country by doctors misdiagnosing withdrawal effects?
MR. BROWN: I'll object --
MR. KELL: Object.
MR. BROWN: -- to the form.
MR. MURGATROYD, III: If you know.
MR. BROWN: Object -- object to the form of the question.
BY MR. MURGATROYD, III:
Q. Are you aware that doctors, meaning many doctors see patients with withdrawal effects and think there's something else and send them out for unnecessary tests?
MR. BROWN: Object to the form of the

question.
MR. KELL: Same objection.
BY MR. MURGATROYD, III:
Q. Are you aware that happens?
A. No, I have no idea.
Q. Okay. Are you aware that, uh --
A. Actually, I would have thought that the discontinuation or withdrawal effects of Paxil have been pretty well-known for quite a while so -- but I don't have any information on the exact numbers or percentages.
Q. Okay. You haven't seen the Harvard report that shows that 75 percent of prescribers are not aware of them?
A. No, I am not.
Q. Okay. Are you aware that, uh, people have gone through unnecessary surgery because they're misdiagnosed -- the withdrawal effects from Paxil were misdiagnosed?
MR. BROWN: Object to the form of the question.
THE WITNESS: Surgery for what?

BY MR. MURGATROYD, III:
Q. God knows. To repair -- to repari the withdrawal reactions.
A. I --
MR. BROWN: Object to the form of the question.
THE WITNESS: I don't understand what that would mean but you --
BY MR. MURGATROYD, III:
Q. Okay. Well, I'm just tell you. There are people who have --
A. Well, the complaints that are listed there as withdrawal reactions are surgically or remediable, so I don't really know what you mean.
Q. Well, are you aware that people have gone through brain scans because of the electrical zaps in their heads?
MR. BROWN: Object to the form of the question.
THE WITNESS: Not aware. It wouldn't surprise he.
BY MR. MURGATROYD, III:

Q. Okay. Are you aware of how many thousands upon thousands have been done that were not needed?
A. No.
MR. BROWN: Object to the form of the question.
MR. MURGATROYD, III: Okay.
BY MR. MURGATROYD, III:
Q. Are you aware that, uh, doctors, uh, often increase the dosage of the drug to handle withdrawal effects?
A. You mean restore the dose to --
Q. No. Actually --
A. -- where it had been?
Q. No. Increasing it.
A. I don't understand the question. They've been tapering it, have they --
Q. Yes.
A. -- where they've stopped it?
Q. Yeah -- no, they're trying to get off it.
A. Trying to get off of it. So instead of

going to where they were they raise it higher than they had been before?
Q. Correct.
A. No, I'm not aware of that. I don't quite know why anybody would do that.
Q. Okay. Um, would you agree that one way to determine that a -- if a drug -- to determine if a drug is addictive is to look at the affects on the neonatals?
A. You mean see whether there's a withdrawal syndrome -- syndrome?
Q. Correct.
A. It can tell you -- I think that is one way to see whether there's physical dependence.
Q. Are you aware of the various studies that have been done that shows newborns suffering seizures and other withdrawal symptoms from Paxil mothers?
MR. BROWN: I'll object to the form of the question. Lack of foundation.
THE WITNESS: Unfamiliar with reports of neonates having withdrawal syndromes, but, again,

it's -- lots of neonates have seizures. So it's not easy to know in any given case whether that was the reason or not. But I'm in a rough way familiar with, uh, those reports. I haven't read them.

BY MR. MURGATROYD, III:

Q. Okay. But you're aware there's literature out there that documents Paxil mothers delivering babies who go through withdrawal and require, uh, extraordinary or extraordinary medical attention?

A. No, I do --

MR. BROWN: Again --

Let -- let me get my objection --

THE WITNESS: Yeah --

MR. BROWN: -- on the record --

THE WITNESS: -- go ahead.

MR. BROWN: -- in the first place.

Object to the form of the question. And lacks a proper foundation.

THE WITNESS: Yeah, I -- just as a general matter, when you assure me that something is -- I have no way of evaluating the quality of

the data or how strong it is. So I can't, in any sense, agree that I know it to be true because I haven't read it.

BY MR. MURGATROYD, III:

Q. Okay.

A. Uh, I have heard about withdrawal syndromes in neonates, but I -- that's the extent of what I have heard.

Q. Okay. And, again, the question --

A. I don't -- I don't find it especially implausible.

Q. Okay. Would that indicate to you, though, as a physician, that is a drug of addiction that's causing it?

A. Well, addiction carries a lot of weight. I think there's a physical dependence. I don't think there's any doubt that these drugs have a withdrawal syndrome on some of the drugs. Maybe all of them.

Q. Okay.

A. I mean, I don't think that's a --

Q. Okay.

A. -- debate.
Q. Okay. When, um, did you first become informed that you were going to be submitting a declaration in the In Re Paxil case?
A. Wow. I have no idea. Sometime before the one I signed but I don't remember when.
Q. Okay. Um, did you have any, um, input into whether or not you were going to get involved in this legal case?
MR. KELL: You can answer that question yes or no.
MR. MURGATROYD, III: Correct.
MR. KELL: And that's all.
THE WITNESS: I mean, I can't say. I don't quite remember.
MR. KELL: Well, you can -- if you don't -- mean if you have --
THE WITNESS: I -- I don't remember. I just don't remember the discussions. Um, I imagine if I had said no way, I wouldn't have done it. But I thought the distinction was real and I signed the -- I agreed to do it because I thought it was

correct.
BY MR. MURGATROYD, III:
Q. Okay. Um, were you aware that your help in this matter was requested by a drug company?
MR. BROWN: Object to the form of the question.
MR. KELL: Object to the form.
THE WITNESS: No, uh-uh.
BY MR. MURGATROYD, III:
Q. Are you aware that a GSK lawyer called up the FDA and asked for their help?
A. No.
MR. BROWN: Object --
MR. KELL: Object.
MR. BROWN: -- to the form of the question and lacks proper foundation.
MR. MURGATROYD, III: Okay.
BY MR. MURGATROYD, III:
Q. Are you aware that when the FDA was interviweing the cases such as this that it has to go through what's called the solicitor general's office?

MR. BROWN: Object --
MR. KELL: Object --
MR. BROWN: -- to the form of the question.
MR. KELL: -- to the form of the question.
BY MR. MURGATROYD, III:
Q. I'm just asking if you're aware of that.
A. I know. I'm waiting for everybody to say what they want to say.
(Laughter.)
Q. Oh.
A. The answer is: No.
Q. Okay. Um, are you aware that the solicit general of the United States is Mr. Brown's former law partner?
MR. BROWN: Object to --
MR. MURGATROYD, III: Are you aware of that --
MR. BROWN: -- the form of the question while he's changing the tape.
THE WITNESS: No.

BY MR. MURGATROYD, III:
Q. Were you aware that, um, Daniel Troy was a drug company attorney prior -- immediately prior to becoming the chief counsel for the FDA?
MR. BROWN: Object to the form of the question.
THE WITNESS: I'm sure I knew that he represented people, including drug companies.
BY MR. MURGATROYD, III:
Q. Okay. Were you aware that he represented Pfizer?
A. No.
Q. Did he represent GSK to your knowledge?
A. I have no idea who he represented.
Q. Okay. Were you -- did you --
A. Mostly Daniel Poper's group. That's the main thing I remember.
Q. Okay. Maybe -- you might want to spell that for the court reporter. He's --
A. P-O-P-E-R.
Q. Okay. Uh --
A. That's -- he writes advertisement

editorials in the Post.
Q. Okay. Um, when your -- when your involvement was brought into this case, was there a document that memorialized that, that -- is there some waiting if I were to do a FOIA request that would tell me why you got involved and how you got involved and who involved you?
A. Certainly nothing written by me or anything that I'm aware of.
Q. Okay.
A. But I told you why. I thought I knew what habit-forming meant and what it didn't mean. And that's all.
Q. Okay. Would you -- you agree that the ad -- it's a TV ad we're talking about. Right?
A. Yes.
Q. And that that's for the general public's consumption?
A. Yes.
Q. Okay. And you agree that it's called DTC ads, right, direct to consumer?
A. That's what they're called.

Q. And they're effective. Correct?
A. That's harder to say. I suppose they are or nobody would do them.
Q. Okay.
A. There's some debates about how -- how effective they are.
Q. Well, have you seen the statistics of about how many people who actually see an ad and then go in to the doctor and say, Yeah, I want that because that looks like that's what I need?
A. We've done a survey on that very matter.
Q. Okay. And what -- what did you come up with?
A. Some people do that and some people get the drug and some people don't. Some people get another drug. I'm just saying there are debats about how effective and how much of a value for money there is.
Q. Do you --
A. A lot of people do it.
Q. Do you know why --
A. I don't have an opinion about that so --

Q. Okay.
A. -- there's no point in pursuing it.
Q. All right.
A. I don't -- I don't -- I don't know.
Q. Well, you understand that this is one of the few countries on the earth that allow that kind of advertising. Right?
A. Yeah, one of two I think.
Q. Yes. New Zealand being second --
A. Right.
Q. -- correct?
And was that decision to allow these types of ads, uh, made since you've been at the FDA?
A. Yes. We don't actually think of it as a decision to allow it. We, uh, have always said that it was allowed under law. And the only question was how to go about it in such a way that you're not violating the regulations.
Q. Okay.
A. But we think the law permits it for better or worse.

Q. Okay. And you agreee that the contents is being shown to people other than doctors and psychiatrists?
A. That's what it means.
Q. Okay. So the words such as "habit-forming" may mean something to the person who's sitting on their couch in their house who has a high school education as opposed to a psychiatrist or a doctor; is that correct?
MR. BROWN: Object to the form of the question.
THE WITNESS: Let me be clear what your asking. Could -- could any given phrase mean different things to a medically trained person than a less trained person?
BY MR. MURGATROYD, III:
Q. Yes.
A. Surely.
Q. Okay. But you understand that this ad is going out to people who are less trained?
A. Yes.
Q. A vast majority?

MR. BROWN: Objection.
BY MR. MURGATROYD, III:
Q. The vast majority of the people who have seen this ad have had no medical training?
A. Yes, that's who perceived direct-to-consumer advertising.
Q. Okay. Who would not know a technical definition of the word "habit-forming?"
A. I don't think it is a technical definition. And that's what I was trying to say. There is no technical distinction. I was really describing how the words are generally used.
Q. Okay. Did you do a survey to see how --
A. No.
Q. -- the public understands that word as it's used by Glaxo SmithKline?
A. No.
Q. Okay. Do you know what percentage of the people who were surveyed thought it meant they could stop the drug whenever they wanted to?
A. I don't know and I'd have to see the nature of the questions in how exactly it was

asked, so -- but I don't know the survey you refer to.

Q. Okay. So you don't know what percentage of people who were surveyed thought that non-habit-forming meant that they could take the drug as they wanted to?

MR. BROWN: Object to the form of the question.

BY MR. MURGATROYD, III:

Q. They can take it occassionally. What percentage of the people believe that?

A. Well, you probably could take it occasionally. I don't think that's the issue. The issue is whether you can stop it when you've been on it for awhile.

Q. Correct.

A. Right. No, I did not -- we did not do a survey to find that out.

Q. Okay.

A. DDMAC did not do a survey when they found that out -- when they decided that that was not a violation.

Q. Well, let me ask you about DDMAC. Did -- are -- are you saying that you personally reviewed this ad before it was shown on TV?
A. No.
Q. Okay. Did, um, did anybody in your department review it to your knowledge?
A. Well, what my -- what it says is that DDMAC reviewed them and thought they were acceptable.
Q. Well, I know. But who -- who at DDMAC?
A. Oh, that's knowable, but I don't know.
Q. Well --
A. I mean you're asking me what person. I don't know a person.
Q. I mean, do you know if any person -- have you -- have you talked to any of your subordinates to see who -- who approved the ad or who approved the --
A. I did --
Q. -- ads?
A. I did not find who did. The head of the office, Tom Abrams, would have been part of that

decision.
Q. Did the person who reviewed the ads specifically look at the issue of whether a nonhabit-forming is misleading to the consumer? Is that -- that specific one --
A. Yeah, I don't --
Q. -- issue.
A. -- I don't know that.
Q. Okay. Um, would you agree that if GSK think it's misleading that it's misleading?
A. No. But it would be a piece of evidence.
Q. Okay. Do you think that would be an important piece of evidence if they, through their analysis, believed it was misleading?
A. Let's be specific. If they think it's mis -- if they think it's misleading to say, quote, not habit-forming --
Q. Correct.
A. -- I'd be interested in knowing whey they think that.
Q. Okay. Were you, uh -- do -- do you --

so I have this straight, how do you differenitate addiction and not habit-forming? Are those -- are those synonymous -- synonymous terms?

A. I did not address the question of addiction. I think addiction carries some of the freight of, um, being something you love. And -- but they're -- they're really -- they're really quite diffent things. Let me give a couple of examples I gave before. We widely believe that things like, um, cocaini and marijuana are addicting or habit-forming, but they claim they don't cause physical dependency.

Q. Okay.

A. So the two are really quite separate things. People can't get off of them because they like the buzz. They love it. It's appealing. It makes them feel good.

Q. Well, let me just stop you for a second. No, I'm not talking about physical dependence. We've passed that.

A. I understand.

Q. I'm just talking about addiction and

habit-forming.
A. What I'm --
Q. Those two terms.
A. What I'm saying is that the terms addiction and habit-forming usually refer to those kinds of feelings that make you want it over and over and over again. Um, there are some well-known physical dependencies that I think no one would describe or consider addiction, like to Beta Blockers. I mean, nobody thinks if someone is addicted to Beta Blockers. It wouldn't make any sense, because there's no pleasure in taking a Beta Block. There is some displeasure in taking it actually.

But there is for sure a withdrawal syndrome and it can be serious. So what I tried to do is distinguish between those two things. So there is physical dependence to Beta Blockers or Clonidine and drugs of its class you have to take with them. There can be serious consequences to not tapering them well enough. And some people have to be put back and tapered more slowly. And

there are individual serious consequences. That is a separable thing. And neither of them is trivial. It's not a statement that they're unimportant. I just think they mean different things. And that's what I said.

Q. Okay. Well, let me -- let me show you an ad.

A. And then I have to say if you tell somebody that's there consequences of discontinuing it, having to communicated the idea that there's a physical dependency potential, I mean, I think you could say that you do now. Maybe people read some things better than another. I can't -- I can't go to that. But that communicates the fact there's a physical dependency. And that could be a very serious physical dependency or less serious, but that's what physical dependency is. And that's a real thing. It's a potential problem.

Q. Okay.

A. It's not what I -- it's not the term that I think people mean when they say habit-forming.

Q. Okay.
A. That can be something else. That's the thrust of my affidavit.
Q. Okay. I understand that and I appreciate that. Let me show you what I think --
How far have gotten along here?
A. Whoop, this is mine.
MR. KELL: We're at 22.
MR. MURGATROYD, III: No, no. I just want to go to the next one. We're going to come back to that. But I just wanted to show you what I've marked as the next exhibit. And I want to --
MS. NORTON: Number 23.
MR. MURGATROYD, III: Twenty-three it is.
(Temple Deposition Exhibit No. 23 was marked for Identification.)
BY MR. MURGATROYD, III:
Q. And here it is. This is a Patient Question & Answer Guide on Paxil. Let me show that to you, please.

A. This is -- this is the company's thing?
Q. Yes, this is the company's thing.
A. Okay.
Q. And -- well, I marked one particular section the addictive section on there. And, um, is it -- this is given to patients by GSK. Is this -- would this fall under advertising?
A. Um, yeah. We might call it commercial labeling, but it's one of those two.
Q. Okay. I mean is this something that would come to your attention if it was found to be false or misleading?
A. Yes.
Q. Okay. Now, you'll see that, um, in the section where its tab there is, Is Paxil addictive? And you see the first sentence, Paxil has been studied both in short- and long-term use and is not associated with dependence or addiction?
A. Yes, I see it.
Q. Okay. Is that language, uh, to your knowledge consistent with Paxil's label? It may be helpful if I showed you the label.

A. Well, the difficulty with all of these things -- I -- I don't think that fully conveys the problem. If -- if they had gone on to then say there's a withdrawal syndrome, I might be happy with that. But in the absence of anything that explains there is something sort of related to those things, I don't think that's a -- I don't think that's complete enough.

Q. Okay. Well, let's actually --

A. It does -- it does however -- well, see, it refers to benzodiazepines and associate them with physical dependences. And that -- it could be said to imply that their drug doesn't. But it seems fairly clear there is something that can be described as physical dependence. And that's what your -- that's what your withdrawal or dis continuation syndrome is caused by.

Q. Right. And -- well, let me -- let me show you what I'll mark as Exhibit 20 -- I'm sorry is that 20 --

MR. BROWN: Twenty-four.

MR. MURGATROYD, III: Four. Thank you,

Marci.

(Temple Deposition Exhibit No. 24 was marked for Identification.)

BY MR. MURGATROYD, III:

Q. Let me actually show you the label for Paxil. And I highlighted -- I mean, I tabbed the part that you may want to look at.

A. This is the current label?

Q. That's the current labe, yes, sir.

A. So I'm looking for the precaution section?

Q. No. Actually we're going right back back to the dependence section, abuse and dependence section. Do you see that?

A. Oh, okay.

Q. And what does the first sentence say?

A. Is not a controlled substance. You don't mean that?

Q. No, sorry.

A. You mean Paxil has not been systematically --

Q. Yes.
A. -- studies in animals for its potential for abuse, tolerance or physical dependence.
What date is this label? Sorry I just need to know. I'll be back in a second.
MR. FARBER: It's current.
BY MR. MURGATROYD, III:
Q. Yeah, that's the current Paxil label.
A. Okay.
Q. Would that statement in the dependence section of that label be inconsistent with the statement in that brochure that I handed you before?
MR. BROWN: Before he answers the question, I'd like to have the record reflect that the date of the brochure that you've asked him to evaluate, because I don't think that's been identified.
MR. MURGATROYD, III: Okay.
MR. BROWN: If you could do that --
MR. MURGATROYD, III: I just want to ask him --

MR. BROWN: -- that would be helpful.
MR. MURGATROYD, III: I can -- well, here. The easiest way is I can show you a label that goes way back.
MR. BROWN: I'm not -- I'm not talking about the prescribing information. I'm talking about the brochure.
MR. FARBER: The patient guide.
MR. BROWN: Can you just --
Right.
Can you just identify for the record the date on that particular patient guide.
MR. FARBER: Those numbers serial in the corner.
BY MR. MURGATROYD, III:
Q. July '97.
A. So that was at a time when the labeling was pretty quiet about all of these matters?
Q. Correct.
A. That would be the March 2001.
Q. All right.
A. -- labeling.

Q. Is that --
A. That may well be consistent with labeling. I don't think it's consistent with it current but --
Q. Okay. Well, let's look at the label that existed at that time.
MR. MURGATROYD, III: We'll mark it as exhibit -- Exhibit No. 25. Thank God for --
(Laughter.)
(Temple Deposition Exhibit No. 25 was marked for Identification.)
BY MR. MURGATROYD, III:
Q. Okay. Let me show you the pre-2001 label. And, again, I've marked the spot.
MR. BROWN: Can you identify -- yeah.
MR. FARBER: The spot that's there.
BY MR. MURGATROYD, III:
Q. Yeah. Do you see the part under Drug Abuse and Dependence?
A. Yes.
Q. The language is the same as in the

current label, correct, where it says, "Paxil has not been systematically studied in animals or humans for its potential for abuse, tolerance or physical dependence." Correct?

A. Right. The part about tolerance, I think, is at least -- and physical dependence are at least debatable. I don't think it's been subjected to -- there are standard tests you do for abuse liability. And I doubt a drug of this class would be subjected to that because there's no mentioned dates of suspicion.

Q. Right. So that statement in the brochure that you have --

A. Right. So --

Q. -- is false. Correct?

A. Well --

MR. BROWN: I'll object to the form of the question.

BY MR. MURGATROYD, III:

Q. Well, let's see. It says, Paxil has been studied both in short-term and long-term term use and is not associated with dependence or

addition.
A. I'm sorry. Say that again. It says has not been.
Q. Yeah. Not -- this -- the label says it has not been, but the brochure says it has been.
MR. KELL: Object to the form.
THE WITNESS: I see. I see.
MR. KELL: Object as to argumentative.
MR. MURGATROYD, III: No. I just asked --
MR. KELL: Its mischaracterizes each of the documents.
You can answer.
MR. BROWN: And I -- I join in those objections.
BY MR. MURGATROYD, III:
Q. Well, do you see Paxil's statement -- the GSK --
A. Uh-hmm.
Q. -- statement that Paxil has been studied both in long-term -- short- and long-term use and is not associated with dependence or addiction.

Do you see that? Correct?
A. Yeah. I'm just looking -- I'm just comparing. Give me a second.
Q. Yeah.
A. Uh, it doesn't say anything about abuse. The word "tolerance," it uses different language. Well, at a quick look they seem in odds with each other.
Q. Okay. Now --
A. But --
Q. -- are you aware --
A. -- I do notice that our labeling continues to say that and is somewhat contradicted by the precautions section.
Q. Correct. Would you, um -- were you aware that, um, in the U.K. GSK took out any reference in its drug advertising and labeling that if does not cause addiction?
MR. BROWN: Again, object to the form of the question.
THE WITNESS: No, I'm certainty not aware. Of course that's not -- that's directed to

physicians in the U.K.
BY MR. MURGATROYD, III:
Q. Well, actually let me show you the --
A. I presume.
Q. Let me show you why. Twenty-six?
MS. REEVES: Twenty-six.
MR. MURGATROYD, III: Twenty-six. Thank you.
(Temple Deposition Exhibit No. 26 was marked for Identification.)
BY MR. MURGATROYD, III:
Q. And upon -- I direct your attention to -- it's right here -- under the section titled "How to take your tablets." And if you would just take a look at that.
A. So this a letter from GSK to doctors in May 2003?
MR. BROWN: Can I see a copy, please? Do you have one?
THE WITNESS: Okay. Read it.
BY MR. MURGATROYD, III:

Q. Okay. Do you see that?
MR. BROWN: Hang on one second, please. Can I see them?
(Mr. Brown reviews document.)
BY MR. MURGATROYD, III:
Q. And the section I'm referring to is the part that says, While Glaxo SmithKline maintains that Seroxat -- that's Paxil in the Ukraine. Correct.
A. Hmm?
Q. Correct, Doctor?
A. Yes, yes.
Q. Okay. -- is not a drug of addiction. We learned from patient feedback that the statement Seroxat is not addictive, did not add the patient's understanding of what to expect whilst -- W-H-I-L-S-T. It must be British.
A. British.
Q. -- stopping Seroxat."
Do you see that?
A. Yeah.
Q. Okay. Um, do you believe that, uh,

Americans are entitled to the same information that these people in the U.K. are getting?

MR. BROWN: Object to the form of the question.

THE WITNESS: Right. I need to know more about the total contents. For example, if you were to emphasize to people that you mustn't stop abruptly, that there is a discontinuation syndrome and bad things can happen, and also called it nonaddictive, then I wouldn't know how that would add up. So I need to know more.

BY MR. MURGATROYD, III:

Q. Okay. Well, let's go to, um, to your declaration again. And let's go to paragraph 8, which I know is one of the ones that you may not have contributed to, but --

A. Eight.

Q. -- let's take a look at it.

A. Eight?

Q. Yeah, paragraph 8 on page 6.

MR. KELL: "In summary."

BY MR. MURGATROYD, III:

Q. And you state -- and, again, I'm not going to put these words in your mouth. It could be a laywer saying this. I don't think we know who wrote this. But it says, The agency concluded that the advertisements were not misleading because there is no scientific evidence that Paxil is a habit-forming drug and consumers are adequately cautioned ('Don't stop taking Paxil before talking to your doctor.')"

Now, as you sit here today, do you believe that that's an adequate precaution that they may experience severe withdrawal reactions --

MR. BROWN: Object --

Q. -- Don't stop taking Paxil before taking your -- talking to your doctor?

MR. BROWN: Object --

MR. KELL: Object --

MR. BROWN: -- to the form of the question.

MR. KELL: -- to the form of the question.

BY MR. MURGATROYD, III:

Q. You can answer.
A. You got remember something about direct-to-consumer advertising, and, that is, there's an assumption that the doctor is doing the doctor's job. So what we don't want is for people to be misled about the enormous benefits of the drugs or something like that. The specific details, though, we often might lead, uh, to them. and --
Q. Yeah. But you're -- you're saying that this, Don't stop talking to Paxil before -- don't stop taking Paxil before talking with your doctor is an adequate caution on withdrawal symptoms. And I -- I just -- if that was you --
A. No. See --
Q. -- would survey that to see if that was true?
A. No, we didn't do a survey.
Q. Okay. Did you know that Pfizer did do a survey?
A. No, I don't.
Q. Let's take a look at their survey.

MR. KELL: Did you mean to say "Pfizer?"
MR. MURGATROYD, III: I didn't mean to say Pfizer. I meant Glaxo SmithKline. Thank you. I get these drug companies mixed up.
THE WITNESS: The sentence also emphasizes that the whole thing is done under the guidance of the physician which is critical to this whole thing.
BY MR. MURGATROYD, III:
Q. Well, I understand.
MR. MURGATROYD, III: We're at 27, right, Marci?
(Temple Deposition Exhibit No. 27 was marked for Identification.)
BY MR. MURGATROYD, III:
Q. I say look at this next document.
MR. BROWN: Can I see that, please?
MR. MURGATROYD, III: Yeah.
BY MR. MURGATROYD, III:
Q. This is, uh -- what I've given you is a Beth Howard e-mail dated, uh, February 21st, 2002.

And it has a section where it says, Beth, In response to your inquiry, here are the findings from the first round of DTC storyboard testing around the issue of the new fair-balance line (Talk to your doctor before stopping Paxil.)

(Witness reviewed document.)

A. Okay.

Q. Okay. And you see that the participants who were surveyed who looked at this ad. Right? Didn't even notice the line. Right?

MR. BROWN: Object to the form of the question.

BY MR. MURGATROYD, III:

Q. So is that -- would you consider that that's an adequate caution, a line that nobody even notices?

MR. BROWN: I'm going to object to that because it calls for an answer based on an, um, an e-mail without the proper foundation associated with the survey and the questions asked based on the limited review of an e-mail.

MR. MURGATROYD, III: Fair enough.

BY MR. MURGATROYD, III:

Q. Doctor, you can answer the question.

A. Well, my main complaint is that you have to take into account the whole role of the DTC advertising and the fact that it's going to be used under physician guidance.

Q. Right.

A. So if the physician is aware of these things, then he can explain all those things.

Q. Yeah. But let me --

A. You don't -- you don't get the drug by yourself.

Q. No. But you could stop the drug by yourself. Do you think all patients go into the doctor and say, I'm not, you know, stop taking this drug?

A. I -- I don't think for one second that a direct-to-consumer ad is adequate instructions for a patient to take the drug. I mean that's just out of the question. The whole idea depends -- I mean, first of all, you don't get the drug. You have to go to the doctor to get it.

Q. Right.
A. The doctor is supposed to tell you a whole bunch of things about how to take it, what to watch for. You know, we were, uh -- we -- we've just added enormously to the instructions about making sure that, uh, your caregiver pays attention to it. There's a mountain of stuff, only one part of which is Don't stop abruptly.

So it never was my thought that, um, you need to capture all of that in the -- in the direct-to-consumer advertising. What we do want you to convey is the main scary business. So you'd decide whether to go bother your doctor about it at all.

So serious adverse rereactions have to be identified and things like that. And one's judgment about how big a problem the withdrawal is could probably influence how much -- how much you would think that needed to be in there.

Q. Okay.
A. I think that's -- that's fair. And if, you know, if it's really worse than we thought,

than you ramp up those kinds of observations.
Q. Okay. Assuming that it is worse than you think, do you think that the public is served by having Glaxo SmithKline state on TV that the drug is non-habit-forming?
MR. KELL: Object.
Q. Does that serve the public.
MR. KELL: Object to the form.
Q. That's your job is to serve the public.
MR. KELL: Object. It's -- and I object to that characterization. There's been no testimony that that's the doctor's job. If he has a person opinion as to whether the public is served by something or not, he can express that opinion.
MR. BROWN: I'll -- I'll join in that objection.
THE WITNESS: If I -- I -- I would say that if it were well documented that the -- but I don't -- to my knowledge, it is not. Um, I know you believe it is. If it's well-documented this is a major problem in the use of, uh, Paxil, worse than other drugs of its class, things like that,

that that should be noted, that withdrawal syndromes, or whatever you want to call them, should be noted clearly as one of the downsides of using the drugs. No question about that.

Q. Okay.

A. Whether -- whether you call it habit-forming or not, seems to turn entirely on what else is in there and on what -- how people react to the term. Um, it's not enough for me to know that they think have -- that some people asked cold in a survey of -- that I haven't seen, think habit-forming and those things are sort of similar, I need to know more about what a whole statement would be.

If, for example, people learned about withdrawal reaction or discontinuation reaction, and then said it's not habit-forming, that might be okay. I have to see the details.

Q. You don't think that -- that would be internally inconsistent to say, Hey, will you stop this drug. And they go --

A. No.

Q. -- through a severe withdrawal reaction to the extent that you're debilitating and can't leave your house but it's not habit-forming?

A. No. I think you need to tell people that it's -- if it is -- if it is, that it's debilitating and some people have great difficulty getting it off, if those things are true and well-documented, you need to tell them that.

The term "habit," it doesn't seem to me that it determines -- the terms on the term habit-forming because that -- is it -- what I said then was to believe is that it's sort of a term of art. Um, for what it's worth, I'm not alone in this. Um, um, you may think these are nice distinctions that only doctors could love. But, um, let me -- sorry. Just give me half a second.

The -- the, uh, recent, um, thing by video safety medicines expert report says in response to the question, Are these drugs addictive? It's been known for some time that all SSRIs cause withdrawal reactions on stopping while they do not appear to cause dependence in the way

that alcohol and opiates do. A significant number of patients experience withdrawal reactions on stopping or reducing their medicines. In some cases in some of these patients the withdrawal reactions are severe and disabling.

So I would endorse that way of putting it entirely. Um, whether it's what we meant by addiction and, you know, things to opiates, is sort of besied the point. What you really need to know is that there is a withdrawal syndrome.

Q. Okay.

A. But I don't think --

Q. But the --

A. -- the terms -- I don't think people usually think of that, Here's what doctors think. And maybe that's the problem. But only doctors think of that as addictive. I don't think that that doctors think of that as habit-forming any more than I think of a Beta Blocker withdrawal --

Q. Againl. We're

A. -- as addictive.

Q. Well, I got them. We're not talking

about doctors. We're talking about patients.
A. No. Listen, I'm saying we're -- we worry a lot about what --
Q. Patients --
A. -- messages patients draw. And we could, I suppose, with enough datat become convinced that, um, the use of the words needs to be modified. But the way the terms habit-forming is used historically and obviously they still are sort of reflecting the same point of view. It isn't quite what it -- that isn't what it means.
Q. Okay. Was there -- do you think that's helpful for them to have those words that Paxil is not habit-forming -- is that helpful to a patient?
MR. BROWN: I'll object.
THE WITNESS: Helpful is not our standard. Violative is our standard.
BY MR. MURGATROYD, III:
Q. Okay. So. If, in fact, 25 to 50 percent of the people who take Paxil experience withdrawal symptoms. So that's fact No. 1. Just assume that's true. And if, in fact, 10 percent of

those experience such severe withdrawal symptoms that they're disabled, okay, just assuming that, would you agree that the term Paxil is nonhabit-forming could, for some people who see it, be misunderstood?

MR. BROWN: Objection.

Hold on one second --

THE WITNESS: Go ahead.

MR. BROWN: -- Dr. Temple.

Let me object on the basis of form of the question. Lacks a foundation. Ask for expert opinion. And it doesn't reflect the evidence in this case.

BY MR. MURGATROYD, III:

Q. Go ahead.

MR. KELL: I'll join in the same objection.

You can answer it, if you have an answer.

THE WITNESS: Okay. I want to make my own observation that I don't know whether any of those facts are true.

BY MR. MURGATROYD, III:
Q. Right.
A. I really think you're talking and mixing two fundamentally separate things. If the rate of the reaction is very high, if it's really debilitating for people, that needs to part of the information provided to doctors and physicians -- to physicians and in a DTC as to the patients. They need to get, you know, how much details debate will matter, but they need to be aware of that.

The word used to define it seems somewhat less important to me. Um, uh, but that could be subject to evidence that people misinterpret the pharase. For example, if you -- a convincing case can be made that when you say it's not habit-forming, they will ignore all the information you have about how there's a discontinuation syndrome or a withdrawal syndrome and say, Oh, hell, it doesn't matter, that would shake me about the use of that term. But I don't have evidence of that currently.

Q. Okay. And, again, you didn't do a

survey but do you think a survey --
A. We didn't do a survey.
Q. Right. Do you think a survey, a proper, like, a survey that showed you that people misunderstood this, would that be helpful to the FDA?
A. Yes.
Q. Okay. Now --
A. Well, it might be depending on how it's done.
Q. Well, I understand.
A. That's right.
Q. Correct. Depending on the validity of the survey, correct. Now --
A. Actually, my understanding is the term "habit-forming has" sense been removed from the -- the promotion is not there anymore.
Q. That's correct. That is correct.
MR. MURGATROYD, III: Um -- okay. Let's go off the record real quick. We're going to take a tape switch. We can take a five-minute break and then we'll come back. And

I'll be finished in half an hour max.
THE VIDEOGRAPHER: Going off the record at three o'clock p.m. This concludes --
MR. MURGATROYD, III: Ah, it's three o'clock?
THE VIDEOGRAPHER: -- video tape No. 2.
MR. MURGATROYD, III: I thought I was faster. I'm sorry.
(Whereupon, at 2:57 p.m., a recess was taken, and the proceedings resumed at 3:08 p.m., this same day.)
THE VIDEOGRAPHER: This is the beginning of videotape No. 3? We're back on the record at 3:11.
BY MR. MURGATROYD, III:
Q. Okay. Okay. I'm just, uh, um -- Marci --
I'm sorry, I forget your last name, Marci.
MS. NORTON: Norton.
BY MR. MURGATROYD, III:
Q. -- Norton brough some documents with her

today that are referenced in your declaration. And, um, that --

A. Yeah.

Q. -- weren't attached. She attached some documents and you didn't attach others.

And one was -- and I just have a question about this. It's the April 13th approval letter. Let he show you.

MR. MURGATROYD, III: Oh, I got to mark this exhibit. Twenty --

MS. NORTON: -- eight.

MR. MURGATROYD, III: Eight, thanks.

(Temple Deposition Exhibit No. 28 was marked for Identification.)

BY MR. MURGATROYD, III:

Q. Um, and I -- I just want you to --

MR. BROWN: Do you have copy --

Q. -- have you take a --

MR. MURGATROYD, III: Yeah, I do.

MR. BROWN: -- for us?

MR. MURGATROYD, III: Yeah. Here you

go.
MR. BROWN: Thank you.
THE WITNESS: And that's before the precautions qwere added.
BY MR. MURGATROYD, III:
Q. Yes, correct.
A. Okay.
Q. Now it says, um, in your -- if you go to page 2 of your declaration, it says, For instance, based on limited data --
A. Hold on. Hold on.
Q. I'm sorry.
A. My declaration. Oh, this might -- no, that's the --
Q. It was attached to that. Gerald has it.
MR. BROWN: That letter is not attached to his declaration --
MR. MURGATROYD, III: I'm sorry?
MR. BROWN: -- correct?
MR. MURGATROYD, III: This document I just marked is not attached to the declaration.
MR. BROWN: Correct.

MR. MURGATROYD, III: Marci brought it with her to today at my request because it's referenced in what we're going to look at right now.

BY MR. MURGATROYD, III:

Q. If you look at the middle of that page, page 2, it says, For instance, based on limited data. Do you see that, the sentence that begins with that?

A. Yeah.

Q. It says, the April 13th, 2001, Paxil package insert that accompanied the approval letter for the generalized anxiety disorder indication included minor comments in the postmarketing reports paragraph of the adverse reaction section signaling a potential problem with discontinuation syndrome.

Now, my question is when you wrote this declaration, did you actually go back and look at that letter and see that?

A. I, uh, I don't remember. Probably though.

Q. Well, I don't understand what it means. Signaling a potential problem. How could a label signal a potential problem?
A. Well, let's look at what the words were. It says, "There have been spontaneous reports of discontinuation, (particulary when abrupt,) may lead to symptoms such as dizziness, sensory disturbances, agitation or anxiety, nausea and swetting; these events are generally self-limiting."
Q. Well, where's the signal? We dhave
A. What's -- what's the question?
Q. Well, where's the -- where in this attached label is there a signal?
A. I just read it to you.
Q. Oh, where were you?
A. It's under postmarketing report. It's the last six lines under Postmarketing Reports on page --
Q. What page --
A. -- 27.
Q. Is that on?

A. Twenty-seven.
Q. Okay. Yeah, but that's been on the label forever.
A. Yeah, that wasn't new.
Q. That's not new?
A. I didn't say it was new.
Q. Oh.
A. I just said it included them.
Q. I know. But I don't -- I don't -- where is the new signal? I mean, this has been in the label since I think the first label that ever came out.
A. It does not say that. I don't know when that language got in there, but there was no change in that section in April. It just mentions it --
Q. I understand that.
A. -- it a sort of weak way compared to how it was changed in the December notice.
Q. Well, I understand but --
A. I don't understand the question, I guess.
Q. The question is, You say here in your

declaration that these postmarketing reports signaled a potential problem. But I'm saying there's no difference in the language between this label and the label that was generated by Pfizer six years before that.

A. I -- I don't think I said there was a labeling -- I don't think I said there was a labeling change.

Q. No. I know you said that the label signaling -- I don't -- I just don't understand the symptoms how a label can -- it says signaling a potential problem.

A. Yeah.

Q. How can a nonlabel change signal a problem?

A. I didn't say it was a change. It just refer to the contents of the labeling. The label identifies that as postmarketing reports.

Q. I know. But it's done that for six years.

A. I didn't say that it changed. It didn't change.

Q. Then how was -- why wasn't the signal six years earlier when it was first put in the --
A. It was.
Q. Oh, it was a signal then.
A. Yeah. The language didn't change at this time, but the labeling has language that indicates that there may be a problem, sort of a weak statement. It's not very strong compared to what went in, in December. You're -- you're reading this as saying we changed the label to reflect something new. And that doesn't say that and it didn't.
Q. I thought this was saying that you looked at the label. And from the label you saw a signal. That's what I thought. This sentence to me means this --
A. Instead of signal --
Q. -- label --
A. -- instead of signalling --
Q. -- was the signal.
A. -- substitute indicating. It doesn't mean anything particular --

(Counsel briefly confers with cou-counsel.)

A. -- by it.

BY MR. MURGATROYD, III:

Q. Well, let me ask you this. Why did you -- this is the FDA -- move the withdrawal warning about warning but it's a withdrawal section of the label into the precaution section?

A. Because we -- we were more convinced that it was real.

Q. Okay.

A. That's -- that's exactly what that piece you read in the letter. You know, the little dark print piece, that explained why.

Q. But that's -- that's referring to this which has been in the label for six years. That's why -- that's where I'm getting confused. There's no change here.

A. When you read the letter, the approval letter, for the -- I don't remember which claim. Um --

MR. FARBER: PTSB.

THE WITNESS: Yeah, probably.
BY MR. MURGATROYD, III:
Q. Oh, yeah, PTSB --
A. Probably.
Q. -- right.
A. There was a little section explaining why the label had been revised to put language about this continuation and to precautions. That's why it was changed from this to that.
Q. But I don't know what -- what was the triggering event? I mean, it could have been six years prior. Why December of 2001 as opposed to -- well, 1994 when it was --
A. I -- I --
Q. -- it showed up in there too.
A. I can't answer that. I don't remember the details of the information. It now convinced them that it was real and deserved to be in precautions.
Q. Okay. So to convince somebody in your division?
A. Yeah.

Q. Okay. So somebody in your division said, Well, this is a bigger problem than we thought.

A. Somebody or a group. Maybe it would have been -- we probably be been watching it for awhile. You know, we read the literature. And it was now convincing enought to be a precaution.

Q. Okay.

A. If people were convinced that it was a really serious problem, they might have called it a warning. Anyway that's --

Q. Okay.

A. -- that's what happened in December. This was not a change. It's -- this is just a statement of what the labeling says. You're reading signally as if it was a change in labeling. And I didn't mean it that way because it wasn't the change --

Q. Well, is the word "signaling," was that your word or was that somebody else's word and you got stuck with it?

A. I don't remember anymore. I -- I could

have changed anything in here. This is my affidavit. Nobody told me what to say.

Q. I understand that.

A. Um, so maybe indicating would have been a better word or something like that. Nothing in what I wrote implies that it was a new change.

Q. Okay.

A. It just says it was there.

Q. Okay.

A. There's no implication that it was newly minted.

Q. Now, let's go to page 4 of your declaration on the top of the -- on the top of the, uh, page.

A. Okay.

Q. Page 3.

A. Okay.

Q. And you see the sentence that says, "DDMAC conducted a review of the television advertising for the drug Paxil and -- that --

A. Um, hold on.

Q. Is that --

A. Tell me -- tell me what line, oh, the top line. Okay.
Q. Yeah, the top line.
A. Yeah.
Q. "DDMAC conducted a review of the television" labeling -- I'm sorry -- "television advertising for the drug Paxil that is the subject of this litigation and I am familiar with its decisions and actions."
I think we've established that. When you say that, you're just saying that as an overall --
A. That's right.
Q. -- view, not that you were personally familiar with this Paxil ad itself?
A. Uh, that's correct. And I'm describing a general familiarity. We have a number of social scientists who are good at implications. We sometimes do surveys, but to my best knowledge nobody did a survey.
Q. Okay.
A. But they presumably exercised their

judgment on the matter.
Q. Okay. Okay. Now let's go to, uh, the next page, page 5. And the second to last sentence says, "DDMAC included that putting this precaution -- and the caution refers to Don't stop taking Paxil before talking with your doctor -- into the television advertisements would ensure that the ads adequately provided for dissemination of the information about possible discontinuation symptoms contained in detail in the products FDA approved insert.

And I think we probably touched on this before. I don't understand how, Don't stop taking Paxil before talking to your doctor tells a person who is seeing the ad that they're getting adequate information about possibe discontinuations.

A. Yeah. There's a -- there's a thought left out. And -- and the clue to it is contained in detail in the products of the FDA approved insert. The -- the assumption is, in all of these, that the ad is used -- the ad triggers your entry into the healthcare system and the physician

carries out the physician's responsibilities. DTC ads in no way make you capable of treating yourself. They're not supposed to. So that's -- that's the theory.

Q. Okay. But you do --

A. Um, you know, I'm not saying it's not arguable but that was the theory.

Q. Okay. And you don't -- you didn't do a survey to see if that theory worked?

A. As, I said, no.

Q. Okay. But we did see that --

A. But, remember --

Q. -- GSK did them certainly then.

A. Yeah. But that stills goes to what an individual would understand from this. If the, uh, the worrisome part of that little bit of a survey you show there's -- that they didn't notice it, so they didn't notice that stopping abrupty is a problem. I think one of our assumptions would be that people are supposed to be paying attention to what's it there. Um, they might ask about that. But in any event, um, one would hope

that physicians would be aware of that.
Q. Yeah.
A. We know that physician aren't always aware of everything. They're supposed to be aware of a problem that has no obvious remedy.
Q. Okay.
A. Um, right.
Q. All right. I appreciate it.
MR. MURGATROYD, III: At this point, I don't have any further questions. I will turn to Mr. Farber who's going to be very brief.
MR. BROWN: Well --
MR. MURGATROYD, III: You're last.
MR. BROWN: I understand that.
(Laughter.)
MR. BROWN: And I'm looking forward to having an -- an opportunity. I will say that, um, I'm -- I'm not accustomed to having two lawyers question one witness while representing the same -- the same party in the litigation. I'm going -- I'll object to Mr. Farber's line of questioning and hopefully it will be limited.

(Laughter.)
MR. MURGATROYD, III: Duly noted.
MR. BROWN: I've -- I've never experienced --
MR. MURGATROYD, III: Oh, you haven't?
MR. BROWN: -- a deposition with Mr. Farber with -- with it being a series of limited questions.
MR. FARBER: Well, Ill --
MR. MURGATROYD, III: Well, hopefully it will be the first time.
MR. FARBER: I'll take that as a compliment too.
MR. BROWN: Well, yeah, yeah.
MR. KELL: And I'll note the same objection. The last time I looked at the Rule it says examination shall proceed as at trial. I know at trial it would be the extremely rare circumstance where a court would ever allow more than one lawyer for a party to question the same witness, certainly, during the same examination.
MR. FARBER: There's not rule against

it, though.
MR. KELL: I --
MR. BROWN: No. I believe Mr. Kell just correctly stateed there is a rule against it. But having expressed the objection on the record --
MR. FARBER: Okay.
MR. BROWN: -- let's --
MR. FARBER: Proceed.
MR. BROWN: -- let's move ahead.
MR. FARBER: Okay. And I will certainly try not to duplicate any subject area of Mr. Murgatroy. And I would anticipate, for your personal information, maybe 45 minutes.

EXAMINATION BY COUNSEL FOR THE DEFENDANTS

BY MR. FARBER: