UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF NEW YORK

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ANNIE TUMMINO, et al., :

Plaintiffs, : No. 05-CV-366(ERK/VVP)

v. : (Korman, C.J.)

ANDREW C. von ESCHENBACH, : (Pohorelsky, M.J.)

as Acting Commissioner of :

the Food & Drug :

Administration, :

Defendant. :

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Videotaped Deposition of STEVEN GALSON, M.D., MPH

Volume 1

Rockville, Maryland

Wednesday, April 26, 2006

9:16 a.m.

Job No.: 1-77261

Pages 1 through 213

Reported by: Cynthia R. Simmons Ott, RMR, CRR

Videotaped deposition of STEVEN GALSON, M.D., MPH, held at the offices of:

FOOD & DRUG ADMINISTRATION
5600 Fishers Lane
Rockville, Maryland 20857
(888) 463-6332

Pursuant to agreement, before Cynthia R. Simmons Ott, Registered Merit Reporter, Certified Realtime Reporter, and Notary Public of the State of Maryland.

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C O N T E N T S

E X H I B I T S

(Attached to the Transcript)

P R O C E E D I N G S

THE VIDEOGRAPHER: Here begins tape number one in the deposition of Steven Galson, in the matter of Annie Tummino, et al., versus Andrew C. von Eschenbach, as Acting Commissioner of the Food & Drug Administration, in the United States District Court, Eastern District of New York, Case Number 05-CV-366. Today's date is April 26th, 2006.

The time is 9:16 a.m. The video operator today is Cali Day of L.A.D. Reporting. This video deposition is taking place at 5600 Fishers Lane, Rockville, Maryland, 20857, and was noticed by Simon Heller, counsel for the plaintiff. Would counsel please identify themselves and state whom they represent?

MR. HELLER: Simon Heller for plaintiffs.

MS. JONES: Bonnie Scott Jones for the plaintiffs.

MS. STRAUSS: Nan Strauss for the plaintiffs.

MS. LABATON: Vivien Labaton for the plaintiffs.

MS. COSTELLO: Andrea Costello for the individual plaintiffs.

MS. REYES: Ana Reyes for Duramed Research, Inc., and Barr Pharmaceuticals, Inc.

MR. AMANAT: Frank -- go ahead.

MS. SCHIFTER: Karen Schifter for the defendant.

MR. WARSHAWSKY: Steven Warshawsky, defendant.

MR. AMANAT: I'm Franklin Amanat for the defendant as well and counsel for the witness today.

THE VIDEOGRAPHER: The court reporter today is Cynthia Simmons Ott. Would the reporter please swear in the witness?

Whereupon --

STEVEN GALSON, M.D., MPH

having been duly sworn, testified as follows:

EXAMINATION BY COUNSEL FOR PLAINTIFFS

BY MR. HELLER:

Q Good morning.

A Good morning.

Q Would you please state your name for the

record?

A Steven Galson.

Q Have you had your deposition taken before?

A No.

Q Okay. Are you familiar with how a deposition works?

A Yes.

Q Do you want me to -- is there anything you'd like me to say about that?

A No.

Q Basically, what I will say is that I'm going to ask you a series of questions. I'd like you to answer them as best you can. If you don't understand a question that I'm asking you, please let me know, and I will try to clarify my question. I sometimes tends to ask somewhat convoluted questions. Please, don't hesitate just to tell me if I'm, if I'm asking a question that you don't understand.

A Sure.

Q During the course of the deposition, one of the lawyers here may object to a question I ask, and there might be a short discussion of the

objection. In general, you would, after the objection has been discussed, unless I withdraw my question, you would go ahead and answer the question, with the proviso that Mr. Amanat or one of the other lawyers for the defendant might instruct you not to answer a question. In that case, don't answer it.

Let me start with just some general background information. Can you tell me -- I have somewhat here some information about you, and I want to ask you if this is correct. What's your, well, first, what's your current employment?

A I'm the director of the Center For Drug Evaluation and Research.

Q Here at the FDA?

A Yes.

Q And what other positions have you had at the FDA?

A I was the acting director of the Center For Drug Evaluation and Research and the deputy director of the Center For Drug Evaluation and Research.

Q And what's the distinction between being

the acting director and the director?

A One is a permanent designation, and one is a temporary designation. I filled in for Dr. Woodcock when she had another temporary position.

Q How does one go from becoming an acting director of -- do you mind, do you, what do you call the Center For Drug Evaluation --

A CDER.

Q Okay. Is it all right if I call it, call it CDER?

A Please.

MR. AMANAT: For the record, that's C-D-E-R.

BY MR. HELLER:

Q How does one go from becoming acting director to director, what has to happen?

A I was appointed the director.

Q By whom?

A By Dr. Crawford.

Q Okay. So once he, he decided that he was going to sort of change your position from acting to permanent director?

A Right.
Q Do you know when that occurred?
A August, July, August.
Q Of --
A It was the end of July.
Q Of 2005?
A Right.
Q And, and then you indicated that before that, you were a deputy director of CDER?
A Before that -- well, before I was acting, I was deputy -- I was hired here in 2001 by Dr. Woodcock as the deputy director of CDER.
Q When did you go from being deputy director to acting director?
A I had a couple different times that I was acting. In approximately October 2001, I started a six-month period of being acting and then went back to being the deputy because Dr. Woodcock took a temporary job up in the Commissioner's office. And then the second time around was more recently, about, I think, about eight months before, eight or nine months before I was appointed.

Q You're a physician, is that correct?
A Right.
Q Where are you licensed to practice medicine?
A In Maryland.
Q And where did, you received your medical degree from --
A Mt. Sinai School of Medicine in New York City.
Q And did you do a residency or internship after that?
A I did two residencies, one in internal medicine at the Medical College of Pennsylvania hospitals and one in preventive medicine with the Centers For Disease Control, and I got a further postgraduate training, a Master's in public health from Harvard University.
Q Do you have board certifications?
A Yes.
Q In internal medicine?
A Not -- in preventive medicine, general preventive medicine and occupational medicine,

they're both by the American Board of Preventive Medicine.

Q And your undergraduate degree is from State University of New York at Stony Brook?

A Correct.

Q Me too.

A Oh, hey. What year?

Q If only I could remember, 1981. What year were you?

A '78.

Q Well, maybe we overlapped. Anyway, what was your degree in from --

A Biochemistry.

Q Okay. Great. Now, you're wearing a uniform today?

A That's right.

Q And that's the uniform of a rear admiral?

A Yes, it's a uniform of an officer in the U.S. Public Health Service. My rank is rear admiral.

Q Would you typically wear your uniform here to the office at the FDA?

A I wear it every day. There's several

different versions of the uniform. This is the formal version of the uniform that you wear providing testimony, at formal meetings.

Q Okay. Well, thank you for doing that today. What -- I'm just not very familiar with what that means. Are you sort of simultaneously in this sort of, I don't know what to call it, military sort of rank system and a civilian employee of the government?

A Right. It's not considered military. It's considered a uniformed service. It's one of the uniformed services of the United States, and the Public Health Service has officers who are placed in all of the Public Health Service agencies, NIH, Centers For Disease Control, and other agencies as well.

They compose a proportion of the staff in each one of those agencies, and they have special responsibilities for emergency response and other sorts of responsibilities, that they're available 24 hours a day if there's an emergency, things like that.

Q Okay. Does that status that you've just described, does it come with the sort of standard, what I think of as sort of standard federal civil service benefits and protections?

A It's a different personnel service. It's not like the civil service. It's like the military, but it's a career appointment. Yes, and you have the same sorts of protections that members of the military have. It's modelled after that, but you're considered a career employee.

Q Who decides -- let's say, is there someone sort of with a higher rank who could say, okay, Dr. Galson, you've been working at the FDA, you've been doing your job, but we're going to send you in a month to some other place where we need --

A Right.

Q -- your, where we need you to work, and they're going to decide to do that?

A It generally doesn't work like that now. It's done only if the officer agrees, and it's highly unusual for someone to be reassigned against their will.

Q So just as an example, if you, if you decided tomorrow you wanted to leave this position, do you get your full pension?

A Tomorrow, no. There is a long, complicated process, we can send you a copy of the regulations, but anyone who retires from the Public Health Service has to go in front of a retirement board, and it takes a few months, but you could -- people decide to go all the time. The way the pension system works is similar to the military services. You have to have 20 years of service.

Q So if you have less than 20 years, what happens?

A You don't get any pension.

Q Oh.

A But you could, you know, if I wanted to leave FDA, I would just go to another agency.

Q Right, where you would continue with your rank?

A Yeah.

Q And continue your service?

A And I've done that multiple times in my

career. People do it all the time.

Q Just to start with some sort of background questions, if you were called by plaintiffs or by the defense to testify in court in this case, would you be available to testify?

MR. AMANAT: I'm going to object to that question. It's a bit speculative.

BY MR. HELLER:

Q Well, I mean, if someone said, you know, you receive a subpoena to come up to New York and testify, in general, do you think you would be willing to testify?

A Sure.

Q And second question, sort of related question, was today the earliest date that you were available to have your deposition taken for seven hours?

MR. AMANAT: Objection.

MR. HELLER: What's the grounds?

MR. AMANAT: Answer the question.

THE WITNESS: I was just going to say my schedule is horrible. I have, you know, dozens of

meetings every week, and it was extremely difficult to find the time even now. My schedule is filled up for months ahead of time.

BY MR. HELLER:

Q Did you have to clear stuff from your schedule to be deposed today?

MR. AMANAT: Objection, again. Go ahead and answer the question.

THE WITNESS: Absolutely, yeah.

BY MR. HELLER:

Q Could you have cleared stuff earlier in the month to have your deposition taken also?

MR. AMANAT: I renew my objection. Go ahead and answer the question.

THE WITNESS: There are always dozens of serious issues underway at the Center. Things have come up this week that I wish I could be spending this time dealing with it, that have to do with drugs that are on the market, and the fact that I'm not available is hurting the resolution of those issues. So there's always a lot going on because we regulate such a large part of the American medical system.

BY MR. HELLER:

Q My question was, could you have cleared something earlier in the month, so you would have been available earlier in the month for a deposition?

MR. AMANAT: Objection. Mr. Heller, what's the point of these questions? I mean, we had, I mean, these depositions were scheduled pursuant to negotiations that took place between counsel and --

MR. HELLER: Actually, they were not scheduled pursuant to negotiations. You told us these were the only dates the witnesses were available.

MR. AMANAT: And these were the only dates.

MR. HELLER: That's why I'm asking the question.

MR. AMANAT: And these were the dates that we had indicated the witness is available, and I don't know what the point of these questions are. You can go ahead and answer the question, but --

THE WITNESS: Yeah, I mean, I don't have my schedule memorized in my head. When we were

looking for a time, Karen Schifter talked to my secretary, and they identified the only block that was available, so, yeah.

BY MR. HELLER:

Q Have you ever been instructed by someone to preserve or keep e-mail or written documents, electronic or written documents related to Plan B?

MR. AMANAT: Objection. Hold on one second. I need to have an opportunity to confer with the witness to see whether his answer to the question may involve attorney-client privileged information.

MR. HELLER: Okay.

MR. AMANAT: So if I may have a moment to discuss that with the witness off the record?

MR. HELLER: Sure. So should we go off the record?

MR. AMANAT: Yes, please.

THE VIDEOGRAPHER: We are going off the record. The time is 9:29 a.m.

(Recess.)

THE VIDEOGRAPHER: We're back on the record. The time is 9:30 a.m.

(The reporter read the record as requested.)

MR. AMANAT: You may answer the question.

THE WITNESS: Yes.

BY MR. HELLER:

Q Do you recall roughly when you received that instruction?

A I don't. Yeah, we have a lot of litigation going on in the Center at any one time, and whenever there's litigation that starts and we get a request for documents, I get a note saying, Preserve documents having to do with subject A, B, and I know I got one of those about Plan B. I don't remember when it was.

Q And did you, when receiving that, did you preserve any documents, electronic or otherwise?

A Well, the default is they're preserved, so I didn't destroy any documents, yeah.

Q By the default, there is, they're preserved, what do you mean?

A Well, I either have documents sitting in files or in my e-mail records, and they just sit

there. They don't, they don't disappear by themselves, so I didn't --

Q Do you automatically delete e-mails at a certain point?

A I automatically -- my e-mail system automatically deletes documents after a certain length of time so that my inbox and the servers don't fill up, but it's not specific to any specific topic. After a certain period of time, it gets deleted, unless I've specifically saved it.

Q Do you know what that time period is for which your e-mail system automatically --

A It deletes things from my, you know, I don't want to get into the details of e-mail, but, you know, when you delete something, it goes into a deleted folder, and my deleted folder is cleaned out about once a week. Otherwise, I get thousands of messages, and the whole thing bogs down.

Q And how soon, when do things go -- do things go automatically to the deleted folder?

A Yeah.

Q When does that happen?

A Immediately.
Q Oh.
A When I delete them.
Q But if you don't delete them?
A I can either leave them in my inbox, or I can save them in a folder.
Q Okay. And --
A And I have saved things in folders for Plan B.
Q Do you know how many e-mails you have saved, or not deleted, so to speak, related to Plan B?
A I don't know the exact number, but it's at least a few dozen, something like that, yeah.
Q And do you know who those -- can you tell me some of the people those e-mails are from or to?
A Most of them are internal CDER e-mails. They've all been provided, as per the requests that we've received through the litigation.
Q All of those that you have been provided?
A Right.
Q Okay.

A Let me just clarify, the way our system works is I provide them to our regulatory experts in the Center, and then they decide whether they're responsive to the request of litigation. They go through OCC. All the ones that were responsive were provided.

Q But you provided them to someone and then they --

A Absolutely, yeah.

Q All right. Let's see, are you familiar with a citizens' petition filed with the FDA approximately February 14th, 2001, which requested that the FDA approve emergency contraceptive products as over-the-counter drugs?

A Yes.

Q I'm going to refer to that as the citizens' petition during the course of this deposition, is that okay?

A Uh-huh.

Q If I make reference to some other citizens' petition, I'll try to make that clear. Are you also familiar with a supplemental new drug

application filed initially by Women's Capital Corporation, and later by Duramed Research and Barr Labs, also seeking to switch a particular drug, Plan B, to over-the-counter?

A Sure.

Q And I'm going to refer to that as something like the Plan B SNDA.

A Okay.

Q All right. Great. As much as you can recall right now, can you tell me about your involvement in the FDA's handling of both the Plan B SNDA and the citizens' petition up until the time the FDA issued a nonapprovable letter on May 6th, 2004? Sort of in general, what was your involvement?

MR. AMANAT: Object to the form of the question. It's a compound question, and it's an awfully long question. If you could please maybe restate it and narrow the focus of your inquiry. Your question involves an awful lot for the witness to take in.

BY MR. HELLER:

Q Well, I'll divide it into two questions.

First, can you tell me about, in general, about your involvement regarding the citizens' petition up to May 6th, 2004? What was your involvement in that, if any?

A You know, I'd really like you to be more specific. You know what my job is running the Center, overseeing the review of all the applications, supervising several thousand people, et cetera, and you have all these records explaining the meetings. So what do you specifically want to know?

Q Well, with respect to the citizens' petition?

A Yeah.

Q Before May 6th, 2004?

A Before May 6th, okay.

Q So before you issued the nonapprovable letter.

A Right, right.

Q Can you tell me, did you have meetings about the citizens' petition?

A Sure, and you're aware of all -- you have records of those meetings.

Q I think I have a record of one meeting about the citizens' petition that I can recall at the moment. Do you know if there were?

A You mean the citizens' petition, as opposed the application?

Q Yeah, just the citizens' petition.

A Yeah. I don't, I don't really recall specific interactions just about the citizens' petition. In my mind, the issue is mixed of the citizens' petition and the application, similar issues were raised, so I can't really tell you about specific meetings or discussions going back that many years ago.

Q And then with respect to the Plan B SNDA, the one you indicated was mixed?

A Right.

Q How -- before the May 6th, 2004 nonapprovable letter, were you involved in the Plan B SNDA, for example, in the same way you were involved in all the other new drug applications you were -- CDER was considering?

MR. AMANAT: Object to the form of the

question. I mean --
BY MR. HELLER:
Q Do you understand my question?
THE WITNESS: Do you want me to answer?
MR. AMANAT: I mean, I object to the form of the question. I mean, he can answer if he understands it.
BY MR. HELLER:
Q That's fine.
A I think I know what you're asking, but the -- I was involved in this application similar to the way that I would be involved in any other high-profile policy or drug approval decision.
Q And what made this a high-profile policy? I'm sorry, what did you say, high-profile --
A "High-profile."
Q -- drug or policy decision?
A Right. We knew it was going to be very contentious.
Q Contentious in what way?
A Possibly among staff in the Center, possibly on the outside, possibly among the people in

the Commissioner's office, or somewhere else.

Q Contentious because the scientific evidence was hotly disputed?

A Because every issue that we deal with that has to do with reproduction and reproductive drugs is contentious.

Q Why?

A I don't know why. They just are. There's a lot of argument and emotion around these issues.

Q That's true. Can you give me an example of another, other than the area of reproductive drugs or devices, another high-profile drug that you've been more heavily involved with because it was a high-profile drug?

A Sure. Isotretinoin, which is a drug for acne, which also causes birth defects, a lot of tension around is it right to have a drug that's used for cosmetic purposes that causes birth defects, and is it worth having even one child that's born with a birth defect because someone took an acne drug? So I've been very closely involved in discussions for years and policy debates over that drug.

Q Getting back to what you said about Plan B --

A Yeah.

Q -- being a high-profile drug, what were some of the -- well, you said that it was -- it was contentious, or you thought it would be contentious, or both?

A We predicted that it would be contentious. There would be Congressional interest. There would be public interest. There would be interest of the staff at the Department of Health & Human Services, of high, of senior people in the Agency and our managers in the Center as well.

Q Tell me about what some of the sort of contentions -- what were some of the contentions you expected or thought might happen?

A I don't think it's a specific contention. It's just that people care a lot about it. You know, for example, in the middle of the review process, we got a request from several members of the House of Representatives to come down and tell them about the drug. It wasn't a specific point of contention.

They were just very, very interested, the caucus in the House.

Q Which caucus was that?

A I was, I think it's the Women's Health Caucus or something like that. It was several female members of the House of Representatives. It's not, it's not a specific point, as much as there's just a high level of interest on these issues, as there is with, you know, mifepristone and other birth control issues, just a fact of life.

Q I think you said that there would, there might be, it might be contentious within the staff of CDER, did I understand you correctly? When you said, "staff," is that what you were referring to?

A Uh-huh.

Q Yes?

A Yeah.

Q I'm sorry, just when you answer, you have to say --

A Yeah, sure, yes, yes.

Q Okay. Was it in fact contentious with the staff?

A Well, it became contentious, as you know, as I ended up overruling the staff.

Q But aside from the contention that existed between you and the staff, so to speak, was it contentious within the staff, other than you, putting you aside for the moment?

A I, as you know, I only participate in the meetings that I participate in. I don't know everything that goes on within the staff, so I'm not there.

Q Okay.

A Yeah.

Q But --

A I'm sure there were things that went on that I'm not aware of.

Q But as far as you're aware, it was not contentious within the professional staff?

A There were disagreements among the professional staff about it, yes.

Q Can you tell me about one of those?

A Well, you've got the copy. There's one of the reviewers that didn't think it should have been

approved.

Q So it was one contention?

A Yeah.

Q Were there others?

A Well, I don't know, the definition of one contention, but, yeah.

Q So if I -- let me see if I understand this right. You predicted, or you thought this might be contentious, is that right?

A Contentious or high-profile, probably "high-profile" is the better description than contentious, that there would be a lot of interest in this decision.

Q You would agree, wouldn't you, though, that if you had not been involved, that is, if it had been, this decision had just been left to the professional staff as it typically is, right, I mean, typically, you are not typically, yourself, involved in approving or not approving specific new drug applications, is that right?

MR. AMANAT: Objection.

MR. HELLER: What's your objection?

MR. AMANAT: I object to the form of the question. You asked like three questions there all in one.

MR. HELLER: Okay.

BY MR. HELLER:

Q Are you typically involved in signing approvable or nonapprovable --

A Let me just make a point. There really is no such thing as typical in CDER. Every single drug is different. Every drug has a different risk benefit assessment, and you never know what's going to happen. When there are high-profile policy or specific drug approval decisions or high-profile issues that arise after a drug is approved, I'm involved.

I typically would involve with the Commissioner's office as well, in making sure they knew what was going on. So there's really no definition of typical.

Q Okay. So I'll be more specific.

A Yeah.

Q Have you ever, other than with Plan B,

with respect to an application, an over-the-counter switch application, have you ever signed an approval letter for that?

A No.

Q Have you ever signed a nonapproval letter for that?

A No, but that doesn't mean very much. One, I haven't been in the Agency very long.

Q Yeah, I know. I'm not saying -- I'm not asking you what it means.

A Yeah.

Q Have you done it before? Have you ever --

A No.

Q No. Have you ever signed a nonapprovable letter for an OTC application?

A No.

Q Have you ever signed an approvable letter for an OTC application?

A No.

Q Who typically does sign those letters?

A It's delegated down a couple levels in the organization.

Q Why wasn't it delegated down for Plan B?

A Because I didn't agree with what they were doing.

Q In other instances where it sort of, where it was delegated down and someone else would have signed the appropriate action letter, in each of those instances, you agreed with what they did?

A Yes, yeah. There are so many regulatory decisions that take place in the Center. I'm not even aware of all of them. And if you understood the Center well, you would know that there are hundreds of regulatory decisions that we make, small and large. When there is something that is high-profile or that the management thinks other people need to know about, it's raised to my attention.

And I'm frequently asked do I think we're going in the right direction or we're not going in the right direction. And I may have meetings and discuss whether I think things are going well or whether I want to have them go in a different direction. So I can't say that I agree with 100 percent of all the decisions that take place because

I'm not necessarily consulted on them. But the assumption is that the, my managers will let me know if there's something that they think that I may not be okay with.

Q Is it something that you might not be okay with or they might not be okay with?

A Either.

Q So in this case, is that what happened, your managers let you know that there might be something you wouldn't be okay with regarding Plan B?

A This process, as you know from the documents, took place over quite a few months, leading up to the May '04 decision. And we knew from the very start that this was going to be a high-profile decision. We started having meetings about it back in the fall, and I started briefing, and Dr. Woodcock as well, letting the office of the Commissioner know about it.

So, you know, there wasn't, you know, overnight, a decision. It evolved slowly over time.

Q I'm just trying to get a sense for this particular -- for Plan B. How did anyone -- who was

the first person to say to you, this is a high-profile drug?

A No one said it to me. It was a realization of joint, a group of people, the senior management in the Center and the office of the Commissioner.

Q Sir, did they come to you and say, we think this is a high-profile or a possibly contentious drug, we want you to pay special attention to it? Or did it, was that your idea initially?

A No, it was the staff coming to me soon after I arrived in the Center, coming to Dr. Woodcock and I and letting us know that we have received this application. They knew intuitively that it was going to be a high-profile kind of decision that we would want to be aware of and be appraised of.

Q So the professional staff within CDER came to you and Dr. Woodcock?

A And just let us know that the application had been received, I think we even knew before, we knew that Barr was working on the application.

MR. AMANAT: The witness answered the question before I could object to the question. When you referred to the professional staff within CDER, that contains an assumption that Dr. Galson and Dr. Woodcock are not subsumed within the professional staff of CDER.

MR. HELLER: I meant to exclude them. I meant other than him and Dr. Woodcock.

MR. AMANAT: What you meant is a subordinate professional staff within CDER?

MR. HELLER: That's what I should have said.

MR. AMANAT: Okay.

BY MR. HELLER:

Q Which subordinate professional staff came to you and --

A I don't remember who it was.

Q You don't remember any of them, not a single one?

A I don't remember -- you're asking a specific question, who came to me. I don't remember whether it was Dr. Jenkins or Dr. Kweder or Dr. Ho.

I don't remember which one of them it was. It was certainly one of them.

Q And so your testimony is that the source of your belief that Plan B, the Plan B OTC switch application might be a high-profile one is the subordinate, your subordinate staff within CDER?

A I would have come to the conclusion myself. What I said is that they first informed us that the application was in-house, and we discussed -- or the application was coming and that we discussed together that this was going to be a high-profile decision.

Q You're aware, are you not, that the FDA has provided us with the administrative record that's been compiled in relation to the Plan B SNDA, is that right?

A Yes.

Q Have you reviewed all or part of that?

A There are, you know, hundreds and hundreds of pages, and I haven't reviewed every single page, but I'm generally familiar with it, yeah.

Q When, when you issued the nonapprovable

letter in 2004, in May of 2004, was there any member of your subordinate staff at CDER who agreed with that decision, as far as you know?

A I don't know. I didn't talk to all my subordinate staff. There are thousands of them, as you know.

Q I mean, as far as you're aware, was there anyone who agreed with that decision?

A I think I have the record of at least one reviewer in the, that you have the record of, who didn't think that it should be approved, so I know about that person.

Q That was Dr. Chen?

A Yeah, I believe that's her name, right. And I also discussed the decision with some of the staff in our pediatrics division.

Q That's a separate division?

A It's separate from the office of new drugs. It was separate then.

Q Is it part of CDER?

A Yes, yes.

Q Okay. And did the people in the pediatric

division agree that there should be a nonapprovable letter?

A You know, I don't think I specifically asked them and briefed them. They were very sympathetic about the reasoning that I was using in the nonapprovable letter.

Q So let me try the question again. Was there anyone -- I understand there are many, many employees, and you didn't talk to each one of them about the nonapprovable letter. But is there anyone you're aware of who agreed with your decision to issue a nonapprovable letter?

A Yeah, I think there were a few people. I don't, I can't tell you specifically who they were. I think some of the pediatricians, and Dr. Chen, I assume, agreed with me.

Q You think they did, but no one told you?

A I didn't ask them.

Q Okay. You didn't ask them, you believe they might have agreed with that?

A I think that's what you're asking me, do I believe --

Q Do you know?
A No one came up to me and said, I agree with you.
Q Did anyone came up to you and say, I don't agree with you?
A Sure.
Q Okay. No one came up to you and said, I agree with you?
A I don't -- I got sympathetic feedback about what I was doing from some of the staff in the pediatrics office, but I don't remember exactly the words that they used, I don't think that I agree with you.
Q Did anyone in the Commissioner's office agree with you?
A Sure, sure.
Q Who?
A I think the Commissioner agreed with it, yeah.
Q Did -- let's see, so who would that have been, Dr. --
A That was Dr. Crawford.

Q Dr. Crawford.
A Yeah, Dr. McClellan had left at that point.
Q Did Dr. Woodcock agree with you?
A Sure.
Q Did, did the other -- is there another Deputy Commissioner?
A I don't remember at that point. I didn't take a poll of whether people agreed with me or not, and I don't remember, you know, all the detailed conversations of -- with people about, you know, whether people were agreeing or not.
Q Do you, as you sit here, continue to believe that the issuance of the nonapprovable letter in 2004 was the correct decision?
A Absolutely.
Q Did you have conversations prior to the 2004 nonapprovable letter with Dr. McClellan about Plan B?
A I met with Dr. McClellan just about every week. I sometimes talked to him on the phone multiple times during the week, and we talked about

Plan B quite a bit over many months.

Q What -- can you tell me some of what he said to you about Plan B?

A I can't quote anything. It was not he said to me, we had discussions about Plan B in my frequent meetings.

Q Just tell -- I don't expect you to be able to quote conversations from several years ago.

A Yeah, yeah.

Q I'm just trying to get a sense of what, what were those discussions about?

A They were about the strength of the science, the planning for the advisory committee, what was happening with getting data from Barr, what was going on in the staff in the analysis and how the reviews were coming out, just typical updating about what was happening. He was very interested, and we discussed the science and back and forth, as we did with many, many other issues, all the issues that I brought to him.

Q Did he ever express his view to you about whether the SNDA should be approved or not?

A I think it's fair to say that Dr. Woodcock, Dr. McClellan, and I were in general agreement about the flaws in the data in Barr's application and what the right course of action was.

Q Well, but did he, Dr. McClellan, ever express to you that he thought the application should not be approved?

A He -- it was clear that it was my decision.

Q Well, I'm not --

A Yeah.

Q Did he ever express to you that he thought it should not be approved? I'm not saying --

A I don't, I don't remember if he expressed that discretely like that.

Q But did you understand him to believe that the application should not be approved?

A Yes, yeah.

Q Can you give me a rough sort of time frame on that? Was it --

A No, I can't. As I described, the conversation took place over many, many months, and

it consisted of scientific back and forth about the data, which is his typical way of conducting business. We talked about issues, we talked about pros and cons and options. There wasn't any discrete moment at which he said, you know, I really think this should not be approved.

Q Were there ever occasions in these discussions where you got the sense that he thought it should be approved?

A No.

Q Never?

A We -- you're misinterpreting the kind of discussions that we have. We don't have -- we didn't have discussions about what final decisions should be. It was more about the data, about the science.

Q So --

A And he knew that the regulatory decision was CDER's call, so we didn't really focus on the final decision. We focused on the scientific questions that would arise.

Q And these discussions took place, I think you said sort of in the course of these weekly

meetings you would have with him and Dr. Woodcock?

A Uh-huh.

Q Is that right?

A Uh-huh.

MR. AMANAT: You have to verbalize your answers.

THE WITNESS: Yes, yes.

MR. HELLER: Thank you, Frank.

BY MR. HELLER:

Q Does, I mean, does the Commissioner, like Dr. McClellan, did he have the authority to say, I'm going to make this decision myself?

A Absolutely.

Q Just as you had the authority to say to someone, a subordinate who would maybe ordinarily be -- on a non high-profile drug, would ordinarily be making the decision, you had the authority to say, I'm going to be making the decision?

A Right. You're very familiar with the Food, Drug, and Cosmetic Act. It gives the authority actually to the Secretary, and it's delegated down to the people who are actually making the decisions. It

can always be -- any decision can be undelegated and made by, at the level of the Commission or at my level, if that's not the normal way.

Q So in these discussions about the science and the data in the Plan B SNDA, was there, was there -- do you ever recall an occasion where Dr. McClellan said something like, you know, maybe this data is good enough to approve this for over-the-counter use, if we look at it this way, you know, sort of did he ever give any indication that the data was sufficient for approval?

A Isn't that sort of -- you're asking me whether he would have used certain words? Can you be more succinct in your question? What are you asking?

Q I can try to be more succinct.

A Yeah.

Q I'm just trying to get a sense, you know, you're in these discussions?

A Yes.

Q And you're talking about the data, and it seems to me there's sort of at least three different kinds of discussions you could have. You could have

a discussion where everyone sort of got an open mind.

A Yes.

Q And they're all sort of sitting around saying, well, what should we do here?

A Yes.

Q There's another kind of discussion, where --

A Yes.

Q Let me finish.

A Yeah.

Q Okay. A second kind of discussion where it's pretty clear that people have reached a sort of tentative view, and they're examining the data to see if that view is correct, and that view could be either approved or not approved, so what I'm trying to get a sense of is, in these discussions, did Dr. McClellan -- was it the first kind of discussion, open mind, let's see what we do here?

A Open mind, definitely.

Q Definitely?

A Yes.

Q If you had -- and same with Dr. Woodcock?

A Absolutely.

Q And yourself?

A Yeah, yeah.

Q If you had come to this meeting or one of these meetings, let's say, April 2004, and said to Dr. Woodcock and Dr. McClellan -- well, maybe it would have been Dr. Crawford by then?

A Yeah, it would have been Dr. Crawford in then, in April.

Q And you said to them, you know, I've thought about this some more, and I agree with my subordinates, I think we should approve this. Do you think there's any chance they would have exercised their authority to make the decision themselves?

A I really can't hypothesize about that.

Q Well, do you think by, let's say by the time Dr. McClellan left the FDA, was no longer Commissioner, do you think he had a firm view that it should, that the Plan B SNDA should not be approved?

MR. AMANAT: Objection, calls for speculation. You can answer the question if you know.

THE WITNESS: I don't know.
BY MR. HELLER:
Q You really don't know?
A No, I'm not -- I can't read his mind.
Q I'm not asking you, from what he said in the discussions, do you think it was his view that it should not be approved?
A I don't think he clearly expressed that to me before he left. We talked about weaknesses in the data.
Q Did he talk to you about strengths in the data?
A We talked about what the data, what the data showed and what the data didn't show.
Q Did Dr. Woodcock express a view that prior to your May 2004 decision, that the application should not be approved?
A We discussed, as I mentioned before, it was a slow decision-making process that evolved over a series of months. I don't recall a discrete point at which anyone said, that's it. It was an evolution of decision-making.

Q Do you know if there were minutes kept of these weekly meetings that you had with Dr. McClellan and Dr. Woodcock?

A I know that there weren't. I don't take notes.

Q I'm sorry?

A I don't take notes in my meetings with the Commissioner.

Q Do they take notes?

A No.

Q And that would also -- do you also continue weekly meetings then when Dr. Crawford became --

A It was weekly, sometimes biweekly, same thing with Dr. McClellan. It wasn't always every week, but I continued regular meetings with him and Dr. Woodcock.

Q And in those meetings where Dr. Crawford was the Acting Commissioner, were notes kept at those meetings?

A No.

Q Did you ever have any communications with

someone in the Department of Health & Human Services, so the Secretary, outside the FDA, but within HHS, about the Plan B application?

A No.

Q Did you ever hear about such conversations or communications?

A No.

Q Did you ever have communications with -- did you ever hear about communications with anyone in the office of the White House about Plan B?

A No.

Q No one ever told you about such conversations or meetings?

A No.

MR. AMANAT: Did you verbalize your answer?

THE COURT REPORTER: Yes.

BY MR. HELLER:

Q Did you ever have conversations about the Plan B application with anyone, with friends, family, about what was going on with the application?

MR. AMANAT: Objection. The question's a

bit broad in terms of time scope.

MR. HELLER: Yeah.

MR. AMANAT: Are you talking about any particular time frame?

MR. HELLER: Yeah, let me make it more specific.

BY MR. HELLER:

Q During the time -- let's say from the time the SNDA was filed, I guess that was April of 2003, through August of 2005, I guess that's a little over two years, did you from time-to-time talk with, not friends or family within the government, but friends or family, in general, about the Plan B application?

A Well, first, let me make sure you realize I never discuss nonpublic information outside of the Agency. But, of course, once this whole thing was public, I discussed it with, you know, friends, family, neighbors who asked me, it was in the newspaper, sure.

Q I didn't mean to suggest you would disclose confidential information.

A Yeah, right.

Q And within CDER, do you -- are there any sort of particular people who you recall having meetings or conversations with about the Plan B SNDA?

MR. AMANAT: Again, during what time frame?

BY MR. HELLER:

Q During the, from April 2003 to August 2005.

A Well, you've got the records of all the meetings that took place.

Q Well, we have records for the ones where there are written records.

A Yeah. The way the management of the Center works is that I have weekly meetings with all of senior managers, the people that report to me, together, and then I've got separate meetings with each member of the senior management team. So I would have been meeting regularly with Dr. Jenkins and Dr. Kweder every week or every other week throughout that time, as well as other managers.

And I'm sure that Plan B came up in many of those meetings during that time.

MR. AMANAT: Mr. Heller, it wasn't clear to me -- I'm sorry. Mr. Heller, it wasn't clear to me whether your last question was intended to ask about meetings that were specifically convened for the purpose of discussing Plan B or whether Plan B came up in the course of a more general meeting that may have been scheduled for purposes not specifically geared to Plan B. Your question was ambiguous.

MR. HELLER: I think, I think it was the latter.

MR. AMANAT: The latter?

MR. HELLER: And I think he answered that in a way.

MR. AMANAT: Okay.

BY MR. HELLER:

Q These meetings that you're describing sort of within CDER, sort of with subordinates, there are typically no minutes or notes kept at those meetings?

A No.

Q And I would imagine that during the course of the two, rough, more than two years that I described, occasionally, you just have conversations,

you know, you're walking down the hall, and you talk to someone about Plan B or any one of a number of other matters that the Agency has pending?

A Sure.

Q And you don't have records of any of that either, of course, right?

A No.

Q Did you have any meetings with members of Congress about the Plan B application?

MR. AMANAT: Again, just for the record, when you say, "meetings," are you including formal testimony before committee, or are you only asking about meetings with individual members of Congress?

MR. HELLER: Communications of any kind with members of Congress or their staff.

MR. AMANAT: Including formal public testimony?

MR. HELLER: Including testimony, yeah.

THE WITNESS: Yeah, I mean, the only -- again, all my interactions with Congress are public. So I, you know, it's possible I don't recollect something, but what I do recall is this briefing that

I already mentioned, where we went down and talked to a number of the members of Congress and just explained what Plan B was, and I went with a group of people from CDER, from the reproductive drugs division, and, again, that was -- it wasn't specifically about the application. It was just they wanted information about the drug.

And then, you know, very recently, over the summer, there was appropriations -- I mean, in the fall, there was -- no, I guess it was just in the last few months, there was appropriations committee, a subcommittee meeting in the House Agricultural Committee for Dr. Von Eschenbach, and Plan B came up, and I answered a couple questions that were asked, but that, those are the only contacts that I recall.

There, you know, there may have been -- there have been Congressional letters that have come in having to do with Plan B, that the Agency has answered, and I've reviewed those responses, but, again, those are all public.

BY MR. HELLER:

Q Somewhere, I hope -- yes, you have in

front of you a notebook. If you could -- and there are tabs?

A Yes.

Q Various numbers and letters tabs there?

A Yes.

Q If you could turn to the tab marked 3030?

A 3030.

Q And it's a one-page document. Do you see it?

A Uh-huh.

Q This, do you, does this, do you know if you attended a May 28th, 2002 meeting?

A My name is certainly on here. I'm sure I did.

Q Do you remember anything about this meeting? I mean, just --

MR. AMANAT: Can you give the witness an opportunity to read the document, please?

MR. HELLER: Sure, yeah, sure.

MS. REYES: And while you're doing that, I don't have a notebook, so I can't tell if the documents are confidential or not. Can you just let

me know if you're about to start reviewing a document that's confidential?

MR. HELLER: Yeah, I will, absolutely.

MR. AMANAT: Let me know when you finish reading the document. Mr. Heller, before we proceed, we haven't talked about what the procedure is going to be during the deposition with regard to documents. You're very kind to produce this notebook for us. Are you, are we going to deal with documents in these depositions, more or less, informally?

Or are you planning on formally marking them for identification as exhibits to the deposition? And how did you want to handle that?

MR. HELLER: My preference is just to handle it informally, not mark them as exhibits, not attach them at the end, particularly because I think virtually every document -- there may be a couple of exceptions, but virtually every document is premarked because it was either produced in the administrative record or through discovery.

MR. AMANAT: Then just to make sure the record is clear, let's just make sure we identify on

the record what document we're dealing with, if we're not going to mark it for identification, so --

MR. HELLER: That's fine. I will do that, okay?

MR. AMANAT: Okay. Because I just don't want there to be any confusion of clarity if there aren't, if we're not going to have documents formally marked for identification of the exhibits to the deposition and attached to the transcript, and you're going to deal with it informally, that's fine with me, as long as we're crystal-clear on the record what the document is that we're talking about.

MR. HELLER: Yeah, and I'll make that clear --

MR. AMANAT: Okay.

MR. HELLER: -- in a moment.

BY MR. HELLER:

Q Have you had a chance to read this document?

A Yes.

Q And it's marked Tummino 30165?

A Right.

Q Okay. Does this document at all sort of remind you of a meeting that occurred in 2002?

A No, I really can't, I can't remember this meeting specifically.

Q Okay. Thank you. Do you recall a meeting a little bit later in 2002, June 5th, 2002, a meeting of the, at the office of the Commissioner regarding an OTC switch, and if you want to look, the next tab, 3031, is a multi-page document with stamped Tummino 30166 through 30174. And I'm just wondering if you recall such a meeting?

MR. AMANAT: Just take a moment to review the document.

THE WITNESS: Yes.

BY MR. HELLER:

Q You have some recollection?

A Yes, I have some recollection of this meeting.

Q Was this a meeting that was called by the office of the Commissioner, do you know?

A I don't remember for sure. My -- I would say probably we set up the meeting in the Center. I

don't remember specifically though. It would have, the typical procedure would have been for us to set this up.

Q Okay. Does this happen with every OTC switch application that there's a -- you set up a meeting with the office of the Commissioner in which you --

A It happens with any high-profile drug approval or policy issue that we think we want to make sure the Commissioner knows about, but not every OTC switch.

Q And by --

A Although we have had meetings with the office of the Commissioner about OTC switches, so I really have to look at the list of OTC switches that I've been involved with and see whether each one of them has had some sort of meeting. I don't know.

Q Okay. So this meeting, if I have the timeline right, this meeting occurred before the Plan B SNDA, which was in 2003, is that right?

MR. AMANAT: When you say before the SNDA, you mean before it was filed?

MR. HELLER: Before it was filed, yes.
BY MR. HELLER:
Q Is that right? You have to say yes.
A Yes, yes.
Q Okay. Thank you. And it was -- so this meeting was called because of the citizens' petition?
A Well, I can't -- that's what it looks like. I can't remember whether we knew at this point that we were going to receive the Barr application, you know, we may have known. It doesn't seem to mention that, but --
Q This would have been the Women's Capital Corporation?
A The Women's Capital -- right, right.
Q It doesn't mention that, but this, it was certainly before it was filed?
A Right.
Q Okay. And do you recall any other instance in which -- well, I guess if you look at the second page of this document, or Tummino 30167, sort of third paragraph down, I think does indicate that Women's Capital Corporation intends to submit --

A Ah, okay.
Q Do you see that?
A Yes.
Q Okay.
A So we knew that then.
MR. AMANAT: Just for the record, there's also a reference on the first page as well.
MR. HELLER: Oh, there is? I missed that.
MR. AMANAT: Under meeting, under meeting purpose.
MR. HELLER: Oh, yes, that's right, under meeting purpose on the first page as well. Thank you, Frank.
BY MR. HELLER:
Q Are you aware of any other instance in which the office of the Commissioner had been briefed or held a meeting in anticipation of an OTC switch application, like this is coming, we better have a meeting?
A I can't come up with a specific example, but I certainly couldn't rule it out either.
Q But as far as you're aware, you don't

know --

A I don't remember any, but there may well have been one. We had extensive meetings about an OTC switch petition that we received about antihistamines, and we may have had a meeting on that with the Commissioner's office early on. There was, that was another situation where there was an application and a citizens' petition, but I don't recall specifically.

Q When sort of minutes like this or memo summarizing a meeting is generated, is this something that you review or read, or does it, sort of, does it come back to you --

A Yes.

Q -- afterwards?

A Yes. Frequently, the process is when there is a formal meeting like this and minutes are taken, each of the participants in the meeting gets a copy of the minutes to review and approve before it gets recorded, so that's typical.

Q So if, so with something like this, you would have reviewed it at either, I mean, do you have

to sort of formally approve it, or do you just say, wait a second, I didn't say that? I mean, what --

A You have to formally approve it.

Q Oh, okay. You formally approve it. Okay. So it would have gone, would it have gone, would this one have gone to all these people listed as attendees on the first page?

A Again, I don't know if it did.

Q Okay.

A The typical procedure is, yes, it does.

Q Okay. And at this time, in June of 2002, that would have -- Dr. McClellan was the Commissioner then, is that right?

A June? You have to tell me the date.

Q I think Dr. McClellan would have been --

A I'm chronologically challenged. Yeah.

Q -- the Commissioner or Acting Commissioner in 2002.

MR. AMANAT: I don't believe that's correct.

MR. HELLER: That's not correct?

BY MR. HELLER:

Q Would Dr. Crawford have been the Commissioner at that time?

A I --

Q Okay.

A He either was, or he wasn't. We don't have to speculate.

Q Okay.

A Someone will have that.

Q Okay.

A Yeah. I want to, I just want to make a point of clarification.

Q Yes, sir.

A It's really -- the right question about whether it's, we typically have these meetings, it's not about whether we do this for OTC switches, it's about whether we do this for high-profile policy citizens' petition and approval decisions. That's the right question.

Q Okay.

A It's not really relevant that we have it or didn't have it for OTC switches. It wasn't because it was an OTC switch. It was because it was

a high-profile issue, and that's totally typical.

Q Okay. I think I understand.

A Yeah.

Q So you could have 20 OTC switches that would be reviewed, and there would never be this kind of meeting because they might not be high-profile?

A Exactly.

Q Okay. I think I understand. And let's go back to the high-profile nature of, I guess, the citizens' petition and the Plan B SNDA for a moment. Can you tell me a little bit more -- and I hope I didn't ask this before -- about what made it high-profile? And for point of reference or -- I'm going to mention another drug, and I hope I don't mispronounce it. N-9, do you know what that is?

A Nonoxynol-9?

Q Yeah, I --

A Spermicide, yeah.

Q Yeah. That's also a reproductive health drug?

A Absolutely, yes.

Q Was that also a high-profile drug?

A Yes.
Q Do you know if similar --
A Many meetings.
Q Commissioner's meetings about it?
A Yes.
Q For the OTC switch for that, were there Commissioner's meetings?
A Oh, I don't remember about the OTC -- I don't think I was here when the OTC switch occurred for N-9.
Q Okay.
A But there were lots of other issues having to do with N-9's impact on HIV transmission that was going on when I was at the Center, and there were lots of meetings about that. As I said, the main criteria that makes this high-profile, and you did already ask this, is that it has to do with human reproduction, and all these issues are contentious nationally, politically, Congress, members of the administration.
It's always been that way, probably always will be.

Q And so when there's a high-profile drug that the FDA is reviewing in some manner, that makes it more likely that higher level people within the FDA will be involved, is that fair to say?

A Sure, yeah, yeah.

Q And does that mean that basically these higher profile drugs get more scrutiny from the Agency?

A They --

MR. AMANAT: Can you define what you mean by, "more scrutiny"?

BY MR. HELLER:

Q I mean, there are more people scrutinizing the decision. You have, like in this case, in the case of Plan B, you had the Commissioner involved, the Deputy Commissioner, you were involved.

A Yeah, I think that's fair to say. When there's a high-profile decision, it gets more people involved.

Q And you --

A Whether that constitutes higher level of scrutiny or just more people with less scrutiny,

that's -- I don't know if it necessarily gets a more detailed treatment, but it gets more people involved.

Q But so going back to, for example, the meetings -- I shouldn't say, "informal" -- the weekly meetings you talked about with yourself, Dr. Woodcock, and Dr. McClellan, at some of which you talked about Plan B?

A Uh-huh.

Q And you talked about scientific issues and the data, you were getting, at these meetings, you were essentially getting the input of more or additional scientific and medical people --

A Absolutely.

Q -- than you would have with a less higher profile drug where the Commissioner and the Deputy Commissioner and even you were not involved?

A Absolutely.

Q Does that improve the process?

A I think it does substantially. And Dr. Woodcock is probably the most experienced drug regulator in the world. Dr. McClellan is a, you know, highly respected health policy expert with

medical public health training, Ph.D., and there's no question that that sort of input has always been very helpful to me because the perspective that they provide and the experience, and I would say the same thing about Dr. Crawford.

He's a very experienced public administrator, a scientist, a veterinarian, a lot of experience at FDA, yeah.

Q But so then thinking about the drugs that are not high-profile, that don't get your involvement in the same way, or the Commissioner, the office of the Commissioner involved, are those drugs somehow -- it seems to me that the, that the inference is that those drugs are -- decisions are being made with sort of a less complete scientific review, is that right?

MR. AMANAT: Object to the question, it assumes facts not in evidence. There's been no testimony to that effect. Go ahead.

MR. HELLER: He just did testify --

THE WITNESS: No, I don't agree with that at all.

BY MR. HELLER:

Q So don't they not get the benefit of Dr. Woodcock's, Dr. Crawford's immense experience?

A We have, we have very, very highly expert staff that are specifically trained in drug review. Not all of our decision-making is very, very complex. It has different ranges of complexity. We have a very well-established system. When there is a more complicated, contentious, or difficult decision, we do get more people involved.

So I would say the level of involvement is commensurate with the difficulty or complexity, you know, implications of the decision. And I think each decision gets about the appropriate -- what it needs, and certainly, our goal is to give each decision the level of scrutiny that it needs.

Q With this particular, with Plan B as a particular high-profile drug, part of the reason that it was high-profile was that a drug that would -- contraceptive drugs are politically controversial in the United States, is that right?

A I guess, yeah.

Q That's true, isn't it?

A Yeah, yeah.
Q And when --
MR. AMANAT: When you, when you say, "politically controversial," you're referring to politics in the philosophical sense, I assume, as opposed to the partisan sense, is that what you're referring to?
MR. HELLER: Yeah, I'm referring to both.
THE WITNESS: Let me, let me tell you, that's not what governs my thinking. It's not political. It's the scientific. It's the fact that two equally trained scientists may have a different perspective on the same data.
BY MR. HELLER:
Q Okay.
A That's the, that's the contentiousness that interests me, not the big P political. That's true, but that's not the world that I operate in.
Q Does the Commissioner of the FDA operate in that world?
A Certainly more -- yeah. I'm a career employee.

Q Okay. But the Commissioner does operate in that world?
A Certainly.
Q Okay. Did the Commissioner bring any of that information to those meetings that you had?
A No.
Q Really?
A No.
Q Okay. Was -- so there are different kinds of things that might make a drug high profile. One of them, among others, would be this kind of political controversy, is that right? I'm just saying -- yes or no, you have to say yes or no.
A Yes.
Q So she can record the answer.
A Yes.
Q Another example would be sort of scientific controversy, where there's significant disagreement about safety or effectiveness of a drug?
A Uh-huh.
Q I'm sorry, you have to say yes or no.
A Yes.

Q Was the safety or effectiveness of Plan B scientifically controversial, in your view?

A Yes.

Q What the nature of the controversy?

MS. REYES: I'm just going to interject. If you start talking about the SNDA or the scientific background, we're going to have to start labeling this a confidential part of the transcript.

MR. HELLER: Well, I think -- we may have to, depending on what his answer includes, of course.

MS. REYES: I'm just flagging the issue.

BY MR. HELLER:

Q Okay. Can you tell me what the -- why Plan B was scientifically controversial?

A One of the key scientific judgments that we make with any application is whether, that there is a sufficient quantity of data to demonstrate safety and efficacy. I felt with this application that we didn't have a significant quantity of data on young teenagers to demonstrate safety.

(The following testimony was designated "PROTECTED TESTIMONY" and is bound separately.)

(This concludes the "PROTECTED TESTIMONY".)

BY MR. HELLER:

Q Roughly, if you know, how many OTC switch applications have been approved during your tenure at

the FDA?

A I don't have that number.

Q It'd be more than 20, probably?

A No, no, no, no.

Q 10?

A OTC switches?

Q Yeah.

A No.

Q 10?

A No.

MR. AMANAT: When you say during his tenure, are you referring only to his tenure as director, or are you including his tenure as acting director of CDER?

MR. HELLER: I said tenure at FDA.

MR. AMANAT: Tenure at FDA, total? Including --

MR. HELLER: Yeah, I --

THE WITNESS: Yeah, I don't -- I'd have to go back and look. It's just been a handful.

BY MR. HELLER:

Q Okay. In those handful of OTC --

A Small handful.

Q -- OTC switches --

A Yeah.

Q Did you look for, did you -- was, were any of those scientifically controversial because they lacked adequate data for young adolescents?

A Every --

MR. AMANAT: Hold on a second. I'm going to object as a general matter to inquiries into drug applications other than the drug application that's at issue in this case.

MR. HELLER: What's the basis for that objection?

MR. AMANAT: The basis is twofold. First of all, I believe it's beyond the scope of the discovery authorized by the magistrate judge in the February 24th decision and order, and secondly, the witness may not be able to answer that question without revealing confidential commercial information that's proprietary to the sponsors of the other drug applications who are not here and able to speak for themselves.

MR. HELLER: Well, when we get to a question where I'm asking him -- my question, I think, was -- let me try to rephrase it, so maybe it addresses --

MR. AMANAT: Well, please, because the magistrate judge, I do not believe in his -- anything in his order can be read to authorize inquiry into the Agency's process for deciding drug applications other than the drug application for Plan B or anything other than its process for considering the citizens' petition, which is the subject of this lawsuit.

So to the extent that your question delves into specifics of other -- of how the Agency has handled other drug applications, I would state an objection for the record.

MR. HELLER: I will, I'll just briefly respond. I sort of find your objection bizarre because the magistrate specifically directed the FDA to answer numerous questions about other drug -- OTC switch applications, and you provided us with charts that summarized that information.

MR. AMANAT: And to the extent you ask questions with the same level of generality that were set forth in your interrogatories in responding in our charts, I have no objection, but the question you asked seemed to request more specifics.

MR. HELLER: It did not.

MR. AMANAT: Okay. Then why don't you restate the question? And I will see if the objection is still -- if I still have an objection. Go ahead.

MR. HELLER: I don't know if I can remember it anymore. I'll rephrase it.

BY MR. HELLER:

Q Were any of the OTC switch applications that have arisen during your tenure at the FDA scientifically controversial because they lacked data, adequate data for young adolescents?

A Your question reflects a lack of understanding of the drug review process, and let me tell you why. Every single application is different. Every application reflects a new set of risk and benefit decisions that have to be made. There's no

two drugs, unless it happens to be the same drug, that requires the exact identical data that has to do with the specific risks and the specific benefits.

With OTC switches, and I'm getting to answer your question, the question about whether people can safely take the drug when it is available over the counter without the intervention of a physician is always there. There's always that question.

Q So I'm not asking you to tell me that all drugs are the same in the OTC switch process. I'm just asking if you can tell me whether there has, in your tenure, been an OTC switch application which you viewed, other than Plan B, which you viewed as scientifically controversial because it lacked adequate data for young adolescents?

MR. AMANAT: Could you, once again, be more specific what you mean by, "tenure"? Are you talking --

MR. HELLER: While he's been working at the FDA.

MR. AMANAT: At CDER, specifically?

MR. HELLER: Wherever, anywhere.
MS. JONES: At the FDA?
MR. HELLER: At the FDA, period, while he's been working in this building.
MR. AMANAT: Well, because he --
MR. HELLER: I know -- that's my question. He can either answer it, or he doesn't answer it, I mean.
THE WITNESS: No, but it doesn't -- you're not making, you're not doing a good job of making your point because we've never had another application for Plan B.
BY MR. HELLER.
Q Let me emphasize what my points are. I have to --
A Of course not. I wouldn't be a good scientist if I was requiring the same thing from every drug. Every drug's different.
Q So the answer, if I'm understanding you correctly, no other OTC switch application during your time at FDA, as far as you're aware, has been scientifically controversial because it lacks data,

it lacks data for young adolescents?

A This issue has come up with a drug that's currently under review, which has nothing to do with Plan B, that I don't really -- it's confidential commercial data.

Q So don't talk about it. Okay.

A Yeah, but, yes, it has come up in another OTC switch application.

Q A current one?

A Uh-huh.

Q Let me narrow my question a little bit more. Has -- well, is the office of the Commissioner involved in that one?

A I've kept the office of the Commissioner informed about it. I don't know that we've had a briefing, but multiple phone calls and discussions and, you know, conference calls about it.

Q With the office of the Commissioner?

A Uh-huh.

Q Yes or no.

A Yes.

Q Is it a reproductive drug?

MR. AMANAT: At this point, I think, again, this is --

MR. HELLER: How can that possibly be confidential information?

MR. AMANAT: Well, because you're, because it's a pending drug application. The interrogatories that you propounded and which the court directed us to respond to all related to completed drug applications in which either a nonapprovable or an approvable letter had been issued, and we gave you the chart with that regard. The FDA's regulations preclude disclosure of any information concerning a pending drug application.

MR. HELLER: Okay. I'll withdraw the question.

BY MR. HELLER:

Q As to completed OTC applications, so ones which were either approved, not approved, or somehow terminated by an Agency action, other than Plan B, are you aware of any which were scientifically controversial because of lack of adequate data about young adolescents?

MR. AMANAT: One second. I'm going to object to the question, again, because your statement, "other than Plan B," assumes that Plan B is something other than a pending drug application, and it is our position, as you well know --

MR. HELLER: Okay. Let me just rephrase the question.

MR. AMANAT: Okay.

BY MR. HELLER:

Q Excluding Plan B from my question completely, do you know of any OTC switch application that's been either approved, not approved -- as to which there's been Agency action, where it was scientifically controversial because it lacked data for young adolescents?

A No.

Q Okay. Thank you.

MR. AMANAT: I'm not trying to be an obstructionist, Mr. Heller. I'm trying to make sure that the witness' testimony is very clear.

MS. JONES: Do your statements to that effect count as part of our seven hours?

MR. AMANAT: It's part of your questions and his answers, yes.

BY MR. HELLER:

Q One of the documents received, we received referred to someone named, someone named Jay Lefkowitz. Do you know who that is?

A It doesn't ring a bell.

MR. AMANAT: Do you have a specific document in mind?

MR. HELLER: He answered the question. We'll take a five-minute break at the request of the court reporter.

THE VIDEOGRAPHER: We're going off the record. The time is 10:37 a.m.

(Recess.)

THE VIDEOGRAPHER: We are back on the record. The time is 10:48 a.m.

BY MR. HELLER:

Q So I want to go back to some, a couple questions I asked you earlier. You said that at some point, you had conversations with people outside the FDA about Plan B, who were those people?

A I mentioned the Congressional briefing.
Q Right.
A Right. And then I mentioned the Congressional, the hearing that just occurred a few months ago, or weeks ago.
Q But you also mentioned you may have talked with friends, family --
A Oh, sure, sure. The neighbor asked me what's Plan B all about.
Q And How --
A We see it in the Washington Post, they want to know what it's all about.
Q What did you say?
A I just explained, you know, what I could.
Q And with other people, other friends, family, did you say more than that to other people?
A I can't remember every conversation that I had.
Q Do you remember any conversation that you had?
A I don't -- can you be more specific? I mean, you're talking about a several year period and

hundreds of people, counting family, neighbors, acquaintances, friends, soccer game, colleagues. What are you asking me? What do you want to know?

Q Let's start with family members. Did you talk with your family members about the Plan B?

A Sure.

Q Who?

A My wife, my children, my parents, my siblings, my aunt, my uncle, my cousins.

Q That's a lot of people too. What did you say to your children about the Plan B application?

MR. AMANAT: I'm going to object -- that seems a little personal.

THE WITNESS: Yeah, it seems --

MR. AMANAT: I mean, I'm going to allow the witness to answer the question. I can't --

THE WITNESS: The conversations I have between my children --

THE COURT REPORTER: I can only take one at a time.

MR. AMANAT: I will allow the witness to answer the question, but I will note my objection for

the record.

MR. HELLER: What's the objection?

MR. AMANAT: Relevance, I mean, what's the relevance?

MR. HELLER: Let's see what his answer is. I don't know, maybe he said that --

BY MR. HELLER:

Q What did you say to your children about this?

A I tried to explain what the application was all about and what they were reading in the newspaper.

Q What did you say to them?

A I can't -- do you want me to try to give you --

Q Summarize what you said to them.

A What the application was about, that it was to switch an emergency contraceptive product from prescription status to over-the-counter status, and why I didn't approve the application in 2004, and the reasons that I didn't approve it, you know, were in, that were public at that point, that, you know,

summarizing as much as you can, remember back a conversation you had a couple years ago.

Q Your parents, what did you say to them about it?

A Same sort of things.

Q Did you say anything about your own, to either parents or children, about your own views about the process that had occurred with respect to Plan B at the FDA?

A I --

MR. AMANAT: I'm going to object. I mean, you haven't even asked him what his views are with regard to the process.

MR. HELLER: So I'm asking him if he expressed his view. Is that -- what is the objection there?

MR. AMANAT: The objection is relevance.

MR. HELLER: Look --

MR. AMANAT: I mean, I'm not instructing him not to answer the question.

MR. HELLER: Since when do you make relevance objections at a deposition?

MR. AMANAT: Since the magistrate judge has specifically defined what's in the scope of the discovery.

MR. HELLER: Should we get him on the phone?

MR. AMANAT: I'm not going to do that, Simon.

MR. HELLER: Well, I'd like to if you're going to continue to make relevance objections on the record.

MR. AMANAT: Answer the question, Dr. Galson.

THE WITNESS: What's the question, what I said to my parents?

BY MR. HELLER:

Q What you said to your parents and your children about your own views about, views or thoughts about the process that had occurred within the FDA about Plan B.

A You know, I really don't remember specifics of what I -- they probably, you know, asked the same question that a million people have asked

me, were you ordered to do this, or did you do it on your own? My children wouldn't have asked that, but probably my parents did, and I said, no, I was never ordered to do anything, it was my decision.

Q Which decision?

A Are you asking about the period going up to 2004?

Q No, the whole period up to the present.

A Yeah, I talk to my parents every week, so that would be more than, you know, 100 conversations. I just, I can't remember everything that I've said about -- you have to be more specific. What are you trying to, what are you trying to get at? I just, I could talk for two hours and tell you everything I talk to my parents about.

Q No, I don't want to know everything you talk to your parents about.

A Yeah, well, what --

Q What did you say to them about Plan B?

A The major question I think they probably asked me is whether I made the decision in May on my own or whether I was pressured to make that decision

because that's what was in the newspaper, so they were asking me about that.

Q Have they asked you about any events since May 2004 with respect to Plan B?

A Sure.

Q What events have they asked you about?

A They probably asked me what, you know, in August, when that decision became known, you know, well, how did you -- what was your role with that?

Q And what did you say?

A I really don't remember what I said. I probably explained the situation, it wasn't my decision, that I wrote a memo supporting the approval of the product with the bifurcated age, and that the Agency made a decision to put out this ANPRM. I would have just discussed the factual, what actually happened.

Q You didn't talk about your views of what happened in August of 2005?

A I really don't remember. I really don't remember.

Q Okay. Could you turn to tab 3081 in this

notebook? It's not too far, not too much further into this.

A Yeah.

Q And I will note that I believe the second page of this document has been marked confidential, in part -- what was designated as confidential, in part.

MR. AMANAT: One paragraph.

MR. HELLER: One paragraph.

MR. AMANAT: On that page.

MR. HELLER: On that page. But the first page of this document is marked Tummino 30393.

BY MR. HELLER:

Q And this appears to be an office of the Commissioner meeting that took place on December 10th, 2003.

A Correct.

Q Do you recall attending this meeting?

A Yes. Actually, wait a minute. Am I on this list?

Q You're listed as an attendee in the third line.

A Yes, okay.
Q I'm not trying to trick you.
A Good.
Q At least about this.
MR. AMANAT: Can the witness have a moment to review the document, if you're going to question him about it?
MR. HELLER: I'm not going to question him about the document.
MR. AMANAT: Okay.
MR. HELLER: I just wanted to see if he remembers being at this meeting.
THE WITNESS: Yeah.
BY MR. HELLER:
Q Okay. So then my question is, do you know who called this meeting?
A I don't remember whether it was called by the Center or called by the Commissioner's office.
Q And this is a meeting that looks like maybe there might have been 20 or 30 people attending, I'm not counting them all there, but a fairly large group attended, is that right?

A Yes. The typical, that's typical for a Commissioner's office meeting, yeah.

Q Do you recall, during your tenure at the FDA, other Commissioner's office meetings regarding OTC switches for other drugs?

A Yes.

Q Can you recall a particular drug where such a meeting was called?

A The one that pops into my head, although I can't remember the specific meeting, but I remember that we had meetings, was the switch of the antihistamines from prescription status, the nonsedating antihistamines.

Q Like Claritin?

A Like Claritin, right.

Q And you recall some sort of Commissioner, office of the Commissioner meeting during that --

A I can't remember the size of it, but, yeah, keeping them informed, talking to Dr. McClellan about it.

Q Do you recall at this December 10th, 2003 meeting whether Dr. McClellan expressed concerns

or -- concerns regarding the OTC switch?

A I don't recall.

Q Are these meetings recorded in any way?

A No, no.

Q They're not recorded?

A Well, there are note takers. They're not --

Q No audio recording?

A No.

Q Okay.

A I was just going to say the purpose of the meeting was to make sure that the folks in the Commissioner's office knew what was going on with this application in advance of the advisory committee because it was going to get a lot of attention and press.

Q Again, because it's high profile?

A Right.

Q In part, because it's scientifically controversial?

A I think the high-profile part is the main operative one there. We knew there'd be millions of

press there, it would be covered, we'd be getting questions from the Department, from Congress. There would be a lot of, I mean, we knew there were a lot of members of the public who were registered already at that point to speak.

Q By the way, the scientific controversy regarding this drug, was it, was that scientific controversy reflected in the expert advisory committees that met regarding this application?

A Was the science --

Q I mean, was it manifest -- was there, was there scientific controversy within the advisory committee?

A Absolutely, sure.

Q What was the nature of that controversy?

A We've -- you've got the transcript and the questions and the votes. There were questions about all the range of data in the application, whether it was adequate, whether they had done a good actual use study. The question about adequacy of the data for children came up, whether this, whether if young people got this drug, they would not go to see

physicians.

All these, all the questions came up at one point or another in this, you know, and the advisory committee lasted a long time.

Q Would you turn to tab D287, which is towards the back a little more? There are some tabs starting with D on it, on them.

MR. AMANAT: These are -- by, "D," I assume these refer to the documents we produced to you in discovery? Is that what the D stands for?

MR. HELLER: I believe so. Yes.

BY MR. HELLER

Q Did you find it?

A Yes.

Q This document is marked Tummino 287.

A Right.

Q Why am I even -- oh, okay. And most of it's blacked out, but there's a notation briefing on Plan B, "10/31, per Jenny Embry, rescheduled from 12/1 with Jenny and June on 11/18." Do you know who Jenny Embry is?

A She was my secretary.

Q Okay. And who is June? Do you know who this person June would be?

A The -- no, I don't know who that was. I could guess. Do you want me to guess?

Q No.

A No, I don't know for sure who June was.

Q And is this a reference to -- do you know what briefing is being referred to in this calendar?

A Well, this, this one --

Q Yeah.

A -- from the previous document, right? It's June 10th, 3:00.

Q Okay. So this is a calendar from --

A Calendar, typical calendar entry.

Q Okay.

A It's Dr. McClellan's calendar, explaining what the --

Q Now, if you'd turn to D511, it's a little further on there. And I think this is how it looked when we got it, but you can sort of make out, if you look at -- let me see if I can find it. Around 11:30 -- and this is marked Tummino 511, right? Do

you see that?

A I really can't read it. I'm sorry.

Q At the -- but you can read Tummino 511 at the bottom, right?

A Yes, yes.

Q So I'm going to read to you what I think it says, and you tell me if you can make this out. "Short call during this time with Dr. Carmona. SG wants to discuss recent ruling on Plan B."

A I can't make that out.

Q Okay. You can't read that?

A Yeah.

Q Do you know, who is Dr. Carmona?

A He's the Surgeon General.

Q Is he still the Surgeon General?

A Yes, yes.

Q Okay. Was he -- do you know if he was Surgeon General on December 17th, 2003 also?

A Yes.

Q Do you recall any -- do you recall a phone call involving Dr. Carmona and Plan B?

A No.

Q Okay. And so --
A This is, this is not my calendar. It's Dr. McClellan's.
Q I realize that.
A Yeah.
Q But I was guessing that, as I read the initials SG, that that's a reference to you?
A No, no, that's Surgeon General, I would think.
Q So the Surgeon General wanted --
A What does it say again?
Q It seems to say, "SG wants to discuss recent ruling of Plan B."
A That would be Surgeon General.
Q Oh, that makes sense.
A Yeah.
Q And you've never heard anything about a phone call between Dr. McClellan and the Surgeon General about Plan B?
A Not until just now.
Q Okay. All right.
MR. AMANAT: Your eyes are better than

mine. I could barely make that out.

MR. HELLER: That's why discovery is so useful. You not only get the discovery, but then you have to discover things about the discovery.

BY MR. HELLER:

Q If you turn back now to the tab marked D10 to 16?

A 10 to 16, it doesn't seem like there's anything in there.

Q Oh, that's no good. We'll put something in there.

A Okay. You want me to put it in the binder?

Q Sure. That would be, you know --

A Okay.

MR. AMANAT: And are you going to ask this witness about this document, can he have a moment to look at it? Or --

MR. HELLER: Sure. I was going to say the first page is marked Tummino 10, and it goes through Tummino 16. Is that right?

BY MR. HELLER:

Q The only thing I'd like to have you actually look at is starting on page Tummino 13, so I guess that's two or three pages in, up to Tummino 15. Please read that over, if you'd like.

A Uh-huh.

Q Have you, can you tell whether -- do you recognize those pages?

A I have to read it.

Q Okay.

A Not immediately.

Q Please go ahead and take a moment. Have you completed up to page 15 yet?

A Yes.

Q Oh, okay. Great. Do you know if you've seen this letter before?

A You know, I believe I have, but I can't say for sure.

Q I'm going to refer to it --

A Yeah.

Q -- as the Hager letter.

A Okay.

Q Do you know who Mr. Hager is?

A Sure.

Q Okay. Do you, have you heard of this letter before that he wrote a letter regarding Plan B?

A Yes, yes.

Q Okay. Do you know if anyone -- do you have any information suggesting that this letter was just solicited, solicited by someone at the FDA, that someone suggested to Dr. Hager that he write a letter to the FDA?

A No.

Q Do you have any information that would suggest that this letter was solicited by someone else in the government, other than within the FDA?

A No.

Q Okay. Now, I'm going to ask you to look at tab D288, which is further on in the book here, and this is marked Tummino 288.

A Uh-huh.

Q And there's a reference at 1:00 p.m., which I think is legible, that refers to a conference call with S. Galson, J. Woodcock at home, re Plan B,

and it says, "We placed call."

A Uh-huh.

Q I'm sorry, yes or no.

A Yes, yes. Sorry.

Q Do you recall, do you have any recollection of a conference call or phone call with yourself and Dr. Woodcock and Dr. McClellan around December 23rd, 2003?

A No.

Q So you don't remember something where Dr. Woodcock was at home and you had to -- I mean, this was like the day before -- two days before Christmas, I guess.

A No, I don't remember it. It's very common that we have conference calls with people who are at home, so that doesn't mean anything, yeah. I don't remember it, no.

Q Would most of -- when there are conference calls like this scheduled?

A Yeah.

Q Would they typically be reflected on someone's calendar?

A Sure. We're scheduled so tightly that everything is on the calendar.

Q Okay. So you don't remember anything about this call?

A No.

Q Putting aside sort of this call, that's the call on December 21st, do you remember having a conference call about Plan B with Dr. Woodcock and Dr. McClellan ever?

A I certainly remember having conversations. I can't, I don't remember conference calls, no, no. It's difficult to describe, you know, I've got thousands of meetings in the last couple years, and I just don't -- unless it was something explosive, I wouldn't remember individual ones that happened.

Q Do you remember any explosive meetings regarding Plan B?

A No.

Q Really? None? Can you give me an example of an explosive meeting you do recall?

A Giving bad feedback to an employee who gets very upset.

Q That's a good example. Can you turn now to tab 3101, which is earlier in the, in the binder?

A 3101.

MR. AMANAT: Before we do that, I think you neglected to mention in regards to the last document that it was page 288.

MR. HELLER: I did mention that.

MR. AMANAT: Oh, you did. Okay. I didn't catch it. I'm sorry.

BY MR. HELLER:

Q And this is a document marked Tummino 30666 through 30670. Do you recognize this document?

A Just give me a few minutes to review it.

Q Sure.

A Okay.

Q Great. And this is a document that bears your electronic signature?

A Right.

Q If you'd turn to the second page of the document marked Tummino 30667, under the heading, "Meeting Objective," and then could you tell me what that says? And then explain, I'm going to ask you to

explain a couple of the terms in that sentence.

A To inform these two offices, which are, you know, administrative groupings in our organization, of the office of the Commissioner's position on the acceptability of application, that's what it says.

Q What is ODE3?

A The Office of Drug Evaluation 3. We have these very creative names. We had Office of Drug Evaluation 1 through 5 -- 6. There were, this application was worked on by two separate parts of the Center, one that regulates nonprescription drug products and one that regulates reproductive health products, so one of those is in O3, and one is in 05.

Q And does that accurately, does that sentence accurately state the objective of that meeting?

A I think so, yes.

Q Okay. And tell me what, when you -- did you conduct the meeting, this meeting?

A Yes, yes.

Q And did you inform those two offices of

the office of the Commissioner's position on the acceptability of the application?

A You know, I don't, beyond what's in the minutes, I don't remember the meeting very well. So I'd have to really rely on what's in here, and it doesn't, it doesn't say that specifically, so --

Q What doesn't it say specifically?

A What you just asked, which is the office of the Commissioner's view on the acceptability.

Q Well, it does say, "The office of the Commissioner's position on the acceptability of the application"?

A That's in the meeting objective, but you asked did I actually, was that actually discussed in the meeting and -- let me just check and double-check it. I have to go by what happened on what the, what is listed there as having taken place under discussion, decision made, and it doesn't say that that was specifically discussed.

Q Do you think some of the other people who attended this meeting would have a recollection of what, whether you expressed that -- let me back up.

Sorry. That was too much, right?

A Yeah, yeah.

Q Do you think, do you know if any of the other people attending that meeting would have a recollection of whether you informed them of the Commissioner's position on the acceptability of the application?

A Yeah. I don't know, but I'm not trying to be evasive. I probably discussed it. I don't know why it didn't get into the minutes, but I probably discussed the fact that these concerns that are listed were shared by Dr. McClellan and by me and by Dr. Woodcock. That's, you know, my recollection of what I would have discussed. Again, I don't know why it's not in -- explicitly there in the discussion.

I didn't draft the minutes. They were drafted by somebody else, and then I just, you know, approved them.

Q Under the heading, "Discussion, Decisions Made," on that same page, does that list describe the concerns of the Commissioner's office at that time?

A And my concerns, yes.

Q My question was, does it --
A Yes.
Q It describes the concerns of the office of the Commissioner?
A Yes.
Q Okay. Who within the office of the Commissioner had those concerns?
A Dr. McClellan and Dr. Woodcock, who was there and -- yes, she was there as --
Q Anyone else at the Commissioner's office that had those concerns, that you know of?
A Probably was in some meetings with Dr. Crawford, I think those were his concerns as well, and then, you know, some of the staff, but I don't -- no, I can't speculate. I don't remember specifically if there were others.
Q Do you know if anyone from outside the Commissioner's office had raised these concerns to someone inside the Commissioner's office prior to this time?
A Well, you -- we just looked at Dr. Hager's memo, that certainly has some of the similar

concerns, and some of the concerns were raised by other members of the advisory committee during the advisory committee. But you're asking express to the Commissioner's office, right?

Q Or conveyed in some way to the Commissioner's office.

A Well, of course, I don't know that because I wasn't part of the Commissioner's --

Q Just what you know.

A Except for what you just showed me, Dr. Hager's letter, which was to Dr. McClellan.

Q So you never, you don't recall conversation, for example, in which Dr. McClellan said to you, so-and-so has expressed these concerns to me?

A No, no.

Q Same with Dr. Woodcock?

A Correct.

Q And you, I think you indicated that you shared this list of concerns as well, is that right?

A Yes.

Q Do you still share them now?

A Let me go through each bullet once more.
Q Sure.
A Make sure there's nothing that's changed. Yeah, the last two bullets are time, you know, issues, but they don't, they're not relevant anymore. But the first ones, yes, the first three, which are still present, still relevant.
Q If you could turn to tab D77 in the binder, please? And it's actually, and it's marked Tummino 77 through Tummino 80.
A Yes.
Q Much of which is just signatures. Just, without reading the document, do you know about this document? Have you seen it before?
A Yeah, I've seen this, and I, you know, again, this is just my faulty memory. This, of course, would count as somebody expressing views to the Commissioner's office. I just --
Q You forgot it at the moment?
A Yeah, I forgot it. Of course, we got letters from the Hill on this.
Q And this, does this letter -- sort of, do

the concerns expressed in this letter overlap with the concerns expressed --

A I'd have to spend a couple minutes and read it.

Q Sure.

A Yeah. December 8th, so that was before the advisory committee. Right. What was the date of the advisory committee?

Q I don't know, but what I was looking at just before was a date where you were expressing concerns shared by you and the Commissioner's office?

A Yeah.

Q And that was a January 15th meeting, so this is before that?

A Yeah, yes. You just want me to look at the first one?

Q Yeah, I think it's all just one --

A Oh, all right.

Q Do you have two things in there?

A There's something reproductive technology project to --

MR. AMANAT: That's that earlier document

that was missing in your book.

THE WITNESS: Oh, it's missing, okay.

BY MR. HELLER:

Q Just the one marked Tummino 77 through 80.

A Okay. So your question is, are these concerns the same?

Q Well, let me --

A Is that your question?

Q Let me back up a moment.

A Yeah.

Q Because there are a number of concerns expressed in this letter.

A Yeah.

Q And -- but my first question is, have you read this letter before?

A I've seen this before, yes.

Q And it's signed by a number of members of Congress?

A Right.

Q And it expresses the view that Plan B should not be switched to over-the-counter status?

A That's correct.

Q And it expresses some reasons for that?
A Right.
MR. HELLER: Okay. And I think -- I'm not sure, how much time do we have left for the videographer?
THE VIDEOGRAPHER: Like two minutes or so.
BY MR. HELLER:
Q Okay. Does -- so my question is, do the concerns expressed in this letter overlap with the concerns of the Commissioner's office that you expressed on January 15th?
A I think we better go through it line-by-line to see whether -- they, certainly, they aren't the same, so there's not complete overlap. So let me make sure there's at least one --
Q Okay.
A -- which would say that they overlap. So you want me to go through --
Q Well, let's start --
A I haven't seen anything in the first two paragraphs that overlaps, you know, the knowledge issue didn't come into my -- knowledge of parents and

family was not relevant.

Q Was it relevant to the Commissioner's office?

A I never heard that it was.

Q They never said that to you?

A No.

Q What about -- okay. So then in the -- did you, so they -- in the first paragraph, the letter says, "We ask you to weigh the serious implications of allowing children access to a powerful drug." Did you, I mean, was that a concern? Namely, that this -- was it a concern of the Commissioner's office that this was a "powerful drug"?

A No.

Q That doesn't even mean anything scientifically, does it?

A No, it doesn't.

Q And then in the second paragraph, I'm going to sort of summarize this, that some people view Plan B as an abortifacient?

A Second paragraph, right.

Q Was it, did the office of the Commissioner

express concern that -- either the office of the Commissioner or other people view this as an abortifacient drug?

A We -- this issue came up in the briefings that we gave, and, you know, the position of the Center is it's not an abortifacient, and that's, we expressed that, and I agree with, and it was never challenged on that.

Q And is that the position also of the Commissioner's office, that it's not an abortifacient?

A Well, I was never -- no one in the Commissioner's office ever challenged that view. They asked questions about it. We explained our position. No one ever said, oh, I don't believe that, or I have alternate views, or anything like that.

Q Can you give me a sense of what type of question they asked about that?

A Why do we think it's not an abortifacient, and so we explained what the position is on whether it is, and that was that.

MR. HELLER: Okay. I think we're going to take a videographer break for a few minutes.

THE VIDEOGRAPHER: This marks the end of tape one. We're going off the record. The time is 11:25 a.m.

(Recess.)

THE VIDEOGRAPHER: This marks the beginning of tape two in the deposition of Mr. Galson. We are back on the record. The time is 11:32 a.m.

BY MR. HELLER:

Q Thank you. Dr. Galson, we were looking at a letter beginning with the page marked Tummino 77, and I think we talked about the first two paragraphs. Without going through -- I guess there are several more paragraphs. Do you know if there are any others here that indicate concerns that were shared by the office of the Commissioner?

A Let me go through it.

Q Okay.

A So the school children could walk next door to the drugstore. I don't see anything else in

common that I heard.

Q If you would now turn to the tab marked -- let me try to find one that someone could read -- D827, towards the back of the binder?

A Uh-huh.

Q And this is marked Tummino 827. And it makes reference to a meeting with Representatives Manzullo, Weldon, and Chris Smith?

A I see that.

Q Do you see that? Do you know of such a meeting?

A No.

Q If you'd now turn back in the binder to tab 3108?

A Okay.

Q And this is a document marked Tummino 30719 through, I believe, 30744. And if you look at the very last page, that's your electronic signature on the last page, is that right? Yes?

A Yes.

Q Okay. And this is, these are meeting minutes from a February 18th, 2004 meeting that you

chaired, is that right?

A Yes.

Q Okay.

MR. AMANAT: Can he have a few minutes to review the document?

MR. HELLER: Yeah, sure, please.

MS. REYES: Can I make a note that pages 30728 to pages 30735 of this document are marked confidential?

MR. HELLER: Okay.

THE WITNESS: Do you want me to look at, review the slides also? Or it depends --

BY MR. HELLER:

Q I don't think I'm going to ask many questions about the slides.

A Okay.

Q So the minutes are the important part. Have you had a chance to review that?

A Yes.

Q And do the minutes accurately summarize what occurred at that meeting?

A As far as I recall, yes.

Q And let's see, Dr. McClellan attended this meeting?
A Uh-huh.
Q I'm sorry. You have to say yes.
A Yes, yes.
Q I want you to look at page 30721 which is, I guess, page three of the memo, or the minutes?
MR. AMANAT: I beg your pardon?
MR. HELLER: The third page of the document.
MR. AMANAT: 30721. I apologize.
MR. HELLER: That's okay.
BY MR. HELLER:
Q And there's a portion that starts, "At the conclusion of the meeting, the Commissioner expressed the following," do you see that?
A Yes.
Q I have a couple questions about that. There's one, one of the things he expressed, he noted a trend towards a potential difference in various parameters between adults and adolescents in the Tina Raine study. Do you see that?

A Yes.

Q Can you tell me what that means? I don't know what that means.

A Tina Raine was the author of one of the studies that was discussed in this meeting. I believe that this was before the study was actually published, we had some preliminary data that she agreed to share with the Agency, and that in various questions -- I would have to refresh my memory -- but in various questions that she asked and the data that she collected about participants in the study, there was a difference in the data, what the data showed between adults and adolescents.

Q Okay.

A This is a term of art, there was a trend towards it. This just means the data may have indicated that there was a different trending towards that difference.

Q So is there a difference between a trend towards a difference and a trend toward a potential difference?

A No. If you add the word "potential," it's

a little more tentative. It means you can't tell for sure from the data, but the data can be interpreted to possibly show a difference.

Q Do you know whether you shared that concern regarding the Tina Raine's study?

A I did, I did.

Q You shared that same concern?

A Yes.

Q And then the next concern or thing expressed by the Commissioner was that, "The potential exists for changes in future contraceptive behaviors after adolescents take Plan B," do you know what that means?

A I think that's -- I reviewed this document a few days ago. I think it's very poorly worded, and I can't remember exactly, since it doesn't really describe anything that makes a lot of sense to me. I think what it meant -- and, again, you know, if I had read this more carefully at the time, I may have reworded it -- is the concern that is in the, in the documents that I signed, the decisional documents, that women who have easy access to Plan B might not

use other forms of birth control as frequently as women who didn't have easy access.

And this is the condom issue, whether availability of Plan B would decrease use of condoms and therefore increase the risk of sexually transmitted disease and HIV. I believe that's what it's about. It's very poorly described in that one-sentence bullet, but I suspect that's what it was about.

Q Do you know if there's any evidence that availability of the hormonal birth control pill by prescription increases sexually transmitted diseases?

A So having nothing to do with Plan B?

Q Yeah. I mean, there's another example where you could take that, not use condoms, and then get diseases?

A Right, right.

Q Is there any evidence for that, that you know of?

A No, no, not that -- I don't know whether there is any evidence. I'm not aware of any evidence.

Q Were you aware, are you aware of any evidence that easy access to Plan B would decrease condom use and therefore have the result of increasing STDs for any women?

A Let me make sure you understand that the burden of proof for an OTC switch application lies with the applicant who has to demonstrate safety. We don't have to prove that something is dangerous. They have to prove that it is safe, and that was exactly my concern, that that had not adequately been done.

(The following testimony was designated "PROTECTED TESTIMONY" and is bound separately.)

(This concludes the "PROTECTED TESTIMONY".)

BY MR. HELLER:

Q Okay. Plan B has been available for a number of years by prescription in the United States.

A Uh-huh.

Q Is that right?

A Yes.

Q Is there any evidence that the availability of Plan B has increased STDs?

A You mean by prescription?

Q By prescription.

A Not that I'm aware of.

Q Is there any evidence from other countries where Plan B is more readily available than in the United States that it's caused an increase in STDs in those countries?

A Not that I'm aware of.

Q Is there any evidence from states that make Plan B more readily available by allowing

pharmacists to provide it or that -- by expanding the number of people who can prescribe it, that that expanded access causes an increase in STDs?

A Please, I have to remind you that it's not relevant to our approval decision, the questions you're asking aren't relevant. They have to prove -- absence of evidence doesn't indicate safety. But, no, there -- I'm not aware of data demonstrating that.

But, again, that's not relevant to our -- unless it's been studied and shown to not result in increased STDs, and I don't know whether it has or not, it wouldn't be relevant to the application, and unless it was the conditions like OTC availability proposed by Barr, it wouldn't be relevant either.

Q Okay. The next concern or issue raised by the Commissioner was that he wasn't convinced that the studies had enough power to determine if there were behavioral differences between adults --

THE COURT REPORTER: I'm sorry, you're going too fast.

BY MR. HELLER:

Q He was not convinced the studies had enough power to determine if there were behavioral differences between adults and adolescents. Can you explain to me what is meant by that statement?

A Yes. "Power" is a statistical term of art indicating that -- or term of science that indicates that the number of participants in a study isn't large enough to demonstrate a difference between groups. That's what is meant by the power of the study.

It's underpowered to demonstrate the difference, or it's adequately powered means if that many people participated in the study and there was a difference between groups, it would be considered statistically valid.

Q Do you know in that sentence -- or in that statement which behavioral differences he was making reference to?

A The behavioral difference we were most focused on was this condom use issue. Again, at this point, I can't remember specifically what was brought up, but that was, that was what we were mainly

focused on.

Q Do you still have that same concern today about decreased condom use as a result of easier access to Plan B?

A I haven't seen any evidence to demonstrate that this isn't an issue, so, yes.

(The following testimony was designated "PROTECTED TESTIMONY" and is bound separately.)

(This concludes the "PROTECTED TESTIMONY".)

BY MR. HELLER:

Q What is your understanding of scientific inference?

A Can you be more specific?

Q Does that term mean anything to you, "scientific inference"?

A Of course, it does. Yeah, yeah.

Q What does it mean to you?

A It means that you can extrapolate, you can take the level of scientific data that's presented, and you can make an inference from it about a larger group. Or it -- yeah. This scientific inference is what drug review and epidemiology is all about.

Q So why would it not be -- let's say you have the following information.

A Right.

Q That, that you expand access to Plan B to some degree, not so far as to make it over-the-counter like toothpaste.

A Right.

Q But to not require a physician's

prescription.

A Right.

Q And under those circumstances, if that does not cause an increase in STDs, isn't it not completely reasonable, scientifically, to infer that expanding access even further also will not cause that? In other words, wouldn't you expect that if expanded access would lead to increased STDs, that any expanded access would increase STDs to some degree?

MR. AMANAT: I object to the form of that question. It calls for speculation. I'm going to allow the witness to answer the question, but it's a rather convoluted question.

BY MR. HELLER:

Q Can you answer the question?

A Well, if I understand you correctly -- well, first, I have to back up a second and make sure that you know that I am a proponent of approving this application. I recommended that the application be approved and that Plan B be available over the counter.

Q For --
A For the older age groups. And I think they --
Q That was not my question.
A Yes.
Q My question is about -- would you not expect that if you increase access, if you make access easier to Plan B, that that would cause more STDs, if the hypothesis is correct that increased access will cause STDs, isn't that correct?
A It's not, it's not causing STDs.
Q It's resulting in --
A Resulting in behavioral change that may result in more STDs.
(The following testimony was designated "PROTECTED TESTIMONY" and is bound separately.)

(This concludes the "PROTECTED TESTIMONY".)

MS. REYES: I'll have to mark that confidential.

THE COURT REPORTER: I'm sorry, what's "that"?

MS. REYES: The question and answer.

THE COURT REPORTER: Thank you.

BY MR. HELLER:

Q Do you know, when Nonoxynol-9 was switched to over-the-counter status, was data submitted showing that it would not cause a decreased use in condoms?

A I wasn't involved in that decision, so I'm not really familiar. I never reviewed the application or the decision memos or all of that, so

I want to -- I don't know.

Q They should have though, right?

A They should have what?

Q They should have checked whether it would, you know, that would be a valid concern, wouldn't it, that it would reduce --

A I don't want to make a judgment of what the Agency should have done, a decision that's passed, without reviewing it.

Q But you would have the same concern, would you not, that this new contraceptive, which is not a barrier method, would cause people to decrease their use of condoms, would you not?

A Uh-huh.

Q You have that same concern?

A Well, it's not exactly the same, you know, there's some thought that Nonoxynol-9 may kill organisms responsible for sexually transmitted diseases, so it's not, it's not exactly analogous. It was a different time period.

Q My question wasn't about STDs.

A Yeah.

Q My question was, would you have the same concern that it would cause people to use condoms less?

A Oh, but the result is sexually transmitted diseases.

Q Forget about that result. Would you have the concern that it would cause people to use condoms less?

A Probably, yeah.

Q The same as you did for Plan B?

A Well, I wasn't involved in the decision, so I can't really put myself back in, whenever it was, 8 years ago or 10 years ago. I don't want to be in a position where I'm disagreeing with the decision that the Agency made, that I wasn't involved in, that was made at a different time with different data. So I'm very careful about trying to extrapolate to a former time.

Q But wouldn't you have --

A But if I would get a new -- I mean, I'll try to help you.

Q I'll ask you, I'll ask a question. If you

got a new application for any nonbarrier contraceptive, wouldn't you have the concern that that might decrease use of condoms?

A If I got it now, yes, and I was reviewing it.

(The following testimony was designated "PROTECTED TESTIMONY" and is bound separately.)

(This concludes the "PROTECTED TESTIMONY".)

MS. REYES: That question and answer will have to be marked confidential.

BY MR. HELLER:

Q Going back to this document and the third point sort of made, expressed by the Commissioner --

MR. AMANAT: Again, this is page 30721?

MR. HELLER: 30721.

BY MR. HELLER:

Q The behavioral differences we were talking about, were there several different behavioral differences that the Commissioner expressed something about? Or was it just --

A The only one I recall -- again, you know, if you have more detailed notes from someone about

this meeting, let me know. The only one I recall is the one we've already talked about, which is the substitution or the, you know, not using condoms. That's the only one I remember.

Q Okay. Under action items on the same page, 30721, CDER was directed to continue work with the sponsor on a marketing plan to limit availability of the product over the counter and to consider the most appropriate age groups to be restricted from access to the product. Who directed CDER to do that?

A I think this reflects a conversation in the meeting, something like Dr. McClellan turning to me and saying, would you guys please work on this as described?

Q You took that to mean a direction?

A Yes, that that's what he thought should happen.

Q The Commissioner, going back to -- the Commissioner also thought that the OTC switch should not be approved, Commissioner McClellan also thought that the OTC switch should not be approved, is that right?

A Are you asking in the context of this meeting?

Q In general.

A Yeah, you already asked me that.

Q That's right.

A Yeah.

Q You took that as a direction also?

A What, took what?

Q That it shouldn't be approved?

A No, I didn't. I've told you already, I didn't take it as a direction. It was his opinion that it shouldn't be approved, but I was never directed to do that.

Q Here, you were directed to do it?

A But this is a different question.

Q Right.

A Yeah.

Q You were directed to do it by a comment like, please do this?

A I want to make sure you're separating -- you're asking two different questions. You're asking about this bullet, and then you're asking about

direction on approval. Let's make those completely separate because that isn't part of the bullet.

Q Okay. I think you've answered my question.

A Yes.

Q Was Doctor -- did he -- he did something like this. In some way, he communicated to you a direction to do this, is that right, to do this, what this statement says under action item?

A Didn't you just say you had the answer? Are you asking something again that you already asked?

Q No.

A What's the question?

Q Did he in fact direct you to continue to work with the sponsor?

A Yeah, I think these are accurate minutes.

Q Was he basically suggesting at that time a dual status for the drug?

A Yes.

Q The second point there, the second bullet point, "The Commissioner expressed that restricted

distribution would deserve another discussion in a public forum before implementation." What did that mean? What did you understand that to mean?

A We talked about this very few times, and I think he meant some sort of public meeting to talk about it, which, of course, we haven't had, but that was what his thinking was.

Q Do you know why there was no such public meeting held?

A We didn't think that it was needed.

Q He thought it might be needed?

A Yeah, yeah.

Q It still hasn't happened?

A That's a good example about, you know, not everything that comes out of the Commissioner's mouth is taken as an order.

Q Going back up to the prior bullet points, where, "The Commissioner expressed that counseling by a learned intermediary may be of benefit particularly to young teens," what was the basis for that statement? Did he give a basis for that, why he thought that was true?

A I didn't, I don't remember whether he gave a basis. You really should ask him that question. This was something that has been expressed, you know, by -- people at the advisory committee expressed it as well. I don't remember in that meeting whether he talked about the reasons or not.

Q Did you share that view at the time?

A I didn't use that in, as you know, from reading the decision memos, but I do have a concern that the younger a woman is, the more likely it is that that person needs to see a physician, if they're sexually active. I think there's -- a young woman engaging in sexual activity is more in need of seeing a physician than, to discuss it, than an old one because there may be other issues involved.

But, again, this wasn't something that I used as a decisional point in the application.

Q I wasn't asking about that though. Did you recall whether Dr. McClellan at this meeting talked at all about the potential health benefits of an OTC switch, why it would be a good thing?

A No, I don't remember that.

Q Do you remember him ever saying anything about why it would be a good thing to switch this to OTC?

A When we -- the discussions that I had with Dr. McClellan and Dr. Woodcock were always discussing all kinds of different options, including potential benefits, like I don't, I can't recall any specific conversation, but it's always balance of benefit and risk. And he was certainly aware of the potential benefits of more easy access to contraceptives and oral contraceptives.

Q But did he ever express that? Did he say --

A I don't remember specifically whether -- we certainly had discussions about the benefits of this product in general, so I can't, you know, if you want to know exactly what he said, I can't tell you, but it was, there were many discussions we had about balancing risks and benefits.

Q Could you turn to a tab marked 3109? It might be the next tab, and the first page of that is marked Tummino 30745.

A Yes.
Q And if you would just look at the third paragraph?
A I'm going to have to read the whole thing or look through it.
Q For this question, you might not have to, so rather than looking through the whole thing --
A All right.
Q -- just let me ask my question, then tell me if you need to read the whole thing.
A Okay.
Q The third paragraph says, "On February 18th, 2004, a presentation of summary data was made to Commissioner McClellan and attended by Janet Woodcock, John Jenkins, Steven Galson, Sandy Kweder, and so forth." The prior document that we were just -- wait, now. Okay.
So that's, I think that refers to the prior document we were looking at, which was a February 18th meeting. The next paragraph, paragraph four, says, "The divisions and ODs subsequently met with Doctors Woodcock, Jenkins, Kweder, and Galson on

February 19th, 2004." Do you see that?

A Yes.

Q So my question is, do you recall that you had sort of this one meeting on February 18th, which was attended by the Commissioner, and then the next day, you had another meeting with Doctors Woodcock, Jenkins, Kweder, and yourself?

MR. AMANAT: Counsel, in order to make sure the witness has adequate context, I would like the witness to have time to review --

MR. HELLER: I think he's already answered.

BY MR. HELLER.

Q You do recall it?

A Yes.

MR. HELLER: Yes, he recalls it. All right. That's my question. So he does recall it, and he doesn't need to review the document further.

BY MR. HELLER:

Q What do you remember -- well, let me ask you this, do you remember who called that second meeting?

A No, I don't.
Q Do you remember what the purpose of that second meeting was?
A And I don't remember, but I can speculate, based on reviewing the document, and that is that there were, there were issues that we thought needed more discussion than we had time for with the Commissioner there on February 18th.
Q Do you recall any specific concerns that Dr. Woodcock expressed at that February 19th meeting?
A Well, discussed this here, Dr. Woodcock expressed --
Q You can look at it, and if that helps you remember something, that's fine, but I --
A Let me just read the paragraph here. Yeah.
Q Do you --
A What I recall of that discussion was a back and forth about the provision of the product to easy access over the counter, the lack of adequate information about adolescents, how we understood that adolescents behaved differently than adults, that

there was a lot of data supporting that adolescents have impulsive behavior that may not be balanced by thinking about the consequences and that we really couldn't be sure how the, how adolescents were going to behave or react to easy availability of the product.

It was that sort of back-and-forth conversation.

Q Do you recall Dr. Woodcock expressing the view that easy access to Plan B might lead to extreme promiscuous behaviors by adolescents?

A No, I don't recall that, no. It wasn't -- it was a back and forth about not, that the point of the discussion was not really knowing what would happen.

Q I think you answered my question.

A Yeah, I don't remember.

Q Did you share the concerns in general that Dr. Woodcock expressed at that meeting?

A In general, yes, absolutely.

Q You don't recall her saying something about an urban legend status and sex-based cults?

A No. When I read this for the first time in the memo, it seemed surprising. I'm not disputing the veracity of it. I just don't remember it, many different things that were discussed.

Q Could you turn to D -- the tab marked D270 to 72? And this is marked Tummino 270 to 272. Have you seen this before?

A I think I have, yes.

Q Do you recall when you reviewed it, at what time?

A I'm sure, since I received it electronically, I'm sure I received -- I reviewed it, you know, within a few days after it was sent to me.

Q Do you know who -- why this document was prepared, who it was that asked for it?

A Sure. Janet Axelrad, who is the associate director of CDER for regulatory policy, asked one of her regulatory specialists and attorneys to look at the regulatory issues that were raised by this bifurcated proposal.

Q But do you know why she was asking someone to do it in the first place?

A Because it was a novel sort of way to distribute a drug and she wanted to get some analysis done on it, which is a typical kind of process.

Q But had you, for example, asked her, look into this, or had someone else asked her look into it?

A I don't remember asking her to work -- to ask her staff specifically to do this analysis. Certainly, we discussed, you know, would this work, this kind of packaging arrangement? And she may have said, you know, we'll look at it. And then she would have tasked her staff to look at it. That's typical sort of back and forth we have.

Q On the second page of this document, Tummino 271, at the very top, it makes reference to a March 11th, 2004 proposal --

A Right.

Q -- to market Plan B with dual status, basically.

A Right.

(The following testimony was designated "PROTECTED TESTIMONY" and is bound separately.)

(This concludes the "PROTECTED TESTIMONY".)

BY MR. HELLER:

Q Did someone else within the FDA suggest that you ask for that, or was it your own idea?

A My recollection is that I discussed this probably with my review staff, with Jane Axelrad and probably with the Commissioner's office, but I don't have any specific memory of that, of who exactly had talked to them when, but I would have discussed it with the whole team.

Q If you'd turn now to the tab marked 3117, which is marked confidential -- I will just note for the record that I believe that although this has been designated as confidential, it was also attached to our complaint in the case, I believe. Do you recognize this document, which is marked Tummino 30904 to 30906?

A Yes.

Q I'm sorry, to 30907.
A Yes.
Q Okay.
MR. AMANAT: Excuse me, Counsel, do you know -- oh, this is May 6th. I was looking for --
THE WITNESS: Yeah, what is the date? It's on the signature, right, that's the May 6th, right.
BY MR. HELLER:
Q Okay. One thing I was curious about, as I looked at this letter, was it sort of describes, if I'm not mistaken, a sort of path forward towards approval, is that right?
A That's correct.
Q And so why was this labeled a nonapprovable letter, as opposed to an approvable letter?
A We have a lot of leeway under the regs for what to call a letter, whether it's a nonapprovable or an approvable letter. You look at the, you look at the guidance language, the statute. It doesn't, it's not very specific, and it's sort of a weight of

evidence decision when we decide to call something an approvable or a nonapprovable. I just felt like it wasn't -- that there were enough problems with the application that it deserved to be called a nonapprovable.

But, you know, you can make the argument the other way, and people did at the time. I just felt like that was, that was the way to go, based on this, so it's really a subjective judgment. If you look, if you look at all these decisions, line them up, you can find inconsistency with other drugs.

Q Was it your decision to, I guess, call this a nonapprovable letter?

A It was my decision, yes.

Q Did anyone from the Commissioner's office --

A I discussed that.

Q Let me finish my question.

A Yes.

Q Did anyone from the Commissioner's office suggest to you that it should be a nonapprovable letter, as opposed to an approvable letter?

A I don't know -- I don't think "suggest" is the right term.
Q What would be then?
A We, we discussed it back and forth.
Q What was their, the Commissioner's view?
A I think the view was that it should be a nonapprovable.
Q Why was it their view?
A Well, I don't remember the exact conversation, so, you know, I think that, similar to what I described to you a minute ago, sort of weight of evidence. But, you know, I do remember that was their view.
Q Do you know if there was anyone from outside the FDA who somehow conveyed information that it should be a nonapprovable letter, rather than an approvable letter?
A Not that I'm aware of, yeah.
Q If you would turn to tab, the tab marked CDER P&P manual, towards the back of the binder?
A P&P?
Q CDER P&P.

A Yeah.

MR. HELLER: Okay. I'm actually going to ask this, because this was not something that was produced in discovery or administrative record, to have this marked as exhibit -- do we have a preference for numbers or letters, Exhibit 1?

MR. AMANAT: I prefer numbers, usually.

MR. HELLER: Exhibit 1?

MR. AMANAT: Did you get this off the internet, or where did you get this?

MR. HELLER: I don't know.

THE WITNESS: These are on the internet, these manuals.

MR. HELLER: Well, I mean, we can -- can we mark the witness' copy? Why don't I -- we can call it Galson Exhibit 1. We may use it with the other witnesses as well.

MR. AMANAT: However you want to do it, as long as it's done consistently.

(Galson Exhibit Number 1 was marked for identification and attached to the transcript.)

BY MR. HELLER:

Q And maybe you should look at the copy that's been marked, just to be careful. You can keep that in there and just look at this copy.

A This is a very complicated document. I'm not -- are you going to have specific questions about it? I can't read it quickly.

Q No, I don't want you to read it quickly.

A Yeah.

Q I mean, can you identify what it is?

A Well, let me read the first page.

Q Okay. Sure.

A This is probably one of several standard operating procedures that the Center uses in the OTC approval process.

Q Okay. If you could turn to page 13 of that document, if you could just read that page, please?

A I'd want to start at the beginning of the section.

Q Okay. The section --

A So I understand what's in context.

Q Sorry. The section starts on page 12.5.

A Let me go back and see what this is. Okay.

Q Thank you. And this is a summary of the general policy of the FDA regarding delegations of OTC switch decisions to the office director level, but in general, it's done by the office director?

A Right.

Q That level, is that right?

A Yeah, in general.

Q And does the FDA generally follow this policy?

A Yes.

Q And at the very top of page 13, there's the statement, "Any action letter on an initial OTC marketing or RX to OTC switch must have the signatures of both division directors or office directors as appropriate." Do you see that?

A Uh-huh.

Q Is it generally the policy within the FDA that action letters are signed by division directors or office directors as appropriate?

A Well, I don't know what you mean by,

"general policy."

Q Was that the policy?

A We follow this, and if you look at the totality of it on the previous page, it says, these authority designations aside it, it should be understood that disagreement, that these stages could benefit from discussions, and the Center director provided prior approval. So, yeah, generally, but they're not binding or anything.

Q But that, that -- what you just read says nothing about signing action letters? It's about discussions.

A No, it's a discussion, yeah.

Q But as in terms of signing action letters, this says that it must have the signatures of division directors or office directors?

A Right.

Q And that's what generally occurs, isn't it?

A Generally, yeah.

Q So actually, the nonapprovable letter you wrote and that you signed in May 6th of 2004 did not

have the signatures of the division directors or office directors, is that right?

A Correct.

Q So it doesn't have to have it, "must" means need not here in this policy?

A Which "must"?

Q The word "must," must have the signatures.

A Yeah, I think the whole document is -- these are not regulations, as you know, these are internal processes.

Q I have no idea what they are.

A And with any -- they're internal standard operating procedures. And, you know, any, as with any of our regulatory decisions that are delegated, they can be undelegated up to a higher level, if there's a disagreement or concern or -- as we discussed at the beginning of the morning.

Q Just to be clear, then the word, in this sentence, the word "must" means need not?

MR. AMANAT: Objection. It says, "must as appropriate," actually. If you're going to rely on the document, the document says, "must as

appropriate."
BY MR. HELLER:
Q Okay. Why was it not appropriate to have the signature -- signatures of either office directors or division directors on your nonapprovable letter?
A They didn't agree with it.
Q So they refused to sign it?
A I'm not sure I asked them to sign it. It was clear there wasn't an overt refusal. It was clear that they didn't agree with my position and the text of the letter, so I didn't ask them to sign it.
Q Under what circumstances would someone other than -- or does someone other than division directors or office directors sign such an action letter? When did that occur?
A If there's a disagreement or someone doesn't want to sign for one reason or another, then it would go up to the next level for signature.
Q Have you ever, other than this, the action letter, the May 6th, 2004 action letter, have you ever signed another action letter?

A For an approval or --
Q Approval, nonapproval.
A I sign so many things, but I haven't got, been involved in another approval decision to this extent. I wouldn't -- I sign, I sign regulatory letters all the time, so I want to be really careful I don't say the wrong thing.
Q All right. Have you signed an --
A I haven't signed another nonapprovable letter.
Q Have you signed any action letter on an OTC application?
A No.
Q Have you ever, have you signed an action letter on a new drug application?
A No.
Q Okay. Could you turn to the tab marked 3111? I hope there is such a tab in here. I actually don't see it, but -- it's not in there. Sorry. Forget about documents for a moment.
Do you recall a memo regarding Plan B, a review memo written by a Dr. Donna --

A Griebel?
Q -- Griebel?
A I know she wrote one. I --
Q Did you review it?
A Yes, yes.
Q And do you recall a memo, similar memo written by Dr. Rosebraugh?
A Rosebraugh.
Q Is that how you say his name?
A Yes. Yes.
Q And you would have reviewed that as well?
A Yeah.
Q You did review that one? Do you recall a memo about Plan B by someone named Julie --
A Beitz.
Q -- Beitz?
A Yes.
Q Did you review that one as well?
A Yes.
Q If you could go back to, if you could go back to tab 3117?
MS. REYES: And I'll note here that this

is not a confidential document.

MR. HELLER: It's not confidential. Okay. Thank you.

BY MR. HELLER:

Q And this is marked Tummino 30904 through 30907, and I wanted to call your attention to -- now, wait a second. I'm sorry. I'm going to go back to the prior tab, 3116, which is marked Tummino 30901 through 30903. Do you -- are you familiar with this document?

A Yes.

Q This is a document you wrote, is that right?

A Right.

Q On, on the first page of this document, the first sentence says, "I have read and carefully considered all of the reviews in the action package for this application." Do you see that?

A Yes.

Q Can you tell me what that involves? When you conduct a careful review --

A Yeah.

Q -- of the action package, what are you doing, what does that entail?

A Well, first, do you know what an action package is? I mean, let me --

Q That would help.

A What that is, is a binder that contains all of the relevant scientific reviews, the data that is prepared by the company and sent to us and any regulatory correspondence, so it's the whole story of our review from A to Z. So I went through every page of that.

Q And that would -- would that have included, for example, the Griebel memo, do you know?

A Yeah. I --

Q Let me ask it -- would it have included summary memos from the medical reviewers?

A Yes, yes.

Q Okay. Just going further down on that page, let me find the exact place, on the second bullet point, the first sentence, the statement, "In making decisions about pediatric use, it is often possible to extrapolate data" on -- "data from one

age group to another, based on knowledge of the similarity of the condition." Do you see that?

A Yes.

Q Later in that same bullet point, towards maybe the fourth line from the bottom, "Because of these large developmental differences, I believe that it is very difficult to extrapolate data on behavior from older ages to younger ages." Is that right?

A Right.

Q And this problem of extrapolating from older ages to younger ages, that could be true for other drugs other than Plan B as well, right?

A It could be, yeah.

Q Because what -- and what is the source of the difficulty, the source of the difficulty is?

A The source of the difficulty with Plan B is that we know that adolescents, particularly young adolescents, have different, are in a different developmental stage than older adolescents. They have more impulsive behavior. They are less controlled by balancing risk and benefits. That's why the suicide rate, the violent crime, the drug

abuse rate is so high in adolescents.

And it's that, those sort of behavioral issues where we know, we have very good evidence that the behavior of young adolescents with regard to balancing risk and benefit to controlling impulsive behavior isn't the same, so that's why, because of the behavioral aspect, and that is the condom use component of this application, I didn't feel like it was valid to extrapolate and just assume that because the older adolescents did what they were expected to do and understood it, that the younger adolescents would.

Q The capacity of younger adolescents to weigh risk and benefits?

A Right.

Q That would be applicable to any drug? Any drug has risk and benefits, right?

A Any drug has risk and benefits, right.

Q And the capacity of younger adolescents to weigh those risk and benefits?

A Right.

Q It is less than the capacity of older

adolescents or adults, is that correct?

A That's true.

Q And so for any drug, it would be very difficult to extrapolate -- let me finish my question -- to extrapolate from older ages to younger ages when it comes to weighing risks and benefits, is that true?

A Every risk and benefit calculation is different, and there's certain ones that are less of an issue with extrapolation than others. That's why we do it on a case-by-case basis.

Q Okay. So tell me what scientific study supports the proposition that Plan B, the decision-making or the weighing of risks and benefits regarding Plan B is somehow different than the weighing of risks and benefits for any other drug?

A That's not the point. The weight of evidence --

Q Is there such a study? Is there a scientific study showing that the capacity to weigh risks and benefits for drugs is especially weak for younger adolescents for Plan B?

A No, but that's not relevant.

Q I get to decide what's relevant at the deposition.

MR. AMANAT: Objection.

THE WITNESS: It's not relevant to my decision-making about the application. That's what I should have said. It's obviously relevant to your deposition.

BY MR. HELLER:

Q In considering any over-the-counter switch, you have to assess, do you not, the capacity of people, who are going to now be able to get it without a prescription, to weigh the risks and benefits of the drug?

A Yeah, behavior is a component of the OTC switch decision, with all OTC switches.

Q And in general, younger ages don't have the same capacity to weigh risks and benefits as older ages, correct?

A It depends on the risk and the benefit.

Q Give me an example of a risk and a benefit that a younger age can weigh.

A Relating to a drug?
Q Yes.
A This case, Plan B. You're asking for another one?
Q I'm asking for a case where younger ages can adequately --
A Oh.
Q -- weigh the risks and benefits of a drug because of this particular risk or benefit?
A Yeah. Well, without the scientific data demonstrating that, you know, that's -- I'm a scientist. I would have to like find some study to show you. I don't know whether it's formally been studied. But, you know, for example, we, we approved switch of antihistamines. And the reason that we weren't concerned about this issue has to do with balancing the risk and the benefit.
We didn't think that there was a large risk with children taking antihistamines. And so it didn't --
Q What did you base that belief on?
A I think you just interrupted me.

Q I did.
A So, well, I can't complete an answer if you interrupt the answer.
Q Okay. Please complete your answer.
A So since it's always weighing risk and benefits, the assessment on risk has to do with the assessment on benefit. So we know that it's beneficial to use antidepressants -- antihistamines. There isn't a big risk to kids taking antihistamines that anybody could come up with. The kid isn't going to get sick if he makes a wrong decision, any more than an adult will about taking the antihistamine.
So every drug, the degree of proof that we demand, having to do with risk and benefit, is individualized, depending on what the risk is.
Q Okay.
A So an antihistamine is an example of one that didn't bother us.
Q You didn't require the manufacturer in this case to prove that the younger ages could weigh the risk and benefits of Claritin, for example --
A Right.

Q -- because you thought they could do it?
A No, because we didn't think there was a risk to them not being able to do it, so they didn't have to prove it in the application. There, there wasn't a risk.
Q Can you take as many of those, can you take a lot of those antihistamines, and there's no risk, you can take like 20 of them, and there's no risk?
A There's a large margin of safety with those drugs, I don't know about 20. But it's not an addictive drug. You don't get high from it. There's no reason to think that, you know, that sort of behavior, which is more prevalent in younger age groups, would be a, would be operative in antihistamines.
Q What about -- what are the risks for a younger adolescent of taking Plan B when she shouldn't be taking it?
A I think we've discussed that already, whether --
Q At once, I mean, she takes Plan B which --

on one day when she shouldn't take it because she doesn't have the indication for it.

A You mean sort of physiologically, she --

Q Yeah, what are the risks?

A Well, one of the review issues -- in other words, this was the company and our staff agreed that one of the key safety issues with switching Plan B is whether people could take it according to the instructions.

We were concerned that substitution of Plan B for regular birth control, in other words, taking it not in an emergency situation, but just as regular birth control would result in children, adult -- I mean adolescents and adults taking too much of this hormone. So that was considered an issue by our review staff.

(The following testimony was designated "PROTECTED TESTIMONY" and is bound separately.)

(This concludes the "PROTECTED TESTIMONY".)

BY MR. HELLER:

Q After the nonapprovable letter on May 6th, 2004, the one you signed, what's been your role in the Plan B process within the FDA since that time?

A Obviously, I've continued to pay very close attention to this because of my involvement in the decision and continued working with the staff on the next regulatory action that the Center took, which was my August memo, recommending that the application, the supplemental application be approved.

Q As I understand what the FDA has done -- did in August, the FDA initiated a proposed rulemaking process, is that your understanding?

A Yeah, we put out an ANPRM, advanced notice of proposed rulemaking, which may or may not indicate that there's going to be a rulemaking. It's a first step, sort of dipping your toe in the water.

Q Did you concur with FDA's decision to do that?

A I wasn't asked to concur. It wasn't my

decision.

Q Do you agree with that decision?

A My recommendation was that the --

Q I'm sorry, just yes or no, do you agree with that decision?

A It doesn't have a simple yes, no answer.

Q Okay.

A I'm sorry, I'm sorry.

Q All right. If it doesn't, that's okay.

A My recommendation was that the application should be approved. The advice that I had from my internal staff was that the packaging configuration would work. But whenever we make a regulatory decision at the Agency, particularly something that's new or complex, we have to seek the advice of our attorneys. And the opinion of those, that group was that there were issues --

MR. AMANAT: I'm sorry, I'm going to object. Don't get into anything that involves any advice that you received from --

THE WITNESS: Yeah.

MR. AMANAT: -- counsel. So I'm going to

instruct the witness not to answer, to the extent that his answer may require him to reveal any advice that he or the Agency may have received from any counsel.

MR. HELLER: I think we just want to preserve the ability to make a motion regarding that subject at a later time.

MR. AMANAT: You have whatever rights you have under Rule 37.

MR. HELLER: I just wanted to state it for the record.

BY MR. HELLER:

Q Let me go back to my question, which I realize might not be simple yes or no. Do you believe that the, that the FDA should have approved Barr's sort of amended SNDA back in August of 2005?

A I made the recommendation that it be approved.

Q So yes?

A Yes.

Q Okay. Now, when I looked at the documents that we have after May 6th, 2004, there are a number

of sort of memos from medical reviewers again, and then as I saw it, leading up to, I think, a January 2005 memo from Dr. Jenkins?

A January 2005, okay.

Q Recommending, I think, approval without age restriction, do you recall that?

A Yes.

Q And then would you have received that back in January of 2005, the Jenkins memo?

A Sure.

Q As well as the prior, the other medical review, medical review memos?

A That were done contemporaneously with that, yes.

Q In January of 2005, were you planning to issue an approval for the Barr application?

A We don't make regulatory decisions until all the documentation is together, so planning to make -- I don't think like that. It's -- I was tending that direction. What happened around that time frame is that Dr. Crawford, who was the Acting Commissioner then, told me that he was concerned

about where we were heading because he knew that I was heading towards this recommendation, and he told me that he was going to make the decision on what to do with the application.

Q So he removed your authority to make the decision?

A Right, right.

Q Had that ever happened before?

A Not to me.

Q Do you know if it's ever happened -- do you know of it happening to anyone else who was in your position?

A No.

Q When did he tell you that he was going to remove that authority?

A I don't remember the exact time, but it was, it was winter, you know, January, February time frame. That's the closest I can come to it.

Q Did you respond to that in any way? Did you tell him what you thought of his decision to do that?

A I don't -- I'm trying to remember the

conversation. I really don't, I don't remember.

Q Had he, had he not done that, if he had not removed your authority, would you have, based on the documentation you had, would you have gone ahead and approved the Barr SNDA?

A Well, you know, it's difficult to address that hypothetically because what we do, as I mentioned before, is we, particularly with something new, we go through a process where our office of chief counsel gives us advice about whether something is legally acceptable or not. And I suppose what probably would have happened is that the same issues that were -- well, I don't know if I should --

MR. AMANAT: Don't get into anything that involves --

THE WITNESS: It's speculative.

MR. AMANAT: -- involves what --

BY MR. HELLER:

Q Go ahead and speculate. I mean, if nobody had come to you and said, you're not -- I don't want -- don't touch this, sort of, would you have gone ahead and signed an action letter saying

approved, for the, sort of the same reasons you said in your August memo?

A I probably would have been asked not to by someone in the Commissioner's office.

Q But, I mean --

A Yeah.

Q If someone hadn't asked you not to, in the ordinary course of things, you would have gone ahead in January?

A Well, the ordinary course of things is when we do something new, it's got to go through a process to have other people look at it, so that the ordinary course is no because --

Q Let me --

A If --

Q The ordinary course would be that an OTC switch application would be approved even below your level?

A But this one wasn't ordinary at all, it wasn't ordinary.

Q When did you first find out that -- maybe I've asked this already. When did you draft your --

there's an August 26th memo.

A Yes, yes.

Q When did you first draft that?

A It was drafted over a series of months, really, in the spring and early summer.

Q Did you, had you drafted something already along those lines in January of 2005, shortly after?

A I can't remember when the first draft was worked on.

Q It could have been in January?

A It could have been in January. I just don't remember. It had many drafts.

Q Do you have any of those drafts anymore?

A I don't.

Q Who does?

A I don't know.

Q Did you provide them to someone, the drafts?

A I don't keep drafts myself.

Q For example, did you send the Commissioner's office a draft?

A No, I don't think I did. I don't

remember. I don't remember. What I did -- I do remember, in my routine meetings with Dr. Crawford, tell him, telling him where I was tending on the application, that I was moving towards recommending that, moving towards approving it, that I thought the data in the application was adequate to approve the bifurcated application, so he knew that.

Q Okay.

A I don't remember how I communicated it.

Q The first time you drafted it, whenever that was?

A Yeah.

Q Was it a draft saying approval?

A Yes.

Q Okay.

A Yes.

Q And that could have -- that was sometime earlier than August of 2005?

A Oh, absolutely. I just don't remember which month, yeah.

Q Do you recall telling anyone in December or January of 2005 that an approval was on the way,

an approval was coming?

A Telling anyone?

Q Yeah. Do you recall --

A Like inside the Agency, anybody?

Q Inside, outside, anybody.

A Well, we certainly discussed it inside CDER, you know, so, yes, I certainly talked to staff about it. And I certainly, as I already said, I talked to the Commissioner's office about it. I don't recall talking about it. I wouldn't, it's a pending application, I wouldn't have talked about it outside the Agency.

Q Within the Agency, would you --

A Yeah.

Q Might you have told someone, approval is coming within a matter of weeks, or something to that effect? Recognizing that this might be before someone told you, you couldn't, but might you have told someone that?

A Well, considering how long it took us to finalize that memo, we wanted to make it really strong, supporting the approval, I don't know how I

could have been ready in time, in a few weeks. It took a few months to get the memo written and documented and all the data in there. So I can't --

Q Why did you want to make the memo strong?

A Well, this is a typical process that, you know, when we know something is going to be litigated, and we knew this was already contentious, and there was the litigation going on, that, you know, we will have to defend this decision, and we want to make sure it's very, very well-documented. We go through this all the time.

Q I guess my question is a little bit different.

A Oh.

Q Did you want the memo to be strong in part because, because you expected people at a higher level to disagree with what you said in the memo?

A I didn't expect that, no. I didn't expect dispute on the science from anybody above me.

Q Was there a dispute on the science?

A No, I've never heard a dispute on the science from anyone above me in the Agency. It's

always been, you know, these regulatory issues.

Q I believe there was something like a January 21st, 2005 action deadline --

A Right.

Q -- for the FDA --

A Yeah.

Q -- to act on the application, is that right?

A Right.

MR. AMANAT: Hold on. I'm going to object to that question.

MR. HELLER: He answered it already. What's the objection?

MR. AMANAT: The objection is to your use of the word "deadline." And --

MR. HELLER: Well, I can use whatever words I want, and this is not -- your coaching the witness about how to respond is inappropriate.

MR. AMANAT: I'm not coaching the witness, Mr. Heller.

MR. HELLER: He answered it already.

MR. AMANAT: Your question assumed facts

not in evidence, it was evidentiarily improper. He answered the question, but I wanted to state my objection for the record.

BY MR. HELLER:

Q Who made the decision to delay action beyond the January 21st date?

MR. AMANAT: Objection, assumes a fact not in evidence.

BY MR. HELLER:

Q Do you know --

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

BY MR. HELLER:

Q Do you know who made that decision?

MR. AMANAT: The question assumes that a decision was made to delay action.

MR. HELLER: He already said, he already said he knew about the deadline. I'm asking who made the decision --

MR. AMANAT: The witness never testified that anybody made a decision to delay action past any particular date.

BY MR. HELLER:

Q Well, did anyone make a decision to delay action past, past the January 21st date?

THE WITNESS: Do I answer?

MR. AMANAT: You may answer.

THE WITNESS: We weren't done with the documentation of the decision, so we couldn't make the decision on that --

BY MR. HELLER:

Q What was, what was --

A -- on that target date, which is what these dates are. They're not deadlines. They're not statutory deadlines. They're target time frames.

Q Thank you for being properly advised by your lawyer what to say in your answer.

MR. AMANAT: An objection is in order.

MR. HELLER: What?

MR. AMANAT: I said objections are in order.

MR. HELLER: Well, that's what you're doing, you're making speaking objections that are inappropriate. We can call the magistrate about this

again.

MR. AMANAT: Objection to the form of the question.

MR. HELLER: In fact, we have a lunch break coming up. That would be a perfect time to do it.

MR. AMANAT: Do what you want.

MR. HELLER: And maybe -- I think we will, so -- and we can see what the magistrate thinks of that kind of objection, okay?

BY MR. HELLER:

Q So what was left to do as of January 21st that had not yet been completed?

A Document the reason and the support for the decision that I was making.

Q Had, but had the decision already been taken away from you at that point?

A I don't remember, as I said, the exact -- the correspondence of that discussion with Dr. Crawford and that target date, that PDUFA goal date.

THE COURT REPORTER: I'm sorry, the?

THE WITNESS: PDUFA, PDUFA is the Prescription Drug User Fee Act, and we call these dates PDUFA goal dates. That's the official term of them.

BY MR. HELLER:

Q As I understand it, everyone up to you -- by January 12th, I think.

A Yeah.

Q Had finished, finished their part of the action package?

A Right.

Q So what was left was your memo?

A Right.

Q And that was not done as of January 21st?

A Right.

Q And then it took you seven months to finalize it?

A Well, I know --

Q Is that right? It did take seven months for you to finish it?

A Yeah, I don't, again, I don't remember when the first draft of that memo was written, so I

don't know if it took seven months at all. I don't know if the first draft was written by that January.

Q Seven months, seven months from the time you got the action package from Dr. Jenkins or -- including Dr. Jenkins' memo?

A Yeah.

Q It took seven months for you to do your memo, is that right?

A Right.

Q Has it ever taken you seven months before?

A Yes, things take seven months all the time at FDA.

Q For you to write?

A Well, I've never written a memo like this before.

Q So it's unique?

A There really isn't any precedent. But we do responses to, we do responses to citizens' petitions and other administrative actions that take seven months all the time.

Q I think you said that the decision about Plan B was taken away from you earlier than August,

maybe February even?

A Oh, yeah, it was definitely before August. It was --

Q It could have been --

A Yeah.

Q -- February?

A January, February, yeah.

Q Why did, why bother continuing working on your memo when the decision isn't yours anyway? Why not just delegate it back to John Jenkins or someone below him?

A Because I felt that for the integrity of the process, I really had to document what my views are, I spent a lot of time on this issue, felt very strongly about it, and I wanted to make sure that it was really clear how I felt in relation to all of the reviews that were on the record already from the folks on my staff.

Q When -- maybe you answered this already, tell me if you did. When the decision was taken away from you, at whatever point that occurred, were you given a reason why it was being taken away from you?

A Yeah, Dr. Crawford was concerned about this packaging configuration, that this was something new, and despite the fact that I saw a clear path to approve it, he had those concerns.

Q Do you believe his concerns were valid?

A I don't make -- I don't second-guess the opinions of our attorneys in the Agency. That's their expertise.

Q I'm talking about Dr. Crawford's views.

A Well --

Q Were they valid?

A Yeah, I think he had an educated view of it, based on discussions I wasn't in, but I assume -- he's not an attorney either, so I assume that he had discussions that informed him, and so it wasn't, it wasn't really my role.

Q He had no scientific basis to disagree with your intended goal -- intended decision?

A No, and he didn't, didn't attempt to bring science into the question.

Q Okay. And why were you not included in these other discussions that he was having about Plan

B?

A I don't know.

Q Have you ever --

A I don't know for sure. I'm speculating that he had -- that his concerns were informed by discussions, but since I wasn't in those discussions, I didn't hear about them, I don't, you know, I don't know, I don't know for sure that I was excluded from anything.

Q Isn't it -- don't you find it remarkable and strange that the head of CDER, you --

A Yeah.

Q -- who had under active consideration this OTC switch application, was not included in every discussion about it that was being held?

A I may have been, I may have been included in every discussion for all I know. I certainly, I have to -- this would get into discussions that I had with --

Q You certainly -- what is the nature of what you're going to say?

A The nature is my communications with the

attorneys at FDA.

Q Well, but you, were you not in communication with the attorneys at FDA?

MR. AMANAT: I'm going to object to that question. Instruct the witness not to answer.

MR. HELLER: That's -- on what basis, what's your basis?

MR. AMANAT: You don't have any basis to delve into whether --

MR. HELLER: What's the basis for your objection?

MR. AMANAT: Attorney-client privilege.

MR. HELLER: It's privileged whether or not he spoke to attorneys?

MR. AMANAT: Yes.

MR. HELLER: Really?

MR. AMANAT: It is.

MR. HELLER: I don't think that's true. We're going to have another thing to ask the magistrate about.

BY MR. HELLER:

Q So you believe that there were some

discussions Dr. Crawford was involved in about Plan B that you were not included in, is that right?

A I can't say it that strongly.

Q Where did he come up with his concerns from? Where did this idea to take the authority away from you come from?

A You'll have to ask him that. I didn't, I didn't ask him.

Q We'll have a chance to ask him.

A I bet you will.

Q Between January -- between the time that the decision was taken away from you and August 26th, do you recall any meetings taking place regarding Plan B?

A Meetings with me, meetings including me?

Q Yeah, yeah.

A I certainly met with the staff about, you know, my staff helping -- who were helping me prepare the memo and with the scientific staff to get pieces of information that I needed.

Q But you don't, you didn't have any more meetings with the Commissioner's office about Plan B?

A I wouldn't say that. I don't remember. I probably was, I mean, I had, as I told you, I had regular meetings with Dr. Crawford. And so --

Q It might have come up?

A It would have come up. It definitely would have come up. So I'm sure I talked to them. I don't recall any formal meetings about it.

Q Did he give you sort of regular or intermittent updates about whatever it was he was doing, now that he had taken the decision away from you?

A No, no. He knew that I was working on finalizing my decision memo, and he wanted to make it really clear that he wanted me to do that. So he, you know, asked me to go ahead and finalize that. He didn't want to be involved in the details of it and that I needed to forward that to him when it was done. That was, that was the only way we --

Q Was he waiting, I mean, there's this time -- date coincidence on August 26th. August 26th is the date of your memo?

A Right.

Q And it's also the date on which Dr. Crawford sent his letter to the manufacturer?

A Yeah, it's not a coincidence.

Q Was he waiting for your memo, or was it the other way around?

A No, he was waiting for my memo. I didn't know what he was going to do, so he didn't make -- what he told me is that he didn't know what he was going to do either. He was just, he was communicating to me that he was, he was going to make the decision, and I didn't know whether he was going to go ahead and accept my recommendation.

I talked to him about, you know, the fact that he's making the decision, what format should my decision make -- take, and he asked me to have it take the form of a recommendation to him. And I didn't know what his decision was going to be until just before he made it. So, you know, my hope was that he would accept it, and the drug would be approved.

MR. AMANAT: Is this a good time to break for lunch, Mr. Heller?

MR. HELLER: I just have one more question, and then let's break.

BY MR. HELLER:

Q When did Dr. Crawford tell you what his decision was going to be?

A Very shortly before the decision was announced, maybe 36 hours, something like that.

Q And that just happened to coincide with when you finished your memo?

A No, I was working on getting the thing finished, and I think we wanted all the dates to line up. I mean, it was almost done, but not only didn't I know what the decision was going to be, I didn't know exactly when it was going to take place, so he told me --

Q So my question is sort of this --

A Yeah.

Q -- if he had contacted you on July 15th, saying, I know what my decision is going to be, I'm going to issue it in two days, well, would your memo, would you have gotten your memo ready in time?

A Yes, I would have.

Q Okay.

A Absolutely. And he knew what the memo said. He knew that I was going to make the recommendation to approve the product.

Q Because he had seen your memo?

A No, I don't think he'd seen it. I told him. I told him that's where I was heading.

Q My last question before we break for lunch, I think, is sort of, how early could we push that back? Like could we push it back to April or May, if he had come to you in April of 2005 and said, now, I'm ready to make my decision --

A Wouldn't have been done, no.

Q You would have said, I need a little bit longer? How much longer would you have asked for, do you think?

A Well, we, you know, you understand the weight of work that we have. We have millions of things going on at the same time, and I would not -- I think the summer, I may have been able to accelerate it sometime in the summer, but certainly not April, May.

MR. HELLER: Okay. All right. Good time to break for lunch.

THE VIDEOGRAPHER: This marks the end of tape two. We're going off the record. The time is 1:04 p.m.

(Signature having been not waived, the deposition of STEVEN GALSON, M.D., MPH, was concluded at 1:04 p.m.)

ACKNOWLEDGMENT OF DEPONENT

I, STEVEN GALSON, M.D., MPH, do hereby acknowledge that I read and examined the foregoing testimony, and the same is a true, correct, and complete transcription of the testimony given by me and any corrections appear on the attached Errata sheet signed by me.

_____ _____

(DATE) (SIGNATURE)

CERTIFICATE OF SHORTHAND REPORTER - NOTARY PUBLIC

I, Cynthia R. Simmons Ott, Registered Merit Reporter, Certified Realtime Reporter, the officer before whom the foregoing hearing was taken, do hereby certify that the foregoing transcript is a true and correct record of the testimony given; that said testimony was taken by me stenographically and thereafter reduced to typewriting under my supervision; and that I am neither counsel for or related to, nor employed by any of the parties to this case and have no interest, financial or otherwise, in its outcome.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my notarial seal this 1st day of May 2006.

My commission expires:

August 1, 2006

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