UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF NEW YORK

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ANNIE TUMMINO, et al., :

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

v. : (Korman, C.J.)

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

as Acting Commissioner of :

the Food & Drug :

Administration, :

Defendant. :

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Videotaped Deposition of JANET WOODCOCK, M.D.

Volume 1

Rockville, Maryland

Wednesday, April 26, 2006

2:05 p.m.

Job No.: 1-77261

Pages 1 through 116

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

Videotaped deposition of JANET WOODCOCK, M.D., held at the offices of:

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

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

A P P E A R A N C E S

ON BEHALF OF THE CENTER FOR REPRODUCTIVE RIGHTS:

SIMON HELLER, ESQUIRE

BONNIE SCOTT JONES, ESQUIRE

NAN STRAUSS, ESQUIRE

VIVIEN LABATON, ESQUIRE

THE CENTER FOR REPRODUCTIVE RIGHTS

120 Wall Street

New York, New York 10005

(917) 637-3600

ON BEHALF OF THE INDIVIDUAL PLAINTIFFS:

ANDREA COSTELLO, ESQUIRE

SOUTHERN LEGAL COUNSEL, INC.

1229 NW 12th Avenue

Gainesville, Florida 32601

(352) 271-8890

A P P E A R A N C E S C O N T I N U E D

ON BEHALF OF THE DEFENDANT:

F. FRANKLIN AMANAT, ESQUIRE
STEVEN WARSHAWSKY, ESQUIRE
UNITED STATES ATTORNEY
EASTERN DISTRICT OF NEW YORK
One Pierrepont Plaza, 14th Floor
Brooklyn, New York 11201
(718) 254-6024

and

KAREN SCHIFTER, ESQUIRE
OFFICE OF THE CHIEF COUNSEL
FOOD AND DRUG ADMINISTRATION
5600 Fishers Lane, GCF-1
Rockville, Maryland 20857
(301) 827-1152

A P P E A R A N C E S C O N T I N U E D

ON BEHALF OF DURAMED RESEARCH, INC., AND BARR PHARMACEUTICALS, INC.:

ANA C. REYES, ESQUIRE
WILLIAMS & CONNOLLY LLP
725 12th Street, Northwest
Washington, D.C. 20005
(202) 434-5276

ALSO PRESENT: Cali Day, Videographer

C O N T E N T S

E X H I B I T S

(None)

P R O C E E D I N G S

THE VIDEOGRAPHER: Here begins tape number one in the deposition of Janet Woodcock, M.D., in the matter of Annie Tummino, et al., versus Andrew C. von Eschenbach, as Acting Commissioner of the Food & Drug Administration, in the United States District Court, Eastern District of New York, Case Number 05-CV-366. Today's date is April 26th, 2006. The time is 2:05 p.m.

The video operator today is Cali Day of L.A.D. Reporting. This video deposition is taking place at 5600 Fishers Lane, Rockville, Maryland, 20857. Would counsel please identify themselves and state whom they represent?

MS. JONES: Bonnie Scott Jones for the plaintiffs.

MR. HELLER: Simon Heller for the plaintiffs.

MS. STRAUSS: Nan Strauss for the plaintiffs.

MS. LABATON: Vivien Labaton for the plaintiffs.

MS. COSTELLO: Andrea Costello for the individual plaintiffs.

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

MS. SCHIFTER: Karen Schifter for the defendant.

MR. WARSHAWSKY: Steven Warshawsky, the defendant.

MR. AMANAT: Franklin Amanat on behalf of the defendant and the witness.

THE VIDEOGRAPHER: The court reporter today is Cynthia Simmons Ott of L.A.D. Reporting. Would the reporter please swear in the witness? Whereupon--

JANET WOODCOCK, M.D.

having been duly sworn, testified as follows:

EXAMINATION BY COUNSEL FOR PLAINTIFFS

BY MS. JONES:

Q Good afternoon, Dr. Woodcock. Have you ever had your deposition taken before?

A Yes.

Q Okay. So you're familiar with the basic

drills that we're going to go through here today?

A Yes.

Q Okay. The only thing I would just remind you now is that if at any point you don't understand one of my questions or you find it ambiguous, would you please just let me know, so that I can rephrase it?

A I will do that.

Q Thanks. And if you want a break at any time, just let me know.

A Thank you.

Q I want to just define a couple terms at the get-go, so we're both on the same page. Are you familiar with a citizens' petition that was filed on February 14th, 2001 seeking to make FDA approved emergency contraceptive products available over the counter?

A Yes.

Q Okay. I'm going to refer to that from now on as the citizens' petition, is that okay?

A Yes.

Q Okay. And are you familiar with a

supplemental new drug application that was filed by Women's Capital Corp and later by Duramed and Barr Labs?

A Yes.

Q Again, seeking to make Plan B available over the counter?

A Yes.

Q Okay. And I'm going to call that the Plan B SNDA, is that okay?

A Yes.

Q Could you just describe, in general terms, what your involvement has been in the FDA's handling of the citizens' petition and the Plan B SNDA, up to the time of the May 2004 nonapprovable letter?

A What my personal involvement --

Q Yes.

A I was Director of the Center For Drugs at the time of the submission of the citizens' petition and the time of the submission of the supplemental application for OTC switch. As such, I had broad oversight of Center activities. With respect to the citizens' petition, I participated, to my

recollection, in a meeting or so about the briefing, really, for me and others about contents of the citizens' petition.

As far as the supplemental application, while I was head of the Center For Drugs, I simply, of course, assured that the review of that product was in progress. In the fall of 2003, I was, I transferred over to the Commissioner's office on detail, and Steven Galson was then the acting head of the Center For Drugs.

And in that time period, my actions were more advisory to Steven, rather than I was not in direct line management over the Center For Drugs.

Q Did you have an advisory role in the decision to issue the May 6th, 2004 nonapprovable letter?

A Yes, I discussed that with Steven and others.

Q In that advisory role, were you advisor to Dr. Galson or advisor to Dr. Crawford or to both?

A Primarily, to Dr. Galson.

Q And during your time in the Commissioner's

office, were you also playing some sort of advisory role to Dr. McClellan with respect to the Plan B SNDA?

A I was working for Dr. McClellan, and occasionally, he would ask me questions about the application, and I would relay them to the Center, for them to give him answers. I did not have extensive consultations with Dr. McClellan about this application.

Q Did you concur with the Agency's decision to issue the nonapprovable letter on May 6th 2004?

A Yes.

Q Do you still agree that that was the correct decision?

A Yes.

Q And at any time, did you disagree with that decision?

A No.

Q I'd like, if possible, for you to identify for me any persons outside of CDER -- well, let me rewind for a minute.

CDER, when I refer to CDER, I'm talking

about the Center For Drug Evaluation and Research. Is that okay if we use that term?

A Yes.

Q Okay. And when I refer to the Commissioner's office, obviously, I'm talking about the office in which you still work, is that okay?

A Yes.

Q I'd like for you to identify for me any person outside of CDER and outside of the Commissioner's office with whom you have communicated about the citizens' petition, other than your family and friends?

A I don't recollect having any conversations with outside folks, except perhaps, and I don't remember this, but perhaps petitioners' organizations themselves, all right, who I have had occasional conversations with about various matters before the Agency may have discussed the petition that they'd submitted.

Q Okay. So the only persons that would fall in this category might be the organizations who are petitioners, but you don't recall any specific such

communications, is that right?

A No, I do not. That's correct.

Q Okay. Okay. And could you identify for me any persons outside, again, of CDER and the Commissioner's office with whom you have had any communications regarding the Plan B SNDA. Other than family or friends?

A There are none.

Q Have you discussed the citizens' petition or the Plan B SNDA with family or friends?

A Subsequent to the actions that were taken. I alluded to my involvement in the actions, subsequent to they're being made public. Prior to that. I do not -- did not have conversations with family and friends because of the confidential nature of the matters.

Q Okay. So when you say the actions being taken, are you referring to the May 6th, 2004 decision?

A Whenever an action would be made public --

Q Okay.

A -- then parties who were my acquaintances

would ask me about that, and I would respond that, yes, that action was taken, yes, I had been involved in that action, that type of thing.

Q And what did you tell those people in any of those conversations about your, what your involvement was?

A I told them that I was involved when I was head of the Center For Drugs, as the Center -- head of the Center For Drugs, and when I was working in the Commissioner's office, I told them I was involved in an advisory role.

Q And did you tell them that you concurred with the decision?

A Yes, if they asked that.

Q Did you have any communications with those people about who made the decision to issue the May 6th, 2004 letter?

A This is the letter Steven Galson signed?

Q Yes.

A No, other than, obviously, people who knew about this letter knew that Steven signed it, right, and I, if they asked me, if people asked me, I told

them I concurred in that decision. That was it.

Q So just so I'm sure we're covering all the bases here, you do not recall communicating with anyone within Health & Human Services, for example, about the citizens' petition or the Plan B SNDA, other than persons in CDER and the Commissioner's office, is that right?

A I can say, definitely, I did not communicate with anyone within Health & Human Services about either of these matters.

Q Okay. How about anyone within Congress, either Congress people or their staff?

A The only communications that we would have with members of Congress or their staff are the official correspondence from members of Congress to the Agency and back.

Q And any communications with anyone in the White House or anyone's staff from the White House?

A No.

Q There's a notebook in front of you that has a bunch of documents in it that I'm going to ask you to look at, at various points in the deposition,

and if you could now -- you'll see there's tabs down it. If you could look at a document that has the tab 3030? And for the record, that is Tummino 30165. This refers, this document refers to a meeting held May 28th, 2002. Do you recall that meeting at all?

A I don't know that I recall the specific meeting. We had a series of meetings about this issue, which I recall in general.

Q I am correct that you are listed as one of the attendees, right?

A That's correct.

Q I understand this is a long time ago. So you have no recollection at this moment of what transpired during that meeting, is that right?

A My recollection, we had a series of meetings around the citizens' petition and other issues related to this product, and I remember the general matters that we discussed at numerous meetings, but I don't remember this specific meeting.

Q Okay. Do you have any idea who called this meeting?

A I can't tell you that, no.

Q Do you know why this meeting was held? It may help you if you would look at tab 3029, which is Tummino 30106 through 30164, which purports to be background, a background package for the Tuesday's briefing. I don't need you to look all through it, but if you can glance at it and if it refreshes your memory, feel free to do that.

A If I can respond only to the first page --

Q Sure.

A -- that you have given me? This was an informational briefing, as it says here, for the Center director, which was me.

Q Okay.

A So this would be -- I still cannot tell you who called it because the staff can propose these, the Center director can request them. However, this was an informational briefing for the senior management about the status for this issue.

Q Okay. Can you look, again, back at 3030, document 3030? Under the action items, it says, "For this particular issue, all inquiries that are received from outside of CDER will be referred to

Maureen Hess for response."

A Yes.

Q Who was Maureen Hess?

A Maureen Hess at that time was a project manager within the office of executive operations within the Center For Drugs. The structure that exists within the Center For Drugs is that all correspondence in and out are managed through a central group, like an executive secretariat, that keeps close contact with the particular issue and then manages the correspondence out of the Center. And she was one of those people.

Q Okay. Do you recall at this time whether anything was decided at this meeting about the citizens' petition?

A I do not recall.

Q If you could take a look at tab 3031, which is Tummino 30166 through 30174, this refers to an office of the Commissioner meeting held on June 5th, 2002. Do you recall that meeting?

A Yes.

Q And you were in attendance at that

meeting, is that right?

A Yes.

Q Do you know why that meeting was held?

A This meeting was held to brief the, I think the then Acting Commissioner or Deputy Commissioner, who was Acting Commissioner, on the status of this product or application or citizens' petition.

Q So this meeting was about the citizens' petition, rather than the SNDA, is that right?

A Well, no. What it says right here in the document is that there was an NDA submission -- an SNDA, actually, expected for the prescription to OTC switch. And this was to brief Dr. Crawford on that, as well as, obviously, the citizens' petition that had been pending before the Agency.

Q Is it typical to have an office of the Commissioner meeting in anticipation of an OTC switch application?

A It is common to have briefings of the Commissioner on subjects that are of interest to the public and where there are actions or potential

action's ongoing. For example, there are many high-profile issues across the Agency where Commissioners are routinely briefed on the progress of such issues.

Q Do you know if anything was decided at this meeting with respect to action on the citizens' petition?

A What I remember is that, certainly, the Center For Drugs had carefully evaluated the citizens' petition already, and our conclusion was we required a sponsor for an over-the-counter switch because additional information would need to be submitted that we did not have. Therefore, we knew there was an intent of a sponsor to submit an application.

Therefore, our position was we were awaiting the application, and we were briefing the Acting Commissioner because of the interest, this was not a decisional type of meeting, but simply so the Acting Commissioner would be aware of the issues and what the progress of this whole issue was.

Q Let me make sure I get this right. You're

saying that CDER had decided that any action on the citizens' petition would require further information, is that right?

A We had looked at the issues in the citizens' -- the request of the citizens' petition, and it requested various actions by the Agency. We did not feel we could take an action on that without a sponsor.

Q And why did CDER feel that a sponsor was necessary in order to take that action?

A Because additional information would be required.

Q Did the Agency ask the citizens -- sorry, the petitioners, to submit the missing information at any point?

A We were expecting the sponsor to submit information.

Q Does that mean, no, that the petitioners themselves weren't asked because you were expecting it to come from the sponsor?

A I do not know if we specifically asked the petitioner. I do not believe that we did, but I

cannot attest to that.

Q In the discussion section of this, on the second page of this document, one of the bullet points is political sensitivity. Do you recall what was discussed with respect to that topic?

A Well, as I said, we brief Commissioners or Acting Commissioners on issues that are likely to come up in the press or inquiries by Congress or when they go around and give speeches, that they're likely to be asked about, so that they are up to speed on what's going on, on that particular issue.

This obviously, with some people on the outside, was an important issue on several sides, and the Acting Commissioner was likely to be asked about this in different venues.

Q So what exactly -- what were you telling the Commissioner about the political sensitivity of this issue?

A That it was, that there were various opinions about this product that had been voiced. We had received some letters and inquiries by some parties, and this is very frequent in drug

regulation, that this product perhaps was an abortifacient. That was one of the main foe side interests at that time, and we had done a variety of scientific entries to look at the mechanism of the action of the product.

Q Okay. So would it be fair to say that the main topic of political sensitivity that was discussed was the question of whether emergency contraception is an abortifacient?

A My recollection of this meeting is that that was the main topic of discussion.

Q And on the last bullet point under discussion, it says, "Regulatory Issues." Do you recall what regulatory issues were discussed there?

A No.

Q Do you know who Jay Lefkowitz is?

A The name sounds familiar, but I cannot place it.

Q I'm in the same position. Could you look at tab 3037, please, which is Tummino 30219 through 30235? This appears to be a memo to Dr. Crawford from you, dated July 10th, 2002, is that correct?

A Yes.
Q Do you recall this memo?
A Yes.
Q Okay. Did you draft it?
A I participated in its drafting.
Q Did -- was this memo written in response to a request from somebody?
A I'll have to look at this whole memo.
Q Sure. Take your time.
A All right. Can you repeat your question?
(The reporter read the record as requested.)
THE WITNESS: My -- what I remember is that this memo was written in request from Dr. Crawford, who asked for further scientific documentation of some of the findings of mechanism of action and adverse events and so forth for emergency contraception in general at the briefing we had for him.
BY MS. JONES:
Q You're saying he wanted further information about these issues that were discussed at

the briefing earlier? Is that what you mean?

A Yes.

Q Okay. And do you know if there was any particular reason why he wanted this information?

A Dr. Crawford is a pharmacologist, and I recall the briefing of Dr. Crawford, he was quite interested in these matters from a mechanism of action point of view.

Q Was Dr. Crawford in agreement with the Agency's position that emergency contraception is not an abortifacient?

A I do not know. He did not voice at the briefing disagreement, but I do not know.

Q Did he at any time express to you a concern on his part that emergency contraception was an abortifacient?

A No.

Q Could you take a look -- there's some later tabs in the notebook that start with D, and there's a tab D331. This is a calendar page that was given to us in discovery as a document related to either the Plan B SNDA or the citizens' petition.

And I'm wondering if you could take a look at it, and let me know if you know why this page relates to either the Plan B SNDA or the citizens' petition.

A No.

Q You don't know?

A No.

Q Do you know who Vicky Powers is? Her name is at the bottom of the agenda page.

A Do I know Vicky Powers? I should.

Q I'm guessing she's someone's assistant, but I don't know.

A I think so too.

Q But the name's not familiar at this moment?

A No.

Q Okay. If you could turn to document 3081, which is Tummino 30393 through 30420?

MR. AMANAT: Again, a portion of the second page of this document is marked confidential.

MS. JONES: Why don't we wait and see if my question elicits anything confidential. I'm not sure if it will.

BY MS. JONES:

Q This is the minutes of a meeting at the office of the Commissioner held on December 10th, 2003. Do you recall that meeting?

A No.

Q And you were not an attendee?

A I'm not listed as an attendee.

Q Okay. And do you recall anyone telling you about that meeting?

A No.

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

A No.

Q No one ever told you about such a phone call?

A No.

Q And you were not one of the participants on such a phone call?

A No.

Q Do you -- are you aware of any communications between either the Commissioner's

office or CDER and the Surgeon General's office regarding either the Plan B SNDA or the citizens' petition?

A No.

Q Okay. Could you look at tab D. The tab is marked D10 through 16, but you actually only need to look at pages Tummino 13 through 15.

MR. AMANAT: 13 through 15, you said?

MS. JONES: 13 through 15, yeah, Tummino 13 through 15.

MR. AMANAT: The letter from University of Kentucky?

MS. JONES: Correct.

THE WITNESS: So I'm supposed to look at this?

BY MS. JONES:

Q I think you're on the wrong page. 13? It should be D13. It's marked D10 through 16.

MR. AMANAT: This three-page letter, 13, 14, 15.

THE WITNESS: Oh, I see, of tab D10 through 16?

BY MS. JONES:

Q Sorry about that. It's a bit confusing.

A All right. I'll have to read this.

Q Okay. Take your time.

A Okay. I've read it.

Q Had you read that letter before today?

A No.

Q Had you ever seen that letter before today?

A I was aware of its existence.

Q How did you become aware of its existence?

A I don't remember who told me, but I was told a member of the advisory committee had written to Dr. McClellan on this issue.

Q Did you discuss that fact with Dr. McClellan?

A No.

Q Did you discuss it with Dr. Galson?

A Not -- I don't remember discussing it with Dr. Galson, since I never read this letter.

Q Do you have any information that might suggest that this letter was solicited by someone

within the FDA?

A I have no information to that, to attribute to that.

Q Do you have any information that might suggest that this letter was solicited by someone else from within the federal government?

A No.

Q Do you recall a telephone conference call that was conducted on December 23rd, 2003 between yourself, Dr. McClellan, and Dr. Galson?

A No.

Q If you want to take a look at D288, which is Tummino 288, this is a page from Dr. McClellan's calendar that indicates that such a meeting was held on that day and that they called you at home. I guess it was a couple days before Christmas. Does that refresh your recollection at all about this meeting?

A No.

Q Okay. Do you recollect having a conference call with Dr. Galson and Dr. McClellan around this time period about Plan B?

A I do remember that we talked intermittently about the progress of this application.

Q Do you know what you might have been discussing around this time period?

A I can't specifically relate anything to this particular telephone conversation.

Q If you would look at document 3101, Tummino 30666 through 30670, these are meeting minutes from a meeting held January 15th, 2004. Could you take a look at that and tell me if you recall that meeting?

A I don't recall this meeting. It appears I was not at this meeting.

Q Did anyone discuss this meeting with you?

A I believe Steven Galson told me that he'd had a meeting with the staff about this issue, yes.

Q Did you ever -- were you ever shown the minutes from this meeting?

A I don't believe so, no.

Q And as you said, you did not attend this meeting?

A Correct.

Q The minutes states that, "The objective of the meeting was to inform ODE3 and ODE5 of the office of the Commissioner's position on the acceptability of the application," meaning the Plan B SNDA. Do you know what the Commissioner's position was at the time of this meeting?

A Yes, I had talked to Dr. McClellan and Dr. Galson about this several times, and concern was that there was not adequate data in the younger age group on use of this product.

Q That was a concern of Dr. McClellan?

A Yes.

Q Okay. Was that a concern of you also?

A Yes.

Q To your knowledge, had anyone from outside of the Commissioner's office ever raised those concerns to yourself or to Dr. McClellan?

A Could you define outside the Commissioner's office?

Q Anyone in the world that was not a member of the Commissioner's office.

A Certainly, members of CDER had discussed this issue.

Q Okay. Who from CDER shared those concerns, to your knowledge?

A My point is that the issue of the paucity of data in the younger age groups had been raised and discussed. I don't know that, for others, that it reached the point of feeling there were inadequate data for approving the switch. However, people in CDER had discussed the paucity of data in that age group with me.

Q Do you know who those people were?

A I don't recall exactly.

Q And outside of people from CDER, had anyone else from outside the Commissioner's office raised these concerns with people within the Commissioner's office?

A Not to my knowledge, not to me, other than the letter you just showed me.

Q Right. I'm going to ask you about another meeting that perhaps you did not attend, which was a meeting held on January 27th, 2004 between

Dr. McClellan and three Congressmembers, Smith, Weldon, and Manzullo. Were you at that meeting?

A No.

Q Do you know anything about that meeting?

A No.

Q Did anyone ever discuss anything about that meeting with you?

A No.

Q Could you turn to document 3108, please, which is Tummino 30719 through 30744? These are the minutes of a February 18th, 2004 meeting chaired by Dr. Galson. Did you attend this meeting?

A Yes.

Q Do you recall this meeting?

A Yes.

Q If you could look at the page marked Tummino 30721, about halfway down, it says, "At the conclusion of the meeting, the Commissioner expressed the following," then there's four bullet points?

A I'm not well-adjusted to your numbering system.

Q The same document. Okay. Sorry about

that. It's a little confusing with the document numbers and page numbers. The document we're on is 3108, and the page is 30721.

MR. AMANAT: So the memo starts here, and she's asking for this.

THE WITNESS: Right. Okay. I'm going to have to look at this.

BY MS. JONES:

Q Sure. Just let me know when you're ready, and take your time.

MS. REYES: Can I just make a note, if we're going to start talking about the slides, we're going to have to start marking this confidential.

MS. JONES: I don't plan to ask her about them.

THE WITNESS: Okay.

BY MS. JONES:

Q So on Tummino 30721, it says that, "At the conclusion of the meeting, the Commissioner expressed the following," and the first point is, "He noted a trend toward a potential difference in various parameters between adults and adolescents in the Tina

Raine's study." Do you know what that means?

A Data were presented to the Commissioner about the various changes in behaviors or contraceptive use and things like that, those were the parameters, and the Commissioner was simply noting that there was a potential trend. You couldn't rule out a trend towards a difference between adults and teenagers in those parameters.

Q Did you agree with that at the time?

A My position would be that there was not adequate power in the young adolescents to determine -- to fix a point. There isn't, in other words, there weren't enough subjects. The confidence limits on any estimate you would have would be extremely wide, and therefore, you could -- it's difficult to assert.

There was a trend, that is true. However, it would be difficult to assert whether, whether there was any real difference or whether there was a potential for a very large difference because the number of subjects are so small.

Q Does the FDA generally require a certain

number of young adolescent subjects in an actual use study before it will grant an OTC switch?

A The requirements for age group representation depend on the scientific questions that arise in the course of the review or in the course of putting together the application.

Q Do you know of any drug -- during your tenure with the FDA, do you know of any OTC switch where the FDA required a certain number of adolescent subjects in the actual use study before it would grant the switch?

A No.

Q If you look in this second bullet point about the Commissioner's comments, it said that, "He expressed that the potential exists for changes in future contraceptive behaviors after adolescents take Plan B." Do you know what that means?

A Other than the literal statement that's written here, no.

Q Does the literal statement as it's written here mean that if adolescents take Plan B, they might then do something differently with their

contraception after using Plan B than they would have otherwise?

A That's how I would interpret this statement.

Q Okay. Was that a concern of the Commissioner at the time, to your knowledge?

A I believe it was part of a general concern that, number one, there weren't enough data in the younger adolescent age group to determine whether there would be changes in contraceptive behavior or health seeking -- healthcare seeking behavior.

Q Were you concerned that if adolescents took Plan B, they would then -- sorry.

Were you concerned that if adolescents took Plan B, this would result in them making negative decisions or negative changes in their future contraceptive behavior?

A I was concerned that there was not enough data to predict the effects on younger adolescent group.

Q When you're talking about the younger adolescent group, what ages are you talking about?

A From menarche to age 16 or so.

Q Was there any evidence before the FDA indicating that the use of Plan B by adolescents did not lead to negative changes in future contraceptive behaviors?

A I don't understand your question.

Q Okay. It's my understanding there were a number of studies that were part of this SNDA application in the consideration by the FDA. I'm wondering if any of those studies indicated that use of Plan B would not result in negative changes in contraceptive use by adolescents?

A The studies that were submitted, in my judgment, were not, were not generally, were not completely extrapolatable to the OTC situation. They were often done in health clinics or in other situations where the contact with the healthcare professional had already been established. This is not an OTC situation.

Therefore, many of those studies were not able to establish, to my judgment, what would happen with free OTC availability of the product.

Q So would it be fair to say that you thought the studies, apart from the actual use study, simply weren't relevant to the question of subsequent contraceptive use by adolescents?

A No, I think that would be an overstatement. They had some relevance. However, they were not able to fully address the question because of the setting, and this is often true with questions that arise in the over-the-counter use setting. It's very difficult to do a naturalistic study, and in this case, it was extremely difficult because of the issues of informed consent for minors.

Q Could they have submitted a study that would have been enough?

A It's the sponsor's obligation to, you know, generate the data showing that a product is safe and effective for its intended use.

Q But given the issues that you just talked about, about the difficulties of doing an actual use study, particularly informed consent with younger people, would it have been possible for the sponsor to create an actual use study that produced, that

could have produced the data that you are saying would have been necessary to show safety and efficacy in the younger adolescent group?

A I can't judge that.

Q You don't know?

A I don't know. But as I said, it is the obligation of the sponsor to demonstrate the safety and effectiveness.

Q Many other drug sponsors have shown safety and efficacy for over the counter without an actual use study with large numbers of younger adolescents, right?

MR. AMANAT: Could you read back the last question?

(The reporter read the record as requested.)

THE WITNESS: There certainly have been over-the-counter switches that indicate 12 years and over, without extensive study in the youngest population. However, as I said, it depends on the scientific issues that arise in the course of assessing the safety and effectiveness in the

population.
BY MS. JONES:
Q Who defines the scientific issues for each OTC application?
A The FDA.
Q CDER?
A The FDA, in general. The Center For Drugs, in concert with its advisory committees, tries to set general parameters for safety and effectiveness. However, for each product, obviously, there are unique issues that arise.
Q So what was the scientific issue that arose here requiring data about younger adolescents that didn't arise in these other OTC switches?
A The issue is the extrapolation of findings from actual use that were in an older age group and the ability to extrapolate those and be confident about the results in the younger age group.
Q Under the -- I'm sorry, I'm referring back now, again, to this document, Tummino 30721. There's a heading a bit further on. It says, "Action Items."
THE COURT REPORTER: I'm sorry, 30?

BY MS. JONES:

Q 30721. Under the heading, "Action Items," and the first action item says, "CDER was directed to continue to work with the sponsor on a marketing plan to limit availability of the product over the counter and to consider the most appropriate age groups to be restricted from access to the product." Is that your understanding of the Commissioner's position at that time?

A I think I had to leave this meeting early, and I don't remember this particular part, but I believe -- I had to leave the meeting early.

Q Okay.

A In my recollection.

Q So, okay. So I won't ask you to base your answer on your recollection of the meeting.

A Okay.

Q Apart from your recollection of the meeting, basing your answer on your understanding of what the Commissioner's position was, was this the Commissioner's position at the time of this meeting?

A Yes.

Q Okay. Am I correct that the Commissioner was basically suggesting a dual status product at that time, a product that would be partly over-the-counter and partly prescription only?

A I don't know.

Q And then the second action item says that, "The Commissioner expressed that restricted distribution would deserve another discussion in a public forum before implementation." Do you know what public forum is being referred to there?

A No.

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

(Conclusion of "PROTECTED TESTIMONY.")

BY MS. JONES:

Q Let's go back a bit to where we were. Let's go back to the May 6th, 2004 nonapprovable letter, which is at document 3117, which is Tummino 30904 through 30907. Who decided to issue that letter?

A I'll have to look at this letter again --

Q Sure.

A -- refamiliarize myself with it. What was the date of this letter? Did you say?

Q May 6th, 2004.
A Now, can you ask your question?
MS. JONES: Can you read my question back, please?
(The reporter read the record as requested.)
THE WITNESS: Dr. Galson.
BY MS. JONES:
Q And what role did the Commissioner's office play in that decision?
A I, as part of the Commissioner's office, concurred with this path, and I believe Steven had conferred with the Commissioner and then the Acting Commissioner. I'm not really sure who was in charge this time in the Commissioner's office. Sorry.
Q That's okay. I have a chart somewhere. Who decided that the letter should be defined as a nonapprovable letter, rather than an approvable letter?
A I don't know.
Q Did you ever discuss that issue with Dr. Galson?

A Yes, I believe so, yes.

Q Did you have an opinion at that time about whether it should be issued as an approvable versus a nonapprovable letter?

A I don't recall whether I had an opinion or not.

Q Do you at this time have an opinion as to whether it should have been deemed an approvable versus a nonapprovable letter?

A The boundary between an approvable letter and a nonapprovable letter is actually very slim, and it's a matter of judgment. What was raised here is some legal issues about whether or not this dual marketing was feasible and what the label would look like and everything. These were major issues that had to be dealt with before we could decide it was approvable under the dual marketing scheme.

The nonapprovable is also for the original application, and its original form is a switch, which the sponsor indicated they still would like to have that evaluated. So in some ways, the nonapprovable is a fair assessment description of the responses in

this letter.

Q But this letter also could have also been characterized as an approvable letter, is that right?

A As I said, the boundary between those two actions is somewhat elastic.

Q Does that mean, yes, it could have been, depending on -- it could have, someone could have made a different judgment call and called this an approvable letter, is that right?

A It potentially would, could have been called an approvable letter. However, that would be more risky because of the major issues that have to be resolved. Approvable letters are generally reserved where there are minor issues and questions back and forth that need to be resolved before an application can go on to be approved.

Q Do you know if anyone from the Commissioner's office gave input to Dr. Galson on the question of whether this should be an approvable versus a nonapprovable letter?

A Yes, I believe Dr. McClellan felt it should be a nonapprovable letter.

Q And it's your understanding that he communicated that opinion to Dr. Galson in some way?

A Yes, and he communicated that to me as well.

Q And do you know what was the basis for Dr. McClellan's opinion in that regard?

A He believed that the -- all I know is that he believed that the adolescent, younger adolescent data were inadequate to support the original application, which was the over-the-counter switch.

Q How long were you either director or acting director of CDER?

A I was director of CDER from May of 1994 until I went, came over and took a detail in the Commissioner's office in October, I guess of -- I'm very bad with dates -- of perhaps 2003, is that right?

Q Somewhere in the neighborhood of 10 years, you were at CDER?

A Yes.

Q That's good enough for me. I just wanted a general idea, somewhere around 10 years.

A Over 10 years, yes.
Q Okay. Do you have any idea how many OTC switch applications got processed through CDER during that time?
A No.
Q More than 10, right?
A Yes.
Q More than 30?
A No, I don't think so.
Q Something in the realm of a couple of a year that go through, that are decided by the office in a year?
A There were quite a few in the '90s, and then there were fewer after that, which was one reason we had the Part 15 hearing about what could be the next generation of types of products that could be switched.
Q During your time as director of CDER, did you ever sign an action letter on an OTC switch application?
A No.
Q Okay. And during the time that you were

director of CDER, was the delegated authority to decide an OTC switch application ever taken away by someone higher up?

A I don't recall an instance where that occurred.

Q All right. I'm going to shift our time period now to the time --

MR. AMANAT: Before you do that, can we just take a break for a few minutes?

MS. JONES: Sure.

MR. AMANAT: This seems to be an opportune time.

MS. JONES: How much time you want, 10 minutes?

THE VIDEOGRAPHER: This marks the end of tape one in the deposition of Dr. Woodcock. The time is 3:32 p.m.

(Recess.)

THE VIDEOGRAPHER: This marks the beginning of tape two in the deposition of Dr. Woodcock. We are back on the record. The time is 3:44 p.m.

BY MS. JONES:

Q Dr. Woodcock, was your authority, when you were director of CDER, was your authority to decide an NDA ever withdrawn from above?

A No.

Q And during your time as director of CDER, did you ever withdraw the delegated authority of your subordinates to decide an OTC switch?

A No.

Q Okay. Could you, again, describe in general terms your involvement in the FDA's handling of the Plan B SNDA and the citizens' petition following the issuance of the May 6th, '04 letter and up through the present?

A I recall very little involvement, subsequent to the issuing of this letter. I was interested, of course, in seeing if this scheme, dual marketing scheme could fly. And I did ask Steven about it and how it's coming and what do we think and so forth, but I was not directly involved in managing the SNDA subsequent to this.

Q Did you agree with the Agency's decision

to initiate rulemaking prior to ruling on the Plan B dual status application?

A I neither agreed nor disagreed because I wasn't privy to the issues.

Q In your professional judgment, was the decision to initiate rulemaking at that point before deciding the application the correct decision?

A Well, let us put it this way, as the FDA lawyers have explained to me repeatedly, I'm not a lawyer.

MR. AMANAT: Go ahead.

THE WITNESS: It's a joke. All right.

BY MS. JONES:

Q You scared him.

A Not about -- in other contexts, they have explained to me repeatedly that I'm not a lawyer, so my professional opinion on legal matters turns out is worth not as much as my professional opinion on other matters. So I do not know, if insuperable legal obstacles arose, when a detailed analysis of this proposal was made.

Q Do you know whether a legal analysis was

made of the dual status application?

A I do not know.

Q So if such an analysis exists either in a conversation or in a document, you were not privy to it, is that correct?

A What -- correct.

Q To your knowledge, in January of 2005, was Dr. Galson planning to issue an approval on the Plan B dual status application?

A The plan was if all -- any remaining regulatory and legal issues could be resolved, that the product would be approved under dual marketing status the sponsor had submitted an application for.

Q So that was his plan at that time?

A That's my understanding.

Q What derailed that plan?

A My understanding is that the legal and regulatory issues were not resolved in the minds of those who were evaluating this application.

Q Whose minds were those? Whose minds are you talking about?

A As I said, I was not really privy to that

decision or who was, you know, giving opinions on that.

Q Well, you said that some -- at least someone perceived that the legal and regulatory issues were not resolved. To your understanding, who was it that perceived that the legal and regulatory issues were not resolved?

A By the Commissioner or Acting Commissioner at the time.

Q Which was Dr. Crawford?

A Yeah.

Q Did Dr. Crawford say to you anything about that?

A No. I asked him.

Q You asked him?

A Repeatedly about status of the application and he just said it was under evaluation.

Q Other than Dr. Crawford, were there other people within the Commissioner's office or CDER who felt that the legal and regulatory issues were not sufficiently resolved to make a decision?

MR. AMANAT: Could you hold on one second,

please? I apologize.

MS. JONES: No problem.

MR. AMANAT: It's just that some of these questions may delve into possibly privileged territory. You might like to have --

MS. JONES: Is she the expert?

MR. AMANAT: Well, she's better able to advise me on that.

MS. JONES: No, I know.

MR. AMANAT: At least she can kick me if something comes up. Please, you may answer the question.

THE WITNESS: I'm sorry. Can you repeat the question?

MS. JONES: Sure. Can you read it back? Thank you.

(The reporter read the record as requested.)

THE WITNESS: I don't know.

BY MS. JONES:

Q Do you know if anyone within the federal government, but outside of the FDA, believed in

January of '05 that the legal and regulatory issues were not sufficiently resolved to make a decision?

A I don't know.

Q Who made the decision to delay action on the Plan B SNDA beyond the target date of January 21st, 2005?

MR. AMANAT: Objection, assumes a fact not in evidence. Object to the form of the question, and lack of foundation as well.

MS. JONES: Do you really want me to spend time on that? Okay.

MR. AMANAT: You haven't laid the foundation.

BY MS. JONES:

Q Are you aware there was a January 21st, 2005 action target date in this application?

A I was aware there was a January target date.

Q Good enough. Are you aware that at some point, someone must have made a decision to delay action beyond that date?

A Yes.

Q Okay. Do you know if a decision was made by someone at some point in time to delay action on the SNDA beyond that target date?

A All I know is what Steven told me, is that he could not approve the application. That's all I know.

Q Did he tell you why he could not approve the application?

A He didn't, I mean, he didn't.

Q Did you have some understanding of why he couldn't?

A Well, I assumed that Dr. Crawford, and if he was consulting anyone else or himself, had decided that these legal and regulatory issues had not been satisfactorily resolved.

Q Did Dr. Crawford talk to you about the decision to postpone action beyond the January target deadline?

A No.

Q Do you know what the Agency was doing on the Plan B SNDA between January 2005 and August 2005?

A No.

Q Were you in any way involved in working on or advising on the Plan B SNDA during that time period?

A I have a great deal of trouble with time periods, remembering them, especially when they're far away like this. I certainly had discussions with Steven Galson about various issues around the packaging, various technical issues about this dual marketing plan. I don't remember if some of them were after January or not, but if you are specifically asking me about the decision, no.

Q And by that, you mean you were not involved in or advising on the actual decision to initiate rulemaking?

A That's correct.

Q Okay. Did Dr. Galson ever indicate to you that action on the Plan B SNDA was going to be held up due to review by someone in the department of Health & Human Services?

A No.

Q Okay. Going back to the initiation of rulemaking, am I correct that you stated that the

decision to initiate rulemaking was made by Dr. Crawford?

A I believe so.

Q Okay. And do you know if anyone from outside the Commissioner's office gave him input on that decision?

A I do not know.

Q Do you know if anyone else within the FDA had suggested that as a possible course on this application?

A I don't know.

Q Just going back to the legal analysis, or the analysis of the legality of dual status, we looked before at the Axelrad memo from April of 2004. I just want to make sure I'm correct about this, you don't know of any analysis of the legality of dual status approval for Plan B after that memo, is that right?

A That's right.

Q Had anyone within CDER asked for further analysis of the legal issues?

MR. AMANAT: Objection, I'm going to

instruct the witness not to answer that question, attorney-client privilege.

MS. JONES: The fact of whether they asked for legal advice? I'm not asking her the contents of any legal advice that might have been obtained. I just want to know if it was asked for.

MR. AMANAT: I'll withdraw the objection. You can go ahead and answer the question.

THE WITNESS: I believe legal advice was requested.

BY MS. JONES:

Q By whom?

A By the Center.

Q By CDER?

A Yes.

Q By someone within CDER? Do you know who within CDER?

A No.

Q Do you know if that legal advice or guidance was given to them?

A I do not know.

Q Do you know approximately at what time

period that advice was asked for?

A No.

Q Do you know if there was anything that held up the Agency's analysis of the legal and regulatory issues involved with the dual status application?

MR. AMANAT: During what time period are you asking about, Ms. Jones?

MS. JONES: Say from 2004 to the present.

THE WITNESS: I don't know.

BY MS. JONES:

Q When were you first informed about the possibility that the Agency would initiate rulemaking prior to deciding on the Plan B dual status application?

A I believe it was the day before the notice issued, but as I said, I'm not very good at time, dates.

Q But it was very close in time to the public announcement of that decision, is that right?

A Yes, yes.

Q So would it be fair to say that you were

informed of the decision itself, rather than included in the decision-making process in that regard?

A That's correct.

Q Was that unusual that you would not be informed of a decision of that nature until the day before its announcement?

A Ordinarily, I would have been more involved, but not in all cases. In this case, I was not involved.

Q Was it Dr. Crawford himself who told you about --

A Yes.

Q Why weren't you involved?

A I don't know.

Q You still don't know?

A No.

Q Did you ever ask Dr. Crawford why you weren't involved?

A Yes. He said he was, you know, going to take this decision himself, and that's what he told me.

Q Did he give you any other answer than

that?

A No.

Q Okay. So until you were informed that that was the decision, you were not previously informed that that might be the decision, is that right? In other words, prior to the day of the notice or the day before the notice, sometime in August '05, did Dr. Crawford or someone else from the Commissioner's office tell you that this was a possible course of action on the Plan B SNDA?

A I believe so, but I believe it was within the week or 10 days prior to the action that I was told this might be contemplated.

Q By whom?

A And I don't remember who told me that.

Q Okay. But it was not Dr. Crawford?

A It may well have been.

Q Okay. Was the person who had told you about it asking for your input or just notifying you?

A Notifying me.

Q So you were never asked for your input on the decision to initiate rulemaking?

A That's correct.

Q Do you know anything about a meeting on August 24th of 2005 between Dr. Crawford, Dr. Galson, Mr. Bradshaw, and Mr. Ronan regarding Plan B?

A I do not recall such a meeting being mentioned to me.

Q You were not present at that meeting, is that right?

A To my knowledge.

Q Okay. Could you take a look at document 3151? That is Dr. Galson's memorandum of August 26th, 2005, and this is Tummino 31214 through 31226. Were you a recipient of that memo?

A I'll need to look it over.

Q Okay. Sure.

A Okay.

(The reporter read the record as requested.)

THE WITNESS: Well, I received a copy of this memo, if that's the question.

BY MS. JONES:

Q Okay. Do you know approximately when you

received it?

A No.

Q Dr. Galson indicated earlier today that he was in the process of drafting that memo for quite some time. There may have been earlier drafts. Do you recall if you ever received an earlier draft of that memo?

A I don't know if I received an earlier draft. I certainly discussed this with him several times.

Q Okay. The nonapprovable letter that had been issued in May of '04 talked about a lack of data for under 16-year-olds, and then in this memo, Dr. Galson says he doesn't think that there is enough evidence to permit OTC status for -- until age 17. Do you know what led to the shift in his concern from under 16 to under 17?

A As I said earlier, I believe a detailed analysis of by each year and the data that were available at each year and the way the analyses were submitted, putting 16 and younger together was what caused these conclusions.

Q Who undertook that analysis, looking year-by-year?

A I don't know.

Q Do you know if someone -- if the Commissioner asked that that analysis be done?

A I don't know.

Q Do you have any idea why the Commissioner would have cut you out of his decision-making process regarding the initiation of rulemaking when you had played a significant advisory role on the Plan B SNDA up to that time?

A No.

Q No idea?

A No.

Q None at all?

A No.

Q Has Dr. Galson ever communicated to you his speculation on that question?

A Dr. Galson and I discussed the pending application a number of times. He requested to me to request to Dr. Crawford what the status would be and what would be expected. I would do that, and

Dr. Crawford would tell me it was under evaluation.

Q But Dr. Galson never told you why he might think that Dr. Crawford had cut you out of that decision on rulemaking?

A There was -- he speculated that there might be pressures on Dr. Crawford.

Q And who did he speculate those pressures were coming from?

A Congress, the administration, and so forth.

Q Did he name anyone specific within Congress or the administration who he thought was exerting those pressures?

A No.

Q Do you know who he was referring to within Congress or the administration?

A No, and I would use those as examples, not limited to Congress and the administration. We were under a blitz of write-in campaigns, call-in campaigns, all sorts of opinions were being given to the Agency.

Q Did Dr. Crawford ask Dr. Galson to sign

the letter to the sponsor regarding the initiation of rulemaking?

A I don't know.

Q Do you know of any other instance in which the FDA has stopped or delayed its process on an OTC application in order to engage in rulemaking?

A That's a very difficult question to answer. There certainly have been safety issues that have arisen in the past around OTC products that have required rulemaking of different sorts, and I can't answer that question because I just don't, can't remember.

Q You just don't know, as you sit here today?

A That's correct, yeah.

Q Okay. Did you meet with Dr. Wood the week before she resigned from the FDA?

A I recall meeting with her the day before she resigned.

Q And you don't recall whether you also met with her the week before?

A No, I don't.

Q Okay. When you met with her the day before, was that meeting, in part, for her to notify you that she was resigning from the FDA?

A Yes.

Q During that meeting, did you say anything to Dr. Wood about Plan B or the initiation of rulemaking?

A She asked me why I hadn't told her that this action was going to take place, and I told her because I didn't know.

Q All right.

A And she asked me or -- well, so that was my explanation for that. She told me that her reason for resigning was related to this action.

Q I hope I didn't ask you this already. Can you tell me who Pat Ronan is?

A Pat Ronan is currently the FDA chief of staff.

Q Did you have any communications with him at any point about the Plan B SNDA?

A Not to my recollection, no. Could I add something to that?

Q Sure.
A During that time period, he was the head of legislative affairs for FDA.
Q And in that capacity, did you have any communications with him regarding the Plan B SNDA?
A Not to my knowledge.
Q Has the FDA entered into a contract with a company called Booz Allen Hamilton in relation to the proposed rulemaking?
A I do not know. I know the Agency stated -- had a contractor assembling the comments, organizing the comments. I don't know who that was.
Q Okay. Do you know what the contractor was charged with doing?
A Vaguely. I wasn't involved in a statement of work or anything like that. Usually, when we get a lot of comments, we get somebody to organize them.
Q Okay. So whoever the contractor is was charged with organizing the comments?
A They're tabulated, they're grouped into like comments, so that you can deal with all the similar comments at once. That's a standard process

that is gone through.

Q Is it standard to contract that work out?

A It depends on the size of the response and the current internal staff available to do the work, so it could be done contracted or internally.

Q Do you know what the contract delivery dates are for that contract?

A No.

Q Do you have any idea about the timeline on that?

A None.

Q Okay. Do you know if the contract was entered into from the FDA side by CDER or by the Commissioner's office?

A Yes, because that was discussed at a hearing we were at, and it was -- I don't know about the contract, per se, but it's being managed by the office of Policy, what was said at the hearing.

Q Office of Policy?

A In the Commissioner's office.

Q Okay. Is that the part of the FDA that would normally manage such a contract?

A That's a the part of FDA that deals with rulemaking, issues the rules out of the office of Policy, often manages rules or manages comments to rules.

Q When you were director of CDER, did CDER enter into any contracts of this nature regarding rulemaking?

A I honestly can't answer you factually because I don't remember.

Q Okay.

A It would have been extraordinary to have done that, but we didn't have much money.

Q Okay. With respect to this rulemaking, what is the role of the CDER professional staff?

A I do not know.

Q Do you know when the rulemaking process is going to be completed?

A No.

Q Any idea, even in general terms?

A Absolutely none.

Q All right. Do you know if the work on that contract has been completed?

A No, I don't know.
Q Would it be possible for you to bring us a copy of the contract tomorrow when you come for the remainder of your deposition?
A I have nothing to do with the contract. I don't have a contract.
Q You don't have access to it?
A No.
Q You mentioned that the contract was discussed at a hearing. What was the hearing that you were referring to?
A Appropriations hearing.
Q Do you know when that was?
A No.
Q Past couple months?
A Usually, they're in the spring, so I guess this is the spring. I'm sorry. I'm very bad with dates.
Q Was it before a subcommittee?
A Our appropriations subcommittee in the House.
Q In the House, okay. Would it be possible

for you to ask the office of Policy to give you a copy of the contract to bring with you tomorrow?

MR. AMANAT: I'm going to object to that. I don't, you know, if you've got a document request, I would appreciate it if you would direct that to me.

MS. JONES: Is the contract a confidential document?

MR. AMANAT: I don't know if it is. I've never seen it. I don't know. But, I mean, the House appropriations subcommittee testimony to which she referred to, I gave you all this morning a copy of an unofficial transcript of that testimony that Dr. Galson had presented.

MS. JONES: I assume the contract is not attached to that though, right?

MR. AMANAT: I don't know. I mean --

MS. JONES: It's not attached to what you gave us, is what I mean.

MR. AMANAT: No, it's not attached to what I gave you, but I don't know whether it was submitted to the subcommittee or not. I don't know.

MS. JONES: Do you have some objection to

her providing us with the contract?

MR. AMANAT: I have an objection to her providing it to you. Whether I have an objection to FDA, the defendant, providing it to you, I have to evaluate it.

MS. JONES: What is your objection to her providing it to us?

MR. AMANAT: Because she's just a witness, she indicated she doesn't have any involvement in it. She hasn't had involvement in the contract. She hasn't had an involvement in supervising the contract. She is not familiar with the details of the contract. So I think it's inappropriate to ask the witness to produce it. If you want to ask us to produce it, we'll take it under advisement.

We'll review the document. We'll give you a response as to whether, whether the defendant, as a party, will produce it to you.

MS. JONES: Okay.

MR. AMANAT: But, you know, I think it's inappropriate to ask the witness --

MS. JONES: I request that you produce it

to us. Please take it under advisement.

MR. AMANAT: Okay. We'll take it under advisement.

MS. JONES: Thank you.

MR. AMANAT: I'll have to look at the documents and consult --

MS. JONES: I understand.

MR. AMANAT: -- consult with the Agency. And the "it" that you're requesting production of is just the contract --

MS. JONES: Correct.

MR. AMANAT: -- with the outside contractor for the review --

MS. JONES: Correct.

MR. AMANAT: -- of the public comments submitted for the ANPRM?

MS. JONES: That's correct.

BY MS. JONES:

Q Do you know whether Nonoxynol-9 was switched to OTC status while you were at FDA?

A At FDA or head of the Center For Drugs?

Q At the FDA at all.

A I don't know.

Q Do you know if it was switched -- well, obviously, you must not know if it was while you were director of CDER, if you don't know if it was while you were at the FDA.

MR. AMANAT: Do you know what date that was, that happened?

MS. JONES: I do not know off the top of my head. I'm not playing games. I would tell her if I knew.

MR. AMANAT: I understand.

BY MS. JONES:

Q Do you know whether the FDA required adolescent trials before switching Nonoxynol-9 to OTC status?

A I do not know.

Q Do you know whether the FDA required adolescent trials before switching any of the other OTC contraceptive products that are on the market?

A Such as?

Q I'll get you a list. I don't have a list off the top of my head. Is Nonoxynol-9 the only

contraceptive product that you're familiar with that's available over the counter?

A It's an ingredient, right, in a number of products.

Q Are there any other?

MR. AMANAT: You mean other than condoms?

MS. JONES: Yes. I'm talking drugs, not devices at the moment. Strike that.

BY MS. JONES:

Q I believe that there are a number of laxatives that are available over the counter, is that right?

A Yes.

Q Do you know if the FDA required adolescent -- data on adolescent use prior to approving the switch on those drugs?

A Most of the laxatives on the market are under monograph status, which means there was a review of the safety and efficacy data extant in the literature at the time of the DBE review, we call it, and --

THE COURT REPORTER: I'm sorry, DBE?

THE WITNESS: I'm sorry. There was a review -- well, let me start over again.

OTC products are, that are regulated under monographs are -- that's a rule that is made, and there's a evaluation of all extant safety and efficacy data, and then the ingredient and its strength and use and so forth is put into the monograph, and then different manufacturers can market the product with different brand names and so forth under this monograph.

So most of the laxative products are marketed under that scheme, OTC, in the United States. During that time of making a monograph, there's a public notice and comment period and so forth looking at all the issues, like use in children and this and that and whether the data can be extrapolated, so this was evaluated at the time of the review of laxatives.

BY MS. JONES:

Q And was OTC status granted to those laxatives, despite a lack of data on adolescent use, or was there data on adolescent use supporting the

application?

A I don't know.

Q Do you know whether adolescent data was required before switching dextromethorphan to OTC status?

A Again, I don't know. Dextromethorphan is a very, is an old ingredient and probably comes under this earlier -- does come under the earlier scheme. You have to recognize that in the regulation of drugs in the past, children and adolescents were a neglected age group, and products were approved for various indications without studying the appropriate age groups.

And that has been remedied under the Best Pharmaceuticals For Children Act to some extent, and more studies are done as we become more sophisticated about the differences between adults and different age groups. So my point is drug regulation has evolved over time, and the things that we did in the time for older drugs are not the way we conduct our business nowadays.

Q Do you know if, for any OTC switch

application considered by CDER in the past five years, other than Plan B, whether the Agency has required submission of data on adolescent use?

A To my knowledge, no.

Q To your knowledge, has CDER ever before, before Plan B, ruled on an OTC switch application in a manner contrary to the unanimous decision of the relevant office directors?

A No, I don't recall such an instance before.

Q And to your knowledge, has CDER ever before rejected a switch application, an OTC switch application, when an advisory committee voted to recommend approval of the switch?

A I don't know the answer to that. It's certainly not at all unprecedented for us to go against the advice of our advisory committees.

Q I understand that. I'm wondering if the, if CDER's ever gone against the advice of its advisory committees when what the advisory committee recommended was granting an OTC switch?

A Right. And as I said, I don't know --

Q You don't know of any instance?
A -- know of any instance. However, the numbers are very small there, and certainly, as a general matter, advisory committees may recommend approval of various products, and the Center may decide not to approve them, and that happens.
Q That's why they're called advisory committees, right?
A That's correct.
Q They only get to advise?
A Yes.
Q I believe it's stated in the GAO report that you delete your e-mails on a routine basis, is that right?
A I do that, yes.
Q I think it said every 16 days, something to that effect, is that right?
A Okay. Well, perhaps you're confusing the -- I delete my own personal e-mails. However, the backup is kept by the Agency according to their records policy, and so they have a records policy that deletes e-mails on some basis or does something

to them.

Q If you get an e-mail and you save it to a folder, it wouldn't get deleted under that process, right?

A That's correct.

Q It would be saved?

A That's correct.

Q Okay. Did you save, prior to being instructed by the counsel here today to keep e-mails from now on about Plan B, did you save your e-mails regarding the Plan B SNDA?

A No.

Q Why not?

A I routinely delete my e-mails off the file. I take action on them. I get hundreds of e-mails a day, and I can't just have them littering up my inbox or set up an elaborate file system.

Q If you get a written memo, even a short written memo, about a switch application, do you keep those?

A No. Ordinarily -- there's a difference here, and let me explain the difference. I tried to

set up a very formal system in CDER whereby official records were copied and kept in the official files, whether they were in the office of the Center director or within the official file of the application. Other -- there were records and minutes of meetings kept in the file of the application.

E-mails that people might get inviting them to meetings and everything are these kind of e-mails where someone would keep a record of that meeting. However, I didn't keep my invitations or reminders about meetings and so forth.

Q Okay.

A And I didn't keep -- if I got a copy of something that was going to be in the official file, I didn't keep my own copy. Too many people do that. It's a bad practice.

Q You end up with 100 copies of the same thing?

A You end up with 100 copies of the same thing, you have hundreds of file cabinets all over the Agency and so forth and so on.

Q Okay. Do you know why Dr. Crawford

declined to be interviewed for the GAO report?

MR. AMANAT: Objection.

MS. JONES: Grounds?

MR. AMANAT: Assumes a fact not in evidence.

BY MS. JONES:

Q Okay. Do you know whether Dr. Crawford was interviewed for the GAO report?

A No.

Q Were you interviewed for the GAO report?

A Yes.

Q Do you know if anyone else within the Commissioner's office was interviewed?

A I don't know.

Q And you are not aware of whether an interview was sought with Dr. Crawford for the report?

A I believe an interview was sought. I believe that's what they told me.

Q Okay. And you do not know whether he granted that interview or not?

A Right, although I think he didn't.

Q Okay. Do you know why he didn't, assuming that he didn't?

A No, I don't know why.

Q Okay. Could you take a look at D275? It's Tummino 275. In the middle of -- this is a series of e-mails between Martin Gahart and Catherine Songster, and in the middle of the page, there is an e-mail that begins, "Hi, Cathy," and ends from -- "Thanks again for your help, Marty," that says, "We won't receive any documents from the office of the Commissioner because the office does not keep memos or other written communications."

Is that a correct statement of commission policy -- policy of the Commissioner's office?

A The Commissioner's office document policy, I believe it's a little overly broad. I believe the executive secretariat obviously keeps records of incoming correspondence of meetings that -- briefings that they staff with the Commissioner and like matters.

Q Other than that, is it the office policy not to keep memos or other written communications?

A I don't know what the office of the Executive Secretariat's policy is on this matter. I obviously -- I keep all memos I originate. I keep a copy and memos that are actually sent to me as the recipient, I keep a copy of that.

Q Did you retain e-mails you received from Dr. McClellan when Dr. McClellan was Commissioner or from Dr. Crawford when Dr. Crawford was commissioner?

A By, "retain," you mean did I copy them into a file?

Q Did you save them somewhere so that they would --

A No.

Q -- still be stored?

A No.

Q In other words, they got deleted along with any other e-mails?

A Yes.

Q According to the same policy?

A Yes.

Q Could you take a look at D150 through 154, which is Tummino 150 through 154?

A I would like to say one thing though.
Q Yes.
A You'd asked me previously about whether I talked to anybody about Plan B.
Q Yes.
A I did talk to the GAO.
Q Okay. Thank you for clarifying.
A I just wasn't considering them like --
Q I understand.
A I did talk to them, but that's a matter of public record.
Q Okay.
A Okay. So I wasn't trying to conceal that. Now, sorry.
Q No problem. Are you familiar with this document?
A Yes.
Q The first page of Tummino 150 appears to be an e-mail passing along the attached document. Tummino 151 is a letter to Marcia Cross from you, is that right?
A That's correct.

Q Okay. And then following that, in Tummino 152 through 154, is a document entitled, "General comments to GAO's draft report," et cetera. Were you the author of the document that's at Tummino 152 through 154?

A All right. I'll have to read it first.

Q Sure. Go ahead. I think what I asked you was, were you the author of the document that is Tummino 152 through 4?

A No.

Q Okay. So you transmitted these comments, but you did not write these comments, is that right?

A That's correct, yes.

Q Who wrote these comments?

A The Center For Drugs.

Q CDER?

A Yes.

Q Okay. Do you know who within CDER?

A No.

Q Okay. Who transmitted them to you?

A An executive secretariat of the office of Commissioner who handles correspondence in and out of

the office of Commissioner.

Q Did you play any role in the preparation of these comments, other than transmitting them to the GAO?

A I read the draft report in this scheme that the GAO had, where you went up there and looked at it, and then I looked at these comments that was provided by CDER, and I did not modify them in any way.

Q Did you agree with them?

A Yes. Otherwise, I would have modified them.

Q So you had authority to modify them?

A Yes.

Q Paragraph one concludes with the sentence, "Such discussions are part of the Center director's responsibilities," then there's a parenthetical, and then it says, "and are typical for high-profile, controversial applications." What, what is it that makes the Plan B SNDA controversial?

A There was, as I said, tremendous public interest, write-in campaigns. We had several

citizens' petitions. We had numerous letters. We had members of Congress, this is my recollection, opining on this matter, and that makes things controversial.

Q Okay. So just the fact that there's a lot of people voicing their opinion on the matter is what makes it controversial?

A Right. As the review progressed, another matter of controversy was that there was disagreement on the course of action. That only became controversial as it actually, as the reviews unfolded, and there were differences of opinion.

Q Okay. Do you know of any other OTC switch application in which the CDER director or the Commissioner's office were involved to the extent they were with the Plan B SNDA?

A If you mean that where the Center director signed the final letter, no. I believe in the past that there were other controversial over-the-counter switches where the Center director was quite involved.

Q And what would those have been?

A I was not personally involved, but I believe there was a great deal of controversy about the vaginal anti-fungals, for example, and the issue there, again, was that use of the product would sort of lull the women who were HIV infected into not seeking appropriate medical care, and therefore, they would progress in their disease because they were only treating the symptoms and that more harm than good could come of this approval or the switch to OTC.

And I believe a variety of people were involved in the discussions around that.

Q Including the Commissioner's office?

A I don't know about that, the Commissioner's office. I was not in the Center For Drugs at the time. I will say though the Commissioner's office is routinely involved in controversial applications of different types. It just happens the period you're referring to there were not that many controversial over-the-counter switches.

Q Do you know whether the FDA required data

on adolescent use for the switch of vaginal anti-fungals?

A I don't know. I don't think that was really the issue. The issue was that use of the product could give people a false sense of security and make them not seek appropriate medical care. It's a very, very common concern about OTC switches. And I guess -- there was a lot of Commissioner's office involvement in the nonsedating antihistamine switches because that, again, was a controversial issue.

Q Why was that a controversial issue?

A The Agency received a citizens' petition from an insurance company asking us to switch the nonsedating antihistamines to over the counter, and in some cases, that would have been a forced switch. So there were, again, questions of the legal and regulatory framework that could be involved and also the safety and efficacy and all sorts of things like that.

And there was a great deal of involvement by all areas of the Agency and actually above the

Agency in discussing that matter.

Q And that switch was granted?

A Well, the drug went off patent, the drugs in question went off patent and were switched.

Q Who from above the Agency was involved in those discussions?

A People at the HHS level.

Q Was that because of the insurance payment element of that or --

A No, because it was a major policy issue, and they have a role in oversight of policy.

Q Let me -- I want to make sure I understand this correctly. The switch was approved for some of those drugs, correct, some of those antihistamine drugs?

A Yes.

Q Okay. And it was approved on the basis -- well, it was approved without an SNDA having been filed, is that right?

A I don't remember the mechanism. I think, in most cases, a SNDA was filed to switch, and that switch is an innovator product, all right. If

someone wants to come up with a generic and go directly over the counter, they have to go through, you know, an NDA or a 505(b)(2), or, you know, they have different routes that they have to file. So I can't give you the exact -- I mean, I realize I'm supposed to give you the right answer all the time. Okay.

Q Only if you have it.

A So I don't, I don't know. But some of the manufacturers, yeah, would switch under an SNDA, that's correct.

Q I think you used the term for a "forced switch"?

A Right.

Q What's that?

A That's where the Agency makes a finding that a product is safe and effective, although the manufacturer has not applied for that.

Q And has the Agency made a forced switch?

A No.

Q Ever?

A I don't think so, not to my knowledge.

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

(Conclusion of "PROTECTED TESTIMONY.")

MS. JONES: Okay. Let's adjourn for the day, and we can resume tomorrow at 10:00 a.m.

THE WITNESS: Okay.

MS. JONES: Thank you very much.

THE WITNESS: Thank you.

THE VIDEOGRAPHER: This marks the end of volume one of the deposition of Dr. Woodcock. The total number of tapes used today was two. We are going off the record. The time is 4:58 p.m.

(Signature having been not waived, the deposition of JANET WOODCOCK, M.D., was concluded at 4:58 p.m.)

ACKNOWLEDGMENT OF DEPONENT

I, JANET WOODCOCK, M.D., do hereby acknowledge that I read and examined the foregoing testimony, and the same is a true, correct, and complete transcription of the testimony given by me and any corrections appear on the attached Errata sheet signed by me.

_____ _____

(DATE) (SIGNATURE)

CERTIFICATE OF SHORTHAND REPORTER - NOTARY PUBLIC

I, Cynthia R. Simmons Ott, Registered Merit Reporter, Certified Realtime Reporter, the officer before whom the foregoing hearing was taken, do hereby certify that the foregoing transcript is a true and correct record of the testimony given; that said testimony was taken by me stenographically and thereafter reduced to typewriting under my supervision; and that I am neither counsel for or related to, nor employed by any of the parties to this case and have no interest, financial or otherwise, in its outcome.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my notarial seal this 1st day of May 2006.

My commission expires:

August 1, 2006

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