UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF NEW YORK

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ANNIE TUMMINO, et al., :

Plaintiffs, :

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

ANDREW C. VON ESCHENBACH, : (Korman, C.J.)

as Acting Commissioner of : (Pohorelsky, M.J.

The Food & Drug :

Administration, :

Defendant. :

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Videotaped Deposition Of

LESTER M. CRAWFORD, D.V.M., Ph.D.

Washington, D.C.

Wednesday, May 24, 2006

9:11 a.m.

Job No. 1-78974

Pages 1 - 244

Reported by: Jacquelyn C. Jarboe

Videotaped deposition of LESTER M. CRAWFORD, D.V.M., Ph.D., held at the offices of:

Arnold & Porter LLP
555 Twelfth Street, Northwest
Washington, D.C. 20004
(202) 827-1152

Pursuant to agreement, before Jacquelyn C. Jarboe, Notary Public in and for the District of Columbia.

A P P E A R A N C E S

ON BEHALF OF THE PLAINTIFFS:

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A P P E A R A N C E S (Continued)

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A P P E A R A N C E S (Continued)

ON BEHALF OF THE DEPONENT:

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ALSO PRESENT:

CALI DAY, Videographer

C O N T E N T S

E X H I B I T S

P R O C E E D I N G S

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

THE VIDEOGRAPHER: Here begins tape number 1 in the deposition of Lester M. Crawford, M.D., in the matter of Annie Tummino, et al., versus Andrew C. von Eschenbach, as Acting Commissioner of the Food and Drug Administration, pending in the United States District Court, Eastern District of New York, Case Number 05-CV-366.

Today's date is May 24th, 2006. The time is 9:11 a.m.

The video operator today is Cali Day of L.A.D. Reporting.

This deposition is taking place at Arnold & Porter, 555 Twelfth Street, Northwest, Washington, D.C. 20004.

Would counsel please identify themselves and state whom they represent.

MS. JONES: Bonnie Scott Jones, from the Center for Reproductive Rights, for the plaintiffs.

MS. STRAUSS: Nan Strauss, for the

plaintiffs.

MS. LABATON: Vivian Labaton, for the plaintiffs.

MR. AMANAT: Franklin Amanat, U.S. Attorney, for the defendant, FDA.

MS. SCHIFTER: Karen Schifter, for FDA.

MR. WARSHAWSKY: Steve Warshawsky, U.S. Attorney, for FDA.

MS. REYES: Ana Reyes, Williams & Connolly LLP, for Duramed Research, Inc., and Barr Pharmaceuticals, Inc.

MR. STURM: Michael Sturm, Wiley, Rein & Fielding, for the witness.

THE VIDEOGRAPHER: The court reporter today is Jackie Jarboe of L.A.D. Reporting.

Would the Reporter please swear in the witness.

Whereupon,

LESTER M. CRAWFORD, D.V.M., Ph.D.

having been duly sworn, testified as follows:

EXAMINATION BY COUNSEL FOR THE PLAINTIFFS

BY MS. JONES:

Q Good morning, Dr. Crawford.
A Good morning.
Q Have you ever had your deposition taken before?
A Yes.
Q So you are familiar with the basic procedures?
A Yes.
Q Okay. Just let me remind you that if you need a break at any time, that's fine, we'll take a break. Just let me know, we'll finish the question we're on, and move to a break as soon as we can. And if you have any confusion about a question that I ask, please let me know. If you don't ask me to rephrase my question, I'm going to assume you understand it. Is that okay with you?
A Yes.
Q Okay. We originally had planned to depose you on April 28th of this year. Do you remember that?
A I do.
Q That deposition was postponed until today.
We were informed, I believe, on April 26th

that we would be changing the date of deposition. My question is, since April 26th have you or your attorneys engaged in any kind of communication with the Justice Department?

A April 26 was on what -- it was like a Wednesday, was it?

Q I believe it was a Wednesday, yes.

MR. AMANAT: Counsel, when you say Justice Department, are you referring to any particular component?

MS. JONES: Any members of the Justice Department --

MR. AMANAT: Regardless of which component?

MS. JONES: -- in its entirety.

Correct.

A I have not. I believe my attorneys may have.

BY MS. JONES:

Q Okay, which attorney, your attorney here today, Mr. Sturm?

A Yes.

Q Okay. Who has he spoken to in the Justice

Department, or who has he communicated with in the Justice Department?

A I believe Mr. Amanat.

Q Do you know when that communication took place?

A Yesterday, I believe. I don't know about others.

Q Was that a phone conversation?

A I don't know.

Q Okay, was it a conversation as opposed to a written communication?

A I heard mention of it this morning, that's all I know. I can't even -- I can't tell you any details about it.

Q Okay, were you not a party to whatever the communication was?

A I was not.

Q Do you know what the topic of the communication was?

A No.

Q Do you know why your attorney talked to Mr. Amanat?

A I do not.

Q Do you know of any other communication between your attorneys and the Justice Department since April 26th?

A I do not know of any, no.

Q Do you believe that you are currently under any kind of criminal investigation that relates to Plan B?

A I do not. I -- would you rephrase that. I'm sorry.

Q Repeat or rephrase?

A Repeat and rephrase.

Q Well, I'll repeat, and then you tell me if you need it rephrased.

A That's fine.

Q How's that?

A Yes.

Q The question was whether you believe that you are currently under any criminal investigation that relates to Plan B.

A I do not think that I am.

Q Okay. And you understood my question?

A I did. What I was having trouble with was my answer. I didn't know whether I said that right.

Q But now you're comfortable?

A I am.

Q Okay. I'm going to hand you a document that has been marked Crawford Exhibit 1. Take a look at that.

A Okay.

Q That is the subpoena that you were served with in this case; is that right?

A That's correct.

Q That subpoena ordered you to come here today and bring certain documents; is that right?

A Yes.

Q Did you or your attorneys produce any documents here today in response to that subpoena?

A Yes, my attorney did.

Q Okay. I have here a document, that I'm going to hand you in a minute, marked Crawford Exhibit 2. Is this the document that your attorney gave me?

A I'll have to look.

Q Okay.

(Crawford Exhibit 2 was marked for identification and was attached to the transcript.)

MR. STURM: And I will just state on the record that I did produce this morning documents marked LC01 through I believe it's LC09 in response to the subpoena. And I believe that those with are what have also been marked now as Crawford Deposition Exhibit 2.

A Yes, these are the documents.

BY MS. JONES:

Q Did you or your attorneys bring any other documents today to give me in response to the subpoena?

MR. STURM: No, we did not.

MS. JONES: Okay. I just want it on the record.

MR. STURM: Right.

BY MS. JONES:

Q Do you have within your custody or control any e-mails or other correspondence related to Plan B?

A Do you mean from when I was at FDA?

Q Do you have in your custody or control now?

A No.
Q In your present life?
A I do not.
Q You don't have a home computer that has any e-mails on it related to Plan B?
A I do not.
Q You don't have any files at home that would have correspondence related to Plan B?
A No.
Q Do you have a calendar of any kind, whether paper, BlackBerry, Palm Pilot, that would contain meetings that might relate to Plan B?
A No.
Q Do you keep an electronic calendar.
A I do.
Q Like a BlackBerry or something like that?
A Yes.
Q How long have you kept a calendar in that form?
A Well, I've had these kind of devices at different offices that I worked in. At Georgetown I had a Palm Pilot, and that was the first time I used

one. And that would have been in -- in 1997.

And then when I came to FDA I initially tried to refuse a BlackBerry, because of the same reason I couldn't make that coffee, and they wouldn't let me. So I had to learn to use a BlackBerry, and I did that throughout the three and a half years I was at FDA. And then I now have a different one. So that's the brief history of it.

Q Where is the BlackBerry that you used when you were at FDA?

A I have no idea.

Q Was it your property, or was it the government's property?

A Government's.

Q When you left FDA, did you take it with you?

A No.

Q And was that Blackberry that you used when you were at the FDA, was that backed up to your home computer in any way?

A No, it was not.

Q It was backed up to your computer at the office at the FDA; is that right?

A Yes.
Q At any time has anyone instructed you to preserve e-mail correspondence related to Plan B?
A No.
Q Okay, I'm going to define a couple terms just so that we're on the same page during the deposition. Are you familiar with the citizens' petition that was filed on February 14th, 2001, seeking to make FDA-approved emergency contraceptive products available over the counter?
A I am familiar with that, yes.
Q Okay, I'm going to refer to that as the citizens' petition. If I talk about a citizens' petition, that's the only one I'm talking about, okay?
A (Nods head.)
Q And --
MR. STURM: You need to make an oral answer so she can get it on the record.
A I understand --
BY MS. JONES:
Q Okay.
A -- what you said.

Q Thanks.

And are you familiar with a Supplemental New Drug Application or SNDA filed by Women's Capital Corporation and later by Duramed/Barr Labs seeking to make Plan B available over the counter?

A Yes, I am.

Q And I'm going to refer to that as the Plan B SNDA. Is that all right?

A That's -- in your -- that one is the one that's referring to the 2004 situation, or do you look upon it as being amended later?

Q I'm looking upon it as a continuous, the whole --

A Okay.

Q The whole application, starting with Women's Capital Corp. and then taken over by Duramed/Barr Labs, the entire effort to make --

A When you refer to it, just so we get the glossary right --

Q Yes.

A -- you will be referring to it as a continuum?

Q Correct.
A Okay.
Q If that's okay with you. And I'll just call it the Plan B SNDA.
A Okay.
Q But with any question you have any confusion about what I'm asking about, please just ask me to clarify.
I'd like to start by asking you to name for me every person outside of CDER -- you know what I'm talking about when I say CDER, right?
A (Nods head.)
Q Okay, every person outside of CDER -- which is CDER for the reporter -- and outside of the commissioner's office at the FDA with whom you communicated about the citizens' petition.
MR. AMANAT: Between what period of time are you referring to?
MS. JONES: Any period of time.
A So outside of CDER?
BY MS. JONES:
Q Outside of CDER and outside of the FDA

Commissioner's Office.

A And that would be independent of the SND?

Q Anyone that you communicated with about the citizens' petition. If the communications also included the SNDA, I'd like to know about those, too. But anyone outside those two offices with whom you communicated about the citizens' petition.

A About the citizens' petition itself, I think there was probably only one person, and her name was Laura Lawlor, L-A-W-L-O-R. She worked in the Department of Health and Human Services.

Q What is her title there, or what was her title at the time?

A She was called "counselor."

Q And when did your first communication with her about the citizens' petition take place?

A That would have been in -- sometime in August of 2005.

Q And was this a verbal conversation?

A Yes.

Q By telephone or in person?

A Telephone.

Q Okay. And what was the content, what were you talking about with her?

A She -- may I explain what her role was?

Q Certainly, certainly.

A In the administration of Secretary Leavitt she was -- he instituted a new management organization which consisted of four counselors, and these people were over various agencies within HHS. She was the one that was over FDA.

And the purpose was to -- of her job was to explain to her what was coming up, what was about to happen. We had a meeting by -- usually by telephone once a week, and then if we needed to talk further, we'd talk, you know, around that.

That meeting was also with Rich McKeown, who's the chief of staff of HHS.

Now, I talked to her when we were about to announce the decision on Plan B in August, and reminded her that the citizens' petition was part of what we were dealing with. And I believe she didn't know about the citizens' petition, so I explained to her what it was.

Q Let me make sure I understand this. When you talk about her role within HHS and the role of these meetings, was it the purpose of these meetings for you to communicate to her what was about to happen?

A Yes.

Q So that HHS would know what was going on?

A She was a conduit for information.

Q But you were conveying information to her as opposed to her conveying information to you in that meeting; is that right?

A That is correct.

Q Okay. So you were letting her know you were about to make a decision on the Plan B SNDA and that it would implicate in some way the citizens' petition; is that right?

A Yes.

Q And how did you tell her that it implicated the citizens' petition?

A I just reminded her that in addition to the application, there was this citizens' petition.

Q And in your view, or what were you were

explaining to her? Were you explaining that the decision you were about to announce also was a decision in some way on the citizens' petition?

A Yes.

Q Is that the only communication that you had with Ms. Lawlor regarding the citizens' petition?

A Later in the week that the decision was announced, which was on a Friday, there came a time when we needed to prepare a press document announcing what we were doing and giving some context for it.

These sorts of things, which I used as a text for the press conference, and later this document was also disseminated not only to the press but generally, and, I believe, posted on the FDA website, those kinds of documents have to be approved by the Department of Health and Human Services. So she would have been the one that got it and got the clearance within HHS. And I think there was some like technical/grammatical kinds of changes, not very much. But she would have been the one that discussed that with me.

Q Okay. Again, would those have been phone

conversations?

A I believe every one of my discussions with her were phone conversations. It was not uncommon for me to be down at HHS, although, as you may know, FDA is a 36-mile round trip away. But I was down there often, and I may have bumped into her. I cannot say for sure. I believe they were all telephone conversations.

Q Now, when you had the phone conversation with her in which you told her about the upcoming decision on the Plan B SNDA and on the citizens' petition, what did you explain to her was the action the agency was going to take?

A I explained to her that we were going to announce a comment period to seek information and clarification on the enforceability of this particular application. And basically, that was it.

Q Other than Ms. Lawlor, is there anyone else outside of CDER in the commissioner's office with whom you communicated in any way about the citizens' petition?

A No, not that I recall. And she would

have -- under the Leavitt situation, she would have been, you know, the person that you went to.

Q Okay. Could you now identify for me every person, again, outside of CDER and outside of the commissioner's office with whom you communicated in any way about the Plan B SNDA?

A Over what time frame?

Q Any time period.

A Okay.

Q The entirety of the time in which you've known about the Plan B SNDA.

A And this would be not in FDA?

Q Not in CDER and not in the commissioner's office.

A But would include HHS and anywhere else in the government?

Q Anywhere else in the world.

MR. AMANAT: I'm going to object to the question. You can go ahead and answer it.

A I'll do the best I can.

This was something that was on the FDA agenda, you know, when I first came back to FDA in

February of 2002. And I'm going to try to do it by context, because I didn't -- you know, I didn't really just volunteer to talk to people about it, it was basically in the nature of an update.

The person who had the Laura Lawlor role in the Thompson administration, which would have been two thousand -- I was in it from 2002 until early 2005, would have been a man named Ladd Wiley. And he was -- he was special assistant to the secretary. It was a different structure, but I certainly talked to him about it. And I talked to the chief of staff, whose name was Scott Whittaker.

Q He was chief of staff of HHS?

A Yes.

And I talked to the -- the general counsel of HHS, and his name is Alex Azar. He is now the deputy secretary.

Forgive me, but I'm running through these lines of communication.

Q Take your time. I understand it's a very big question.

A There's one person who talked to me about

it, who rang me up, in the White House, and that was a woman named Kristen Silverberg. And her role was -- she was domestic policy counselor, or something like that. And she's no longer there, but this was in January of 2005.

And her question was, I've just read a press report that FDA missed the PDUFA deadline, Prescription Drug User Fee Act deadline on Plan B, what does that mean, what is a PDUFA deadline, I believe she said, and why did you miss it.

And so I explained to her that we from time to time did miss these. And that was about the substance of that conversation. It was her calling to verify something.

Now, in the Thompson administration, you know, once in a while you did get a call from the White House, but it wasn't -- it didn't happen very much in the Leavitt Administration. But she was the one person who called from outside that I recall. But I do remember that distinctly.

And elsewhere in the government, I just can't think of anything -- and these were -- anyone

else. And these were, all except for the Silverberg call, were updates, they were like appearing on FDA's calendar of events, or something like that.

Q Okay. Well, we'll start talking about these, and if others come to mind as we go through, please just feel free to amend your answer.

The conversation, sounds like you had maybe more than one conversation with Ladd Wiley about the Plan B SNDA; is that right?

A Yes, there would have been more than one.

Q Okay, when did those take place?

A That took -- they would have taken place from sometime in 2002 up until the time he left, which was in January of 2005.

Q Approximately how many conversations did you have with him or communications did you have with him that related to Plan B?

A Probably two or three.

Q Okay. And do you recall the content of those communications?

A It would have been with Mr. Wiley. We didn't have regular meetings, but we were obligated to

keep him up to date on what was coming, what was happening. And so it would have been in the nature of an update and in a litany of other things.

In other words, when I went to meet with, you know, those kind of people I usually tried to have five different things to sort of bring them up to date on, and at FDA you had no problem coming up with five, so they kind of rotated. But I distinctly remember that being brought up by me on an update basis a couple or three times.

Q And what did you tell him about the Plan B SNDA during those meetings?

A I would have told him -- in the first meeting I probably told him what it -- you know, what Plan B was, because it was in the press and so forth, and probably about the fact that the company was interested in it going over the counter. That would have been a later conversation. And then I may have told him about the PDUFA deadline, but I don't remember that.

Q Did you give him any indication during any of those communications about what you thought the

FDA's action would be on the application?

A No, I did not. I did not.

Q And at any of those -- during any of those communications did he communicate anything to you about the application or make any suggestions or comments about the application?

A You know, I don't recall that. His style is he was, as are some of us here, an attorney, and so he would typically say, you know, what does that mean, what does this mean. His job was to convey what was going on in the agency either to the secretary or to the chief of staff. He worked for the chief of staff. So he had to understand it and it would have been clarification points generally, but I don't recall the substance of the conversations.

Q Did he ever give you any indication that the secretary of HHS had any position on the application?

A No.

Q Or did he give you any indication that he had a position or any opinion about the application?

A No.

Q Okay, then you also said you talked to Scott

Whittaker or you communicated with Scott Whittaker about the Plan B SNDA?

A Yes.

Q What sorts of communications were those, written, verbal?

A Again, the style in the Thompson administration was what you might call random type meetings. I generally felt that if they hadn't asked to see me or to get updated on what was going on that I probably should try to find time to tell them. Sometimes that was, you know, weeks and weeks apart, depending on what was going on.

So I would have -- the meeting that I normally would have had with Ladd Wiley sometimes got combined with something from Scott Whittaker generally when he wanted either to know something further or to alert me to something. And I would have mentioned that plan -- you know, some stage of Plan B developments. It was basically an update.

Q How many times did you have communications with him regarding Plan B?

A Regarding Plan B?

Q Yes.
A You know, I cannot say for sure, but I would say like one, maybe two times.
Q And do you recall what you told him about what was going on with the application?
A I don't, but it would have been in the nature of something's about to happen or something the company had done. Usually these would have been triggered by a press report and I would be telling them, you know, FDA's perspective on it.
Q And did he ever communicate with you his opinion on the application?
A He did not.
Q Did he ever convey any information to you relating to Plan B?
A May I ask what "information" encompasses?
Q Well, it sounds like you're describing this communication as basically you're giving him an update.
A Yes.
Q So you're the giver of information, he's the receiver. I'm asking you whether there was ever a

time where Scott Whittaker ever conveyed information to you from him or from HHS about -- that related in any way to Plan B.

A No, not that I recall.

Q Then you also mentioned Alex -- Azar?

A Azar.

Q How many times did you communicate with him about Plan B?

A He -- it was only when he was general counsel, and -- is that privileged, or --

MR. AMANAT: You can say how many times you met with him, but don't discuss the content of your discussions.

MS. JONES: Is he your witness, do you represent him at this deposition?

MR. AMANAT: I represent the agency. The attorney/client privilege belongs to the agency.

MS. JONES: I just wanted to know if at this deposition you're representing him.

MR. AMANAT: I do not, no.

MR. STURM: I am representing the witness.

MS. JONES: Okay.

A I would have met with him on an -- again, on an update basis maybe once. And the general counsel frequently came to FDA. The chief counsel of FDA works for the general counsel, not for me, and so he would come out and meet with the chief counsel, and then he would meet with me, because obviously it was kind of a tenuous arrangement, because, you know, he was -- the chief counsel was my attorney, and yet he didn't report to me.

So following those meetings Alex would sometimes come by, and I believe in the context of one of them he would have asked me, you know, what --

MR. AMANAT: Again, don't get into the contents of the conversations.

THE WITNESS: Okay.

BY MS. JONES:

Q As far as you recall, there was only one communication with him regarding Plan B; is that right?

A You know, I can't -- one or two, something like that.

Q Do you recall approximately when those

communications took place?

A Well, they would have been when I was acting commissioner the first time, which was February through parts -- into October of 2002.

Q And you've described earlier a conversation you had with Kristen Silverberg of the White House. You said that took place in January of 2005?

A Mm-hmm.

Q She called you?

A She did.

Q With a question about the PDUFA deadline and why the agency hadn't met it; is that right?

A Yes. Well, it was -- if I may.

Q Please.

A It was to clarify what was a PDUFA deadline, and what did it mean, and why did we miss it.

Q Okay, and what did you explain to her about why you missed it?

A I told her that we miss them, we try not to, but they are basically targets. So we try to get through the process, but sometimes we don't. And I didn't know, you know, when we would get through the

process. And that was about it.

Q Okay, so at that time you informed her that you did not know when you would take action on the Plan B SNDA?

A Right.

Q Did she ask you when the agency planned to take action on the Plan B SNDA?

A She mainly wanted to know why we had missed it and what was a PDUFA deadline.

Q Did she ask you anything else?

A No.

Q Do you know why she called?

A She'd seen a -- I believe she had seen a news report saying that we missed the PDUFA deadline, and it wasn't clear to her what that was.

Q Had someone else within the White House or within the government instructed her to call and find out this information?

A I don't know.

Q Did you ever speak with her again about the Plan B SNDA?

A No. She left that position shortly after

that.

Q Okay, other than the people we've just talked about, is there anyone else that at this time you recall talking to about the Plan B SNDA outside of CDER and outside of the commissioner's office?

A I can't remember anyone else.

MR. AMANAT: Counsel, just to make sure the witness -- he, of course, did have conversations with us in the course of preparing for his deposition, so he may just not realize that your questioning, you know, would include that, but --

BY MS. JONES:

Q I assume you talked to these attorneys here in order to prepare for your deposition.

A I did.

Q That would have been prior to the scheduled April 28th deposition date?

A Yes.

Q And you haven't talked to them since that time, you haven't talked to Mr.Amanat or anyone else from the U.S. Attorney's Office --

A No.

Q -- since that time directly?

In these various updates that you described that you would give to various people at HHS, did you update them about other OTC switch applications?

A Yes, I'm sure I did, yes, because some of them were the kinds of things that I would have put in that list of five.

Q I guess I'm asking what were the kinds of things that you would --

A Put in the list of five?

Q -- give updates about, exactly.

A I assume you want a straight answer. A straight answer is something that was going to show up in the newspaper or have Congressional interest. And I judged Congressional interest by letters from Capitol Hill, generally. So I would be trying to explain to them the FDA perspective on these.

Q So it was something that was going to be scrutinized either by the press or Congress, things like that?

A Yes, it's something that was becoming either a national or an international issue.

Q Now, when you first -- I think you said that maybe one of the first of these updates you gave could have been as early as 2002 before the Plan B SNDA was even filed, when it was being considered; is that right?

A Yes. I can explain to you how that would have happened.

Q Sure.

A How it did happen.

When I came in to be acting commissioner in very late February of 2002, it is customary, typical, and routine that the new commissioner be -- it's called an orientation session, sessions, and they run through various issues. There's meeting after meeting after meeting after meeting to do that.

In my case those were protracted, because in March of 2002 there were the Congressional hearings on the budget for FDA. And so 10 days after coming on board I had to present the budget to the Congress. And first, you know, to both the Senate and to the House.

And so in the month of February I didn't get

any of these kinds of orientation sessions, neither did I in March. And then in the month of April we had to renew the Prescription Drug User Fee Act, we had to have those negotiation sessions.

And somewhat startlingly, there also came on the table a proposal to have user fees for the Medical Device Center. So that also had to be negotiated with the Congress and with the industry. And so these were like all-night sessions.

And then, since everybody was doing it, the Center for Veterinary Medicine also developed an interest in it, and so we had to have those negotiations.

So April was subsumed with that, and so we didn't really get into the orientation sessions until May and June. I think the last one was completed in June. And one of those was on Plan B, one of the orientation-type sessions.

Q That would have been May or June of 2002, right?

A Yes.

Q Okay. Who participated in the orientation

session?

A The reason I can tell you with such confidence that there was such a session is because I've seen the minutes in -- I believe it's probably in here somewhere.

Q Okay.

A I don't have much memory of the session, but I -- you know, I know that it took place, and the list of participants are in there.

Q Okay.

A And I was one of them, of course.

Q Could you turn in the notebook in front of you to the tab that's marked 3031, which, for the record, is Tummino 30166 through 30174. I'll ask you more about this later, but just for the moment, is this the meeting you're referring to?

A Yes.

Q This June 5th, 2002, meeting?

A Yes.

Q So you're saying this was an orientation session?

A Mm-hmm, that's my memory of it, yeah.

Q And this is an orientation session that's held when there's a new commissioner?

A Mm-hmm.

Q Okay, so this was because you were a new commissioner, had been busy for a few months, but finally were coming up for air, and you had this orientation session?

A Yes. There would have been 20 or 25 of these.

Q Okay. And this was one of the topics?

A Mm-hmm.

Q Who selected what the topics would be for these?

A I wish I knew. I don't know how that's done. It's -- we have in FDA an executive secretariat, and what they -- obviously, what that person that heads it up is executive secretariat to the commissioner. So she would be the person who normally would organize the meetings and probably, based on -- executive secretariat also does correspondence, Congressional letters, those sorts of things, probably based on what she perceived to be the

hot topics. I did not select them. And that is also typically not done.

Now, another way that she -- I mean, she had an advantage, because we had the Congressional hearings on the budget in March, as I mentioned. And, you know, those are like national plebiscites on what FDA is doing. So the -- it wasn't so much what we presented which basically are the nuts and bolts of the budget, as it is what they ask when the congresspersons ask when it's their time to talk.

So she probably would have gauged it by them, too.

Q In other words, she might have based some of the topics or selected some of the topics based on Congressional interest that was shown during the budget talks?

A Yes.

Q Okay. During the budget talks was there Congressional interest expressed in the Plan B over-the-counter application?

A I don't remember that.

Q Okay. Going back to these update

communications you had with HHS, I think you said that at some point in 2002 you would have given them some kind of update, I think you said that might have been to Ladd Wiley. Does that sound right?

A Could have been, yes.

Q Okay. Why in 2002 would the Plan B application have been something that would make it onto your list of five?

A Well, because of this briefing.

Q Because the brief -- can you explain that? Why does the briefing mean -- why does the fact that you had an orientation briefing on it mean that it would be something you would update HHS about?

A Well, at that point, like in June of 2002, you know, just having gone through that busy time, I would have done -- I think I would have been trying to bring them up to date on the status of most of these things that I had been oriented on. And so I would be surprised if I didn't mention all of them at some point to HHS people.

Q At that time in 2002, did you have a perception that the Plan B application was going to be

one of these things that was going to draw public and Congressional scrutiny?

A It said in the briefing that it was politically sensitive. So I took that at face value.

Q Okay. So your perception at that point that this might become one of those scrutinized issues came out of the briefing in which you were told that it was a politically-sensitive issue; is that right?

A Yes.

Q Could you just give me an overview of what your involvement was in the FDA's handling of the Plan B SNDA up to the time of the nonapprovable letter on May 6th, 2004?

A I had very little involvement. As you may recall, we got a permanent commissioner in October of 2002. At that point I became deputy commissioner. And so I had very little involvement in that.

Q Did you have any involvement?

A Not in the decision, no.

Q Did you have any involvement in the decision-making process at all within the agency?

A No.

Q Did you review any parts of administrative record compiled by the agency for the Plan B SNDA prior to the issuance of the May 6th, 2004, nonapprovable letter?

A The only thing I did was Dr. Galson, who was the acting director of CDER, briefed me on what his decision was going to be. This is after the permanent commissioner left and I was acting commissioner again. And he, Dr. Galson, explained to me what his decision was going to be in a -- again, a routine update meeting. I met with him once every two weeks at least. And I asked him questions about the decision, and then I concurred in his decision. And I mentioned that publicly, that I concurred in the decision.

Q So this would have been a meeting -- was this a face-to-face meeting that you had with Mr. Galson?

A Yes.

Q Do you know when that took place?

A It would have been about the time of the announcement, maybe a few days before, maybe even a day before.

Q I'm going to come back to that conversation. I just want to make sure I have the answer to my question about before May 6th, 2004, did you review any parts of the administrative record, any of the staff memos, any of the studies, anything at all in the administrative record related to the Plan B SNDA?

A No.

Q Okay, so you just met with Dr. Galson and discussed the matter with him?

A Yes.

Q Okay. You said he presented to you his planned decision and you asked him some questions about it. What questions did you ask him?

A Well, you know, this was our -- the customary way that I dealt with the center directors is the center directors I held responsible for any and all decisions, and it was their obligation to bring to my attention the major decisions. Some of them even brought minor decisions forward.

So essentially what they would do is they would say we're going to go this way, and I would ask them why, and then I might say, well, I don't -- I

don't agree with that approach, why don't you go back and give us -- you know, give me some more information, I want you to put this off, or something like that. Or I would say I concur, and -- but I would have asked them substantive questions about these kinds of actions.

I don't remember precisely what I asked him, but I -- we got into the substance of it at some -- in some detail.

Q Do you remember any of the topics that you discussed with him?

A No, you know, I can't say exactly what I asked him. I don't recall that.

Q Do you remember anything at all about what you might have discussed or what concerns might have been raised in that conversation?

A No.

Q And again, that conversation would have taken place a few days, couple days to a few days before the decision was announced?

A It could have been that late. It may have been a few -- you know, maybe a week or so before.

Q But very close to the decision announcement?
A Yes.
Q Other than that meeting with him, did you have any other communications with him about what the agency's decision would be on the Plan B SNDA?
A No.
Q It was just that one communication?
A Mm-hmm.
Q Okay. No other written communications, either?
A No.
Q And during that meeting when you asked him whatever questions you asked him and he answered, in the end of the meeting you concurred with his decision; is that right?
A I did concur, yes.
Q Do you remember why you concurred?
A Well, he convinced me, you know, that that was the right decision after I asked him some questions.
Q But you don't remember right now why you thought it was the right decision?

A No.
Q Who within the FDA decided to issue a nonapprovable letter on the Plan B SNDA?
A In 2004?
Q On May 6th '04, yes.
A Dr. Galson.
Q Prior to the meeting with him that we just discussed, did you have any opinion or idea about whether the application should be approved or denied?
A Again, I think it's germane for me to tell you about what was going on in the agency at that time and what I was doing. We were back into these orientation sessions again, although, you know, I believe I had canceled some of those, because I felt like I was up to date on them. But the main thing that was going on was in December of 2003 we had the first bovine spongiform encephalopathy case, mad cow disease case, two days before Christmas, and I'm an expert in that area, and so on behalf of the government I was given assignments about that, to communicate with the public and also to meet with, you know, various people in the government about what I

thought. And we joined with USDA.

So up to the time that the commissioner left, I was devoting almost full time to that. And so, you know, normally I would have been in some of these meetings, probably, where Plan B would have been discussed as well as other things, but I wasn't even -- I mean, I was basically out of that. And so that is the reason that that's sort of a blank spot.

And then I had to make some decisions when Dr. McClellan left as to whether or not I would agree to be acting commissioner again, and that occupied quite a bit of time and so forth.

So that's why I was -- even though I was the number two person throughout that time, that's why I was not particularly involved.

Q Okay, I appreciate the explanation. I just want to make sure I'm clear on the answer to my question.

Prior to the meeting that you talked about in early May with Dr. Galson, had you formed any sort of opinion about whether the Plan B SNDA should be denied or granted?

A No.

Q So sort of going into that meeting with Dr. Galson, you had pretty much a blank slate or open mind about what should be done on that application?

A Yes, I did.

Q Okay. What role did the commissioner's office play in the decision to issue the nonapprovable letter?

A Again, you're talking about 2004?

Q Yes, May 6th, 2004.

MR. AMANAT: When you say the commissioner's office, are you talking about --

MS. JONES: I'm talking about the commissioner's office, the entire -- anyone with the commissioner's office.

MR. AMANAT: So you're including both at the time it was Commissioner McClellan and at the time it was Acting Commissioner Crawford?

MS. JONES: Correct.

MR. AMANAT: Okay.

A I mean, I was -- as far as I -- I can only speak for myself. There's 700 people in the

commissioner's office, as you may know, and I didn't even know all of them. So some of them could have done something that I don't know anything about, but ultimately it had to come to me. And as far as I know Galson made the decision, he got -- presented it to me and I concurred, and that was it.

BY MS. JONES:

Q So as far as you know, that's the only role that the commissioner's office played in the decision?

A As far as I know, yes.

Q Let's turn back to that document that I think you still have open in front of you, the document beginning Tummino 30166. Again, this was an orientation session held pretty much for your benefit as new commissioner; is that right?

A Yes, that's my memory of it, and I believe that's the case.

Q Okay. What were some of the other topics that were the subject of these orientation meetings?

A Well, different drugs, like Isotretinoin was one of them I remember. The antidepressant drugs as a class. The COX-2 inhibitors like Vioxx was another

one. And I am not going to be able to name the 20 --

Q That's okay, I'm just trying to get a general idea.

A Many of them were related to specific classes of drugs. But the other -- as you know, there are five centers, so the other four centers would have gotten equal billing, so we would have had things like -- probably had mad cow disease, probably would have had qualified health claims for foods and dietary supplements, certainly would have had things like breast implants from the devices center, and I'm sure we had flu vaccine from the biologics center. But, you know, I can't name all of them.

Q Okay. So would it be fair to say there's probably a handful or so of these orientations that were from CDER, topics?

A Well, they were careful to make it proportional, so they probably would have had 20 -- 15, 20 percent.

Q Okay. And as a general matter did they cover -- were the topics drugs which had some form of application before the FDA or anticipated application

before the FDA that the FDA was going to have to take action on?

A No. They would have been in some cases drugs that maybe needed to come off the market that were already on the market. In other cases it would have been applications that had languished for years and hadn't been approved. Others could have been petitions that had -- you know, the average length of time on a petition is a long time.

So in the interest of good government, they would have probably brought up here are some petitions that you could dispense with. There could have been proceedings against products that were on the market, you know, like there was an animal drug that proceedings were going forward to take it off the market because of antibiotic resistance.

I would say probably -- it probably would have been half and half, something trying to get on the market and something -- if you just talk about the drug center.

Q Right, okay.

Do you know if any of the other ones

concerned a drug that was being considered for an OTC switch?

A Well, yes. I don't know whether we had an orientation session about it, but Claritin was still an issue.

Q That's what I'm asking you about, if any of the other orientation sessions concerned a drug that was being considered for an OTC switch.

A I'm pretty sure we had one on the antihistamines, but I can't say for certain.

Q That's fine.

As you pointed out, on page 31 -- 30167 of this document under discussion, one of the topics is political sensitivity. What was the political sensitivity that was discussed at this meeting?

A That was a code word for Congressional interest. We would never put that in one of these documents, so we talk about political sensitivity.

Q Okay, but the bottom line was the agency thought Congress was going to be interested in this application?

A I believe that's what it meant in this case,

yes.

Q And what was discussed about -- on that topic at this meeting?

A I do not recall -- I have -- do not recall.

Q Nothing about it?

A No.

Q There was also at this meeting, as you can see from later pages, an explanation given of mechanism of action, which starts on 30168.

A May I --

Q Feel free to take -- just let me know when you're done.

A Okay.

Q I'm not going to ask you about the science of it, just so you know.

A Okay.

Q Did anyone at this meeting question or dispute the explanation of mechanism of action given here?

A I don't remember. I -- no, I just -- I don't recall that. Now, we would have taken -- I mean, everyone gets these things, these are what's

called goldenrods, and they're called goldenrods because the cover sheet is the color of a goldenrod. And you're obligated and expected to read this, come to the meeting, and if there's something you don't agree with or whatever, the purpose of the meeting is to make commentary.

Since this is -- obviously was -- this was part of the goldenrod, this mechanism of action thing? What do we know about it?

Q All I know is I was given these pages in this order and that it says on -- on 30167, it says, CEDR's Dr. Dena Hixon has prepared an explanatory piece which is immediately attached.

A Was she in the meeting, or he?

Q I believe she was in the meeting. Was she in the meeting? Yes, she was in the meeting.

A Okay.

Q And it says that she has prepared an explanatory piece entitled "Mechanism of Action, Emergency Contraception," which is immediately attached. So --

A Yeah, well --

Q I assumed it was attached.

A Yes, everybody would have seen it. And, you know, I don't remember any debate about the substance of this.

Generally, a subject matter expert like she must have been is not challenged on the science.

Q Do you have any reason to disagree with this explanation of the mechanism of action?

A No.

Q Do you know who Jay Lefkowitz is?

A Yes.

Q Who is he?

A He had some big job at the White House, but what his title was, I don't know. I think it was domestic policy advisor to the president, or, you know, you have like a deputy, an assistant deputy, and, you know, a novice, and all that stuff. So something to do with domestic policy. But he was a prominent member of the first Bush administration.

Q Do you know him?

A Yes.

Q You've met him personally?

A Yes.
Q When did you meet him?
A I met him during the -- when I was acting commissioner. I don't know which month, but fairly early in the time that I was acting commissioner.
Q In what context did you meet him?
A He would have meetings in the White House about crises of one sort or another, and I went to two or three of those.
Q Do you remember what crises were at issue at the meetings you went to?
A I think one of them was Mad Cow Disease, because we had some serious meetings on it in 2002.
One of them would have probably have been on ephedra, ephedrine, the dietary supplement, because we had a crisis there.
And another one, I believe, was on -- you know how you can buy cough medicines and convert them into methamphetamine? FDA had some concerns about that, because we believed people needed the cough and asthma medications, and it was the opinion of some of the law enforcement type people in the administration

that you ought to just ban them all and make them prescription.

And what Lefkowitz did was -- and his successors, I assume -- is when there was a difference of opinion between two departments about something, then he would try to get the principals together and try to iron out the differences. That's what his job was.

Q So you met with him a couple times at the White House about these various crises?

A Yes.

Q Would the first of those meetings have been in 2002 at some point?

A Yes. I'm pretty sure.

Now, he left the government. He would have come on board in 2001, and he would have left probably 2003, early 2003.

Q Did you have any communications with Mr. Lefkowitz other than these meetings at the White House?

A Yes, he would call every once in a while.

Q He would call you?

A Yes.
Q To discuss what?
A Some crisis, usually.
Q Did you ever discuss the Plan B SNDA or the citizens' petition with him?
A No.
Q Never in any context?
A No.
Q Never in an e-mail, no communication whatsoever?
A No, not that I recall. I think I would remember that.
Q To your knowledge, have any FDA personnel communicated with Mr. Lefkowitz regarding the Plan B SNDA or the petition?
A Well, something like that could have happened during the time that Dr. McClellan was there, but I -- and I might not know about it. It also, you know, could have happened, you know, before I got to FDA, because I didn't -- the administration was a year old when I got there. But I don't know of that, no. I have no knowledge of such a meeting, and I

think -- anybody who talked to the White House, you know, during the time that I was acting or permanent commissioner should have let me know. And I don't think -- you know, I doubt he would have called somebody other than me. But, you know, you never know. I can't be certain.

Q But to your knowledge, you don't know of any communications between Mr. Lefkowitz and anyone from the FDA regarding Plan B or the citizens' petition?

A I don't, no.

Q And none of these meetings you had at the White House had anything to do with FDA; is that right?

MR. STURM: With Plan B, you mean?

BY MS. JONES:

Q None of these meetings that you had at the White House with Mr. Lefkowitz had anything to do with Plan B?

A No.

Q Could you look in the notebook in front of you. Could you turn to the next tab, which is 3037, which is Tummino 30219 through 30235.

A Mm-hmm.
Q This is a July 10th, 2002, memorandum from Dr. Woodcock to you. Are you familiar with this memorandum? Would you like a moment to look at it?
A If I could, that would be great. Now, it goes to -- you want me to go to 30225, or --
Q All the way to the end. This whole tab, basically.
A Okay, to 3081.
Q Exactly.
A Okay.
Q Are you familiar with that memorandum?
A No, I'm not. I'm sure I saw it, but it's been four years ago, and -- but I don't remember seeing it.
Q It is addressed to you, correct?
A Yes, it is.
Q But sitting here looking at it now, you don't recall whether you actually received this or read it at around the time?
A If it's addressed to me, I'm quite confident I would have seen it.

Q Okay.

A Those are always delivered to me, and my executive assistant demanded before I left that I read all this stuff and then take a test. So I'm sure I did.

Q But sitting here today, you don't recall the memorandum?

A You know, I don't, I'm sorry.

Q That's fine. I just want to know for the record.

A Okay.

Q I believe that it states that it's from Janet Woodcock, or that Janet Woodcock drafted it. Is that your recollection or do you have any recollection about who drafted it?

A I don't, but that's her signature.

Q Okay. Do you -- well, in the first line of the body of it, it says, "At the briefing on June 5th, 2002, on emergency contraception, CDER was asked to provide additional information," and then it says some various topics. Do you know who asked CDER to provide additional information on those topics?

A No. One of the key people in there was the acting deputy commissioner of FDA, and that was Dr. Mack Lumpkin. He's a pediatrician and also an expert in this area, and if anybody asked about mechanism of action, it would have been -- I would guess it would be him, because of his knowledge ability of the subject area.

It's addressed to both me and the chief counsel. And I don't know who all she copied. Yes, well, she copied the relevant folks down the line.

So, I mean, that would give you a tip that maybe one of us asked or one of these directors asked. I don't know.

Q Did you ask?

A I don't remember asking. I was interested in things like that because of my scientific background, but I -- I doubt I asked. That was not usually something I would do.

Q When you say I was interested in things like that, are you referring to the mechanism of action?

A Just physiology and pharmacology.

Q Okay. Do you know why this was also

addressed to Mr. Troy, the chief counsel?

A I don't know that. The only thing I can think of is that, you know, he may have expressed some interest. That's July 10, so I don't know.

Q Would a memorandum of this kind, discussing scientific issues, ordinarily have been sent also to the chief counsel?

A He likely would have been copied on -- if he were in the meeting, he would likely have been copied on it.

Q But it wouldn't ordinarily be also addressed to him?

A Well, you know, he was -- the chief counsel is very important in FDA, and I would think it would be unusual if he wasn't copied if he was in the meeting. This seems to be unusual to me. Most of these kinds of memos came directly to me. Why he was copied, I don't know. I mean, why he was sent on the "to" line.

Q To your knowledge had anyone from outside of the commissioner's office inquired or asked about this information that's discussed in the memo?

A Specifically what, or everything?
Q Any of it.
A No.
Q To your knowledge, had anyone from outside the commissioner's office expressed to the commissioner concerns about the mechanism of action on Plan B?
A Not that I know of.
Q Were you concerned about the mechanism of action for Plan B?
A No.
Q Do you consider Plan B to be an abortifacient or a contraceptive?
A Well, some of that resides in how you define them. Generally, abortion is something that happens after five months of pregnancy, that's -- it was the old rule of thumb among physicians and also people that worked on the physiology/pharmacology of it. So something that is an abortifacient would have been something that, you know, took action on the fetus itself.
The complicating factor comes when you read

about the mechanism of action and so forth, and that is that fertilization can occur in the -- within the fallopian tube and also even before in that space between the ovary and the fallopian tube. And so that, you know, it's fertilized and then it gets introduced into the uterus.

And there is -- if it's fertilized and it's not able to implant, some people, I think, think that life is there, and I respect that. I -- my training would have me not believe that in terms of making a decision on labeling to call it an abortifacient or something like that.

But I would for the most part respect what the center came to me with, in other words, Dr. Woodcock. You know, I wouldn't presume to second-guess among nomenclature, or labeling language, or something like that. So --

Q Well, am I correct that the agency in dealing with the Plan B application considered this to be a contraceptive product; is that right?

A That is correct.

Q Did you have any disagreement with that?

A No.
Q Could you look -- if you turn sort of towards the back of your notebook there's a tab D331, which is Tummino 331. It's not that far back.
A Okay.
Q Let me help you find it. Let's see here. Here you go.
A Okay.
Q Could you take a look at that page.
A Mm-hmm.
Q Am I correct that this is a page from your calendar?
A I don't know.
Q Is Vicki Powers your assistant?
A No.
Q Or, sorry, was Vicki Powers your assistant?
A No.
Q Who's Vicki Powers?
A Vicki Powers works on BlackBerrys.
Q Vicki Powers works on BlackBerrys?
A Mm-hmm.
Q For the FDA?

A Mm-hmm.
Q Okay.
A She --
Q I raise her name because it's at the bottom of the page. She was your BlackBerry expert there?
A She was, yes. Is she on here?
Q She's at the very bottom left-hand corner.
A Oh.
Q She may be the person that printed this out.
A Yes, she would have been involved in that, probably.
Q Okay.
A Or the people that did it worked for her, I think.
Q Okay. In any event, is this a page from your calendar for the date December 15th, 2003?
A I don't know how you could tell. Let me -- well, it says LMC to chair the Obesity External Meeting. And the Obesity Working Group, I chaired that, for sure. And we were going to reschedule the Food Safety Research Consortium. And Mary Lacey Ruther worked for me, as well as Dr. McClellan. I

think it is, I think -- I don't -- you know, they all look alike.

Q I understand.

This page was given to us in discovery in this case as somehow related to this case. Do you have any idea what on this page relates to the Plan B SNDA or the citizens' petition?

MR. AMANAT: I'm going to object to the characterization of why this page was produced to you in discovery.

You can answer the question.

A Well, I'll have to try to -- let me just spend a moment, not long --

BY MS. JONES:

Q Sure, take as long as you need.

A -- trying to decipher what the -- you know, whose this is. All the LMCs clearly mean it must be mine.

The first -- the morning into the afternoon is all about obesity. For some reason we didn't schedule 12:00 to 1:00, which was a first. And I don't know why they rescheduled the -- NAI is -- that

was -- that has to do with the North American Free Trade Agreement. It may have -- I can't imagine it went longer than an hour, but that may have been the reason. Ms. Ruther, they don't say what she wanted, but it was a telecon. I don't know. I have no idea.

Q Who is Mary Lacey Ruther?

A She was a special assistant to me and to Dr. McClellan.

Q Did you ever discuss Plan B or emergency contraception with her in any way?

A Well, I mean, she would have been, you know, like -- no, I don't think so. She -- you know, she was like an assistant, not what we used to call a secretary, but something -- somebody who kept up with your schedule.

Q Okay.

A Now, at that point, though, December 15, she had transferred over to Dr. McClellan, so she no longer worked for me. And we were having a telephone conference, and -- which -- you know, I remember, I remember that, though, because she was over in CDER, and she wanted to know about -- oh, she was -- had

some questions about the organization of CDER, about, you know, what the organization chart looked like, and she wanted to report that, and she didn't get back in time, so we put it down for then. I remember her doing that.

And the reason I do is because I didn't -- you know, I didn't think she ought to be getting involved in that. And I told her that, I recall. That was, you know, not something that I would normally remember.

But I can't answer the question as to why this was submitted, unless it was by accident.

Q Okay. Do you recall this, the listing at 6:00 o'clock for a Kirkland & Ellis cocktail reception to welcome Jay Lefkowitz?

A I do, because I didn't go.

Q You did not go?

A Unh-uh.

Q Okay. What was he being welcomed to, do you know?

A To the firm, I think. He left the -- ah, I was right, it was 2003 when he left.

So he had left the White House and he was going to this law firm.

Q And you were invited?

A I was invited, yes.

Q You did not attend?

A I did not go.

Q Why did you not go?

A Probably because of Mary Lacey Ruther. I can tell you why I didn't go. They always -- you know, we always got -- would get invited, and -- to these things, and it's downtown, this was at the Willard Hotel. And we're way, way out there in Rockville, and we just hardly ever made any of them. So we got known primarily by the unpicked-up name tag.

Q Okay. If you could turn back to, let's see here, tab 3081, is that right? Which is Tummino 30393 through 30420, which appears to be minutes of a December 10th, 2003, Office of the Commissioner meeting.

A Mm-hmm.

Q Do you recall that meeting?

A Can I -- do you want me to look through it a

little bit.

Q Sure, take your time.

A Because it may...

No, I don't think I was in this meeting.

Q You don't think you were in this meeting?

A Unh-uh. I was -- I think this was when I was in Argentina.

Q You're listed as an attendee. Is that sometimes not accurate?

A It's sometimes not accurate, yes. It's often not accurate. The attendee list sometimes was taken off the invitee list and just included.

I think -- I'm pretty sure I was in Argentina.

Q And you would have not participated by phone from Argentina?

A No, no, that would be -- that would take technology that isn't present everywhere.

Q Do you know who called this meeting?

A I don't.

Q Do you know whether the commissioner's office usually holds meetings like this on OTC

switches?

A Well, it would depend on what the center -- you know, if the center wanted to bring it to the attention of the commissioner, we generally honored that and had the meeting. That's just a rule of thumb. If they didn't press hard for it or if they didn't bring it to our attention, then we didn't have the meetings.

Q So the initiative as a general rule would come from CDER?

A Yes, because otherwise we wouldn't know about it.

Q Okay.

A Not just CDER, but all centers.

Q Okay. Did you ever attend an Office of the Commissioner meeting on another OTC switch?

A Oh, yes, we did those antihistamines, for sure.

Q Any others that you recall?

A There were some that we didn't actually switch, like Isotretinoin. And we considered the statin drugs, for example. There would have been a

number of them.

Q Okay. Do you know anything about a phone call on December 17th of 2003 between Dr. McClellan and Surgeon General Carmona?

A No.

Q Do you know whether such a call took place?

A I do not.

Q Could you take a look at the tab marked D13, which should be about --

A In the back?

Q Yes, towards the back. Actually, the tab is marked D10 through 16.

A Ah.

Q A little further.

A Okay.

Q This one right here.

A Okay, thank you.

Q And the pages that I'd like you to look at are marked Tummino 13 through Tummino 15, actually. It's a letter addressed to Dr. McClellan from Dr. Hagar.

A Mm-hmm.

Q Hagar.
A Okay.
Q Are you familiar with that letter?
A I am.
Q How are you familiar with that letter?
A It was the subject of a lot of press attention and so forth, and at FDA we had a morning staff meeting every day, and that's probably why I found out about it. I chaired those sometimes. Mostly Dr. McClellan did when he was there.

But I remember about the letter now. I don't think I was in town at the time that this letter was received, so I would have found out about it later than this date. I went on a -- I'm an expert advisor to the World Health Organization, which is one of the few things I was able to continue to do, and so I went to Argentina for a worldwide meeting on food safety or food poisoning. And I was down there for about a week and -- to 10 days, and then from that point I went on vacation in West Virginia. So I wasn't there very much at all.

And then on December 23 we had the mad cow

disease thing happen. And I continued to stay in West Virginia, but I was -- from that point on I was involved with that very heavily.

So I don't know when it came to my attention, but I know about the letter, yes.

Q Do you know who brought it to your attention?

A I don't. It probably was in one of those staff meetings.

Q Okay. Do you have any information that might suggest that the letter was solicited by someone in the FDA?

A No.

Q Do you have any information that might suggest that this letter was solicited by someone else from the Federal Government?

A No.

Q Do you have any information about what might have motivated Dr. Hagar to submit this letter to the FDA?

A I do not.

Q Do you know anything about -- I'm going to

ask you about a conference call on December 23rd '03, when is I think when you said you were very involved in the mad cow disease business; is that right?

A Mm-hmm. I was on a conference call then.

Q Okay, well, I think I'm going to ask you about a different conference call, but we'll find out.

A Mine was a day long.

Q Yes, I think this was a different one.

Do you know anything about a conference call on that date between Drs. McClellan, Galson, and Woodcock related to Plan B?

A The three of them?

Q Yes.

A No, I don't.

Q That was not a conference call you were participating in in any way?

A No.

Q Okay. Do you know anything about a meeting held on January 15th, 2004, that was chaired by Dr. Galson regarding the Plan B SNDA? And if you want to take a look at the minutes of it, it's 3101, is the tab.

A Okay. Not with a D, but just 303 what?
Q Exactly, 3101.
A Okay.
Q Which for the record is Tummino 30666 through 30670.
A 3101, I have it.
Q Just so you don't waste too much time looking for your name, I don't believe that you're listed as one of the attendees.
A Okay.
Q But being as that might be wrong, I want to make sure that you didn't have this meeting.
A This was a -- this was a center meeting, right, a CDER meeting?
Q I don't know anything more about it than what it says here, to be honest with you.
A Okay, I can figure that out, I think.
No, I was -- I think that was a CDER meeting. I don't see anybody on here that -- you know, I don't know all of them, but looking at the titles, I think they're in CDER.
Q Okay. Is it correct to assume that you did

not attend this meeting, since you're not listed?

A I would not have attended a CDER meeting, no.

Q On the second page of this document it says that the meeting objective is to inform ODE-3 and ODE-5 of the Office of the Commissioner's position on the acceptability of the Plan B SNDA. And then if you look down under discussions and decisions made, it says, describes the issues discussed by Dr. Galson. Did you have a chance to look at that?

A Mm-hmm.

Q Does that list to the best of your knowledge describe concerns held by the commissioner's office at this time?

A Yes, I don't -- I was not involved in that, and I don't know what -- you know, what all the concerns were. Again, it was at a time when I was sort of out of the picture, and I -- you know, I don't know.

Q Were any -- did you hold any of these concerns?

A Okay, let me just go through them carefully.

What is the AUS, do we know that?

Q I think it's the Actual Use Study.

A Okay, okay.

And a learned intermediary is a doctor, a medical doctor, I believe.

No, I didn't focus on this at the time and I didn't -- you know, I didn't have any of those opinions, and I wasn't involved in the decision.

So the answer is -- would you restate the question? Because I want to be sure.

Q Sure. I'd like to know -- let's start with at the time of this meeting whether you held any of these concerns described in the discussion decisions made section of these minutes?

A No, you know, I hadn't focused on it. And if I had been, you know, acting commissioner then, I may have. But I don't -- I didn't form any opinions, and I certainly didn't bring any of those opinions out in any of these meetings.

Q Subsequent to that time and up to date, do you share any of these concerns?

MR. AMANAT: I'm going to object to the form

of that question. Both compound and ambiguous.

A Well, some of this would have been what Dr. Galson, you know, discussed with me, like the nonapprovable letter and so forth, and I did concur in that. The rest of this stuff I didn't form any opinion on.

BY MS. JONES:

Q So what is the part that you concurred in?

A He talked about the nonapprovable letter to me, and I concurred in that. That was, you know, in May, or whenever it was done, of 2004.

Q All right, it says here, "A nonapprovable letter is recommended based on need for more data to more clearly establish appropriate use in younger women and/or the need to develop a restricted distribution plan that is monitorable to address use in younger women."

Did you also concur in that reasoning?

A No, I -- basically, I don't remember what all he brought out, but I was convinced that his decision to issue a nonapprovable letter was correct.

Q So you don't recall whether you agreed with

that reasoning or not?

A I do not.

Q Okay. Do you know whether any members of Congress wrote to the FDA about the possible switch, OTC switch of Plan B?

A I'm sure they did. I mean, I don't know who did, or when, or what the substance was, but I'm reasonably sure there were Congressional letters on Plan B.

Q But you don't remember from whom?

A No.

Q Can you take a look at D-77 through 80, which is, again, about halfway through the binder. It's Tummino 77 through 80?

A D-77?

Q Correct.

A Yes.

Q Would you like a minute to take a look at it?

A Yes.

I believe I've seen is this.

Q So you're familiar with that letter?

A I believe I've seen it at some point, right. But I would not have seen it when it came in on December 8th.

Q Why is that?

A I was in Argentina.

Q Okay. All right, do you recall who gave you this letter to look at?

A I do not.

Q But at some point you looked at it?

A I did see it, yes.

Excuse me, I believe I can tell you how I would have gotten it.

Q Sure.

A When we do the Congressional hearings, the one time when you have to know something about all the major topics is during the budget hearings. And once again, in 2004, I had a few days to prepare for those. And there would be a -- you know, a big set of books, briefing books, and there would be 4 or 500 topics in there. And under each topic they would have Congressional interest. And I suspect, I'm reasonably sure that in the briefing book for 2004, this was in

there.

Q Okay.

A And I did -- was required to read all that, so -- one that has these many correspondents you would take note of.

Q Okay. Did you discuss this letter with anybody?

A The only thing I may have discussed was answering it. We had -- about this time we had an abysmal record of answering Congressional letters. We were supposed to do it within 15 days, but very often I would, you know, be with members of Congress or be testifying and they would say, why don't you answer your letters, it's been a year since such and such a letter. So I would come back from those meetings and I would get in touch with the executive secretariat and I'd say, you know, I need a list of these letters and I want to know why it hasn't gone out.

Often I would be told that it didn't go out for strategic reasons, and I wouldn't know what that was, because that's not -- they shouldn't be making those kind of decisions.

Q The secretariat shouldn't make those decisions for you, is that what you're saying?
A Yes.
Q Do you know if you ever responded to this letter?
A I don't know. I don't know that.
Q Do you consider this letter to be political pressure on the agency's decision?
A Well, it is and it isn't. They seem to be focusing on the inhibition of implantation, otherwise known as nidation. So it's couched in a way that they're bringing new and different information to FDA. And, quite frankly, technical information. But on the other -- so gainsaying that, I mean, you would have to say, though, that if this many Congressmen sign anything, it's -- it is perceived as being something very important to them, and so it -- you know, it's a bit of political pressure, yes.
Q What's the part of this that brings new technical information to the FDA?
A Well, they think that they did where they say, "The Plan B manufacturer says on its website, in

addition, it may inhibit implantation by altering, endometrium, and though both the FDA and the manufacturer say the morning-after pill may inhibit implantation, it is not clear that women are fully informed." So they're telling us that, you know, women don't know this technical effect.

Q Do you know anything about a meeting that was held on January 27th, 2004, between Dr. McClellan and Congressmembers Smith, Weldon, and Manzullo?

A I do not.

MS. JONES: I've been informed that we're almost out of videotape, so we're going to take a break for about 15 minutes, if that's okay with everybody.

THE WITNESS: Okay, sure.

THE VIDEOGRAPHER: This marks the end of tape 1 of the deposition of Dr. Crawford. We are going off the record. The time is 11:04 a.m.

(A brief recess was taken.)

THE VIDEOGRAPHER: This marks the beginning of tape 2 in the deposition of Dr. Crawford. We are back on the record. The time is 11:23 a.m.

MR. AMANAT: Just for record, since that break was requested by plaintiffs and the videographer, according to the terms of our Rule 20 stipulation, the time taken for that break does count toward the seven-hour allocation for this witness.

MS. JONES: Although it was requested by the videographer because --

MR. AMANAT: Because --

MS. JONES: It does count or it does not count?

MR. AMANAT: It does count, according to the terms of our stipulation.

MS. JONES: A break requested by the videographer?

MR. AMANAT: That's right.

MS. JONES: All right, I'll check it later. I'm sure we're not going to need to litigate this issue.

BY MS. JONES:

Q Dr. Crawford, when did the agency first start considering the possibility of approving OTC status for Plan B for certain ages and keeping it

prescription for other ages?

A I -- well, I assume when the company submitted the application. However, I think there were discussions with the company before then, which could have involved, you know, several options for them. I don't know the substance of those conversations. I believe, though, that they took place. And when I first got informed of what was going on was when they submitted the application.

Q When they submitted the application when?

A I don't know when it was. It was -- I don't know.

Q Are you talking about the submission of an application prior to 2004, when they first submitted their SNDA?

A Well, no, they submitted another one later on, and that's what I was talking about.

Q Do you know approximately when that was?

A I don't know. It would have been after May of 2004 and in advance, certainly, of January of 2005, but I can't -- I don't know the exact date.

(The following testimony was designated

"PROTECTED TESTIMONY".)

(Conclusion of "PROTECTED TESTIMONY")

BY MS. JONES:

Q When did the agency first become concerned about possible legal obstacles to dual status approval?

A By "legal," you mean like enforceability, regulatory?

Q Anything related to the law.

A To the law, okay.

Well, I think that there is -- there is some input from the legal side into the center as they're reviewing an application, and I think that begins early on in CDER's case, but it would not have come to the attention of the chief counsel until much later on than that.

Q When did it first come to the attention of the chief counsel?

A Well, we had -- we had a change in chief counsels. Mr. Troy, who was there, left in November of 2004, and he was replaced by a Mr. Masudi on an acting basis immediately. And he served on that acting basis for about six months, and then Mr. Bradshaw came in. And he is the one that I conferred with with respect to my decision and so forth, not with -- not with the other two.

Q And what month would those conversations first have started taking place?

A Well, we announced our action in late August of 2005, and the serious conversations would have taken place in that same month. However, general conversations about that and some other approvals

would have taken place right after he got there. And I was concerned about various aspects of the application in January of 2005.

Q All right. We'll get back to that in a little while.

Could you take a look at D-270 through D-272, which I believe are now marked confidential.

MS. REYES: Yes.

A Yes.

Okay.

BY MS. JONES:

Q Are you familiar with that document?

A No.

Q Never seen it before?

A No.

Q Does it surprise you that no one ever showed you this document?

A No. She actually indicates here that it should be kept close hold. That means, you know, don't let it out of your possession. It's a typical FDA term. It also means don't let it get, you know, leaked somewhere from your possession, like the press,

and then maybe don't -- make sure the commissioner's office doesn't know, although she did copy Dr. Woodcock, who was by that time in the commissioner's office. Well, no, no, she wasn't. She was going to be in a few days, but I don't think she was then.

So anyway, people who would have gotten that would not have shared it. Ms. Axelrad is very strict about those matters.

Q So close hold might include don't talk about this to the commissioner's office?

A Mm-hmm.

Q Why would they want to keep this from the commissioner's office?

A I don't know. I don't know why they would do that. Some of it is, you know, not to bother the commissioner, his staff. We're not ready yet, is another reason. They might call for some kind of meaning, and we don't -- we haven't gotten all this figured out yet. Third reason could be if it gets in the commissioner's office it's far more likely to be leaked to the press. It's like, you know, they

believe in the First Amendment and sometimes to a fault. So that could be. That's just speculation, though.

Q Do you disagree in any way with the analysis in this?

A Well, I just have seen it. I think this was early on in them thinking about it, so I'm sure they weren't ready to discuss it probably even with Galson yet. Although they didn't, in fact, copy him. And I don't think they'd worked out the labeling or even the packaging at this point. So, you know, I think this represents sort of like a work in progress.

I do -- I do have questions about, you know, whether or not, you know, this could be marketed safely. At this point they hadn't decided on the application, I'm sure. I'm not even sure they had the application yet.

So I would have raised -- had this been the final, I would have raised some questions about enforceability.

Q Well, this talks about an application that was submitted on March 11th, 2004, by Barr to market

Plan B as over the counter to women aged 16 and older while maintaining the product's prescription status for patients under 16.

A Mm-hmm.

(The following testimony was designated "PROTECTED TESTIMONY.")

(Conclusion of "PROTECTED TESTIMONY.")

BY MS. JONES:

Q Is the drug you were just talking about in your example a drug that is only for adults?

A We have a lot of drugs that are -- that say

cannot be -- you know, for adults only or something like that. I don't know whether it is or not. I'm just using that as an example.

Q And in her second bullet point she makes the conclusion that "Rx and OTC Plan B could be marketed in the same package and comply with applicable statutory and regulatory provisions, including," and then she lists some provisions.

A Mm-hmm.

(The following testimony was designated "PROTECTED TESTIMONY.")

(Conclusion of "PROTECTED TESTIMONY.")

Q If you'll turn to tab 3117, Tummino 30904 through 30907.

A 311 --

Q It's tab 3117.

A Okay.

Q It's probably a bit --

A I've got 331. Not D, not D.

Q No D.

A Oh, I'm sorry.

Q No problem.

A Okay, I have it.

Q I'll represent to you that that's the May 6th, 2004, nonapprovable letter.

A Mm-hmm.

Q Did you play any role in deciding to define that letter as a nonapprovable letter rather than as an approvable letter?

A What I did was when Dr. Galson got ready to act, as I mentioned earlier, he had a -- we had a meeting where he described what he was about to do, including the nonapprovable part, and I asked him some

questions about it, and then I concurred in his decision.

Q Whose idea was it to make it a nonapprovable letter?

A It was Dr. Galson's.

Q Did you prior to the meeting you had in early May with him give him any input on whether the letter should be deemed a nonapprovable letter versus an approvable letter?

A No.

Q Do you know if anyone from outside the agency gave any input on that issue?

A No, I don't think so.

Q Okay, let's turn to the time period following the issuance of this letter. Could you just in general terms describe to me your involvement in the handling of the Plan B SNDA following the issuance of the nonapprovable letter on May 6th '04?

A No time frame?

Q From then --

A Until now?

Q From that point forward, yes.

A Mm-hmm.

MR. AMANAT: Could you read back the question? I missed part of the verbiage. Did you say "handling?

(The Reporter read the record as follows:

"Q Could you just in general terms describe to me your involvement in the handling of the Plan B --")

MR. AMANAT: That's all right.

THE REPORTER: Okay.

A And by handling, you mean the management within FDA?

Q Exactly.

A I didn't have much involvement with the handling of it within CDER. In fact, none. Periodically Dr. Galson would mention something about it in our biweekly meetings. But I didn't really tell him what to do or whatever.

And then he -- there came a time in January of 2005 when he indicated to me that they were moving along a path of this dual approval. And I asked him to explain that to me in detail, and he did. And then

I asked him if he'd made a decision yet, and he said, no, but the PDUFA deadline is, you know, I think he said a week away or something like that.

And I said to him, I said, well, this is an important decision, do you feel comfortable with it or something like that, and he said, well, we're not there yet. I said, well, we're going to do two things. One is I don't want you to worry about the PDUFA deadline, I want you to make the right decision, and I want to reserve the right to make that decision, I don't want you approving this without conferring with me, and then at that point we'll decide who makes the decision. I said, but I want you to be very sure what you're recommending to me. And that was basically the substance of it.

Q And that occurred in January of 2005?

A It did.

Q So you were the person that decided to delay the action on the SNDA past the PDUFA deadline; is that right?

A Yes.

Q Did Dr. Galson indicate that he was not

ready to make a decision within the PDUFA deadline?

A He -- I believe he said something like -- like he could use some more time, something like that. He didn't argue about it.

Q What was the basis for your decision to delay action beyond the deadline?

A Well, I was -- I was concerned about the dual packaging and whether or not that can be enforced. And, you know, I wanted to -- you know, I wanted them to think that through and give me some answers, and also confer with the regulatory affairs people who were going to be in charge of enforcing it. So I wanted him to be very careful. And I had some serious questions about the enforceability of it.

Q Let's talk about the time period from May 6th '04 through January of '05. It sounds like from what you described earlier today that really up to the decision on the nonapprovable letter you were very much not involved in the decision-making process for the Plan B SNDA; is that right?

A That is correct.

Q So up through May you were not involved as a

general matter, except to concur in Dr. Galson's decision, right?

A Right.

Q Then by January of '05 you seemed to know quite a bit about the application, and are concerned about the application, and are indicating to Dr. Galson the various things that you just told me; is that right?

A That's correct.

Q Okay. So what happened between May and January to get you involved in the way that you became involved?

A Well, Dr. McClellan left to go to CMS, and so I became acting commissioner again. And as commissioner you get involved in those things, I mean, the center director meets with you, he or she tells you what they're doing, and so you necessarily are more involved.

Prior to his going back to CMS, I was deputy commissioner, I basically did like operations and special projects, like the Obesity Working Group and BSE that I mentioned, so forth.

Q You became acting commissioner in March of '04; is that right?

A Either March -- very late March or early April. There was a complicating factor, which is the fact that Dr. McClellan was voted in by the Senate, in other words, they approved his nomination sometime in March, but then he couldn't be sworn in until, I think it was another three weeks. And then during that time he was basically still running the agency, so that's why there's a slide of like three weeks.

Q So when did he actually get sworn in?

A He got sworn in, I believe the vote on him was something like the last week of March, and I think it was another, maybe as much as three more weeks, so it would have been like maybe the third week of April.

Q Okay.

But by the time of the issuance of the nonapprovable letter you were acting commissioner?

A I was, yes.

Q Okay. But it seems from what you testified to earlier that you didn't become very much involved with the decision on the Plan B SNDA until after the

issuance of the nonapprovable letter.

A That's correct.

Q So when did you start becoming very involved in that?

A When I became -- you know, when I became acting commissioner, I, you know, took time to get up to date on the issues, you know, that I hadn't been dealing with. I'm a food safety expert, and Dr. McClellan is a medical and economics expert, so he basically -- he generally did the medical part, you know, the drug part of FDA and I did the food part on the big issues. And the center directors, though, reported to the commissioner, not -- even the ones in foods and veterinary medicine reported to Dr. McClellan rather than me.

So, you know, once he left and once I had a few days to get up to date on the issues, which would have been something like May 1, then I became involved in all those kind of decisions.

Q So in early May you --

A Mm-hmm.

Q In early May you started getting well-versed

in the Plan B SNDA?

A Well, the time I got well versed in it was when he briefed me. I don't think we had had a conversation about it until then. And he said the decision is cooked, in other words, it's ready for announcement, and this is what he was going to do, and he wanted to make sure that I concurred. So, you know, as I mentioned earlier, I asked him some questions and got comfortable with his thought pattern, the reasoning, and concurred.

Q Okay. And then after that, after May 6 of '04, what led you to becoming involved with the Plan B SNDA in the way that you were by, it sounds like, January of '05?

A The biweekly updates. He would come in and spend an hour and talk about what was on the plate in CDER and what I needed to know about. And he mentioned Plan B a couple times. And then I think I also asked him, you know, how is that coming, and he would tell me, you know, sort of where they were. Or frequently he would say, well, I have to get back to you on that. And so he would go back to the center,

ask the people who were in charge of processing the application where it was and what was going on, and he would give me a call.

Q Did you during the period of May 6th up to January of '05, May 6th, 2004, up to January 5th of '05, read any parts of the record that had been compiled within the agency on the Plan B SNDA?

A No.

Q I think you said that by January of '05 you were concerned about the possibility of approval of a dual-status application. Were there any communications, or meetings, or -- well, let's just say that, were there any meetings or communications that gave rise to those concerns that you had?

A Well, the reason I got concerned is because he was, you know, telling me how it was going to be marketed and all that sort of thing. And then I said -- one of the questions I asked him was -- went to the issue of how -- what was the science telling him, and how was this likely to come out. And he said, well, the science tells us that it's safe to be over the counter for someone who's either 16 or 17.

At that point, in January, he hadn't decided whether it should be 16 or 17.

And I said, well, what about those that are younger, and he said, the science is telling us that they need a learned intermediary, they need some kind of -- they need a prescription, they need to be examined by a physician before getting the product and so forth. And therefore, I think that's how the center is going to come out.

I said, well, you know, I'm holding you responsible for how the center comes out, so I want you to be very careful about that. If there is a public health reason for those that are 16 and under, 17 and under, or 18 and under, I think he was even thinking about 18 and under at one point, I -- you know, I want you to give me, you know, your best recommendation and analysis of the science, I don't -- you know, I don't want anything trumped up or whatever, I want to know what your decision is on the science.

And I said, I also want you to be very careful about where you set that date, because this is

going to be very important if we put the product out on a nonprescription basis when the other forms of contraceptive are without exception on a prescription basis, I said, you know, we could have ramifications for that, I want to know -- I want you to have thought about that and I want you to come in here and make the decision, and then I'll go forward and either announce it or I'll concur like we did before.

And he said he would look into all that. And that was it.

Q Was it your understanding -- I think I'm getting this right from what you said. Is it your understanding that all other kinds of contraception are available only by prescription?

A Well, not if it's condoms and that sort of thing. But the regular, what's called birth control pills or oral contraceptives are prescription. And so this would be kind of a departure from that, even though, you know, you could make the case that it's -- since it's a progestin only and there's a special form, a special dosage, that it's sufficiently different to where it wouldn't be precedent. I just

asked him to think about that.

Q And again, the conversation you're describing new is the conversation you had with Dr. Galson in January of '05?

A Yes.

Q At some point did you indicate to Dr. Galson that you were revoking CDER's authority to decide the Plan B SNDA?

A At some point I told him that I was going to make the decision.

Q When was that?

A That would have been sometime after January. But in January I told him I was going to reserve the right to make the decision, which meant for him not to make it, you know, without checking with me.

Q What was his reaction to that?

A He was fine with it.

Q Okay, so --

A I mean, as you know, under the law those decisions are made by the secretary, but they delegate them in some administrations to the commissioner, sometimes to the center director, and then sometimes

further. But at any time the secretary can, for example, say he's going to make the decision or she's going to make the decision.

Q So when did you communicate to him that you were going to make this decision?

A I don't know exactly when. He knew that he was not to make it without concurrence in January. Finally I would have told him in August, for sure.

Q Not before then?

A I don't think so. He knew it was reserved, which was sort of the same thing, you know, sort of splitting hairs. I could have, up until the final decision date, though, said, you know, you go ahead and make the decision, or, you know, even the secretary could have said they wanted to make the decision or something like that. But I didn't, that never happened.

Q What was your motivation for revoking the authority that ordinarily would have been delegated to CDER on this?

A Well, I didn't revoke the authority in a formal way, I just said that I was going to be the

person who he had to check with before he did anything on this decision.

Q Then you said that later you told him that you were the one that was going to make the decision, right?

A I did, mm-hmm.

Q Why did you decide that you were going to be the one to make this decision rather than CDER?

A Well, I did, because I was the one concerned about the enforceability. I couldn't get any good questions about it. And the only decision I could make was to ask for this notice and comment rulemaking period, 60-day comment period, try to get some information in about enforceability, also to have the public be able to make comments.

FDA's best decisions, in my personal opinion, have been made after notice and comment and compilation of those. That's been a tradition in the agency. And I believe very strongly in the final analysis by late August that that's what should be done.

And since I knew that was going to be, you

know, subject of some general interest, I thought that since I was ordering that, then I should be the one to do it.

Q I guess my question is why did you make the determination that you would be the one to decide the outcome on this application rather than letting CDER exercise the authority as you normally would with an OTC switch application?

A Well, you know, because as I just said, it was, you know, my judgment that we were going to do this notice and comment rulemaking, and therefore I thought I should be the one to make that decision.

Q Have you ever revoked CDER's delegated authority to decide any other drug application?

A You have to tell me what you mean by "revoke."

Q Let me use different words.

A That's like a regulatory term.

Q Okay.

A Let me explain. I don't mean to be argumentative, but let me explain why I think it's important to get that, my understanding, your

understanding, the same. It's because delegations of authority are redone at FDA every year generally, and so they move up and move down, and revocation is used to characterize that process. And this was not done in this case, it was basically a face-to-face thing.

I'm sorry.

Q No, that's helpful, thank you. Let me just make sure I understand.

Generally, CDER is delegated the authority to decide drug applications -- sorry, OTC switch applications; is that right?

A Well, with OTC switch, OTC switch applications, it's more like that, you know, Galson would make the decision after concurring with me. With regular drug applications, those are, you know, delegated to CDER.

Q So you're saying the ordinary OTC application, CDER would not make the decision except with the concurrence of the commissioner?

A No, those are -- those are significant decisions, and so they almost always are done that way.

Now, your question may go to who actually signs the order. But I can tell you that none of those switches were done in my experience without concurrence of the commissioner.

Q Do you know of any other switch application in which the commissioner's office has overridden CDER's conclusion as to how to act on an OTC application?

A Well, that's a question that can't really be answered, and I'll tell you why. It's because when they get ready to do something like an OTC switch, like the Claritin decision, isotretinoin decision, even major changes like Lotronex, they will come in and there will be a serious meeting with the commissioner, and the center director might say, well, you know, I think we ought to do it this way, and then the commissioner will say, no, no, you shouldn't do it that way, you have to do it the other way. Then there might be some, you know, back-and-forth discussion, and then commissioner can order a decision meeting.

And what happens there is the center is obligated to come in with four, five, or more options

in an options paper that they have prepared, and then they have to defend that in front of the commissioner with other invited people from FDA. And then the commissioner makes the decision based on the option, and -- or the commissioner may say these options are no good, we're going to spend some more time on this, and so I want you to go back and prepare some more options, throw these out, forget it.

When the commissioner makes that decision on the option, he or she might not actually sign it, but they tell the center director.

So, you know, you couldn't say -- I mean, that process is basically the commissioner's decision, but it's done in a way that it's hard to tell who actually made the decision, because the public and most people will believe that whoever signs the order is the decision maker.

Q Do you know of any other switch where CDER has decided that the action should come out one way and the commissioner's office has overruled that?

A Well, it's not the center. You have to hold the center director responsible.

Q Okay, the center director.
A Yes. I'm sure there've been some. Your question is --
Q Do you know of any?
A -- OTC switches?
Q Exactly, do you know of any OTC switches where the head of CDER recommended one action and the commissioner said, no, we're not going to do that, we're going to do something different instead?
A Well, you know, I don't have access to those files, but I can tell you that with every OTC switch there was fundamental -- that I'm aware of, there was fundamental involvement by the commissioner. And as I just mentioned, you know, sometimes it will look like a joint decision, but actually it's the commissioner's decision.
Q Do you know of any such application where the commissioner overruled what the head of CDER recommended?
A Well, I mean, you would have to have been that commissioner. I did not, no.
Q So you don't know of any?

A Not that I did, no.
Q Do you know of any that anyone else did?
A Historically? I'd have to go through those records, and then I don't know whether you could determine it even then.
Q Well, sitting here today, do you know of any?
A No.
Q Did anyone from outside the FDA suggest to you in any manner that the agency should delay decision on the Plan B SNDA past the January PDUFA date?
A No.
Q Forgive me if I asked you this already. Can you tell me, up to the time -- between May 6 '04 and January, when you decided to go beyond the PDUFA date, what parts of the administrative record, if any, had you yourself read on the Plan B SNDA?
A By administrative record, do you mean the accumulated document?
Q Studies, staff memos, anything like that.
A I would have discussed those kind of things

with Galson. And he may have submitted something to me, but I don't recall that, no paper. It was primarily one-on-one conversation.

Q And the one-on-one conversations would have been you had the discussion in May '04 about nonapprovable letter, then you said you had sort of biweekly updates?

A Yes.

Q And was that the extent of the communications with him about the Plan B SNDA up until January '05?

A Well, you, again, go into the boring bureaucratic stuff. I mean, I would have heard from every center director wherever I was at least once a day by telephone or in person, and sometimes five to 20 times a day. And in those -- you know, especially if they were like out of the country or something like that, they would want to try to keep me up to date. There would always be an acting center director during that time. But I held -- as did Dr. McClellan, I think -- held the center directors responsible.

So it could have come up in phone

conversations or it could have come up, you know, just by bumping into him in the hall. And then in these briefings for the commissioner, you know, he would have conducted those, so we would always have a little time to spend. Sometimes we'd be together as much as half a day.

Q Okay.

What was the -- well, let me ask about you first. What were you doing with respect to the Plan B SNDA between January of 2005 and August of 2005?

A I was -- I thought about it a lot, and I also talked to Galson to see how he was coming with all this stuff, sort of, you know, like he would try to manage the process, not just Plan B, but other things that were on that center's plate as well as the other centers. But then I was nominated to be commissioner in February of 2005, and that process, you know, took a lot of time, I was involved with that almost nonstop for five months. And there was a period of time when I did only that.

And as you may know, there were some complications with the process. It should have taken,

you know, maybe half that amount of time. And, you know, so I was involved in other things, but I tried to, you know, keep steering things in the direction of, you know, them getting a document to me.

And then finally, as a result of the confirmation process, a hold was placed on my nomination, and that hold was broken only by a letter from Secretary Leavitt in which he indicated we would make a decision on Plan B by September 1.

And so once that happened, which I think was like in mid July, I told Dr. Galson, you know, that we had to meet that deadline. So they had to go ahead and finish up their record and all that sort of stuff and come to see me as soon as he could.

And he indicated whenever I talked to him that there would be -- they needed a certain amount of more time. I said, well, it can't be any later than mid August, because we have to move out on it. And so, you know, now we've got a deadline that we have said we're going to meet.

And so that's what brought it to a head.

Q And what was CDER doing on the application

between January of '05 and August of '05?

A Well, they were -- they never completed, you know, all of their considerations until August, so I assume they were working on it. He always told me they were working on it. Whenever I'd ask him how is it coming in considering something like enforceability, he would either give me an update or he would call back after the meeting. So I assumed they were working on it.

But I have to say that there was a period of time when I was sort of out of touch with what they were doing here.

Q To your knowledge, was CEDR studying the issue of enforceability of a dual-status application?

A I think they considered it. I know that they did look into state pharmacy acts to see whether or not they were consistent and would allow a behind-the-counter kind of approach in every state and every possession of the U.S. And so, yes, I think they were looking into that.

Q Did you ever meet privately with any U.S. senators or their staff in connection with your

confirmation?

A Rounded off, about a hundred of them.

Q Did you talk with any of them about Plan B?

A Some of them brought Plan B up on both sides. Some people wanted it on the market, others wanted to know primarily what we were doing about it, because, you know, by that time the PDUFA deadline was common knowledge, and the fact that it hadn't -- no action had been taken was common knowledge.

And then on the -- the people, the two senators who put the hold on in order to require a deadline date, I met with both of them on more -- more than one occasion, I don't know how many occasions, and what they indicated to me was that they were not telling me what to do, they were telling me that they wanted a decision, you know, and the decision could be not approving it or approving it. And I -- and then on the other side of the ledger there were congressmen and senators -- I met also with people in the House of Representatives during this process. It was quite clear why we did that, but that was set up. And some of them brought up Plan B, and essentially they wanted

to know when it was going to be done.

So they had the same kind of views to be sure.

Q Who were the two senators who held up the nomination?

A Clinton and Murry. Clinton of New York and Murry of Washington.

Q How many congresspeople did you meet with privately and discuss Plan B?

A A minority of them. I met with about -- there were about 50 total visits. Well, I don't know how many total visits, I guess I can't answer that. But there were a lot of meetings.

And so your question was -- I'm sorry, your question was --

Q With which -- how many congresspeople did you meet with and discuss Plan B?

A Well, the Democrats generally were just the two.

Q Murry and --

A Clinton and Murry.

Q Okay.

A And then the Republicans didn't want to -- they didn't -- those that raised reproductive issues didn't raise Plan B, they raised RU-486 generally, which was a bigger issue for them. So the Republicans that raised Plan B would have been maybe one or two.

Q Who were those?

A You know, I can't recall. It could have been -- I better not say, because I don't know for sure. That would have been somewhat in the context of RU-486, in other words, they sort of said, well, we're interested in Plan B, and RU-486, and all those kinds of things. Generally, they would then say what can you tell us about RU-486, because they had gotten the information that there had been some deaths, and there were rumors of more deaths from RU-486, and at that particular point in time they were actually more interested in it.

Q Did any of the senators or congresspeople with whom you met indicate to you that they did not think the Plan B SNDA should be approved?

A No, I don't remember that. I don't remember

that at all. And again, as I mentioned earlier, even on the side of -- on the Democrat side they were careful to say a decision one way or the other, they didn't tell me what to do.

Q And what did you tell them about when a decision would be coming?

A In my hearing, there was one hearing, and I told them that -- they said -- Senator Kennedy, I believe, said when are you going to make that decision. And I said I don't know, I said we're in the process of looking at it, but I can't tell you when. And he said, well, are we talking about weeks, or days, or -- I said, well, I wouldn't say days, and he said, would you say weeks, and I said, yes, probably weeks. And that would have been in March.

Q What was the basis for that estimation on your part?

A Sort of -- I mean, I knew we had to go ahead and get it forward, and I felt like we'd probably make the decision sometime in the summer.

Q What did you think the decision would be at that point, when you made that estimation?

A I didn't know at that point.

Q In any of your private meetings with the congresspeople, did you give them any indication about the timing of a decision on the Plan B SNDA?

A You mean like a date?

Q Like anything. About how long it would take.

A Or a frame. I'm sorry.

No, I did not. Never did that.

Q And in those private meetings did you give anyone any indication of what the decision might be?

A No.

Q You said you meet with Senators Murry and Clinton more than once; is that right?

A Yes.

Q Do you know when those meetings took place?

A Well, as a result of the hearing Senator Mikulski proposed that I meet with Senator Clinton and Senator Murry, and she was also going to be in the meeting. And Chairman Enzi also said he would like to be in the meeting, and Senator Kennedy said he would like to be in the meeting. And then Mikulski said,

well. We might want to invite the Women's Senatorial Caucus, also.

But in the meeting there was only Senators Murry, Clinton, and Kennedy.

Q Do you know approximately when that meeting was?

A It would have been after the hearing, and the hearing was on March -- it was on Saint Patrick's Day, whenever that was. Is that March 17th? Something like that.

And then the meeting would have been set up in two to four weeks after that.

Q And then when was it -- you had other meetings. When did the other meetings occur with Murry and Clinton?

A I think those were individual meetings. I went back to see Senator Murry one more time for sure, and Senator Clinton was to have been there, but she was only there for like -- just to shake hands and, you know, say that she still had the same opinion, and then she had to leave. So that was with Murry, and that would have been like another couple months -- I

mean, a couple of weeks after the first one.

Q What was the opinion that she was referring to?

A Make a decision as soon as you can.

Q Other than discussing the timing of a decision, did you discuss anything else about Plan B at any of those meetings?

A No, no, I didn't get into that. In the hearing I did say this is a very complicated decision, and I may have used the word "unique," also. But I know I said complicated.

Q Did you consider this a unique decision?

A I considered it very complicated for sure. And also, in terms of this kind of product, you know, being sold in the same container and so forth, I think this was a uniqueness to it.

Q You said that you testified at your hearing that you thought a decision would come within a matter of weeks. That turned out to be not correct; is that right?

A Well, it was weeks.

Q In the same way a year is weeks.

A Yes, forgive me. It was weeks, but I didn't say how many weeks, but I wasn't trying to be deceptive. I knew it couldn't be in days, so I said weeks. And in retrospect I might should have said two and a half months, but I didn't know that at that time.

Q Did the decision end up taking longer than you thought?

A It did, and it did because I had reserved the decision more or less, and because I was more tied up with the confirmation process and some -- we also had two other issues that were as big as Plan B, in some cases probably were more time-consuming. By "big" I mean time-consuming. So they impinged on the time that I had to deal with, also.

Q So would this decision have moved forward a bit faster if you had not reserved decision on it, reserved the right to make the decision, basically?

A It would certainly have moved faster if I had already been commissioner and not have to go through the confirmation process.

Q Would it have moved faster if you had just

let Galson make the decision as he ordinarily would?

A I can't say that. I'm not sure.

Q Do you recall testifying at your confirmation hearing that this lawsuit in which you're giving a deposition here today had complicated the approval process for the Plan B SNDA?

A I remember saying something like I didn't know what the implications -- they wanted -- the question that that was in response to was something like what is the status of it. And I tried to give an answer on that, and then I said I'm not -- that we have been sued on this decision, and what I intended to imply is I don't know what the implications of that are.

Q I don't want to unfairly ask you about something you don't have in front of you, so let me refer you to, I think the last tab in your notebook is the confirmation hearing transcript. And on page 18, I believe.

MR. AMANAT: Can I ask counsel, we did produce this morning the official transcript.

MS. JONES: I'd already prepared all the

notebooks before you produced that this morning.

MR. AMANAT: Okay, that's fine, I just wanted to --

MS. JONES: That's why you have this.

A I don't see it.

BY MS. JONES:

Q Page 8.

A I don't see a number on them.

Q The page numbers are on the top. No, you don't have page numbers on yours?

MR. AMANAT: What's the tab number? It's not in my book, either.

(Discussion off record.)

MS. JONES: Tell you what, I'll come back to this question after my co-counsel finds the page. It appears we have different copies.

MR. AMANAT: I have a copy of the official version, if you can give me a landmark as to how to find what you're asking about.

MS. JONES: I can give you the text of what I'm asking about.

MR. AMANAT: Yes, thank you.

BY MS. JONES:

Q In the meantime, let's take a look at tab D-81, which is Tummino 81.

A D-81?

Q D-81, yes. Which is a July 13th '05 letter from Chairman Enzi -- I'm sorry, to Chairman Enzi from Michael Leavitt?

A Mm-hmm.

Q Is this the letter to which you referred earlier?

A Yes.

Q Okay, so this is the letter that sort of broke the block on your confirmation process; is that right?

A Yes.

Q Okay. Have you seen this letter before?

A I have.

Q Who showed it to you, or who gave it to you?

A I think it was sent from the secretary's office.

Q Secretary of HHS?

A Yes.
Q To you?
A To me, yes.
Q At the time it was sent?
A Yes.
Q Like you were blind-copied on it, is that what you're saying?
A I don't know about that, but I did see it around about that time.
Q Do you know who -- the letter says, Michael Leavitt says, "I have spoken to the FDA, and based on the feedback I have received the FDA will act on this application by December 1, 2005." Do you know who Mr. Leavitt spoke to within FDA to get that information?
A I do not.
Q Was it you?
A No.
Q Okay.
At this time, July 13th '05, was the commissioner's office considering the possibility of filing a Notice of Proposed Rulemaking in connection

with the Plan B SNDA?

A I was thinking about that as a possibility, yes.

Q Was that communicated to Secretary Leavitt in any way?

A I had conversations with our chief counsel, and so I don't know whether he -- I did not communicate it to his office.

Q So you don't know if the secretary's office knew at this point in time of the possibility of proposed rulemaking?

A I doubt that they did.

Q Okay.

A Because the decision hadn't been made, anyway.

Q Do you recall a meeting that was held on August 24th of 2005 between yourself, Dr. Galson, Mr. Bradshaw, and Mr. Ronan?

A I do.

Q You did attend that meeting, am I right?

A I did.

Q All right. Who called that meeting?

A I did.
Q You did. What was the purpose of that meeting?
A To make a final decision on the Plan B application.
Q So that was the meeting at which a final decision was made?
A Mm-hmm.
Q Who made the decision?
A I did.
Q What was discussed at that meeting?
A The primary discussion was with the chief counsel, about --
MR. AMANAT: Objection. I'm going to instruct him not to answer to the extent that his answer would require him to discuss conversations he had with chief counsel. Don't get into the substance of those conversations.
BY MS. JONES:
Q Were you seeking legal advice during this meeting?
A Yes.

Q On what matter?

MR. AMANAT: Objection. Instruct the witness not to answer that question.

BY MS. JONES:

Q Did Dr. Galson make a recommendation to you at this meeting of what he thought the action should be on the Plan B SNDA?

THE WITNESS: Is that all right?

MR. AMANAT: Mm-hmm, you can answer that.

THE WITNESS: Sorry.

MS. JONES: It's okay.

A Yes, Dr. Galson, he said I want to tell you about, you asked me some time back about the science, and he said I want you to know that I am comfortable with the science and the demarcation of the 17-year-old and up. And so I said or I asked him, tell me why you're comfortable with it going over the counter to 17 years and up. And he, you know, told me, basically summarized the scientific literature and, you know, told me why under the statutes and so forth as he understood them that it -- you know, it should be approved over the counter for 17 and up.

And then I said, what about 16 and under, and he said that he felt comfortable that this required a physician prescription, and it should stay on a prescription order basis.

And I said are you -- I said, fine, and so that is what you've concluded. And I said, is there -- basically, I said the science, how would you describe it, is it significant, is there significant scientific agreement? And he said, well, he would -- he'd like to see more scientific papers, but he felt comfortable that you can make that distinction based on the science. And he said beyond that he was not prepared to go.

And I said -- I said, you know, I've raised the question of enforceability, do you think this can be enforced, and how would it be enforced. So he talked about, you know, the behind-the-counter aspect. And he did say that he believed that most pharmacy laws would allow this dual kind of thing, and I said who would enforce it, would it be FDA, would it be the states, and what would be the penalties in case this kind of thing happened, and how serious would it be.

He said, well, we made the decision based on public health. We think that for women in this category of 16 and under it should be on a prescription basis, and that's for health reasons.

And I said fine, I said, I'm not going to challenge that determination, but I am sufficiently concerned about enforceability that I think we're going to have to have a notice and comment period.

And so that was about it.

Q All right.

Was anyone else at that meeting other than yourself, Dr. Galson, Mr. Bradshaw, and Mr. Ronan?

A Yes.

Q Who else was there?

A Dr. Scott Gottlieb.

Q Who is that?

A He is deputy commissioner for medical affairs. He was in and out of the meeting, but he was there.

Q So would it be fair to say by the close of this meeting you had made your final decision?

A Yes.

MR. AMANAT: I'm sorry, Counsel, what document was that, the August 24th, calendar? I'm not finding it in the book.

MS. JONES: I didn't refer him to any document.

MR. AMANAT: Oh, okay.

BY MS. JONES:

Q Could you take a look at document 3151 in the notebook.

A Not D, but 3151.

Q Exactly, which is Tummino 31214 through 31226.

A Okay.

Q Are you familiar with that document?

A Let me just be sure.

I am familiar with it, yes.

Q Before we get to this document I want to back up for one second.

You said the other person who attended the August 24th '05 meeting was Dr. Scott Gottlieb?

A Mm-hmm.

Q Why was he there?

A He's the relevant deputy commissioner. We have three deputy commissioners, and he's the one over medical affairs. One is for international affairs and one is for operations.

Q Did he play any role in the agency's decision on the Plan B SNDA?

A No, I did that. He was, you know, the relevant deputy commissioner, and he's a medical doctor and has a specialty in internal medicine. And, you know, that's why he was -- he's in that position.

Q Did he give you any input on the decision, on the Plan B SNDA?

A Yes, we discussed it, yes.

Q What was his input?

A He basically concurred with the need for the notice and comment.

Q Did he give you any input on the science?

A No, that came from the center.

Q So his only input would have been related to enforceability?

A Yes.

Q And at that same meeting Dr. Galson

obviously, well, I won't say obviously. Am I correct that Dr. Galson at that meeting recommended granting the Plan B SNDA that was for dual status?

A Not all together. He -- as you know from reading this document, he basically left the door open for a further decision under his -- under Section VIII, conclusion, and, you know, if additional data comes in. And then the other thing was that he -- you know, he was careful in the meeting to say that he's comfortable with the science and he's -- you know, this is his position, he doesn't -- and I said, well, I'm not arguing with the science, I said, we're basically going to declare that we consider this safe for women 17 and older and we're going to say that we think it should be prescription basis for those that are younger, but I am concerned about enforceability. And that was basically it.

Q So is it your understanding -- well, what is your understanding of what his recommendation was as to how the agency should act on the Plan B SNDA?

A Well, I mean, he's saying that it's safe to be used if it can be enforced, and I told him we were

going to go for this notice and comment rulemaking thing in order to get more information, give it a 60-day comment period, and he was fine with that.

Q So it's your understanding that he agreed with that decision, your decision?

A Yes. Now, if I had said, I mean, to him that I don't believe -- don't agree with the science, I think he would -- he would not have agreed with that. But I didn't challenge that.

Q So you were not under the impression that he was recommending to you that the agency go ahead and approve this dual-status application?

A No, not really. He -- I was careful to say to him that after reading this and after discussing it with him that I still had problems with enforceability. So he -- you know, he just didn't challenge that. You know, I don't -- he -- that was about it.

Q Okay. So looking back at this memo, 21031214 through 31226, did you receive this memorandum? It's dated August 26th '05. Do you know if at some point you received this memorandum?

A I did, yes.
Q Was it around that time?
A It was. There were some earlier drafts of it. So I'm not sure which one I got, but whatever I got was substantially the same as this. And then I did have this in my possession, sure.
Q How many earlier drafts did you receive?
A I didn't really look at the earlier drafts, he just sort of told me what was in them, and I relied on this one.
Q But he sent you the earlier drafts?
A He sent it to my office, yes, because we were trying to use this information in order to prepare the press release and the statement that would come from FDA.
Q When did you first receive a draft of this memo?
A I don't really know. Let's see, the 26th was the Friday, right?
Q I don't know that off the top of my head, I'm sorry to say. I can tell you that it's the same day that you issued your decision.

A Mm-hmm. So I would have gotten --

MR. STURM: According to 3149, the 26th was a Friday.

A And the meeting with him that you just talked about was when?

BY MS. JONES:

Q That was on the 24th, two days earlier.

A Yes, so they would have -- you know, the assignments that were given was, you know, go ahead and finish this. So I think he worked off an earlier draft. I didn't really read it or anything, but I know there was an earlier draft.

Q Do you know approximately when that was?

A I think -- I think he worked it up that intervening day between the meeting and the announcement.

Q When you had the meeting on the 24th, did he have a draft at that point?

A He had firmly fixed in his mind what he -- you know, what the substance of this is, but I don't know that he had a draft. I didn't -- you know, the draft was used by my office only to try to get ready

to do the press release. We didn't really change anything about it.

Q Did you look at any of the drafts, if any, that he might have prepared between January of '05 and August 24th of '05?

A No.

Q To the extent you saw any drafts of this memo, were they any different in substance than this memo?

A No.

Q Did you at any point in time receive a draft approval letter for the Plan B SNDA from Dr. Galson?

A I didn't usually receive drafts, but I don't remember anything like that, no.

Q Do you know whether Dr. Galson prepared an approval letter for the Plan B SNDA?

A No, I don't think he would have done that, because I told him, you know, not to do that until he talked to me.

MS. JONES: Okay, can we mark this document.

(Crawford Exhibit 3 was marked for identification and was attached to the transcript.)

BY MS. JONES:

Q I'm going to hand to you what's been marked as Crawford Exhibit 3, which is pages Tummino 874 through Tummino 893, which is a transcript of your confirmation hearing. I'm going to ask you to take a look at page Tummino 880. It's a little section marked off in pen in the middle there.

A That's all you're going to ask about?

Q That's all I'm going to ask you about, but feel free to look at whatever you want.

MR. AMANAT: The passage that's marked is the first testimony on that page from Dr. Crawford, the part that you marked?

MS. JONES: I'll read it for the record.

BY MS. JONES:

Q Senator Clinton asked you a question, "When might we expect the approval to be forthcoming?" Your answer was, "I can't say for sure, because we might could have predicted it, but the lawsuit has complicated it a little bit. We have to work through that. It is for the prior approval, and what effect

it has on it I can't really say at this time, but I don't think it's going to be a long delay."

A Okay.

Q Do you see that portion?

A I do.

Q Were you suggesting there that this lawsuit somehow delayed the agency's decision-making process on the Plan B SNDA?

A No, what I was trying to indicate was that there was a lawsuit and I didn't know what the implications of it would be, because it seemed to relate to the earlier nonapprovable letter.

Q Did you think that this lawsuit could in any way affect the timing of the agency's decision on the Plan B SNDA?

A I didn't know at that point. I was -- I basically said it is for the prior approval, and what effect it has on it I can't really say, but I don't think it's going to be a long delay. So if in the back of my mind there was a worst-case scenario where this, you know, might slow it down some, obviously I didn't think it would be long.

Q How could it conceivably have slowed it down at all?

A I didn't, I don't know. I said I didn't know.

Q Well, how -- let me just see the language. How had the lawsuit complicated matters? You used the words "complicated matters."

A I said it complicated it a little bit.

Q Right.

A And what I was trying to imply, this is kind of a foggy paragraph here, but what I was trying to imply is that there was this lawsuit and I wanted to point that out, and to the extent that it would complicate matters I didn't really know. And I used the term "a little bit," and then I said "I can't really say."

Q Who first had the idea of initiating rulemaking in connection with the Plan B SNDA?

A This came out of conversations with the chief counsel.

MR. AMANAT: And again, I'm going to instruct the witness not to answer, not to give any

further details about that, the content of those conversations.

MS. JONES: Could you read me back the last answer?

(The Reporter read the record as follows:

"A This came out of conversations with the chief counsel.")

BY MS. JONES:

Q Was the possibility of initiating rulemaking in connection with the Plan B SNDA ever discussed with you by anyone other than the agency's attorneys?

MR. AMANAT: You can answer that.

A No.

BY MS. JONES:

Q Did you ever discuss the possibility with anyone other than the agency's attorneys?

A Well, in this meeting where Gottlieb was.

Q On August 24th?

A Yes, I basically hold them what I was going to do. So that was -- to the extent that that's -- is relevant to your question, the answer is yes, with Gottlieb.

Q When did you first start considering rulemaking in connection with the Plan B SNDA to be a possibility?

A Well, it grew out of my concerns about enforceability. And so, you know, it would have been sometime between January and the time I made the final decision.

I've always been, you know, a proponent of notice and comment rulemaking, because, as I said earlier, I think it does give a good referendum on what we're doing. And we get -- you know, FDA gets good comments that are helpful and instructive. The exact time that I made this decision was very late, you know, just prior to the announcement, but it was in the back of my mind for some weeks.

Q Was it in the back of your mind in January of '05 as a possibility?

A Well, I guess the main thing I believed is that we should find out how it was going to be enforced in great detail. And it may have been, I don't know, I don't --

Q How about by February or March of '05, was

it in your mind then?

A It could very well have been, but I don't know for sure.

Q How about April of '05, was it in your mind then as a possibility?

A I mean, I can't say the exact date. I didn't make the final decision until August, that I can say. And beyond that, I don't know.

Q Is there a point at which you know for sure you were at least thinking about it? Let's say in July of '05. Do you know if in July of '05 you were definitely thinking of it as a possibility?

A Once I got confirmed, which was July 16th or something like that, it certainly was in my mind, because I was then moving forward to try to figure out how we were going to meet this September 1 deadline and what were the possibilities. So yes, I can say with certainty then.

Q During your confirmation hearings or the time of your confirmation hearings, confirmation process, did you mention the possibility of rulemaking to either -- in the hearings itself or to any

congresspeople?

A No, I'm sure I didn't do that.

Q Why not?

A Never really came up. They all mentioned the fact that what they wanted was a decision. They didn't really tell me, didn't ask me what the mechanism would be or anything like that. And none of them raised the issue of notice and comment, so -- and I didn't volunteer it. I don't know whether I was, you know, thinking about it or not, but I don't -- I don't remember bringing it up, certainly to anyone.

Q Your understanding was that their concern was that some decision be made on this application?

A Yes.

Q Do you think initiating rulemaking constituted making a decision in terms of the concerns those congresspeople had?

A The decisions were the following. One is the science, as evinced by Dr. Galson's memorandum. I made a decision that that was correct. What I could not decide on is whether or not I could stand before the American people and say this will be successfully

enforced. That I could not decide.

And I believed that the input would help, and obviously, I understand from newspaper accounts, I don't know as a matter of direct record, that they've had an impressive number of comments. And so I -- you know, I think maybe it's -- you know, we were correct to do this.

So the decision was on the science, and then the rulemaking process is on the enforceability.

Q Okay, my question is you felt like there were a number of congresspeople who were concerned that a decision be made --

A Mm-hmm.

Q -- on the application.

My question is whether you believed that initiating rulemaking constituted making a decision in a way that addressed the concerns of those congresspeople.

A Well, I had to decide it, and, you know, I decided it on the basis of public health concerns. The center says in the Galson memo, and obviously, as I mentioned earlier, I hold Galson responsible, they

said that it was not in the best interests of public health for this product to go over the counter for women of all ages. So that's a signal to me and to the regulatory apparatus of FDA that it needs to be enforced. You can't just put it out there and not worry about it anymore. And it's complicated considerably by the fact that the enforceability is to some extent referent to state laws, state laws that are not homogeneous, that have great variability.

So I was -- I was very concerned about the enforceability, and I had to -- I mean, you know, I had -- the fact that I decided to go to rulemaking is, in fact, a decision. But always at FDA some people say, well, you know, this application is four years overdue, that petition has been in FDA for 12 years. You know, deadlines are always trumped by science in FDA. If I felt or if a center director felt or the regulatory affairs people felt that there was a public health concern, you don't make a decision on a deadline date if you have those concerns. Public health concerns trump science -- I mean, trump deadline dates every time.

Q So in your understanding did the FDA decide the Plan B SNDA on August 26 of '05?

A Except for the enforceability, yes.

Q What did it decide?

A It decided that it can be safely used without a prescription in women that are 17 and older, and it requires a prescription for women that are younger than that. That's a big decision.

Q Is that approval?

A It's approval once the enforceability gets straightened out.

Q And once the enforceability issue is decided, could it also turn out to be a denial?

A Well, I think -- I think the obligation that the agency has is to make a sincere effort, this is what we've been doing, to put together an enforcement package that can be -- that we can say will work. Once that's done, then I think -- you know, I think the other issues have been handled, so they can move forward with the application.

Q Depending on how the rulemaking process comes out, is it possible that the FDA is going to

deny Plan B's SNDA?

A I'm not there and I can't comment on that.

Q It hasn't been decided yet, right?

A I don't know. I've been gone for a long time.

Q You don't know whether the agency decided?

A What they've done after October 1 when I left, I don't know.

Q Well, as of August 26th, 2005, was it possible that the Plan B SNDA would be denied depending on the outcome of the rulemaking process?

A I'll have to think about that.

There was no -- no talk of denial, there was talk of trying to get straight what the enforcement procedures would be. So I don't remember that coming up. And certainly on the strength of Galson's memorandum, that would be very hard to do.

Q Well, is the purpose of the rulemaking process to make a determination of whether enforceability is feasible?

A No, to put together -- based on notice and comment, to put together an enforcement package that

is realistic and is going to be effective. I think that's clear in the preamble to the Notice of Proposed Rulemaking.

Q So is it your position that it has already been decided that enforcement will be possible, and once the exact mechanisms for enforcement are set up that this Plan B SNDA will be approved?

A No. I cannot make that judgment, because I will not be making that decision. So I don't know what the new commissioner will decide and I cannot speculate.

Q On August 26th of '05, was it your position that once the rulemaking process was completed that some enforcement mechanism would be possible and that the application would be approved?

A Well, the short answer is, is I did not know whether or not we'd be able to come up with a viable enforcement package. I assumed that we would, and I did indicate in my statement to the press and also to everyone else that the science had been concluded, that it was possible for women 17 and older to receive the product without a prescription, and that women

younger than that needed a prescription. So that part was taken care of. And now the issue was enforceability. It was my judgment that we needed notice and comment on that.

Q Are there over-the-counter drugs that are not suitable for persons under a particular age to take?

A Yes, there are many over-the-counter drugs that say not for children 12 and under, not for children five and under, yes.

Q How is that enforced?

A That's enforced using state laws. And in most cases those particular products can be used at a lower dose, you know, in other words, with aspirin the cutoff is 12 years of age, and if you're 12 or older you take two pills, if you're younger you take, I think it's one pill.

Q Are there some that are not suitable for people that are not adults at all, in any dose? Let me give you an example. This might be one, I'm not sure.

A Okay.

Q Are diet pills, are diet pills --
A Not suitable for adults, but suitable for children?
Q No, the opposite.
A Okay, okay.
Q Are diet pills one of the drugs that is not suitable for people to use if they are not an adult?
A Mm-hmm, I think there are some like that. Certainly, Dexedrine was.
Q Okay. And those drugs would be labeled, is that right, with something about who they're appropriate for?
A Actually, the ones that come to my mind, like Dexedrine, are prescription.
Q Okay. Are there any over-the-counter drugs of that nature?
A I think -- I can't think of any right off the top of my head.
Q So the ones you know about would be labeled not suitable for children under a certain age, or not suitable for under 12, or something to that effect?
A Mm-hmm.

Q And the enforcement of that is done pursuant to state law?

A It's done by state law with FDA oversight.

Q Are there many drugs like that?

A Well, there are about -- I believe there are about 600 active approved drugs, something like that, and it would be a small percentage of that.

MS. JONES: Since it's 1:00 o'clock, why don't we take a lunch break. Let's go for like an hour.

MR. AMANAT: Come back at 2:00?

MS. JONES: Yes.

THE VIDEOGRAPHER: This marks the end of tape 2 in the deposition of Dr. Crawford. We are going off the record. The time is 1:01 p.m.

(A luncheon recess was taken.)

THE VIDEOGRAPHER: This marks the beginning of tape 3 in the deposition of Dr. Crawford. We are back on the record. The time is 2:05 p.m.

BY MS. JONES:

Q Dr. Crawford, I just want to make sure that I understand something perfectly well, which is can

you just spell out for me very clearly what it was that the agency was doing on the Plan B SNDA between January of '05 and your decision in August 2005?

A Well, the center was completing its work, they were -- I don't know what all they were doing, but they were continuing to work on it. And I believe they did explore enforceability issues. And as I've mentioned earlier, you know, I was otherwise occupied myself a good bit of that time. And that's essentially it.

Q What work remained for CDER to do in January of '05 that it did not complete until August of '05?

A You know, I don't -- I don't know all of that, but I assume, you know, checking into the science to be sure they were right and completing, you know, the necessary memos and so forth and discrete studies that are usually required for an approval. I assume that's right.

Q So do you know what memos or studies still remained to be completed --

A I do not.

Q -- in January of '05?

A I do not.

Q Is it possible that Dr. Galson's memo was the only matter that remained outstanding at that point?

A No, I doubt that very seriously. But I don't -- I don't know. I mean, he could tell you that. I'm not trying to pass off the story, but I don't really know.

Q And how did the fact that you were otherwise occupied affect the progression of events on the Plan B SNDA?

A I didn't have as much time to spend on being commissioner. I had to go through the review process, and also we had, you know, a number of other Congressional hearings and, as I mentioned earlier, some inquiries from Congress in the various different classes of drugs.

Q Did you spend any time on the Plan B SNDA prior to August of '05?

A Oh, yes, well, you know, I considered what to do and continued to talk to Dr. Galson about the progress he was making and to regularly ask him, you

know, to -- those things I've already outlined, those categories of things, to what sort of progress was he making. So I spent some time.

Q You knew, right, that in January of '05 that Dr. Galson was in favor of a dual-status approval and that he was writing a memorandum supporting dual-status approval; is that right?

A He didn't finalize that. I -- we talked through that very carefully, and the way he put it was that this was the way he was leaning. And so I knew that much for sure.

Q When did you know that that was going to be his recommendation?

A Well, you know, not to give, you know, an incomplete answer, but you don't ever really know that until you get that memo from him. We had had further conversations, he told me several times that I'm still leaning in that direction, and so I knew that's probably what was going to happen. But it's not official until you get that memorandum.

Q Okay, but you knew -- you knew from January '05 that he was leaning in that direction --

A Yes.
Q Is that fair to say?
A Yes, absolutely.
Q And did you know from January of '05 that you were leaning in a different direction, namely, in the direction of initiating rulemaking?
A No, I did not. I didn't get really uncomfortable with enforceability until later, although it was an issue in January '05. But I did not know that I was going to come to this conclusion.
Q And what led you to becoming really uncomfortable with the issue of enforceability?
A No one -- I mean, as I looked through what I knew about the situation and when I asked him questions, that is, Galson, I didn't really get, you know, a sense of comfort with enforceability. I got more and more discomfort.
Q When you say when you looked into what you knew about the situation, what were you looking into?
A I was asking him about the pharmacy laws and the behind-the-counter situation, and talking to him about that. And then also, then I had conversations,

as I mentioned earlier, later with the chief counsel.

Q Right. And I won't ask you about the content of those.

Am I correct that you said that it was at the August 24th '05 meeting that you finally decided to issue the Notice of -- Advance Notice of Proposed Rulemaking?

A Yes.

Q When did you communicate that decision to Dr. Galson?

A At the meeting that we discussed on that day.

Q That day?

A Mm-hmm.

Q And when did you communicate that decision to Dr. Woodcock?

A I did not communicate it to her.

Q Ever?

A No.

Q Prior to August 24th of '05, did you discuss with Dr. Galson or Dr. Woodcock the fact that you were considering the rulemaking route? Did you discuss

that decision-making process with them?

A Not with Dr. Woodcock. I probably at some point mentioned it to Galson as a possibility, but it would have been only vaguely, because it was not formed in my mind. But I -- you know, I always, particularly in August, gave him to understand that he should go ahead and complete his work. But I reserved the judgment.

Q Did you at any point ask Dr. Galson or Dr. Woodcock for their input on the possibility of initiating rulemaking in connection with the Plan B SNDA?

A Well, that's what I discussed with the general counsel, chief counsel. I did not, you know, solicit the input of the two of them, and never did of Dr. Woodcock.

At the meeting on August 24th I told Galson what I was doing and gave him an opportunity thereby to object, which he did not.

Q Did you ask him for his opinion on the proposal?

A I told him what I was planning to do, and I

asked him if he had any questions, and he didn't.

Q But you didn't ask him for his opinion?

A It's the same kind of thing. But I didn't say what is your opinion of this, no.

Q Why did you exclude Dr. Galson and Dr. Woodcock from your decision-making process on the rulemaking?

A Well, I didn't exclude Galson, because I didn't form in my mind the decision to go in this direction until around about August 24. So I did tell Galson about that in that meeting.

Dr. Woodcock is -- formally was director of the Center for Drug Evaluation and Research, but she was not at that time. She went into the position of deputy commissioner for operations, which is budget, personnel, general management of the agency, and Dr. Gottlieb came in as deputy commissioner for medical affairs. As I mentioned earlier, Dr. Lumpkin was deputy commissioner for international affairs. And so I used them in that way.

Although they're deputy commissioners, they were, like I was, staff, and they have specific

responsibilities, and those were the responsibilities for the three of them. So the relevant deputy commissioner was Gottlieb.

Q Was it unusual for you to exclude Dr. Woodcock from your decision making on this matter of rulemaking?

A Well, I hadn't made a decision like rulemaking. But you mean like on a drug approval?

Q Was it unusual that you would -- for you to make a decision about proposed -- about initiating proposed rulemaking with respect to the Plan B SNDA and to not include Dr. Woodcock in your decision-making process in any way?

A No. She was not the relevant deputy commissioner.

Q Had you discussed the Plan B SNDA with Dr. Woodcock at any time?

A I'm sure I said something to her. I don't recall what it was. She and I, you know, were in offices -- basically, we shared this big office complex. Well, not that big, but we shared it. And so I saw her many times every day.

Our conversations were, you know, part social, because of the propinquity of our suites, but they were primarily to do with the budget, with personnel, with things like the building of a new campus. That's -- that's what she was doing. And she had, you know, as all of them did, more than she could possibly say grace over. So she concentrated on her specific responsibilities, as did Lumpkin, as did Gottlieb.

Q So you never had any sort of substantive conversation with Dr. Woodcock about the Plan B SNDA at any point?

A No.

Q Now, you said -- I think you said that you didn't exclude Dr. Galson from your decision-making process; is that right?

A He was -- he was in the meeting when I announced what my decision was. And as I've already said, I asked him did he have any questions. Actually, I asked the whole group, probably, if they had any questions, and they didn't.

Q Did you include Dr. Galson in your

decision-making process on this matter at any time before that August 24th meeting?

A On the overall decision?

Q On your decision to initiate rulemaking.

A I may have mentioned it to him as a possibility, as I've said earlier. But that's about it.

Q Why didn't you ever seek his input or his opinion on the possibility of initiating rulemaking?

A Well, the relevant person for rulemaking was the general -- chief counsel, so I depended on him.

Q So Dr. Galson's opinion on that matter would not have been relevant to you?

A Well, that's not his expertise. As you know, he's a medical doctor and a public health expert, not a regulatory expert.

Q So am I right that his opinion on that matter would not have been relevant to your decision?

A He -- well, I mean, it wouldn't -- he wouldn't be the one you would naturally go to to ask about that, because he didn't have expertise in that area. You see, the centers, although, you know, there

are five of them for various different things, as I've said, they don't have regulatory responsibilities. They can advise the Office of Regulatory Affairs, there is an associate commissioner for regulatory affairs. That person manages 4,000 field personnel who actually do the enforcement. And they may get advice from the centers, but they're the ones that do it. So you would go to where they get their, you know, basic interpretations of the law from and the regulations, and that is the chief counsel.

Q I understand. But had Dr. Galson had an opinion on whether it was appropriate to initiate rulemaking on the Plan B SNDA, would you have considered his opinion relevant?

A Well, not as relevant as the chief counsel. I mean, I'd be happy to hear from any and all of them and never would say your opinion's irrelevant. But he wouldn't be the one I'd go ask, you know, for specific advice on that. I would ask him about the safety of the product, and the efficacy of the product, and these kinds of things.

Q Did anyone within the FDA other than your

counsel provide any input on your decision to initiate rulemaking in connection with the Plan B SNDA?

A No. I went directly to him.

Q Did anyone from outside of the FDA provide any input on that decision?

A No.

Q Did you discuss that decision with anyone from outside the FDA prior to August 26th, 2005?

A On the 24th or thereabouts I would have told the department, you know, what we're doing, and told them that we're going to announce it on Friday, and that I needed them to designate someone to help us with the press release and statement.

Q Who would you have told that to on the 24th?

A Laura Lawlor.

Q Other than that conversation, did you have any other conversations with anyone else outside the FDA about the decision to initiate rulemaking prior to August 26 of '05?

A No.

Q During your time at the FDA did you make any -- or during your time as commissioner or acting

commissioner, did you make any other decision on a human drug product that was contrary to the recommendation of the director of CEDR?

A Yes.

Q What was that?

A Lotronex.

Q What was the recommendation of CEDR?

A Lotronex is a drug for irritable bowel syndrome, and it was taken off the market because of the number of deaths. And then CDER decided that they wanted to bring it back on the market. And I was not satisfied with that, because, you know, the people had died and, you know, the rationale was essentially that -- that there is no other therapy, and 10 percent of the patients, I believe it was, are going to die anyway, so it's not -- you know, and more will die without the drug than will die with the drug. But I was not comfortable with that.

So I asked, you know, for this option paper thing like I talked about, and they came up with a series of what's called a management program. And essentially what that means is that you put it on

prescription, but you don't allow it to be sold by just any medical doctor. You pick out certain doctors who want to be involved in the program. They sign an agreement that they will be trained and that they will be retrained each year in the use of the drug, and that they will monitor on a certain period, I think it was weekly, probably, what was to be done.

And there was a disagreement between the general counsel and CDER at some point after I took it over, and the disagreement was, you know, not all that serious, but I had to decide, you know, which approach was best, and I did.

Q So that was a case where CDER had made a recommendation and the general counsel disagreed with the recommendation or didn't think it was possible?

A They didn't think it was legal.

Q They didn't think it was legal?

A Mm-hmm.

Q And so you had to decide which you were going to follow?

A Yes.

Q And you went with what the general counsel

thought?

A No.

Q What did you do?

A I went with what the center had come back with.

Q Okay.

A Not what they did originally.

Q Okay, so CDER made a recommendation and the general counsel said that's not legal, is that right, that's the first thing that happened?

A No, the center made a recommendation, I said I don't like that because you're just turning around a year later and putting it back on the market, I need to know what you're going to do to protect these patients. So then CDER comes back with this management program, and it's called the FDA putting a fence around it. And when they came out with the management program, then the chief counsel decided that the law didn't support such as that. So I had to then at that point decide between the two.

Q Okay, and at that point you went with what CDER had come back with?

A I did.

Q Why was the letter to the Plan B sponsor notifying them about the rulemaking signed by you?

A Because I made the decision.

Q Did you sign any other letters on OTC switch applications during your time at the FDA?

A I don't recall whether I signed the isotretinoin and the Claritin letters. I essentially was involved in that process and testified to that effect. But I don't know, I don't know whether -- I don't believe I signed it, though. I do not recall that.

Q Did you ask Dr. Galson to sign the letter?

A Which letter?

Q The letter notifying the Plan B sponsor about the proposed rulemaking.

A I'm sorry.

No, I did not. I told him earlier that I was reserving the judgment on that for myself, possibly, and then I decided to do that. So I didn't ask him to sign it.

Q Do you know of any other action letter on an

OTC switch application that was signed by the commissioner's office?

A I did not as far, as I can recall. Don't hold me to that, though, I may very well have. But I'm sure there have been some in the past that have been done.

Q Do you know of any?

A I cannot, sitting here today, like I said, describe it.

Q Could you take a look at the document marked tab 1041. It's the second document in your notebook. And that's Tummino 10813 through 10815.

Could you identify that document?

A Yes, it's a letter from me to Duramed Research.

Q And this is the letter to the Plan B sponsor telling them about the proposed rulemaking; is that right?

A Yes.

Q In the last paragraph of the first page of that letter, there's a part that says, "The agency has never determined whether a drug may be both Rx and OTC

based on the age of the individual using the drug."
Do you see that?
A Mm-hmm.
Q Do nicotine patches fall within that category?
A I don't know.
Q You don't know? You don't know whether nicotine patches are available to some ages by prescription and some ages over the counter?
A I do not.
Q Do you know of any other instance in which the FDA has delayed its process on an OTC switch application in order to engage in rulemaking?
A I can't say for sure. I can't cite one, no.
Q You don't know of any instance sitting here today?
A Unh-uh.
Q We talked about Pat Ronan earlier. I believe he was one of the people at the August 24th meeting; is that right?
A Yes.
Q What is his title?

A Chief of staff for FDA.

Q Other than the August 24th '05 meeting, did you have any other communications with him about Plan B?

A I'm sure I mentioned, you know, the subject to him. And he would have been in that meeting for sure, and he also would have been involved when -- he would have been in the room, I'm relatively certain, when I called Laura Lawlor, told them what we're going to do, so forth, because he had to be in that process, because remember that the department was going to help us with the statement and so forth. So he would have been the one who got the statement sent to him and then, you know, modified it or made some changes. He also brought it to me and -- you know, for my review, which I reviewed and suggested some changes. They were primarily grammatical. But he was like manager of that kind of process.

Q Did he give any input on your decision to initiate rulemaking in connection with the Plan B SNDA?

A He offered no objections to it.

Q Did he give any other kind of input on the decision?

A No, no, not that I remember.

Q Did you ever ask for his opinion about the matter?

A No. Again, he's not -- you know, I was depending on the chief counsel, and so I would not have asked him. That's not his expertise.

Q How long do you expect the ANPR process to take?

A Well, I'm not there now, so I don't really know what's happening, and so I couldn't speculate on that.

Q Well, when you made your decision in late August of '05, how long did you expect the ANPR process to take?

A Well, you know, we gave it the quickest comment period that we could, 60 days. And then, obviously, we'd -- if I'd stayed there we would have collected the information, processed it as soon as we could, and then tried to make a decision. You know, sometimes those -- you know, those things take a long

time, sometimes they don't. It just depends on, you know, how fast you can get through them.

The similar one was a Nutrition Labeling and Education Act. And what was done with it was an outside firm was hired to collate, prepare, and analyze the comments. And it was done, I think, in about -- somewhere between six months, around six months, I think, total. And they gave -- they also gave a brief comment period.

Q When you say total, do you mean from the announcement until the conclusion of rulemaking?

A Right.

Q When you say some of these processes take a long time and some take a short time, what sort of time frame are we talking about, what's a short time for rulemaking and a long time for rulemaking?

A Well, there's some emergency rulemaking where you have only 30 days. And in those cases, like when I was at Agriculture, we actually put one out where we made the rule effective immediately, and then we took comments for 30 days thereafter. So that's the quickest that you can do, but you must bear the

burden of proving that it truly is an emergency. Now, that one certainly was.

Some FDA rules, particularly if they give like 90 days' comment period and then grant one or two or more extensions, those are the ones that take four years or so. But, you know, if it's managed correctly and if you go and get some extra help to deal with it, it shouldn't take that long.

Q So in those circumstances how long should you expect it would take?

A Well, I mean, I would have said about like Nutrition Labeling and Education Act, they had about the same number of comments, had the same time frame for comment, so I would say six months, maybe nine months tops.

Q Do you know where in the process the FDA is?

A No. Under the rules I can't -- I can't contact them for any reason until October 1. So if they were to call me up and say let me tell you where the rule is, I would have to say good-bye.

Q Under what rules?

A These are like the Ethics in Government Act.

Q I think you said there's a period of time, which in this case is 60 days, to receive comments, correct?

A Mm-hmm.

Q Then there's a period of time to gather and sort of analyze the comments?

A Yes.

Q And then there's a period of actual rulemaking; is that right?

A Mm-hmm.

Q Once the comments have been gathered and analyzed, how long does it take typically to get from there to rulemaking?

A It varies with each one. And it also varies with how many people you've got working on it. One of the centers that's slowest about it is the Center for Foods. And, you know, that's because they're strapped for personnel. And if they don't hire somebody, like, you know, to come in and help with the processing, you know, they set new records all the time for taking a long time. And we would not have wanted to do that with this one, sure. In fact, I went on the record as

saying that I personally selected the 60-day comment period and -- you know, and I wanted it done expeditiously.

Q Well, when you said that and you knew the comment period would be 60 days, how long did you foresee the rulemaking taking after that, after the gathering of the comments?

A Well, as I said earlier, the two months would be, you know, what the comment period is, and then I think it would take, you know, maybe total of six months to maybe nine months to get it.

Q Beyond that, beyond the --

A No, no, no, total.

Q Okay, six to nine months?

A Mm-hmm.

Q Do you know anything about a contract between the FDA and Booz Hamilton regarding this rulemaking process?

A I have no direct knowledge of it.

Q Do you have any knowledge direct, indirect, or otherwise about that contract?

A Not about the firm, I've never seen that

before. I've heard that there are stories in the press about them doing the same thing they did with NLEA, and that is hiring some outside help. NLEA was not a recognizable firm, they just, you know, had gotten some temporary FTEs and then moved people in. It wasn't contracted to a firm as I remember, it was contracted to -- you know, they got, I think, maybe a hundred positions to do all this. So they hired temps to do it.

Q But you have some awareness that a contract exists between Booz Hamilton and the FDA in relation to this?

A I don't. I don't really. I'm aware of press reports saying that that's the case, but I don't know. I have no knowledge of it.

Q Do you have any idea what the contract delivery dates are under that contract?

A I do not.

Q When you were at the FDA, did you routinely delete e-mails that you received?

A My assistant handled that for me. I didn't. It wasn't that I was illiterate with it, it's just

that I didn't do that.

Q Do you know if your assistant routinely deleted e-mails you received?

A I don't, really.

Q Do you know whether your assistant deleted any e-mails related to Plan B?

A I do not. The way the setup was, she had her computer on her desk, and she could push some kind of button and then get my e-mails, in other words, get into my stuff. And so she could do everything out there, including send them, and delete them, and whatever. And I don't know what the situation was there.

Q Who was your assistant there?

A Her name is Janice Sheehy.

Q Did the U.S. Government accountability office ever request to interview you regarding Plan B?

A They did after I left, after October 1.

Q Did you decline that request?

A No.

Q Did you agree to that request?

A Yes.

Q Were you interviewed by them?
A They submitted -- they suggested submitting questions, which they did, and I answered them.
Q Did they request to interview you in person?
A No, they -- the way the paragraph went, as I recall it, and it hasn't been four years, but it's been like six months or whatever, they said we would like to submit questions, alternatively we can do an interview. So we chose to answer the questions.
Q And did you prepare answers to those questions?
A With my attorney, yes.
Q Did you produce your answers to those questions to me today?
MR. STURM: I believe that's one of the documents, yes.
BY MS. JONES:
Q Why don't I hand you what's been marked as Crawford Exhibit 2, and you can help me figure out what it is. Let's just go through page by page.
The first page of it is marked LC01, which appears to be a fax cover sheet from Barbara Van

Gelder to Helen Desaulniers. Is Barbara Van Gelder your attorney?

A She is.

Q Okay. Do you know who Helen DeSaulniers is?

A No.

Q The next two pages, LC02 through LC03, are a letter dated October 18th, 2005, from Dayna Shah of the Government Accountability Office to Barbara Van Gelder. Did you produce this letter to me here today?

A Mm-hmm, yes.

Q Was this letter in your possession up until this morning when you gave it to me?

A It was in my attorney's possession.

Q Do you know what this letter is?

A The LC202, or 02?

Q Yes, LC02 through 03.

A Let me just look at it here.

It seems to be in response to a letter from Ms. Van Gelder in which there was -- I believe there was a press story that I refused to cooperate with GAO, and she was correcting the record for that.

Q Who was correcting the record?

A My attorney.
Q Okay, but this letter is actually to your attorney; is that right?
A No.
Q This letter is to your attorney from Dayna Shah?
A Yes, yes.
Q Okay, so do you know what this letter is?
A It's antecedent. It follows, I believe. Yes, see, that letter LC05 is the letter she's responding to.
Q So LC05, which is a letter dated October 24th, 2005, to Dayna Shah from Barbara Van Gelder, is the letter you were referring to that was correcting the record --
A Mm-hmm.
Q -- about your cooperation with the GAO?
A Yes.
Q Okay, am I correct that the letter marked LC02 through LC03 is a letter from Ms. Shaw to your attorney, again including questions that they would like you to respond to?

A There are letters attached, I mean, the questions attached as LC04.

Q Okay. And the letter appears to say, "We reiterate our invitation for him," namely you, Dr. Crawford, "to provide written responses to our questions or otherwise comment on his involvement in the May 2004 decision on Plan B. We have included the questions submitted in September 2005 as an enclosure to this letter and would appreciate Dr. Crawford's response no later than October 25th, 2005." Is that right?

A Mm-hmm.

Q Okay. And then am I correct that the letter that follows that date of October 24th, 2005, is your attorney's response to the previous letter?

A Which LC are you talking about?

Q LC05 to 06?

A Yes, she wrote Ms. Shaw about the GAO questions.

Q So does this letter, LC05 through LC06, constitute your response to the GAO questions?

A That I don't know. Let me see.

No, I think this is where she's correcting the record.

Q Okay, so this is the letter correcting the record.

A Mm-hmm.

Q Okay, let's look at the next letter, LC07 through LC08, which is dated November 17th, 2005, to you, Dr. Crawford, from Carl Levin. Do you know what this letter is?

A That's indicating the senator's interest in talking to me about the issue.

Q So this senator wanted to meet with you to discuss the Plan B application?

A Yes, it appears so, right.

Q Did you meet with Mr. Levin to discuss the Plan B application?

A I did not.

Q Why did you not?

A I left the government then, had no access to files or any kind of information about it, and felt like it was better not to.

Q Okay, and if we turn to the next page, LC09,

this is a letter to Senator Levin from your attorney, Barbara Van Gelder?

A Mm-hmm.

Q And what is this letter?

A Let me see.

This is the formal declination to meet with him.

Q Okay. Am I correct that this set of documents you gave me today does not include your written responses to the GAO questions?

A It doesn't appear that it does.

MR. STURM: Well, Counsel, I would direct -- I don't think --

MS. JONES: I think he already answered the question.

MR. STURM: But I think it's a misleading question. He hasn't, perhaps, had enough time to study it, because if you look at the bottom of LC05, there's a question, one of the questions was regarding a meeting of December 10th '05, and he says -- and at LC05 it states that he didn't attend the meeting in December. So --

A Yes, I was looking for, you know, a numbered version. But actually this is where she answers the question.

Q So the letter at LC05 through LC06 represents the entirety of your responses to the written questions of the GAO?

A Yes, I believe that's right, yes.

Q So if you look at the questions from the GAO on LC04, the first question is, "In general what was your role in the review of the Plan B switch application? Could you please describe your interactions with Dr. McClellan, Dr. Galson, and Dr. Woodcock about this issue." Did you or your attorney answer that question in writing somewhere?

MR. STURM: Take a minute and read LC05 and LC06.

MS. JONES: Are you going to let him testify about it?

MR. STURM: Yes. I'd just like him to read the letter before he testifies.

A Yes, in LC05, in the third paragraph, she divulges that Dr. Galson briefed me on the thing. And

that's the answer, that's all that I was involved in.
BY MS. JONES:
Q So that's your answer to question 1?
A Mm-hmm.
Q Okay. And can you tell me where in the letter is your answer to question 2 on LC04?
A I assume that it's implied at least in the fact that Galson briefed me. Yes, here it is, it says, "Dr. Galson briefed him on his conclusions regarding Plan B. Dr. Crawford, although he came in later in the process, concurred with Dr. Galson's decision."
Q Okay.
A So he made the decision.
Q When did you first see this letter that's marked LC05 through LC06?
A When it came out, I guess, end of October sometime.
Q Did you discuss it with your attorney at that time?
A Yes.
Q Did you review it prior to its being sent

out?

A In some form or another.

Q Could you turn to page LC09, which is the letter from Ms. Van Gelder to Senator Levin.

A Mm-hmm.

Q Again, you said this was the formal declination of the invitation to go speak to him about Plan B; is that right?

A Mm-hmm.

Q In explanation of why you would not do that it says, "More importantly, the Inspector General of the Department of Health and Human Services now is conducting an investigation which may encompass this issue. Therefore, Dr. Crawford must decline to speak on any matter related to his tenure at FDA until that investigation is resolved.

When it says that the inspector general is conducting an investigation which may encompass this issue, what issue is being referred to there?

A Plan B.

Q Is it your understanding that the inspector general with the Department of Health and Human

Services was at that time conducting investigation into Plan B?

MR. STURM: You can answer that question yes or no.

A They were not conducting an investigation of Plan B, we now know.

BY MS. JONES:

Q You now know?

A Mm-hmm.

Q At that time did you believe they were conducting an investigation that related to you in some way?

A Yes.

Q And is it fair to say that you didn't know what the scope of the investigation was?

A I did not.

Q Did you believe that it may include something related to Plan B?

A Possibility, yes.

Q How did you come to believe that it may be related to Plan B?

A There was a letter from the health

committee, Health, Education, Labor and Pensions, from the chairman of that committee, to the Office of the Inspector General asking him to -- the inspector general to look into -- you know, I've forgotten how it's written, I don't have it in front of me, but to look into matters in general about me. And I don't know whether they mentioned that or not, but it was fairly broad.

So you couldn't in terms of reading that letter say what they were looking at.

Q What were the broad things they said they were looking into?

A I don't remember.

Q No idea?

A No, I can't really --

Q Well, what about it might have included Plan B?

A I don't know. It just wasn't clear what they were looking into.

Q Do you possess that document?

A No.

Q Did you see it ever?

A I saw it in the newspaper, but that's about it.

Q You saw it in the news -- what was the document that you saw in the newspaper?

A A news story about the investigation.

Q Which described the scope of the investigation?

A No. It mentioned that -- I don't know whether it used the term "broad" or not, but it's not possible to know what they were looking at from the news report.

Q Okay, I thought you said there was some sort of document addressed to the Department of Health and Human Services Inspector General.

A The news report said that there was. I never saw it.

Q They said that there was a document, and they said that the document described the areas of inquiry, but you never saw that document?

A I never saw it.

Q And you have no recollection of the areas of inquiry described in the news story?

A I do not. It was broad, is all I remember.
Q Do you know what newspaper it was?
A I don't know which one it was.
Q And I think you stated that you now have the understanding that the investigation does not concern Plan B; is that right?
A Can we --
MR. STURM: You can answer that question.
A Yes, we do.
BY MS. JONES:
Q When did you come to believe that the investigation does not relate to Plan B?
A Within the last three weeks or so.
Q And how did you come to that new understanding?
A We got a letter from the investigators indicating that.
Q You got a letter from the investigators indicating that the investigation does not relate to Plan B?
A Yes.
Q Did you bring me a copy of that letter

today?

A I did not, but we can -- I don't know.

MS. JONES: That seems to me to be a letter in his possession related to Plan B.

MR. STURM: Well, it says there's an e-mail saying that there is not an investigation related to Plan B. That's the substance of it.

MS. JONES: Can you produce it to us?

MR. STURM: I don't have it on me.

MS. JONES: Well, I don't mean at this minute. How about tomorrow morning?

MR. STURM: We'll let you know by tomorrow morning.

MS. JONES: You'll produce it to me by tomorrow morning?

MR. STURM: No, I said I'll take the request under advisement and let you know by tomorrow.

MS. JONES: I believe it's within the scope of the subpoena, so I'd appreciate if you'd produce it.

BY MS. JONES:

Q Who did the e-mail come from?

A I don't know.
Q Was it received by -- was it sent to you or to your attorneys?
A Attorney.
Q But it was from someone within the Inspector General's office?
A I don't know, somebody who was doing the investigation, yes. I don't really know that answer.
MR. STURM: Don't speculate on this. Answer what you know.
BY MS. JONES:
Q What prompted the Inspector General to send an e-mail to your attorney tell them about the scope of your investigation?
A I don't really know why she -- why that happened. I --
Q Do you know if your attorney inquired to the inspector general what the scope of the investigation was?
A That could have been.
Q You don't know?
A I don't know.

Q Do you know who exactly the e-mail came from?

A No.

MS. JONES: I think I'm going to take a break now, and we'll wrap up. I don't have a whole lot more.

MR. STURM: Okay.

THE VIDEOGRAPHER: We're going off the record. The time is 2:59 p.m.

(A brief recess was taken.)

THE VIDEOGRAPHER: We are back on the record. The time is 3:09 p.m.

BY MS. JONES:

Q Dr. Crawford, what was the basis for your belief, while you had it, that the inspector general investigation might in some way relate to Plan B?

MR. AMANAT: Objection. Asked and answered.

MR. STURM: Objection. Asked and answered.

BY MS. JONES:

Q Go ahead and answer it.

A Okay, sorry.

I just didn't know whether it did or it did

not. You know, I couldn't say one way or the other.

Q Do you think the investigation could include any -- or anything or everything that occurred during your time at the FDA?

A I had no idea.

Q So it was just as likely that it would include some other matter as that it would include Plan B?

A Yes.

Q There was no particular reason why you thought it might have to do with Plan B; is that right?

A No.

Q Does the Office of the Commissioner have an policy about retaining memoranda, internal memoranda?

A You mean -- by that do you mean written memoranda?

Q Yes.

A In other words, files, any kind of paper?

Q If someone writes a memo to someone else about an agency matter, is there a policy about keeping those or disposing of those?

A I don't know what the current circumstances are. When I was there it was pretty much a paperless office, you know, and I would get these briefing papers and all that sort of thing. And I don't know what happened to them after then. It was the executive secretariat's responsibility, and so I don't know.

Now, when I left FDA, you know, I couldn't take anything with me, I know that for sure. And, in fact, my own files that I did take, which some of them dated back to the '50s, had to be examined, so -- to be sure that I didn't take anything with me. And that happened the other three times I was at FDA, also.

Q Is it fair to say that you don't know what the office's policy was on keeping internal memoranda?

A That is correct.

Q Do you know if the office had a policy not to keep such memoranda, as in not to retain such memoranda?

A I don't know.

Q Okay. Did the GAO request an interview with you at any point related to Plan B?

A Not -- not while I was in office, no. Not up until -- that I'm aware of. I mean, they -- a lot of people would call and talk to -- we had three secretaries, four, actually, and a lot of people would call and talk to somebody about scheduling something, but I don't know of that. And I'm quite sure it wasn't on the schedule. So I do not believe it was requested. And then that's about all I know about it.

Q Did the GAO request an interview with you in connection with Plan B after the time that you left the agency?

A No. There was a report, though, in the Washington Post that I had refused an interview, but it was ambiguous, it was not easy to determine whether it was Dr. McClellan or me. They used the word "commissioner," and it was supposedly footnoted in a draft of the GAO report. And how the Post got that, I don't know, but they were -- they did run a story saying that the commissioner had refused to testify, and then later on they mentioned my name in the thing.

So that's why we made the inquiry, did they really want to talk to me, because I didn't know that

they did.

Q Well, what was the purpose of the phone call between your attorney and Mr. Amanat that you said took place, I think, yesterday?

A I think it -- all I know is it had to do with the logistics of, you know, where to go and stuff. I don't really know, frankly.

Q Did you talk to anyone about this deposition other than your attorney?

A Well, it was in the news that this was going to take place, so some people have said to me, so, you know, you're having the deposition or something like that. I didn't -- didn't point it out to anybody that I recall. But people know about it.

Q What people have said that to you?

A People that I work with. And then, you know, colleagues that read it in the newspaper.

Q Did you talk to anyone other than your attorneys in preparing for this deposition?

A No. As I mentioned earlier, you know, I'm actually not allowed to talk to the FDA folks, and I did not. And there's no one else, except them.

Q Why did you resign from the FDA two months after being confirmed by the Senate?

MR. AMANAT: Objection. I'm going to instruct the witness not to answer that question.

MS. JONES: On what grounds would those be?

MR. AMANAT: On grounds, among other things, that it's -- and if you want, we can call the magistrate judge and I can formally state the reasons.

MS. JONES: Well, why don't you state your grounds first, and I'll decide if we need to call the magistrate.

MR. AMANAT: Among other things, it's an invasion of his personal privacy. It's beyond the scope of the inquiry. If you want to ask him whether the controversy surrounding Plan B factored in or contributed to his decision to resign, I have no problem with that. But if you're getting into any reasons beyond that are not related to the question of whether Plan B or the regulatory process with regard to Plan B or the controversy surrounding Plan B contributed to his decision to retire from the agency, I think it's an invasion of his personal privacy, it's

beyond the scope of the discovery that the magistrate judge authorized. And if we need to seek a formal protective order on a 30(b)(4), we will.

MS. JONES: I don't think that's a valid grounds to instruct a witness not to answer. So if you're going to instruct him not to answer on that grounds, then let's call the magistrate.

MR. AMANAT: I'm happy to that.

MR. STURM: I join in the objection and the instruction. I mean, the case is about Plan B, and we have no objection, or at least I have no objection to him answering whether Plan B factored into that decision in any way. But other than that, I think what factored into his decision to retire doesn't have anything to do with this lawsuit.

MS. JONES: Is your grounds relevance?

MR. STURM: An invasion of his personal privacy.

MS. JONES: Is it your understanding that that's a basis for instructing a witness not to answer at a deposition?

MR. STURM: Yeah.

MS. JONES: Okay, then let's go off the record and call the magistrate.

MR. AMANAT: Of course it is.

THE VIDEOGRAPHER: We're going off the record. The time is 3:17 p.m.

(A brief recess was taken.)

THE VIDEOGRAPHER: We are back on the record. The time is 3:23 p.m.

MS. JONES: Okay, I'm going to move ahead, and at the close of the deposition I'm going to leave it open for continuation should we move to compel an answer to the question and should the judge grant that motion to compel.

Just for the record, Mr. Amanat, you do not represent this witness at this deposition; is that right?

MR. AMANAT: I do not, that's correct.

MS. JONES: Okay. I just want to make sure.

BY MS. JONES:

Q Dr. Crawford, did your resignation relate in any way to the agency's resolution of the Plan B SNDA?

A No.

Q Did your resignation relate in any way to the GAO investigation of that matter?

A No.

MS. JONES: I have no further questions, and leave the deposition open in the manner I just described.

EXAMINATION BY COUNSEL FOR THE DEFENDANT

BY MR. AMANAT:

Q Dr. Crawford, if you don't mind, I have a -- I do have a few questions for you.

First, I'd like to get on the record a little bit about your background. And so let me just start by asking you a few questions about that, if you don't mind.

I understand from the initials that follow your name that you hold a doctorate in veterinary medicine.

A Yes.

Q From what institution did you obtain your DVM?

A Auburn University.

Q And what year was that?

A 1963.
Q And I also see that your name has Ph.D. after it.
A Yes.
Q You hold a doctorate in philosophy in what discipline, in what field?
A Pharmacology.
Q Pharmacology. And from what institution was that?
A University of Georgia.
Q And what year did you get your Ph.D.?
A 1969.
Q Did you spend some time in academia?
A Yes.
Q Tell us a little about what your history is in academia.
MS. JONES: For the record, I object to the entire line of questioning as beyond the scope of direct.
BY MR. AMANAT:
Q You may answer.
MS. JONES: That being said, you may answer.

A I taught 13 years at the University of Georgia and four years at Georgetown University.

BY MR. AMANAT:

Q Now, you mentioned earlier that you, I believe, became -- your first stint as acting commissioner of FDA was, I believe you said, sometime in the early part of 2002; is that correct?

A Yes.

Q Okay. Was that the first time you'd worked at FDA, I mean, did you come there for the first time as acting commissioner, deputy commissioner, or had you been there before at some point?

A No, I was there a total of four times, including that time, over a 30-year period.

Q 30-year period.

A Mm-hmm.

Q Do you recall in what year you first joined FDA?

A 1975.

Q 1975, okay. And tell us in what capacity you served within FDA during the four different stints that you served in the agency.

A The first time was a year, and I was on a sabbatical leave from the University of Georgia, and I was staff pharmacologist.

Q Okay. And what about the second time?

A Second time was from 1978 to 1980, and I was director of the Center for Veterinary Medicine.

Q So it's one of the center directors, I guess, that reports to the commissioner; is that right?

A Yes.

Q Okay. By the way, are those center director positions, are those political appointments, or do those tend to be filled by career scientists?

A They're always career.

Q Okay. So you served as the director of the Center for Veterinary Medicine for a couple years back during the Carter Administration; is that correct?

A I did, yes.

Q Okay. And then I take it at some point you left FDA again.

A I left in 1980 and came back in '82.

Q Okay. And what did you do then, in 1982,

what position did you have?

A I was director of the Center for Veterinary Medicine again.

Q So you resumed that position that you had before of center director?

A Yes.

Q Okay. And then, did you then remain at FDA for the entire period of time after that, or did you leave the agency again at some point?

A No, in December of 1985 I went and did a brief assignment at the World Health Organization in Geneva, Switzerland. And then I came back -- I was on leave from the government, and I came back to the Department of Agriculture, where I was associate administrator, that's like deputy commissioner, of the Food Safety and Inspection Service. And 18 months later I was named administrator of the Food Safety and Inspection Service.

Q And are those politically-appointed positions, or do those tend to be occupied by career scientists?

A They can be either one. When I was doing

them, they were career.

Q Okay.

A I was always career until this past time at FDA.

Q Okay. So is it fair to say that when you became deputy commissioner in 2002, and acting commissioner, was that the first political appointment you'd ever held in your career?

A Yes.

Q Now, did you obtain your position as deputy commissioner because of a personal relationship with Secretary Thompson?

A No, I'd never met Secretary Thompson before.

Q Did you obtain your appointment as deputy commissioner because of a personal relationship with somebody in the White House?

A No.

Q Now, let me ask you a couple other questions. Are you -- have you received any kind of special commendations or recognitions by your peers, either in the veterinary or in the pharmacological or the food sciences industries or communities?

A Yes.

Q What commendations or recognitions have you received?

A I'm member of the Institute of Medicine, National Academy of Sciences, and also a fellow of the Royal Society of Medicine, United Kingdom. And I am a fellow of the International Conference on Food Safety and Technology, and I'm on the expert advisory panel on food safety for the World Health Organization.

Q When you made the decision in May of 2004 to concur in Dr. Galson's decision to issue a nonapprovable letter, did any political factors or political considerations contribute to that decision in any way?

A No.

Q Did any ideological factors or ideological considerations factor into that concurrence in any way?

A No.

Q Now, when you -- now, how about your decision in August of 2005 to issue the -- basically, the second nonapprovable letter to Barr and to proceed

with the Advance Notice of Proposed Rulemaking, did political factors or political considerations contribute in any way to your decision to take that course of action?

A No.

Q Did ideological factors, ideological considerations contribute in any way to your decision to take that course of action?

A No.

Q Did you ever receive any instructions of any kind from anybody in the White House with regard to how either you as commissioner or the agency should act with regard to Plan B?

A No, I did not.

Q Did you ever receive any instructions of any kind from anybody in the White House either as to how you as commissioner -- as to the timetable within which you as commissioner or FDA as an agency were expected to decide or make a decision with regard to Plan B?

A No.

Q Did you ever receive an instruction from

anybody in the White House as to the effect that either you as commissioner or FDA as an agency should not decide the application, but should delay decision, or should sit on it, or something like that?

A I received no such instructions.

Q How about from the Office of Secretary of Health and Human Services, did you receive any instructions either from Secretary Thompson's office or from Secretary Leavitt's office as to how you as commissioner or the FDA as an agency should decide the applications with regard to Plan B?

A I did not.

Q And other than the letter that we've already looked at from Secretary Leavitt to Senator Enzi which described a September 1 deadline, did you receive or are you aware of any other instructions from the secretary's office with regard to the timetable within which the agency was, or you, were expected to make a decision with regard to Plan B?

A No.

Q The -- bear with me one second.

One of the allegations that the plaintiffs

have raised in this case, in their complaint in this case, is, quote, "The FDA applied a different and higher standard to Plan B's OTC switch than it has applied to OTC switches of other drugs." I'll read that to you again. Quote, "The FDA applied a different and higher standard to Plan B's OTC switch than it has applied to OTC switches of other drugs."

To the best of your knowledge, is that a truthful statement?

A No.

Q Can you explain why?

A I don't think we applied a different standard. I think we -- you know, each drug is different, but I think we applied tried and true FDA standards to this application.

Q Okay. The plaintiffs also go on to allege as follows: Quote, "There is no medical and scientific basis for the FDA's application of a different and higher standard to Plan B's OTC switch." To the best of your knowledge, is that a truthful statement?

A No.

Q Do you believe that there was a medical or scientific basis for the FDA's application of the standard that it did apply to the OTC switch to Plan B?

A Yes.

Q Plaintiffs go on to allege in their complaint as follows: Quote, "The FDA's failure to a approve Plan B for OTC use is based in part on outmoded stereotypes of women and girls."

A That's absolutely not --

Q Is that a truthful statement?

A That's absolutely not true.

Q Do you want to elaborate on that at all?

A No, I just -- that's just not a true statement.

Q There was a question that Ms. Jones asked you during your testimony about a meeting that took place at some point between Commissioner McClellan and Congressmen Weldon, Pitts, and Smith. And I believe you said you were not in attendance at that meeting.

A That's correct.

Q Do you recall whether any of those

congressmen invited you to a meeting with them on the subject of Plan B once you became acting commissioner?

A No, I don't recall that.

Q Okay. I'm going to hand you a document, sir, I'd like you to look at.

MR. AMANAT: Let's mark this, please, for identification as Government's Exhibit 1.

MS. REYES: Could we go off the record for a second?

THE VIDEOGRAPHER: We are going off the record. The time is 3:37 p.m.

(Discussion off record.)

(Crawford Exhibit 4 was marked for identification and was attached to the transcript.)

THE VIDEOGRAPHER: We are back on the record. The time is 3:38 p.m.

BY MR. AMANAT:

Q I've handed you what's been marked for identification as Crawford Exhibit 4. It's a three-page document consisting of documents labeled Tummino 804, Tummino 829, and Tummino 830. Let me ask you to take a moment to read those documents, please,

those three pages.

A Okay.

Q Okay. Does that refresh your recollection as to whether these congressmen invited you to meet with them on the subject of Plan B?

A I remember that we declined a meeting. I've forgotten which congressmen.

Q Okay, so is it fair to say that the e-mail that's set forth on Tummino 829 and 830 is an e-mail from a staffer from the office of Congressman Manzullo inviting you to meet with him and Congressman Weldon, Pitts, and Smith on the subject of Plan B; is that correct?

A That is correct.

Q Okay. And is it fair to say that the document on page 804 is a correspondence on your behalf declining the invitation to meet with those four congressmen, or memorialization of the fact that you had declined to meet with those congressmen; is that correct?

A It is.

Q Okay. Did you ever meet with any of these

congressmen, Manzullo, Weldon, Pitts, and Smith, on the subject of Plan B?

A Not to my recollection.

Q Now, Dr. Crawford, there is in the record, the parties have exchanged in discovery a number of correspondence which has been addressed to the Office of the Commissioner from a variety of different Members of Congress, both sides of the aisle, both the Senate and the House of Representatives, articulating various positions on Plan B. Ms. Jones showed you one such document earlier. Do you recall that?

A I do.

Q Okay. And do you recall whether there were also other correspondence addressed to the Office of the Commissioner from Members of Congress who were urging FDA in a different direction from the letter that Ms. Jones showed you. Do you recall, or are you aware of such letters as well?

A I know we got a body of correspondence from Congress, but I don't specifically remember, you know, who wrote them or whatever.

Q I believe in response to some questioning

from Ms. Jones you testified in response -- with regard to that particular letter that was signed by all those different Members of Congress that to some extent you understood that letter to be an effort on the part of those members of Congress to exert some form of political pressure on the agency simply by virtue of the number of signatories of the letter. Is that consistent with how you testified?

A Yes, it's -- you know, I mentioned that there both was the transmission of some information that I believe in good faith they thought needed to be brought to the attention of the agency. There also was, any time you get a letter with those many signatories from the Congress, there certainly is pressure.

Q Is it the FDA's practice to succumb to such pressure?

A No, we try very hard to be fair and open.

Q Does the FDA make its regulatory and drug approval decisions based on the views expressed by Members of the Congress to the commissioner?

A No, it does not.

Q Did it do so in this case of Plan B?
A No.
Q Was there any correspondence from any Member of Congress which was addressed to the commissioner's office or anyone else at FDA which contributed in any way to your decision to concur in Dr. Galson's May 2004 nonapprovable letter?
A Are you asking about Congressional correspondence?
Q Yes, yes.
A No, there was not.
Q Was there any correspondence from any member of Congress which influenced or affected your decision in any way in August of 2006 to issue a second nonapprovable letter to Barr and to proceed with an Advance Notice of Proposed Rulemaking?
A No.
Q 2005, I apologize.
A Yes, sir.
Q The answer was?
A No.
MR. AMANAT: Let's mark this, please,

Crawford Exhibit 5.

(Crawford Exhibit 5 was marked for identification and was attached to the transcript.)

BY MR. AMANAT:

Q If I could ask you, sir, to read this from the bottom up, read it from the end backwards, if you don't mind.

A Starting with page 42?

Q Starting at the end and working your way to the beginning.

A Okay.

Q I've handed you what's been marked for identification as Crawford Deposition Exhibit 5, a three-page document carrying Bates numbers Tummino 414 to 416.

Now, Dr. Crawford, one of the themes of the questioning that you received from Ms. Jones related to this question of whether you had, for lack of a better expression, cooperated with the GAO investigation and whether you had agreed to submit to an interview by GAO in connection with that engagement that they had undertaken. Do you recall that line of

questioning that you got from Ms. Jones?

A I do recall.

Q Now, let me direct your attention to, there's an e-mail correspondence at the bottom of the first page of this document, bottom of page 414.

A Okay.

Q Do you see that? There's an e-mail from Doris Tucker to Marty Gayheart, do you see that?

A I do.

Q Okay. Now, and listed on that, in that e-mail are two dates, Wednesday, October 12, and Monday, October 17. Do you see where those are listed?

A Mm-hmm.

Q Okay. Is it fair to say, sir, that those are dates that you were prepared to sit down for an in-person meeting with the GAO representatives to answer their questions and talk to them with regard to their inquiry into Plan B?

A I believe that must be the case. I don't recall this, having made a decision with respect to it. However, my secretary, you know, would have -- if

the GAO called through whatever intermediary, she would not, you know, have tried to put it off and not schedule it. So she didn't really have to come to me for that. I was not aware of this, to tell you the truth.

Q And so -- okay, but is it -- so the e-mail that's right above that, September 20th e-mail from Marty Gayheart to Doris Tucker, based on your reading of that e-mail is it fair to say that GAO was basically saying that those dates were too late for them and they would rather have you provide written responses to their questions?

A Yes, it appears to be that way. I don't know why they asked for the dates as late as they did. That's the one missing piece.

Q Okay. Now, we looked earlier at a letter from your counsel. This is part of, I believe, Crawford Exhibit 3, a letter dated October 24th, 2005, from Ms. Van Gelder to Dayna Shah.

A You're talking about Crawford 2.

Q Yes, LC05 to LC06.

A Okay.

Q Crawford Exhibit 2, do you see that?
A Yes, but I thought you said Crawford 3.
Q I misspoke.
A Okay.
Q It's Crawford 2.
A And LC what?
Q 05 to 06.
A Okay.
Q Remember, we talked about that letter in Ms. Jones's testimony?
A Yes.
Q Ms. Jones's questioning. Okay.
Now, this is a letter dated October 24th, 2005; is that correct?
A It is.
Q Okay. I believe you testified that with regard to the paragraph which is the second paragraph from the bottom of that page LC05, that that paragraph was the response to the GAO's question number -- question number 3.
A Mm-hmm.
Q Do you remember on LC04?

A I do.

Q Okay. So that paragraph in the letter in LC05 was intended to respond to question number 3 that was submitted by the GAO; is that correct?

A Yes.

Q Okay. And it stated there, "I am confident the FDA will confirm that Dr. Crawford was in Argentina on December 10, 2003. Do you see where it says that in that letter?

A Yes.

Q And you, in fact, testified that you -- in response to an earlier set of questions that Ms. Jones asked you, about a document that contained the minutes of a meeting in the Office of the Commissioner, a December 10, 2003, meeting, which listed you as participating, you testified that you were pretty sure that you had not attended that meeting because you were in Argentina at the time; is that correct?

A It is correct.

Q Okay. Now, let me hand you, sir --

MR. AMANAT: Let's have this marked, please, as Crawford Exhibit 5.

MS. REYES: This is 6.

MR. AMANAT: 6, I'm sorry, I can't count.

(Crawford Exhibit 6 was marked for identification and was attached to the transcript.)

BY MR. AMANAT:

Q Now, sir, I've handed you what's been marked for identification as Crawford Exhibit 6. It's a 20-page document carrying numbers 210316 to 335. And let me ask you, please, to just read the first page for now, starting again from the bottom and working your way up.

A This is page 316?

Q That's correct, yes.

A Okay.

Q Okay? Now, I notice that the e-mail at the bottom of that page which is dated October 25 is dated from the day after the letter we looked at a few moments ago from Ms. Van Gelder to Ms. Shah, which was dated April 24th.

A Mm-hmm.

Q Is that correct?

A Yes.

Q And this e-mail in question is an e-mail from Deborah Miller at the Government Accountability Office to Doris Tucker at the Office of the Commissioner of the FDA; is that correct?

A Yes.

Q And it says, "In a document submitted to us by FDA," which I understand to be a reference to the minutes of the December 10 meeting, "we found information that is disputed by Dr. Lester Crawford," presumably a reference to the statement in Ms. Van Gelder's letter. "Therefore, we are requesting a copy of Dr. Crawford's calendar for December 1, 2003, through December 19, 2003. Please call if you have any questions." Okay?

A Mm-hmm.

Q Now, and then above that is an e-mail dated the next day, October 26th, from Doris Tucker back to Deborah Miller, transmitting your calendar for December 1 to 19th.

A Mm-hmm.

Q Now, let me ask you to just quickly flip through the pages that follow, from 317 to 335, and

tell me whether, in fact, those are, in fact, the pages from your calendar for that period, December 1 to December 19.

A Yes, it is.

Q Okay. Let me direct your attention to page 326, please.

A Okay.

Q Is that your calendar for December 10, 2003?

A It is.

Q Okay, and what does it reflect you did that day?

A I was in Argentina.

Q Okay. Let me direct your -- ask you to turn, please, to page 331.

A Okay.

Q Do you recall that you -- that Ms. Jones showed you this document and asked you a few questions about it earlier today?

A Yes.

Q Okay. And in particular she was asking about this Kirkland & Ellis cocktail reception at the bottom of the page.

A Mm-hmm.
Q And there was a question as to why this document was produced and what relationship it had to Plan B. Do you recall that line of questioning?
A I do.
Q Do you have any reason to believe that this document was given to GAO for any reason other than the fact that GAO had asked for your calendars from December 1 to December 19th?
A No, they clearly asked for it, so I don't know of any other reason.
Q Dr. Crawford, are you familiar as to whether there is a regulation by FDA which describes the standards which allow the commissioner to allow a drug to be marketed over the counter?
A Would you state that again? I'm sorry.
Q Yes. Are you familiar as to whether there is a regulation which describes the standards which allow the commissioner to declare -- to allow a drug to be marketed over the counter?
A There are standards, yes.
Q Okay. I'm going to read you a portion of

the regulation. It says, "Any drug limited to prescription use shall be exempted from prescription dispensing requirements when the commissioner finds such requirements are not necessary for the protection of the public health by reason of the drug's toxicity or other potentiality for harmful effect." Are you familiar with that regulation?

A I am, yes.

Q Okay. And as, first, acting commissioner and then commissioner of FDA, was it part of your responsibility to interpret and apply that regulation?

A Yes.

Q Okay. One phrase that is mentioned in there is protection of the public health. Would you please explain to me how your decision in August of 2005 to issue the nonapprovable letter and to pursue the proposed rulemaking route was directed to protecting the public health.

A Yes. The application indicated that, and the decision memo by Dr. Galson indicated that for women that were under 17 years of age it was important from a public health point of view to have the product

be under prescription order, that is, to be sold by or on the order of a practicing physician. And so it was the considered opinion of Dr. Galson that that should be the case.

That being the case, then it was up to me to make sure that this was suitable and also enforceable. And that's what happened.

MR. AMANAT: Thank you, Dr. Crawford. I have no further questions for you at this time.

MR. STURM: I have no questions. Your witness.

MS. JONES: I have no further questions. Just leaving the deposition open, as I described before.

MR. STURM: And we obviously object to that.

MS. JONES: We'll cross that bridge if we get to it.

THE VIDEOGRAPHER: This marks the end of the deposition of Dr. Crawford. The total number of tapes used today was three. We are going off the record. The time is 3:59 p.m.

(Signature not having been waived, the

deposition of LESTER M. CRAWFORD, D.V.M., Ph.D., was concluded at 3:59 p.m.)

ACKNOWLEDGMENT OF DEPONENT

I, LESTER M. CRAWFORD, D.V.M., Ph.D., do hereby acknowledge that I have 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, Jacquelyn C. Jarboe, the officer before whom the foregoing deposition 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, 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 June, 2006.

My commission expires:
April 30, 2009

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NOTARY PUBLIC IN AND FOR THE
DISTRICT OF COLUMBIA

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