IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

ANNIE TUMMINO, et al, Plaintiffs,	
vs.	Civil Action No. 05-CV-366 (ERK/VVP)
ANDREW C. VON ESCHENBACH, as Acting Commissioner of the Food & Drug Administration, Defendant.	

(Volume I)

Videotaped Deposition of

JOHN K. JENKINS, M.D.

Washington, D.C.

Wednesday, June 21st, 2006

1:40 p.m.

Job No. 1-80006

Pages 1 - 170

Reported by: Laurie Bangart-Smith

Videotaped Deposition of

JOHN K. JENKINS, M.D.

Held at the offices of:

WILBUR J. COHEN FEDERAL BUILDING

330 Independence Avenue, S.W.

Washington, D.C. 20036

(202)619-3148

Taken pursuant to the Federal Rules of Civil Procedure, by notice, before Laurie Bangart-Smith, Registered Professional Reporter and 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:

SIMON HELLER, ESQUIRE

NAN E. STRAUSS, ESQUIRE

CENTER FOR REPRODUCTIVE RIGHTS

120 Wall Street

New York, New York 10005

Telephone: (917)637-3615

ON BEHALF OF THE DEFENDANTS:

STEVEN M. WARSHAWSKY, ESQUIRE

Assistant United States Attorney

U.S. Department of Justice

Eastern District of New York

147 Pierrepont Street

Brooklyn, New York 11201

Telephone: (718)254-6060

- and -

KAREN E. SCHIFTER, ESQUIRE

Associate Chief Counsel

U.S. Dept. of Health and Human Services

Office of the Chief Counsel

Food and Drug Administration

5600 Fishers Lane, GCF-1
Rockville, Maryland 20857
Telephone: (301)827-1152

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

ZOE S. POULSON, ESQUIRE
WILLIAMS & CONNOLLY, LLP
725 Twelfth Street, N.W.
Washington, D.C. 20005
Telephone: (202)434-5332

Also present:

Cali Day, Videographer

EXAMINATION INDEX

PAGE

EXAMINATION BY MR. HELLER 7

P R O C E E D I N G S

THE VIDEOGRAPHER: Here begins Tape Number 1 in the deposition of John K. Jenkins, M.D., in the matter of Annie Tummino, et al, versus Andrew C. von Eschenbach, Acting Commissioner in the Food & Drug Administration, pending in United States District Court, Eastern District of New York, Case Number 05-CV-366.

Today's date is June 21, 2006. The time is 1:40 p.m. The video operator today is Cali Day of L.A.D. Reporting. This deposition is taking place at 330 Independence Avenue, Southwest, Washington, D.C., 20201.

Would counsel please identify themselves and state whom they represent.

MR. HELLER: Simon Heller for plaintiffs.

MS. STRAUSS: Nan Strauss for the plaintiffs.

MS. POULSON: Zoe Poulson for Barr Pharmaceuticals, Inc., and Duramed Research, Inc.

MS. SCHIFTER: Karen Schifter from FDA

for the defendant.

MR. WARSHAWSKY: Steven Warshawsky from United States Attorneys Office for the defendant.

THE VIDEOGRAPHER: The court reporter today is Laurie Bangart-Smith of L.A.D. Reporting. Would the reporter please swear in the witness.

JOHN K. JENKINS, M.D.,

having been duly sworn, testified as follows:

EXAMINATION BY COUNSEL FOR PLAINTIFF

BY MR. HELLER:

Q Good afternoon, Dr. Jenkins. My name is Simon Heller. We met briefly before we all sat down.

A Right.

Q I'm one of the lawyers for the plaintiffs in this case.

A Uh-huh.

Q And before I say much more, I want to ask you: Have you had your deposition taken before?

A No.

Q You may already know this from other

sources, but basically I'm going to be asking you a series of questions, which I'd like you to answer to the best of your ability, as completely as possible.

A Uh-huh.

Q If I ask a question that you don't understand, let me know, and I'll try to clarify the question. Mr. Warshawsky might object to some of my questions in general. We might have a short discussion of the objection, but generally what happens after that is that either I ask you to go ahead and answer the question, I may reformulate my question, or he might instruct you not to answer a question, but most of the time after an objection is discussed, you'll go ahead and answer the question if you can anyway. Does that make sense so far?

A Yes.

Q Okay. Thank you. Please also let me know if you need to take a break, and we'll try to do that as soon after as possible.

Just a few preliminary things. How did

you go about preparing to be deposed today?

A I had a preparation session with the U.S. Attorneys and the FDA attorneys I guess about two weeks ago, I believe, or maybe a week ago where they went through some questions and told me how the session would be handled. I also have skimmed the transcripts of some of the other depositions to get an idea of the types of questions you'd be asking so that I'd just be prepared in my mind about areas you were looking into.

Q Okay. Have you -- aside from the lawyers from the U.S. Attorney's Office and the FDA, have you talked with other people about the deposition?

A Only in the sense that I've told people that I would be coming today, it's on my calendar, but no, I haven't spoken to anyone about the substance of the deposition, no.

Q And are you, yourself, represented by the lawyers from the Government?

A As I understand it, they represent the

agency, so I guess in a sense they represent me as well. I don't -- I don't understand that I have any personal liability at risk here, so I don't have a personal attorney.

Q I didn't mean to suggest that you would --

A Okay.

Q -- or should.

Can you describe for me your educational background, I guess post-secondary school.

A Right. I have a B.S. in biology, a bachelor's degree in science and biology from East Tennessee State University in Johnson, Tennessee, as of 1979. I also have an M.D. degree from the University of Tennessee at Memphis, 1983. And subsequent to graduating from medical school, I did an internship and residency in internal medicine, and a fellowship in pulmonary and critical care medicine at Medical College of Virginia, Virginia Commonwealth University in Richmond. So that's my post-graduate education as well.

Q Do you have a board certification?

A Yes. I'm currently board-certified in internal medicine and pulmonary diseases. I previously was also board-certified in critical care medicine, but that certification expired in 2001.

Q After you completed your professional training --

A Uh-huh.

Q -- what employment, or what does your career looked like since then?

A I finished the pulmonary critical care fellowship in 1988 at, as I said, Medical College of Virginia. I stayed on as a faculty member there, first as an instructor, later as an assistant professor of pulmonary and critical care of medicine. I stayed there from '88 to 1992 as a of faculty member. During that time I was also employed by the MacGuire V.A. Medical Center in Richmond as a staff physician in the pulmonary and critical care section. I left those two positions in 1992 and joined FDA as a Medical Officer in

what was then called the Division of Oncology and Pulmonary Products. Do you want the entire FDA --

Q Well, just a rough sketch of the positions you've held.

A Right.

Q I know that things get reorganized from time to time in government.

A Right.

Q But just a sense of what positions you held.

A As I said, I started as a Primary Medical Officer in the Pulmonary Section of the Oncology and Pulmonary Drugs Division. I was later a Medical Team Leader in that same group. A few years later the Division was actually split into an Oncology Division and a Pulmonary Division, and I subsequently became the Division Director for the Pulmonary Drugs Division. I was in that job for approximately five years. I then took a promotion to become the Director of the Office of Drug Evaluation II. I was in that job, I believe, for about three, three and a half

years. I had been the Director of the Office of New Drugs now since January of 2002. That's my current position.

Q Thank you. Can you describe for me what the Office of New Drugs, what is the scope of its activities?

A Right. The Office of New Drugs is the part of the Center for Drug Evaluation and Research, or CDER, that's responsible for overseeing investigations of new drugs and reviewing new drug applications and new biologics applications for whether they should be approved or not, and we also have responsibility for continuing to monitor the safety and effectiveness of drugs after they're approved, so we have very broad responsibilities that start from the first time an investigational drug is introduced into humans in the United States.

It continues through approval, if a product gets approved, and into the post-approval setting. We also -- even though it's called the Office of New Drugs, we also are responsible for

the oversight of the non-prescription drugs or the over-the-counter drugs, some of which are not traditionally considered to be new. So it pretty much encompasses the entire scope of new drug review, approval and post-marketing surveillance.

Q Can you give me a ballpark estimate of how many new drug applications have been processed by the Office of New Drugs during your tenure as director.

A I think we tend to average something in the order of 100 to 120 new drug applications admitted per fiscal year, so I've been there for four and a half years, so you're probably looking at somewhere between 400 and 500 new drug applications.

Q And what about OTC switch applications?

A The number of OTC switch applications is much smaller, probably just -- if I had to guess off the top of my head, we're probably talking in the range of maybe five to ten, maximum, per year, may not even be that many in some years, so it's probably more in the range of 20 to 30 to 40, I

would guess, in the four and a half years that I've been there, recognizing that many of the -- those applications are not for things that are novel going over the counter. They may be new formulations of an ingredient going over the counter.

Q I would imagine that as the head of the Office of New Drugs, your personal -- your professional involvement in all of these NDAs and even in the OTC Switch Applications varies, and you're not equally involved in every single one of them. Is that fair to say?

A Yes, by all means.

Q And is it typical, for example, that if an NDA is approved, would you be the one to write the letter approving it, typically?

A No. I very rarely am the one that actually signs letters approving drugs. That responsibility is delegated in most cases to the Division Director, and in certain other cases it's delegated to the Office of New Drug Evaluation Director below me. I only rarely actually sign an

approval or a Non-Approval Letter.

Q And would the same be true -- I realize "rarely" doesn't maybe mean very much in this context, but in the OTC Switch Applications --

A Uh-huh.

Q -- would it also be the norm that that would, that the Action Letters on those would be at the Division or Office Director level?

A Yes. Most over-the-counter actions occur at the Division level. There are certain Actions; for example, novel switches or first in class switches are signed at the Office Director level, and we actually have a policy in place where it's a dual sign-off between the Office Director overseeing non-prescription products and the Office Director overseeing that therapeutic area. So in the case of Plan B, for example, the Office Director overseeing reproductive products and the Office Director overseeing non-prescription products had joint sign-off responsibility in our normal schema.

Q As you probably know, that normal schema

did not occur with respect to Plan B.

A Correct.

Q And so just following up on your question, do you know why that normal scheme did not take place with Plan B?

A It didn't take place in the normal pathway because we were directed that the decision be made at a higher level within the Center or within the Agency. So the direction was given to us by Dr. Galson that the decision would be made at his level or at the Commissioner's level.

Q Do you recall when you received that information?

A Yes.

Q When?

A It was at a meeting. I don't know the exact date. It was sometime after the Advisory Committee meeting, which I think was in December of 2003 if my memory is correct. It was sometime between the Advisory Committee meeting in December and early January, it may have even been during the week between Christmas and New Year's,

Dr. Galson, Dr. Woodcock, myself and Dr. Kweder had lunch together and it was at that meeting that Dr. Galson and Dr. Woodcock told us about the decision.

Q Did Dr. Galson, in telling you about that decision, explain why the decision -- tell me -- please tell me if I'm mischaracterizing what you said, but did he explain why the decision would be made either by him or even higher up than he was?

A As I recall, Dr. Woodcock and Dr. Galson were explaining the decision and the path forward essentially together. They described that Dr. McClellan, the Commissioner at the time, was not in favor of approving the Application and felt that the Application should not be approved on that cycle, so that's how they explained it.

Q So attending this meeting was yourself, Dr. Galson, Dr. Woodcock and Dr. Kweder; is that right?

A Dr. Kweder.

Q This was a sort of informal lunch

meeting?

A Right. We had lunch at a restaurant near our office.

Q Do you remember what, which restaurant it was at?

A I remember the restaurant. I can't recall the name off the top of my head. It's an Italian restaurant near the Parkline building that's fairly frequent for FDA staff to go to for lunch, but I don't remember the name.

Q When we were up at -- was that in Rockville?

A Yeah.

Q When we were up in Rockville for one of the depositions, I would have loved to have known about a good Italian restaurant nearby, but we can come back to that later.

A I don't know if I can characterize this as a "good" Italian restaurant.

Q Well, an Italian restaurant.

Okay. Would it surprise you to know -- and I'm not going to try to characterize someone

else's testimony, but suppose you found out that Dr. McClellan testified under oath that he never expressed a view about whether Plan B should be approved or not, would that surprise you?

A Yes.

Q Why?

A Because my memory of the meeting that I'm describing, the luncheon meeting, it was very clear that Dr. Woodcock and Dr. Galson were conveying Dr. McClellan's view on the Application.

Q Is it -- I'm trying to sort of understand how this decision came to be, and it sounds as if I guess maybe Dr. McClellan, the Commissioner of the FDA, convey to you about how the Application should be handled and that his view was then implemented by his subordinates essentially, is that right? Am I being, saying it too strongly?

A Well, the decision was implemented by some of the subordinates. I think you're well aware that many of the subordinates did not agree with the decision.

Q What I meant was Dr. McClellan expressed his view, and Dr. Woodcock and, well, let's say Dr. Galson implemented that.

A I think that's a fair characterization.

Q Thank you. Now, I may come back to some of this later. I hope I don't lose track of time, but anyway, are you also aware that there was a Citizen's Petition, maybe two citizens, but at least one Citizen's Petition filed, seeking over-the-counter switch for at the time two emergency contraceptive products?

A Yes, I was aware of that.

Q Are you aware that the Citizen's Petition was recently denied?

A Yes.

Q How did you find out that the Citizen's Petition was denied?

A I was told that it was going to be denied the day before the action was issued.

Q Was CDER, as far as you know, involved in the decision to deny the Citizen's Petition?

A I know that I was told by Jane Axelrad,

who is the Director of the Office of Regulatory Policy in CDER. I think I was also told in advance of the action by Dr. Galson. I don't know how much involvement they had in actually drafting the response, but they were aware, apparently, of the plan, and I know Ms. Axelrad told me about it the day before the Action issued.

Q Did they give -- did either Ms. Axelrad or Dr. Galson give you any indication of why the Citizen's Petition was being denied at the time it was being denied; in other words, why the decision was being issued at that time?

A Ms. Axelrad shared with me that she thought it was related to this pending litigation, and that the original basis for this litigation related to the Citizen Petition and that that was why it was being issued.

Q Do you know if anyone outside FDA was involved in the decision to deny the Citizen's Petition?

A I do not, no.

Q Do you agree with the denial of the

Citizen's Petition?

A I have not read the denial. I received a copy of it on the day it was issued. I printed it and it's sitting on my printer, so I have not read the basis for the denial, so I can't say whether I agree with the positions that were taken in that response or not.

Q Do you know if at some point you actually read the Citizen's Petition itself with its supporting documents?

A I'm sure I never did. I think the Citizen's Petition was actually submitted before I became Director of the Office of New Drugs, so I was aware that there was a petition. I do not normally read Citizen Petitions unless they are specifically sent to my office, asking me to comment or to assist in responding to the petition, even then most of those are delegated to my staff, and at most I might see their responses to the questions, but I rarely actually read the substance of Citizen's Petitions.

Q I'm going to ask you a very broad

question that you might feel is so broad that it can't be answered, so please let me know if that's the case. I would like you, if you can, to give an overview of your involvement in the FDA's handling of the Plan B SNDA up until the time of the issuance of the Non-Approvable Letter in May of 2004, sort of what, what was your role, what happened that you are aware of during that time.

A Right. I recall that I was involved in a meeting with the company sometime shortly after I became the Director of the Office of New Drugs. It may have been in 2002, may have been in 2003, I don't recall, but it was a meeting to discuss the plans for submission of the Supplemental Application. I seem to recall it was not long after I had become Director of the Office of New Drugs. After that meeting I heard about the planning for the submission and the upcoming submission periodically through my subordinate Office Directors and Division Directors. Through our regular meetings they would keep me updated.

Once the Application was submitted -- I

guess that was in the 2003 time frame? I was aware that it was submitted. I don't recall having any specific direct involvement in reviewing or discussing the Application until probably in the fall of that year when we had some internal discussions that I attended, and I think we may have had another meeting with the response, maybe a tele-con with the sponsor. There may have also been -- let me skip back for a second. I think there was also a briefing for Dr. Crawford, who was then the Acting Commissioner, sometime in this time frame that I attended. I don't recall exactly when that was.

Skipping forward, during the fall of 2003 when we were reviewing the Application, we had a meeting with the sponsor at the request of Dr. Woodcock to encourage the sponsor to submit what we called a -- I forget the title he used -- a marketing plan. A responsible marketing plan I think is how we characterized what we were encouraging them to submit as an addition to their pending Application, to address some of the issues

related to where the product would be sold, how it would be made available, what the educational materials would be.

Subsequent to that, I had the usual updates from my staff about the review of the Application, preparation for the Advisory Committee. I know we had a brief briefing from Dr. McClellan about a week or so before the Advisory Committee meeting. I attended the Advisory Committee meeting. As I said, after the Advisory Committee meeting at some point Dr. Woodcock and Dr. Galson gave us the direction about what the Action was going to be.

For the subsequent three or four months until we issued the action, my involvement was to work through the issues that were being raised as the basis for the non-approval of the Action. As you know, the staff sought out additional information from other studies about use in adolescents and young women. There were a series of internal meetings to discuss that information, and then when it came time for the actual Action

to take place, I wrote a memo, a summary review, as it were, stating my conclusions about the Application and my conclusions that it should be approved without age restrictions.

Q I want to go back to, if I can, to the point at which Dr. Woodcock and Dr. Galson conveyed Dr. McClellan's view of the Application.

A Uh-huh.

Q Did they convey to you why Dr. McClellan believed that it should not be approved?

A As I recall, the primary reason they conveyed was concern about use in young women. I don't recall if at that point they identified an age range, but the primary concern was the availability of the product over the counter for use in that younger age group.

Q Was there an opportunity, after you heard about Dr. McClellan's view, for you and the other scientists who work for you to go back to Dr. McClellan and say, look, your concern is unfounded?

A Yes. There was a subsequent briefing

from Dr. McClellan, I think it was probably in February of 2004, and the specific focus of that briefing was to go over what was available in the Application about use in younger age women and also what the staff had been able to uncover from literature reports and studies that they had gained access to about use of Plan B in that younger age set.

Q Was Dr. McClellan at that meeting?

A Yes.

Q Did he have a response to the information that was presented to him?

A I recall that he, you know, engaged in discussion about the data and the scientific merits of the data. I do not recall that he gave a definitive opinion by the end of the meeting.

Q At that meeting where the staff was presenting information to him, did they already -- they already knew that his view was that it should not be approved?

A Right. After Dr. Woodcock and Dr. Galson conveyed to me that the Action was

going to be non-approval, I suggested that they needed to meet with the Team, the Review Team, and convey that information so that they could explain to the Review Team the rationale and the path forward.

They did that sometime in January of 2004, and as part of that meeting, obviously the scientific staff were not pleased with the pathway this Application was taking, because it was not the usual path that before the reviews were completed and before lower level reviewers had reached their conclusions and made their recommendations, that we would get a direction that the Application was not to be approved. So they expressed frustration and concern that the decision was being made before the reviews were completed and before they had had a chance to try to address the basis for the non-approval, which was the use in underage women. I think that's the reason we subsequently had the briefing from Dr. McClellan in February was to give the staff a chance to present in more detail their analyses of

the data and to try to make the case that the data were adequate.

Q Do you have any idea how it would have been possible for Dr. McClellan to come to a view that the Application should not be approved before the scientific reviews were completed?

A I do not.

Q At this February meeting where the staff presented information to him, did you believe at the time that there was any realistic chance that he would change his view based on that information?

A I was not optimistic, no.

Q Are there particular reasons that you wouldn't have been optimistic? Seems to me like you felt strong -- maybe this is not right. Did you feel strongly that the scientific evidence supported over-the-counter approval for women of all ages?

A Yes.

Q And so I'm wondering why -- wouldn't that ordinarily make you feel optimistic that you

could persuade the Commissioner that it should be approved, or were there reasons --

A Ordinarily you would expect that in the scientific process you would have had that optimism that you could carry the day and sway the scientific conclusions. I think I was not optimistic going into the meeting, because we had already been told that the decision had been made not to approve the Application, so I wasn't very optimistic that we were going to be able to overcome a judgment that appeared to have already been made.

Q Do you know if that judgment by Dr. McClellan was made based on his comprehensive review of the SNDA that was submitted by Barr?

A I do not know the full basis of what he reviewed before he made his conclusions. As I said, there was a briefing for him shortly before the Advisory Committee. There would have been a briefing package, a summary of documents that he would have received. We had the discussion probably for an hour, hour and a half at that

briefing. He may have heard about some of the activities that occurred at the Advisory Committee meeting, but he did not attend. I'm quite certain that he did not actually review the Application itself.

Q If I recall correctly, the Advisory Committee sort of overwhelmingly supported over-the-counter. Is that your recollection as well?

A Yes. I think they voted 20 some to three, as I recall, for over-the-counter approval without age restriction.

Q It sounds as if within a matter of a couple weeks, maybe, after that, Dr. McClellan conveyed his view through Dr. Galson and Dr. Woodcock that it should not, in fact, be approved?

A That's correct.

Q Have you ever had anything happen in your whole tenure at the Agency sort of as strange as that?

A No.

Q It seems to me -- and tell me if this is fair to say -- that if the Advisory Committee has voted fairly strongly majority to make it over-the-counter without restriction, that the Commissioner would at least want to very carefully review everything possible before conveying a sort of determination to staff. Does that --

A That would seem reasonable. I think it's important to explain that for most applications the Commissioner's not directly involved in the decision-making of the Application, so for the Commissioner to convey through Dr. Galson a definitive opinion on the Application and an Action before the reviews were completed and before it had gone up through the subsequent levels of the organization is something I've never encountered before.

Q Do you have any idea why that happened?

A I don't have -- I only have speculation. I don't have any direct information other than what Dr. Galson and Dr. Woodcock told us at that meeting and at subsequent meetings where we

continued to discuss it.

Q I usually don't ask a witness to do this, but could you tell me what your speculation is.

MR. WARSHAWSKY: Objection.

MR. HELLER: I take it the objection is that it's speculation.

MR. WARSHAWSKY: The witness has just told you he has no knowledge. It's just speculation.

MR. HELLER: Well, I'd like to hear what his speculation is.

BY MR. HELLER:

Q If you would.

A I think many of us were very concerned that there were policy or political issues that came to play in the decision.

Q Would it be fair to say that a good proportion of the staff within CDER felt that there were political or policy considerations that had come into play with Plan B?

A I would not want to generalize as wide

as you just asked the question. I would say yes if the question were a good percentage of the people directly involved in the review of Plan B.

Q That many of them felt that there were political influences at work?

A Yes.

Q Okay. Would it surprise you or not surprise you to know that Dr. McClellan from time to time gave updates to the White House about the Plan B Application?

A No, it wouldn't surprise me.

Q Did you know that he had done that?

A No.

Q Would it surprise you in general if the Commissioner of the FDA gave updates to the White House about a particular New Drug Application that was pending?

A It wouldn't surprise me for very important applications that might have significant public health impact or particularly controversial issues. I'm not sure that I would normally expect the communication would go directly to the White

House, because the Commissioner I guess technically works for the Secretary of Health and Human Services, but I don't know how that chain of communication operates, but it wouldn't surprise me for the Commissioner to keep his boss informed about, you know, important issues, just as I keep Dr. Galson informed about important issues occurring in my office.

Q Would it surprise you to know that Dr. Galson testified that he was never given any direction from Dr. McClellan about what should be done with the Plan B SNDA?

A Yes.

Q Do you have any concern -- withdraw that question.

Oh, going back to Dr. Kweder, who was at the restaurant with you, is Dr. Kweder a man or a woman?

A A woman.

Q Is she still at the FDA?

A Yes, she is my Deputy Director for the Office of New Drugs.

Q Okay, thank you. To the extent that your speculation and I think that of others who were involved in the review process was that there was political influence in the Plan B process, can you describe a little bit further sort of what, what your speculation was, that it was political influence from where or in what direction.

MR. WARSHAWSKY: Objection. You're asking him to elaborate on his speculation?

MR. HELLER: Yeah, so I understand what the speculation is, okay.

MR. WARSHAWSKY: Okay.

THE WITNESS: Are you asking me to speculate on the reason for why I think there may have been political influence or any basis for reaching that conclusion?

BY MR. HELLER:

Q Well, let's maybe do both if you don't mind. The first -- do you think you had any reason to have that speculation in the first place?

A Well, I think we all knew all along that

this was going to be a controversial Application from a societal or political framework, because it involved emergency contraception and would raise issues that people might find that they had different views on from a societal or a moral or a religious perspective. We knew going in that there might be people who would raise the question about whether Plan B was abortifacient.

We had letters, as I recall, from members of Congress during the course of review of the Application raising concerns about access to Plan B over the counter without a prescription. So issues related to reproduction, we've learned, tend to be very controversial in our society, and those issues have impacted on us at the Agency in the sense that we at least are aware of them and may get pressure or people advising us one way or the other, based more on political or moral or ethical values than on the science of the Application.

Q Okay. When Dr. Woodcock and Dr. Galson

conveyed Commissioner McClellan's view to you, and Dr. Kweder, or any point after that, did they ever convey their own views about Dr. McClellan's determination?

A Yes, they did.

Q Can you tell me -- well, first of all, can you tell me roughly when, or maybe it was a span of time or --

A I don't recall having very many interactions in a private context with Dr. Woodcock after that meeting for lunch. She had -- we had interactions with her when she attended meetings, so most of my interactions were with Dr. Galson. Usually we had weekly meetings, and during those weekly meetings we would often discuss what was happening with Plan B, so it would have been in those discussions that he would have shared, you know, his perspectives about what Dr. McClellan's thinking was or why he may have reached the conclusions that he was transmitting.

Q Can you convey or can you tell me what Dr. Galson said about Dr. McClellan's

determination.

A You know, I can't give you exact words, because it's been a while and there were a series of conversations, but I clearly recall that Dr. Galson felt that there were political issues that played into the decision not to approve it for the underage population on that first cycle, so he never specifically highlighted any particular political aspect of the Application, as I recall, and in fact, I recall him being very clear that Dr. McClellan seemed to be very careful not to convey that sense. It was kind of a derived understanding, I think, that Dr. Galson had versus a direct communication that Dr. McClellan had shared, that it was a political consideration as well.

Q Did Dr. Galson ever indicate to you or convey to you disagreement with the determination that Dr. McClellan had made?

A I do not believe that he agreed with the position initially, so as I recall, when Dr. Woodcock and Dr. Galson shared with us the

plan for the Application not to be approved, I don't believe at that time that they concurred that that was the action that should occur for the Application. I think over time he apparently became comfortable that it was the right decision, because he did write his own review stating his conclusions about why it was not safe to approve for that underage population.

Q Are you and Dr. Galson on a first-name basis?

A Yes.

Q I'm just trying to imagine the conversation.

A Dr. Galson is my direct supervisor. We meet on a very frequent basis and have a good working relationship.

Q And typically these, I think you said weekly meetings during this period that we're talking about, let's say December of 2003 to May of 2004, might -- the subject of Plan B came up frequently?

A Yes.

Q Other than conveying the determination that Dr. McClellan had made and sort of expressing to you his views about that determination, what did these weekly or roughly weekly -- what was said at these roughly weekly meetings about Plan B? Was there a discussion of science? Was it a discussion of how you were going to proceed?

A The discussions were on multiple tracks. There were discussions about, you know, getting the business done and completing the review of the Application and issuing the Action Letter, so there were the mechanics of actually working our way through the process. I think as you recall, there was an extension of the review clock in response to some additional information that was submitted by the sponsor, so we had discussions about making plans to extend the review clock and reviewing that new information.

We talked about seeking legal input from the Office of Chief Counsel about the legality of the proposal that Barr submitted during the first cycle review about a dual marketing status. We

talked about planning for who was going to write the letter and how that would be handled, whether he would sign it, whether I was comfortable signing it. We talked about why the action had to be a Non-Approvable Action instead of an Approvable Action. So we had multiple facets of conversation as part of trying to better understand the decisions on the Application as new information was coming in and new proposals came in from the sponsor, and we also had discussions about the logistics of us getting through the work.

Q The one subject you mentioned was approvable versus non-approvable.

A Right.

Q Can you tell me about that discussion. What was that like?

A I, I questioned why, if we were not going to approve it on the first cycle, it had to be a Non-Approvable Letter. It seemed to me that it could have easily fit into our definition of "approvable," and Dr. Galson shared with me

that -- and this is -- I took from him that he had gotten this word from Dr. McClellan, was that it needed to be a Non-Approvable Action to show that we were taking a tough stand on this issue.

Q I have to ask you -- because you're giving me a lot of information that I had not heard before -- do you have any concern that your testimony in this case puts your position at the FDA in any jeopardy?

A No.

Q And you have a good working relationship with Dr. Galson?

A Yes.

Q Despite occasional disagreements, I take it.

A We clearly do not agree on this Application, but we continue to have an excellent working relationship on, you know, other matters, and, you know, as is typical of the professional staff at FDA, even though we did not agree with this decision, we did the work to complete the Application review and to complete the Action even

though we didn't agree.

Q And even though you sort of knew that it was to some degree an exercise in futility, because the decision had been made?

A Right, but also people felt an expectation that they would do their job, so they completed their work by completing their reviews. I think also people wanted to make very clear on the record how they reached their conclusions about the safety and effectiveness of Plan B for over-the-counter use and how they disagreed with the rationale and the reasons that were being given for the Non-Approvable Action.

Q Going back again -- I'm sorry to bring you back to this again, but this is the first time I've heard of it, of the meeting in which Dr. Galson and Dr. Woodcock conveyed Dr. McClellan's determination.

A Uh-huh.

Q And I think you said that you believed that initially Dr. Galson and Dr. Woodcock didn't concur with that determination. What led you to

believe that they didn't concur in it?

A The conversation -- again I don't remember the specific words, but the conversation at lunch was clearly that they were bringing us bad news, and we needed to map out a plan of how we were going to go forward with the, you know, the review of the Application, how we were going to communicate this to the staff, how we would mitigate the staff's concern that, you know, the decision would be made at a higher level before they had a chance to complete the reviews and go through the normal process, so I clearly did not get the sense at that meeting that they agreed with the decision, or they would have made the decision themselves had they not received input from Dr. McClellan.

Q In about March or April of 2004 Dr. McClellan left the FDA, and Dr. Crawford I think became the Acting Commissioner.

A Right.

Q Do you know if there was -- I mean at that point did you have any reason to believe,

well, now we have a new Commissioner or new Acting Commissioner, maybe the position has changed now and we can get Dr. Crawford to sort of review this afresh and sort of withdraw Dr. McClellan's determination?

A I recall that some of us had a glimmer of hope that someone new looking at it, that there might be a different pathway forward, but we also recognized that Dr. Crawford had been the Deputy Commissioner during the time that Dr. McClellan was Commissioner, so that's why I would characterize it as a "glimmer" of hope.

Q Do you recall any information -- did you actually ever receive any information through any channels that, no, Dr. Crawford is taking the same position as Dr. McClellan?

A I'm sure that Dr. Galson and I discussed it around the time that Dr. McClellan was leaving and Dr. Crawford was becoming Acting Commissioner again. I can't recall a specific conversation, but I'm sure I would have asked him about does this change anything, are we still continuing

forward on the same path.

Q And you presumably said it doesn't change anything?

A As I recall, nothing changed from the path that we were already on. Probably by that time we were looking at the proposal that Barr had submitted about the dual marketing. I would think it was around that time we were probably considering that, but I don't think that we got the sense that anything was changing in the path we were on toward issuing a Non-Approvable Letter.

Q With specific reference to Dr. Woodcock, do you know at what point she came to concur in the decision that the Action should be a Non-Approvable Letter?

A I do not know when she specifically came to concur, because, as I said earlier, most of the interactions after that luncheon meeting were with Dr. Galson, because Dr. Woodcock was the -- she was on a detail as being Acting Deputy Commissioner, I believe, at the time, so Dr. Galson was running the day-to-day operations

of the Center, Dr. Woodcock came to some of the meetings, but I had -- I don't recall having individual conversations with her.

Q In I think April 22, 2004 -- I may have the wrong date -- you finalized your Memorandum --

A Right.

Q -- on Plan B, and I may go through it in a little bit of detail in a little while, but I want to ask you first: Do you know if -- did you ever receive a response to sort of from Dr. Galson or someone higher up saying either "good job" or "oh, come on now, give up," or something of that nature? I mean did anything like that take place?

A No, not that I recall. I completed the review. I submitted it to our electronic archival file system so it became part of the Action Package, so I know that Dr. Galson had access to it. He wrote his review. I do not recall that he shared his review with me before he finalized it, so there was really no substantive discussion, after I wrote my review, of the content.

Q Would it surprise you to learn that

Dr. Galson testified that it was his decision, solely his decision that the letter should be a Non-Approvable Letter rather than Approvable Letter?

A Yes, but I would probably need to explain that a little bit. Definitely I'd find that surprising from December of 2003. I did get the sense over time that Dr. Galson seemed to move toward the position where he seemed to agree on the issues related to use in underage women.

Q Do you know anything about why Dr. Galson moved in that direction? Sort of was it -- there could be a variety of reasons. I mean one could be, for example, Dr. McClellan could have said to him, "well, if you don't agree, you're fired" --

A Uh-huh.

Q -- or, you know, "don't stand in the way of this" or "if you want to continue to be acting head of CDER, you better do what I say." There's a whole -- or it could have been frequent meetings with Dr. McClellan where they discussed the

science and Dr. Galson was persuaded by the science. Do you have any sense of what it was that moved him from maybe the initial non-concurrence with Dr. McClellan's view to the very sort of public concurrence with Dr. McClellan's view in the May 6th letter?

A Uh-huh. I got the sense that he didn't feel he had a voice.

Q In the ordinary course of events, if you had been involved in this particular OTC switch -- would you be involved in most OTC switches? You said there were only about five, but . . .

A There's generally about five to ten a year.

Q Okay. Would you be involved in all of those?

A Almost never, because, as I described earlier, the delegation of responsibility for signatory authority for almost all applications -- well, I should say all applications, the delegation is to my Division Directors or my Office Directors. The sign-off actually only

comes to me -- when there are disagreements at levels below me that cannot be resolved, then it comes to me for adjudication and I make the decision.

Q Assuming that this is an unusual case, and which it came to you for some other reason, but it had come up to you, this OTC switch, and you had analyzed what the reviewers' work had been and done your own analysis if necessary; if you had reached the views expressed in your April 2004 Memo and had not been told what the determination would be, would you have then gone ahead and just approved it yourself?

A There's a lot of "ifs" in there that make it a little bit hard to follow the question. I need to back up and say, had there -- the way we normally handle OTC Switch Applications, the sign-off is at the Office Director level. It's a joint sign-off, so if the two Office Directors responsible agree on the Action, they would keep me aware of where they're headed with the decision, but my involvement would have been

fairly minimal, and I would never have been involved in signing the letter or even crafting the letter. It would only be in a situation where they were not able to agree on the Action, that it would come to me for me to make the decision.

Going back to your question for a second, in that usual paradigm they go forward and approve the Application. Again they let me know what they're planning on doing, and I guess if I had a serious concern that I didn't think they were addressing, I would meet with them and work with them to sort through how they're handling that question, but normally the approvals occur at the Division or ODE Director level.

Q With respect to the Plan B SNDA, other than the determination made by Dr. McClellan, was there any reason that you're aware that this should, this Application should not have simply been handled at the ODE level the way other OTC switches would have been handled?

A No.

Q Plan B, for example, is not a very

dangerous drug that carries huge threats to life and limb? Let me withdraw that question, because it's calling for a comparison that is not fair for me to ask, because you really need to compare it to another drug, and drugs are very different, but let me ask you this: Is there anything unique about Plan B that, from a scientific perspective, required it to be handled by a process that I think you've described as "unusual"?

A I don't think there's anything unique about the science or the clinical trials or the data that were submitted in the Application. I think the unique aspect of Plan B related to the indication that was being sought, and some of the issues that come into play are related to reproductive drugs, contraceptives, particularly in the over-the-counter setting.

Q I think you said this earlier, but I just want to make sure I understood it correctly. Dr. Galson wrote I think a memo dated May 6, 2004 --

A Uh-huh.

Q -- internally, describing the reasons for his issuance of the Non-Approvable Letter. That memo that he wrote, had you seen earlier drafts of that?

A No.

Q Do you know if there was a reason that he would -- I mean it sounds like you were having these regular discussions of Plan B. Was it strange that he didn't say, "here, look over my draft of my member memo," or would that be just because he does it privately and --

A Well, the situation has never occurred before, so it's hard to say whether it was strange in the sense that was it deviation from his normal practice. I can say that my normal practice is -- in this situation to where I'm called upon to make the decision, I routinely share my draft review or my draft decisions with my subordinate staff to give them a chance to help me make sure that I've gotten things correct and that maybe the arguments I'm making are valid, so I think I shared my review with others on the Team before I completed

it to see if they had any comments, but I can't be sure of that.

Q I'm going to try to locate your memo now, but it may take a moment, and I'll give you a copy of it.

So I've given you a copy of a document that's marked at the bottom with the stamp Tummino 30897, and it ends at 30900. Do you recognize this as your memo regarding Plan B?

A Yes.

Q I have some specific questions about it, and if I mischaracterize scientific statements in here, please stop me, because I want to avoid doing that.

First of all, tell me if this is not a fair question. Do you -- have you seen any scientific or medical information since you wrote this memo that would change the opinions you expressed in this?

A No.

Q And so you still hold these opinions; is that fair to say?

A Yes.

Q On the first page, sort of maybe in the second full paragraph towards the end, there's a statement that says, "The data submitted by the sponsor in support of non-prescription use of Plan B are fully consistent with the Agency's usual standards for meeting the criteria for determining that a product is appropriate for such use."

If that is the case, do you know why the data was deemed inadequate by Dr. Galson?

A Uh-huh. Well, first I should say part of this is referencing the fact that the data submitted by the sponsor meet the criteria of the types of studies we're looking for, so part of this is referencing the fact that they had submitted an Actual Use Study, a Label Comprehension Study, you know, a review of the literature, so some of this goes to the fact that they had submitted an adequate Application.

I think the rest of this goes to a conclusion reached about whether, in reviewing those data, that they were adequate to show that

the product could be used safely and effectively in the over-the-counter setting without a learned intermediary, so this sentence encompasses both an assessment of the technical adequacy of the Application as well as my conclusion, based on my review and interpretation of the data, so clearly there's a judgment element in both those categories, so it would be possible that someone else could look at the same set of data and come to a different conclusion.

Q Okay. Would you say that within the Office of New Drugs, insofar as people were familiar with the Plan B Application, there was consensus that it should be approved?

A I, I would say yes to the term "consensus," although I know that there was one primary reviewer in the Non-prescription Division who I think recommended that the Application was approvable and raised some concerns.

Q Is that person still at FDA; do you know?

A As far as I know, the answer is yes, but

I don't know that for certain.

Q Do you know if that person is still in the Office of New Drugs?

A I do not know for certain, no.

Q Was that Dr. Chen?

A Yes.

Q Do you know if Dr. Chen continued to hold that view later on as the Application continued to be reviewed?

A I do not know -- I have not directly interfaced with Dr. Chen to discuss those views. I'm familiar with the review that was written, and I am embarrassed to say I'm not sure if that's a man or a woman. I think it's a man, if I'm not mistaken, and I'm pretty sure he attended some of the internal meetings and expressed some of his thoughts.

Q Do you know if FDA ever consulted with outside experts in its review of the Plan B SNDA?

A Well, of course, we consulted with the Advisory Committee.

Q Aside from the Advisory Committee, which

is known.

A I don't recall consulting with other outside experts. We sometimes do consult with outside experts that we have on a roster called "Special Government Employees," so it's possible that the Division consulted with some SGEs. I know that during the time course toward the end of the first cycle that the staff sought out information from other studies that might address the under-age issue. Some of that I think occurred through telephone conversations with investigators who were either conducting studies, had completed studies, so that probably fall into your umbrella, so yes.

Q But at this point you don't recall any particular names of people, who they might have contacted who were investigators or --

A I recall the name of a Dr. Raines coming up as someone who had done a study that came into focus as we were looking at the issue during the first cycle. I know there were other investigators that they were looking at, either

manuscripts that had been submitted or publications that they were aware of, but Dr. Raines' name is the only one that comes to mind, and I have to say I think it comes to mind because I saw it in the transcript of one of the other depositions. It's not something that I normally would have remembered.

Q Okay, thank you.

If you wouldn't mind turning to the second page of your Memorandum --

A Uh-huh.

Q -- the second or I guess the first full paragraph, last sentence, I think you're describing some additional studies that staff reviewed, and I think your last sentence is, "Further, these studies found that increased access for adolescents to emergency contraception did not result in inappropriate use of Plan B as a routine form of contraception, an increase in the number of sexual partners, an increase in the frequency of unprotected intercourse, or an increase in the frequency of sexually transmitted

diseases."

Do I understand correctly that in this sentence you're referring to studies that were gathered by the staff in your office other than the ones that were submitted by the sponsor, or is it studies that -- is it studies submitted by the sponsor and other studies?

A Right. I would go back to the earlier part of the paragraph where I say, "In addition to the studies submitted by the sponsor, there exists a substantial body of data from recently completed published and unpublished studies on emergency contraception that have enrolled a substantial number of adolescent women." So I think I was saying that the sponsor had submitted the studies they conducted, but in addition there were other data that the staff had reviewed, specifically Drs. Griebel and Rosebraugh in their reviews, that addressed this issue.

Q Did you review any of those studies yourself; do you recall?

A No.

Q So you reviewed the summaries of studies that they might have provided to you?

A I heard presentations by them in meetings where they describe the studies, and we had a scientific give-and-take about the study designs and the findings and conclusions, and then I read the review of the studies that they included in their actual reviews, so I -- but I don't think I personally read the manuscripts myself.

Q Do you know of any contrary studies; in other words, of any studies, for example, showing that increased access for adolescents to emergency contraception does result in inappropriate use as a routine form of contraception or does result in an increase in frequency of unprotected intercourse and so forth?

A I'm not aware of any studies that demonstrate that.

Q After you wrote this memo, did you continue to sort of keep yourself aware of the literature on Plan B at all?

A Only to the extent that my staff would make me aware of any new developments. I think at the time that this Memorandum was written, some of the studies were unpublished and the staff had gotten pre-publication copies, so I believe they may be aware when those studies were actually published in the literature at a later date, but I do not personally scan the literature in this area as part of my routine, keeping up with the literature.

* * * * *

(The portion of the transcript from Page 64, Line 17, through Page 66, Line 11, has been marked confidential and has been redacted and included in a separate transcript called "Protected Testimony" and designated Number 1.)

* * * * *

MR. HELLER: Okay.

BY MR. HELLER:

Q Further on on that page, the last paragraph that starts on that page starts with, with the sentence, "I am sensitive to and respect the concerns that some may have regarding non-prescription access to Plan B by adolescents. Products that are indicated for use as related to sexual activity in adolescents raise concerns for some people that go beyond a finding based on

clinical trial data that the product is safe and effective for its intended use in adolescents, but it goes on further, but my first question about this is: In talking about concerns that some people might have, are you talking about people outside FDA, inside FDA or both?

A Probably both. We heard these types of questions raised at the Advisory Committee. These types of questions were raised in the various letters we received, including letters from Congress. You know, they were the subject of discussions that we had internally trying to understand what the concerns were about access for younger women. So I would say it was both internal and external individuals who raised these concerns.

Q Were any of the internal people who raised these concerns sort of upper management people above you?

A I know that there was a comment that Dr. Woodcock made at one of the meetings where she expressed a concern about Plan B potentially

becoming a cult drug among teenagers where it might be abused and lead to inappropriate behavior. I don't recall if Dr. Galson ever expressed similar concerns or not. I also do not recall that Dr. McClellan ever expressed those in the two meetings that we had with him.

Q Were you at that meeting or at a meeting where Dr. Woodcock expressed what you just described?

A Yes.

Q You then go on to say that "these concerns are derived from individual views and attitudes about the morality of adolescent sexual behavior and also overlap with concerns about the role for parents and health care professionals in decisions about contraceptive use in adolescents." Do you know if there were -- if people who had a role in the decision making about it, about Plan B, were making decisions in part on the basis of their attitudes about morality of adolescent sexual behavior?

A I do not know if that factored into

their decision-making. I think what I'm responding to here is that we heard from various parties along the way, as we were reviewing this Application, concerns about adolescent sexual behavior, of whether access to this type of contraceptive might lead teenagers to be more prone to engage in sexual behavior, because they had a "rescue" mechanism, so to speak, you know.

Most of the other forms of contraception require pre-planning; in other words, you need to have a condom at the time of sexual intercourse or a diaphragm or spermicidal jelly. This one you could take the day after, and I think that raised concerns for some people that we heard that it would lessen the barriers that might be in place between girls deciding to engage in sexual intercourse and not engaging because they would have a "back-stop," so to speak, to protect them.

Q Did anyone -- this that you just mentioned, the comment about a "back-stop" to protect them, were these comments from people within FDA?

A I think we discussed these. I don't know that I can say that people in FDA held these views as reasons to be concerned about over-the-counter access. They were things that we were aware of that others were raising, and going back to what I said earlier, I think it's part of the reason that Dr. Woodcock suggested, during the review of the Application in the fall of 2003, that we encourage the company to submit a responsible marketing plan, because I think she wanted to try to address some of these concerns prospectively; for example, by not having Plan B sold at the 7-11 beside the candy bars.

I think she was hoping the company would adopt an approach where it would only be sold in pharmacies where is there would be a pharmacist available to consult if needed if needed. At that time I do not think she was describing a behind-the-counter scenario. I think it was more trying to address concern people might have if their young daughters could go into 7-11 and buy Plan B off the shelf.

Q I knew you said you hadn't reviewed the Citizen's Petition, but do you have any idea who, what organizations were involved in the Citizen's Petition?

A Um --

Q I'll give you an example. Did you know that the American Public Health Association was one of the petitioners?

A No.

Q Does it surprise you that they were?

A Um, no.

Q Are you aware that the American College of Obstetricians and Gynecologists supports over-the-counter access for emergency contraception?

A Yes.

Q Does that surprise you?

A No.

Q Isn't it fair to say that -- I mean in general an obstetrician or gynecologist would be one specialist who a woman might go to to get a prescription for Plan B --

A Yes.

Q -- and, and that the American -- do you have -- do you view the American College of Obstetricians and Gynecologists as an association of experts in obstetrics and gynecology?

A Yes.

Q So it would be sort of surprising if they supported over-the-counter availability if it were inappropriate for over-the-counter use?

MR. WARSHAWSKY: Objection.

BY MR. HELLER:

Q Well, I'll withdraw that question.

A Okay.

Q I have I think just one more question about this document that we have in front of us on the last page -- well, the last page of text, sort of maybe the tenth line from the bottom, you're starting to talk about a dual marketing proposal, and you say, "This proposal has undergone preliminary review by the Office of Regulatory Policy in CDER, and it appears that it may be feasible under the current statute and

regulations; however, a formal review by the Office of Chief Counsel has not" -- I guess "has not been completed."

A Right.

Q Do you know if the -- was there a formal review by the Office of Chief Counsel that you know of?

A It was reviewed by the Office of Chief Counsel. I have never seen a written review generated by them with their conclusions.

Q Do you know if there ever was even a conclusion by the Office of Chief Counsel?

A I do not know that there was ever a conclusion on this issue by the office of Chief Counsel. There certainly, to my knowledge, was not a written conclusion, and I would speculate that given the decision to do the Advance Notice of Proposed Rule-Making, which in some ways was related to this issue, that maybe they never did reach a final decision, but I'm not privy to what decisions they may have reached on this issue.

* * * * *

(The portion of the transcript on Page 74, Lines 6 - 20, has been marked confidential and has been redacted and included in a separate transcript called "Protected Testimony" and designated Number 2.)

* * * * *

MR. WARSHAWSKY: If we're done with this

document, is now a good time to maybe take a few minute break?

THE WITNESS: Yeah, that would be helpful.

MR. HELLER: Five or ten minutes, that would be great.

THE VIDEOGRAPHER: We are going off the record. The time is 3:03 p.m.

(Whereupon, a short recess was taken.)

THE VIDEOGRAPHER: We are back on the record. The time is 3:27 p.m.

BY MR. HELLER:

Q Dr. Jenkins, good afternoon again.

A Good afternoon.

Q Do you know if there are any other countries in which the emergency contraceptive product that is called Plan B in the United States is available over the counter?

A I believe there are. I actually just saw reports today about Canada and over-the-counter sales of Plan B, so I'm pretty certain that there are other countries around the

world where it's, it's over-the-counter. The only hesitancy I give is that there are different definitions around the world about what we mean by "over-the-counter" versus what it might mean without a prescription. In some countries it means without a prescription, meaning you can go to the pharmacist and they can give you access to it, versus in our country "over-the-counter" means literally it's on the shelf, and you pick it up and you don't have to interface with anyone.

Q As a matter sort of I guess what I would call "scientific inference," if you had evidence that in countries in which Plan B was available without a prescription either by in the sort of behind-the-counter-with-the-pharmacist or on-the-shelf, that in those countries there had been -- if you had studies showing that there had been no untoward effects on adolescents having such access, would that tend to confirm your conclusion that it should be available over the counter in United States?

MR. WARSHAWSKY: Objection. The

question is vague and assumes certain facts that are either not defined or not in evidence.

MR. HELLER: I guess it was partly a hypothetical question.

MR. WARSHAWSKY: "Untoward" and words like that that I think make it sort of --

MR. HELLER: "Bad" instead of "untoward." Bad effects.

BY MR. HELLER:

Q Do you understand my question?

A I think you're asking whether we look at experiences of other countries as part of our review of Applications, and the answer would be yes. In fact, the Application itself may have included information about what other countries' emergency contraception was available without a prescription, may have included any studies that had been done in those countries, and we would certainly consider that to be relevant, supportive information, and we would want to look at that.

* * * * *

(The portion of the transcript on Page 78, Line 6, through Page 80, Line 7, has been marked confidential and has been redacted and included in a separate transcript called "Protected Testimony" and designated Number 3.)

* * * * *

BY MR. HELLER:

Q Did you after May of 2004, as this process unfolded, did you continue to have regular meetings with Dr. Galson about the process?

A We definitely had our regular weekly or every-other-week meeting as part of our normal course of doing business, and Plan B was frequently a topic that we discussed at those meetings. I'm having trouble recalling if we had any specific like internal team meetings of a broader group, and I'm also having trouble recalling if we met with a company or if we may have done much of that communication after the letter through telephone conversations, but I

definitely continued to discuss the progress of the Application, plans for completing the review with Dr. Galson during the second cycle.

Q Am I correct that within the Office of New Drugs, the reviewing staff all recommended, even after May in the second cycle, that they recommended OTC approval for all ages?

A Your question is probably a little bit broad. I think the people involved in the Review Team, the supervisory level staff clearly wrote memos in the second cycle, continuing to believe that it should be approved over-the-counter without age restriction. I don't recall that anyone specifically advocated for the dual status approach. Many of us raised questions about the dual status approach, but I can't say for certain that everyone, you know, continued to advocate for approval without restrictions.

Q So I think now I have located your second Memorandum, dated January 14, 2005, and it's marked at the bottom Tummino 31095 through 31099, and do you recognize that, the document I

gave you as being --

A Yes.

Q Okay. So I have some questions about this. My first question is, sir, it seemed to me when I was reviewing the Administrative Record, that between May of 2004 and your memo, there were other memos written by your subordinates, and that those then contributed to your review in January of 2005. Is that basically correct?

A That's correct. Could I take a few minutes to actually refresh my memory by reading this, or are you going to ask specific questions?

Q Yeah, I'm going to ask specific questions. You can please take time to read it over if you'd like. That's fine.

A Because I'm not sure --

Q Actually, before you start reading, I have a more general question that you won't need to read this for. What I'm wondering about is, do you know -- sir, in the first cycle, you wrote your memo on I think April 22nd, and then Dr. Galson wrote his memo on May 5th or 6th. It

was a fairly short time interval between them.

A Right.

Q You wrote your memo on January 14th. His memo did not come until August 2005.

A Uh-huh.

Q Do you know why there was I guess a seven-month period there between those two?

A I don't know specifically. I know that I wrote my memo in January of 2005, because we were facing the user fee due date for the Application. I don't remember the specific date. It may actually be in here somewhere. Once the company resubmitted the Application, we had a six-month clock that we were expected to complete our review, and we tried to honor that in almost all cases. So I was writing this memo in time to give Dr. Galson time to see my conclusions and to do his review of the Action Package in time to meet the PDUFA goal date.

Q But by this time was it clear that the decision in the second cycle was going to be made by Dr. Galson?

A That was always clear from the first cycle, because he had made the decision in the first cycle. I didn't concur with the decision, and one of the nice things about working at FDA is that if you don't agree with a decision, you don't have to sign off on the, the Action. So given that my position did not change during the second cycle, I never anticipated that I would be signing the Action.

Q Okay, great. Now, thank you for answering those sort of general questions. If you want to take a few questions to read through this --

A Yeah, let me refresh my memory, because it's been a while since I wrote this.

Okay.

Q Thank you, Dr. Jenkins, and so I think I'm about -- well, I shouldn't promise anything. I have a few questions about this.

On the first page of your memo, the second paragraph, second sentence, Dr. Galson stated that, "Adolescence is a time of rapid and

profound physical and emotional change, including the emergence of impulsive behavior without the cognitive ability to perceive the etiology of the impulsive behavior in early adolescence." And it goes on about the sort of general ability of adolescents to think abstractly and integrate cognitive skills into their real life experiences and so forth. And he therefore concluded that "Because of these large developmental differences, I believe it is very difficult to extrapolate data on behavior from older ages to younger ages."

A Uh-huh.

Q So I have a few questions about this. One is: The statements about adolescents that Dr. Galson made and that you describe here, would they not be relevant to the use of any drug by an adolescent without the benefit of the guidance of a learned intermediary?

A I believe they would.

Q And so these "large developmental differences" that you refer to -- and I'm not asking you to say whether they really are large or

small, but the developmental differences that exist between adolescents and adults, that's a factor that comes into play for access to all drugs for adolescents in some sense; is that right?

A Yes, and I actually address that later in the Memo where I express some of my concerns about the dual approach pathway and the policy issues that raises for other products.

Q With respect to Dr. Galson's comment about "given these developmental differences," he thinks it's "very difficult to extrapolate data," doesn't the FDA, and in particular your office, often extrapolate from one age group to another when the data, for one reason or another, is not there for the other age group?

A We do.

Q And in particular are there over-the-counter switches that have been approved even though there was a complete absence of data for young adolescents, for example?

A I can't speak to that directly, because

I'd have to go back and look at the data that were available in the OTC Switch Applications. I can say that I don't recall this issue ever having come up previously in an OTC Switch Application about the ability of the adolescent or the younger group to understand and follow the directions appropriately for the product.

Q Do you know if it has come up since this time with OTC Switch Applicants?

A It has.

Q It has? With several of them?

A One in particular that I'm familiar with that it came up, and I probably cannot discuss any details about the Application other than to say that it has come up for another Application.

Q So for one other that you're aware of?

A That I'm aware of, yes.

Q Can you tell me what type of drug it is.

A Probably not. I'd have to confer with my --

MS. SCHIFTER: It says "Unapproved Application."

THE WITNESS: Unapproved Application.

MS. SCHIFTER: No information that would help identify it at all.

THE WITNESS: Right, so . . .

BY MR. HELLER:

Q Do you know how recently this similar concern with respect to this other pending Application was raised?

A In the last six months.

Q And do you know; was it raised by people within your office at the Office of New Drugs?

A Yes. It was also raised by myself.

Q And with respect to this drug that I don't want you to identify at this point, is there something about the drug that leads you or others to believe that the developmental differences would play a role for that drug whereas it might not for others?

A We were not aware of any concerns in that area. The reason we raised the issue was to try to see where it fit into the Plan B paradigm. We were aware that the pathway the Agency had

taken on Plan B raising this issue about adequate data and ability of adolescents to safely and effectively use a drug without a learned intermediary, and this was probably the first subsequent major OTC Switch Application that we had faced, and we needed to try to understand how we should apply these principles that the Agency had adopted in Plan B to the subsequent case, so that's why we raised the issue to Dr. Galson and to the Office of Chief Counsel.

Q And in this pending Application, was it concluded that the data was inadequate for adolescents, as Dr. Galson concluded for Plan B?

MR. WARSHAWSKY: We're going to have to object to that. Now you're talking about specific data involving a pending Application.

MR. HELLER: I just want to say, I absolutely understand the need to respect the confidentiality of some drug manufacturer. We may seek to get answers to some of these questions. It doesn't have to be from Dr. Jenkins but from the defendant at some point, but I want to sort of

just let you know for the record that I think it's important in what Dr. Jenkins has said.

BY MR. HELLER:

Q Do you know, can you tell me whether Dr. Galson has the same concerns about this other drug that he had about Plan B?

MR. WARSHAWSKY: I'm going to have to object to that as well.

THE WITNESS: And I feel uncomfortable answering those questions because of the fact that it's a pending Application, and, you know, until we have made an approval decision on an Application, it's confidential information, so I just feel uncomfortable getting into the details of the discussion about that Application, but I felt that it was acceptable to let you know that the question has come up subsequently, essentially, of how to apply the Plan B principle to subsequent OTC switch, since we have not had this Agency principle or Agency policy articulated in the past, Plan B occurred and established that policy or principle, it's likely that we will have

to consider the implications of that for all subsequent OTC switches, particularly until we get a better understanding of how the Plan B situation resolves itself.

BY MR. HELLER:

Q Would you have raised the issue you're just talking about if there had not been the Plan B "precedent," so to speak?

A Hard to answer that question.

MR. WARSHAWSKY: Objection.

THE WITNESS: What I would say is that we had not raised this issue prior to Plan B for any other over-the-counter switch that I'm aware of, so prior to Plan B we did not have this policy or this precedent that we needed to take into consideration. As you're probably familiar, there are lots of over-the-counter products that have on their labeling "under a certain age, ask a doctor" or "not for use under a certain age."

BY MR. HELLER:

Q Okay. If you'd turn to the second page of your memo, the paragraph starting, "I continue

to believe" --

A Yes.

Q -- in the middle of the paragraph you say, "I therefore support approval of Plan B as an OTC emergency contraceptive without an age restriction and believe that the sponsor's proposal for dual marketing of Plan B as both a prescription and non-prescription drug should not be approved." Is that still your opinion?

A Yes. The dual marketing approach should not be approved. My view is that the Application should be approved without age restriction.

Q Is it your view that -- maybe you don't know the answer to this -- that the FDA has the authority to approve it over-the-counter without age restriction, even though right now or as of, I guess, sometime in 2004, the manufacturer asked for approval with an age restriction; do you know?

MR. WARSHAWSKY: I'm going to object. I just think the question was a little unclear. I think I know what you meant, but . . .

* * * * *

(The portion of the transcript from Page 93, Line 6, through Page 94, Line 14, has been marked confidential and has been redacted and included in a separate transcript called "Protected Testimony" and designated Number 4.)

* * * * *

BY MR. HELLER:

Q Further down on the same page, I guess the last sentence that starts on that page, says, "Further, I believe that it is entirely reasonable to extrapolate the findings from the older women in these trials to adolescents, given well-established Agency precedent for extrapolating

data from studies in adults and older adolescents to young adolescents, and there was no fact-based data that younger women were less able to use the product correctly in a simulated OTC setting than older women."

A Right.

Q And that's still your view?

A Yes. The standard as we apply to review an OTC Switch Application is, can -- is the product safe and effective for use in the over-the-counter setting without a learned intermediary, so turning that around, can consumers use the product safely and effectively based on the information that's on the labeling without need to interface with a physician or a pharmacist, and I believe they can. The data I saw from the Actual Use Study and the Label Comprehension Study did not suggest to me that there was any substantial difference between the older women and the younger women, and I continue to hold that view.

* * * * *

(The portion of the transcript from Page 96, Line 6, through Page 97, Line 21, has been marked confidential and has been redacted and included in a separate transcript called "Protected Testimony" and designated Number 5.)

* * * * *

(The portion of the transcript from Page 98, Line 6, through Page 99, Line 11, has been marked confidential and has been redacted and included in a separate transcript called "Protected Testimony" and designated Number 6.)

* * * * *

BY MR. HELLER:

Q In the next paragraph in your memo, the second sentence says, "In my opinion, the concerns Dr. Galson raises are more applicable to the ability of adolescents to make reasoned decisions about engaging in sexual intercourse, not their ability to understand how to use Plan B safely and effectively as an emergency contraceptive should they engage in unprotected sexual intercourse."

Could you explain that a little bit

more. What do you -- what do you mean about the concerns being more applicable to the decision about?

A Well, I go on to expand on that in the rest of the paragraph, but basically what we were trying to determine was can the likely users of the product follow directions, dose the product appropriately, understand when they're supposed to use the product, understand when they're supposed to take the second dose of the product, not questions about whether they should engage in sexual intercourse or not. This was a question of, if they have engaged in unprotected sexual intercourse and they desire not to become pregnant, can they understand what Plan B is approved for, how it should be used, and follow the directions.

And as I note in my paragraph there, the regimen for Plan B is very simple. It's a -- you take one tablet, you know, within -- refresh my memory here -- as soon as possible after the intercourse, and the other tablet 12 hours later.

Very simple regimen. We have lots of other over-the-counter products that are labeled in children as young as 12 that have much more complicated dosing instructions.

I personally happen to take an Ibuprofen tablet this morning, and just out of curiosity I read the labeling, and the instructions are much more complicated for how to take Ibuprofen for a 12-year-old than it is for a 12-year-old attempting to take Plan B. You had to make decisions in the Ibuprofen labeling about whether you should take one tablet or two, whether you should take it every four to six hours, how many you could take in a 24-hour period, much more complicated instructions, so I was focusing on can people understand what it's for, read the directions, follow the directions, use it properly.

And I don't see how the developmental issues that Dr. Galson raised have any impact on the ability of a 13-, 14-, 15-year-old girl to follow the instructions appropriately. So that's

why I thought it seemed that the maturity or the developmental differences he's citing seem to have more relationship to making judgments about sexual intercourse. He cited things such as impulsive behavior and inability to rationalize. Those, to me, seemed more about the actions you might take that would lead you to need Plan B, not your ability to understand and safely use Plan B.

THE VIDEOGRAPHER: This marks the end of Tape 1 in the deposition of Dr. Jenkins. We are going off the record. The time is 4:02 p.m.

(Whereupon, a short recess was taken.)

THE VIDEOGRAPHER: This marks the beginning of Tape 2 in the deposition of Dr. Jenkins. We are back on the record. The time is 4:03 p.m.

BY MR. HELLER:

Q Dr. Jenkins, do you know of any other context or do you know of any context in which FDA has sought to regulate individuals' decisions to engage in sexual intercourse?

MR. WARSHAWSKY: Objection. Are you

implying that that's what's going on in this case?

MR. HELLER: I didn't imply anything.

MR. WARSHAWSKY: Well, when you said "any other instances."

MR. HELLER: That's why I changed it to say "any."

MR. WARSHAWSKY: Okay.

THE WITNESS: I am not aware of any situations where FDA has tried to regulate whether people choose to engage in sexual intercourse or not, no.

* * * * *

(The portion of the transcript from Page 103, Line 18, through Page 105, Line 2, has been marked confidential and has been redacted and included in a separate transcript called "Protected Testimony" and designated Number 7.)

* * * * *

BY MR. HELLER:

Q I'm going to make up an analogy here, but I will be astounded if the analogy is apt. So for example, with Ibuprofen, which is available over the counter, would you say it's not within the FDA's purview to, for example, address this question; are people going to have more fist fights, because they know that if they do and they hurt each other, they can take Ibuprofen later and it won't hurt so much?

A We would not be considering that question in our review of an over-the-counter application for Ibuprofen. We would be focusing on can the patient appropriately self-select that they are candidates for using Ibuprofen for the approved indications, and if they select themselves as being appropriate candidates, can they then follow the directions to use it appropriately and also follow the directions not

to use it if they are not good candidates. For example, if they had kidney disease or high blood pressure, they might not be good candidates to take Ibuprofen unless they spoke to their doctor, but we wouldn't be concerned -- I think the analogy you're trying to come up with is we wouldn't be concerned about the source of their pain, but if they had pain, we would want to make sure that they understood how Ibuprofen would be used appropriately to treat that pain.

Q So another analogy -- and I think this came up in the deposition earlier today -- for a drug like Prilosec, which is available over the counter, as I understand it, for digestive, a digestive problem, the Agency would not be concerned about whether the availability of that drug over the counter would cause people to eat more foods that cause indigestion, because they knew that they could then just fix it with Prilosec.

A That would not be the basis for our review. There was a legitimate issue with those

products about whether having that available over the counter might lead people to delay seeking appropriate medical care for their repeated episodes of heartburn, which might be a more serious condition, but the question of whether people might use the product as a way to overeat or overindulge, we were focusing on, if they had heartburn and they had frequent heartburn, could they use it appropriately, and also could they understand that they should not use it for a longer duration of time without checking with their physician, because it might be covering up a more serious condition.

Q Other than the case of Plan B or the OTC switch of Plan B, are you aware of any other OTC switch in which the Agency has taken within its purview a question of the source of the problem that would lead a person to use the product?

MR. WARSHAWSKY: Object to that question.

BY MR. HELLER:

Q If you understand, as you've described

it, the source of the pain, the source of the risk of pregnancy in the case of Plan B.

MR. WARSHAWSKY: I'm going to object. I think the question is vague. I think it's assuming certain facts that aren't in evidence about the Plan B approval process.

BY MR. HELLER:

Q Well, I'm just saying, putting Plan B aside for the moment, are there OTC switches where the Agency has taken something like that into account?

A I have trouble answering that question, because I don't think Dr. Galson raised this issue as part of the basis for his decision. What we're talking about here is that I read his explanation about his concern about developmental differences in adolescents, and as I thought through the consequences of those issues, I couldn't see how they related to decisions about appropriately using Plan B. They seemed to be more applicable to the question of making appropriate decisions about engaging in sexual intercourse, so I don't

know that Dr. Galson stated that as a basis for his decision. It's just that I concluded, from looking at his First Cycle Memo and his raising issues about developmental differences, that I didn't see those as relevant for the ability of adolescents to safely and effectively use Plan B without a doctor's involvement.

Q And if I've understood your previous answers, essentially you had difficulty seeing the connection between the developmental differences he pointed out and the result he reached, given that the regime for actually using Plan B properly was very simple?

MR. WARSHAWSKY: I'm going to object to that question. I just think that at this point you're really not explaining Dr. Galson's analysis or where in his analysis the issue of adolescent development came in. That was an issue of whether you could extrapolate from one set of data to another set of data. That's where that analysis fit into his May 2004 memo.

MR. HELLER: I know.

MR. WARSHAWSKY: So that doesn't seem to be -- so I think you're conflating his overall conclusion, which had lots of different factors, with this narrow issue, and you're asking questions that I don't think are fairly representative of his memo.

BY MR. HELLER:

Q Let's take Dr. Galson out of the question completely.

A Uh-huh.

Q To the extent that there are developmental differences between adolescents and older women in terms of their reasoning ability, cognitive abilities, decision-making abilities --

A Uh-huh.

Q -- if those developmental differences would interfere with their ability to use Plan B over the counter, isn't it also true that they would also be a factor in many other over-the-counter drug products?

MR. WARSHAWSKY: Objection.

THE WITNESS: That would be a concern.

MR. WARSHAWSKY: Asked and answered.

THE WITNESS: You know, what I'm trying to say again is that the data that we had available from the Application, I felt and others felt, had adequately demonstrated that the adolescent age group could safely and effectively use the product without a physician's intervention in the over-the-counter setting.

We did not see any evidence that their behavior or their ability to use the product correctly and safely and effectively was different from the older age group, so bringing in the developmental differences, I didn't understand its relevance, because we had data in front of us that seemed to refute that those developmental differences were consequential.

And we also have a long-standing Agency precedent of extrapolating information from older age groups to younger age groups, so I simply did not agree with the conclusion that this was a concern that would stand in the way of approving the Application.

BY MR. HELLER:

Q Thank you. Further on on that page -- and I think you alluded to this earlier -- I guess the second sentence from the bottom, "Approval of Plan B as a dual product based on age is likely to lead to petitions to the Agency that other OTC contraceptives be similarly restricted." And just referring to the first part of that sentence that I just read, do you continue to believe that such a dual status, if approved, would lead to requests to the Agency that other OTC contraceptives be restricted by age?

A I think it's a possibility. As I stated here, it is likely to lead to petitions. You know, currently available over-the-counter contraceptives do not have an age restriction, so they are not prescription-only for certain age groups in over the counter, and my concern in this area was that there might be groups who would want to seize on this distinction for Plan B and expand it to other contraceptive agents, but my concern is also broader in this paragraph about the

implication of this policy precedent on over-the-counter products in general, because we have, to date, not reached a conclusion in a situation where we needed to distinguish between prescription and over-the-counter simply based on age.

And we have thousands of over-the-counter products that are out there with labeling that say, as we described earlier, "under 12, ask a doctor," "under six, ask a doctor," or "not for use in children under six" or whatever they might say. That's been our long-standing way of handling instructing consumers whether they should or should not use a product in a young age group, and this would be a substantial deviation from that practice, and I think it raised significant concerns for many of us about how it would play out on the broader OTC arena but also specifically the contraceptives.

Q You -- if you'd turn to the last page of your memo, the one before your signature, that is.

A Uh-huh.

Q If you'd read to yourself the last two sentences of that paragraph, and I'm going to ask you to just expand upon I think two things, two separate points you make there. Maybe there are more.

A Uh-huh. All right.

Q So is it still your view that approval of Plan B as a dual product might decrease access to use of the product?

A Yes.

Q And can you explain why a little bit more.

A The dual pathway would essentially put the pharmacist in the decision-making loop for whether the consumer/patient can access the Plan B with or without a prescription, so you're actually putting the pharmacist in a position of having to check I.D. and, you know, verify that someone is at a certain age level. We don't currently have that situation in place for other products that I'm aware of, and it might lead pharmacies not to want to be engaged in that responsibility, so they

might choose not to carry the product, which would mean that they might choose not only not to carry it as an over-the-counter product, but also not as a prescription product, so even those underage women who had a legitimate prescription might have difficulty finding a pharmacy that carried the product, because the pharmacist or the pharmacy would choose not to want to get in the middle of this issue.

Q So I mean, for example, you could have a woman who looks like she might be underage come in, ask for Plan B from the pharmacist, the Plan B -- the pharmacist is for whatever reason unconvinced of her age, doesn't give it to her, and liability might result; is that sort of one of the scenarios you had in mind?

A That's a possibility. I think we're also aware from media reports about, you know, pharmacists who have objected on moral grounds from dispensing emergency contraception, so it's the broader issue that it would be the first time where the pharmacist would be the gatekeeper on

deciding whether someone is above or below a certain age and could have access to this with or without a prescription. It would be a new paradigm for our system that might paradoxically lead to decreased access.

One of the stated goals, I think, of the sponsor of over-the-counter access is to expand the availability of the product, because this product works best when it's used rapidly after unprotected sexual intercourse, so it would be paradoxical for us to approve it under this dual pathway and actually see access decrease, because pharmacies choose not to carry it.

Q There's a second issue you raise in the second sentence about enforceability of the age restriction and how easy it would be to bypass that.

A Right.

Q Do you know if in the dual status -- dual marketing plan -- or I shouldn't say "plan" -- proposal for Plan B, there is any element of enforcing or preventing an adult who

would purchase it over-the-counter from giving it to a younger person?

A I'm not aware of anything specifically in the proposed strategy that the company submitted that would preclude that. I was raising -- I was noting this as a concern, because if the stated reason for the Agency saying it needs to be prescription for the younger age group is that they can only use it safely and effectively if they interface with a doctor or physician or health care provider, it's very easy under this dual pathway to bypass that and have an older friend -- sibling, parent, whoever -- purchase it over the counter and give it to the younger individual, so I'm just raising that. It seems to be a plan that would be very hard to achieve its goals.

Q Thank you. Is it your view that a more demanding standard was applied by FDA to the OTC switch than other for the Plan B OTC switch than other OTC switches?

A It was certainly a different standard

than we applied before, and in a sense it is more demanding, because asking for this demonstration in the younger age group is a very high hurdle, and in particular for this product it would be a very high hurdle to achieve, given some of the difficulties in conducting studies in that younger age group for an emergency contraceptive.

Q Would another way in which it's more demanding is that the usual precedent of extrapolation from one age group to another in some sense was excluded for Plan B or limited for Plan B?

A Well, the decision that Dr. Galson made was that he was not able to extrapolate. I think that's different from most other, if not all other, OTC situations where we have felt comfortable in many cases extrapolating, or we have felt comfortable, if we didn't feel we had enough data, that the product could be labeled "not for use for children under a certain age" or "under a certain age, ask your doctor," so it is in many ways a different standard to make the age

distinction the critical feature of this Application, particularly I would have to say given the product itself, which has a very good safety profile -- going back to my Ibuprofen example, this product probably has a better safety profile than Ibuprofen would in a adolescent age group. I'd probably have more concerns about the safety issues in the adolescents using Ibuprofen than I would using Plan B.

Q Was the data assembled by your staff, the reviewers in your staff, of the type that previously would have been held to be adequate to justify an OTC switch?

A Yes.

MR. WARSHAWSKY: Object to that question. I think that by definition the data provided in the Plan B context is not the same data that was provided in Prilosec or in any other, any other Application, so this is a unique product. I'm just objecting.

MR. HELLER: In what way is it unique?

MR. WARSHAWSKY: It's the first time an

oral contraceptive has been applied for over-the-counter status.

MR. HELLER: Well, I mean there's a first time for everything.

BY MR. HELLER:

Q Did -- when FDA approved Prilosec for over-the-counter use, that was the first time the FDA had approved Prilosec for over-the-counter use; is that right?

A Correct.

Q That was the unique drug, according to counsel's definition?

A Well, every drug is unique in some ways by definition, but what was unique about Prilosec was that it was not only the first proton pump inhibitor approved for over-the-counter use, it was also a new indication for over-the-counter use, because previously drugs had been approved over the counter for treatment of acute heartburn; in other words, they were agents that were relatively and immediately effective so you could take your heartburn relief drug when you had

heartburn and you could expect that dose would probably give you relief. Prilosec is more of a drug that takes some time to garner that relief, so that's why the sponsor proposed, and we eventually accepted, a new over-the-counter indication for chronic heartburn, so Prilosec is not for someone who has acute episode of heartburn, it's for someone who has chronic episodes of heartburn, so it was unique in those two ways.

Q Other than -- putting aside Plan B, has CDER ever previously determined that it could not extrapolate from data about young adults or older adolescents in making decisions applicable to younger adolescents?

A I'm sure we have.

Q Do you know, do you recall any case where you said we just can't extrapolate from one age group to another?

A Well, I'm sure we have, because we have a system under which we can specifically request sponsors to conduct studies. You know, it's

called a pediatric exclusivity provisions of the Best Pharmaceuticals For Children Act, so under that situation if we don't feel comfortable extrapolating the safety or efficacy findings for a drug into the younger age groups, we can specifically ask for studies. So for example, just pulling one off the top of my head of many, we did not extrapolate the effectiveness of antidepressants from the older age group into the younger age groups, and we specifically asked the company to do studies of effectiveness of antidepressants in younger age groups.

And there are many of those situations, so I would say we don't automatically extrapolate from older to younger age group. We look at data and we look at the issues in concern, and we may or may not determine that additional data are needed.

I would give you another example. Antihistamines, we generally have not requested that sponsors demonstrate effectiveness of the antihistamines in these Pediatrics Exclusivity

Studies, we are comfortable extrapolating from adults to younger children based on our experience with prior products and blood levels and other things. We primarily focused in those studies on getting safety information in children and information on the proper dose.

So every case in some ways is unique. You have to look at what are the concerns, what's your comfort level that the data can be extrapolated, and also one of the consequences of extrapolating is you might be incorrect in your extrapolation.

* * * * *

(The portion of the transcript from Page 123, Line 19, through Page 124, Line 6, has been marked confidential and has been redacted and included in a separate transcript called "Protected Testimony" and designated Number 8.)

* * * * *

THE WITNESS: Actually, I would like to probably expand on that. I think we specifically did not issue a written request for Plan B, because we probably did not see a need for data. The product was already -- the prescription labeling for Plan B, now that I'm rethinking this, already incorporates all post-menarchal women in the eligible population for the drug, so we would not have issued a written request even if the sponsor had requested one, because the population of users was already included in the existing prescription labeling. There would be no reason to study it in pre-menarchal women, because they're not at risk of pregnancy. So now that I rethink it, I'm certain that we did not issue a

written request for Plan B.

BY MR. HELLER:

Q Did you have any involvement or do you know -- I don't know when this happened, because I don't remember -- when Viagra was approved as a prescription drug?

A I was not directly involved in that approval, no.

Q Was -- did it happen while you were at the Office of New Drugs, at the head of the Office of New Drugs?

A I think that -- I'm sure that that predated my current position, so I would not have had any involvement in that approval.

Q Are there similar drugs that have been approved since you've been at the Office of New Drugs?

A There have been other drugs for erectile dysfunction that have been approved since I became the Director of the Office of New Drugs, yes.

Q Do you know if, if the Agency examined whether approval of such drugs would influence

people's decision to have sex, like cause people to decide we're going to have sex? Do you know if that was examined or data about that was submitted for those drugs?

A That's a bit of a complex question, because the desired effect of an erectile dysfunction drug is to enable the patient to have sex. I don't think we examined the question of whether it might lead them to, you know, having inappropriate amounts of sex, however you might define that. It's a bit of a different scenario, I would say, from Plan B.

Q Forgive me if I've asked you this already once.

A Uh-huh.

* * * * *

(The portion of the transcript on Page 127, Lines 1 - 9, has been marked confidential and has been redacted and included in a separate transcript called "Protected Testimony" and designated Number 9.)

* * * * *

BY MR. HELLER:

Q With respect to the May 2004 Non-Approvable Letter, was that an instance in which the, I guess Acting Director of CDER ruled on an OTC switch in a manner contrary to the unanimous views of the relevant Office Directors?

A Yes.

Q Has that ever happened before or since, where the Director, Acting Director of CDER put aside the views of the, of the relevant Office Directors?

A For an OTC switch?

Q Yes.

A No.

Q Was the involvement of Commissioner McClellan in the Plan B process unusual as compared to other OTC switches?

A To a degree I would say yes. You know, the Commissioner, as I said earlier, is generally not involved in day-to-day decisions about review of Applications. I think the Commissioner is kept aware of high profile Applications. The Commissioner is definitely kept aware of high profile Approval Actions that are upcoming so that any press attention or need to brief the Department or whatever can occur, so I'm sure that the Commissioner has been involved in other OTC issues. I'm not familiar with the situation where the Commissioner had been directly involved in an OTC Switch Application decision prior to this one with the exception of the situation with the non-sedating antihistamines where we have a Citizen Petition from an insurance company that was submitted many years ago, essentially asking

us to switch the non-sedating antihistamines to over-the-counter status, and that has led to a lot of policy discussions within the Agency and within the Department about our authority to essentially force a manufacturer to switch over the counter as well as our desire to do that, so I know that the Commissioner has been involved in those issues related to the non-sedating antihistamines in that petition.

Q Do you -- I'm just going to ask you a series of questions that may lead nowhere. Do you know anything about a December 17th, 2003, telephone call between Dr. McClellan and Surgeon General Carmona about Plan B?

A No.

Q Do you know anything about a conference call with Dr. McClellan, Dr. Galson and Dr. Woodcock on December 23rd, 2003, about Plan B?

A No.

Q Do you recall a January 15 -- I think we've talked about this -- a January 15, 2004, meeting chaired by Dr. Galson about the Plan B

SNDA?

A Yes.

Q That -- the meeting, what is it called, minutes for that meeting, yeah, the meeting minutes for that meeting indicate 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.

A That's correct.

Q Is that what you recall being the purpose of the meeting as well?

A Yes. Going back to what I discussed earlier, after we had the lunch meeting where Dr. Galson and Dr. Woodcock shared with us the plan for the Action on Plan B, we discussed the need to communicate that to the staff. I think that after that lunch meeting I may have, by phone, communicated to the Office Directors under me that would have been responsible for signing it where we were headed, and they were quite upset that the decision was being made without the reviews being finalized or an opportunity to

present the scientific data and try to argue the case, and that is why this meeting was scheduled to allow Dr. Galson -- and I think Dr. Woodcock was there also -- to explain what the Action was going to be and how we were going to proceed, and as a result of this meeting, it also led to the February briefing by Dr. McClellan at the request of the Review Staff to have a chance to make their case that the data were, in fact, adequate for the adolescents.

Q Did Dr. Galson, at the January 15th meeting -- and I'm not going to say, you know, using these exact words, but did he convey to the people attending that meeting that the Application was going to be acted upon with a Non-Approvable Letter or Non-Approval Letter?

A I know that he conveyed that that was the path forward, was a Non-Approvable Letter. I think he may have used less definitive terms in the sense of saying that the Action was recommended to be non-approvable or something along that line. I think maybe even the meeting

minutes capture it as recommending a non-approval or something along that line.

Q Did he at that meeting convey that the source of that recommendation or path forward was the Commissioner?

A I think he clearly conveyed that the Commissioner had expressed concerns, and I think the objective of the meeting and the meeting minutes makes clear that the objective was to convey the perspective of the Office of the Commissioner. As I recall, Dr. Galson would have signed those minutes as the Chair, so he would have concurred with the statement about what the objective of the meeting was.

Q Thank you. I also have what seems to be a record of a January 23rd, 2004, meeting that I believe was run by Dr. Griebel, which you attended, and it was also attended by the sponsor of the Plan B SNDA, and the purpose seems to be -- well, in the background statement it says "negotiations," I guess, "have been preempted due to concerns of the Office of the Commissioner to

be conveyed through CDER management at this meeting." Forgive me one moment. Well, in the minutes it says, "Dr. Jenkins stated that the Office of the Commissioner and CDER management have raised concerns about the Application to switch Plan B to OTC."

Do you recall a meeting in which you sort of conveyed those concerns to the sponsor?

A Help me refresh my memory. Was that meeting a teleconference? Does it indicate in the meeting minutes? Because I seem to recall that the meeting we had with the sponsor may have been a teleconference.

Q I'm not trying to trick you, so let me pull out the minutes.

A I do recall a meeting in which we conveyed to the company the path on the Application, because we had to let them know that, what the concerns were that had been raised, so that they would understand, for example, why we weren't continuing to engage them in the necessary discussions to get to an approval Action.

* * * * *

(The portion of the transcript from Page 134, Line 6, through Page 135, Line 2, has been marked confidential and has been redacted and included in a separate transcript called "Protected Testimony" and designated Number 10.)

* * * * *

THE WITNESS: Basically we had to let the sponsor know what was happening, because we had an Advisory Committee where the recommendation was overwhelmingly for approval. Our staff had not raised any concern at the Review Division at office level. I think the sponsor was aware of that, and they would have been expecting us to working on labeling, any post-marketing commitments, et cetera, that are necessary to bring an Application to closure and actually issue the approval by the user fee goal date, so since we were not going to be doing any of those activities, we had to tell them why.

BY MR. HELLER:

Q I then have minutes from a meeting, which it appears Commissioner McClellan attended. I think this is the meeting you're referring to where the staff were able to convey some of their views to the Commissioner.

A Right. This was the meeting that followed up the January discussion with Dr. Galson where the staff specifically raised questions about how the Commissioner could have reached his decision about the Application in the absence of having seen the completed reviews, attending the Advisory Committee, or interfacing with the staff. So this was the meeting where the staff went over specifically trying to address the concerns that had been raised about the adolescent use and the numbers of adolescents, and I think probably at this meeting they also presented some of the emerging data they had gleaned from the published and unpublished literature.

Q Did the staff or you ever receive a response to what it sounds like was a question about how the Commissioner could have reached a determination about the Plan B SNDA without having read the completed reviews, without having attended the Advisory Committee meetings, without even having had a discussion with the reviewing staff?

MR. WARSHAWSKY: I'm going to object to that. I think it's argumentative and it assumes a lot of facts that are simply not in evidence. The witness testified earlier in the day that he doesn't know specifically what Dr. McClellan looked at, so unless you want to break it down to a more specific point in time --

MR. HELLER: Yeah.

BY MR. HELLER:

Q At the time that you found out about Dr. McClellan's determination that the Action should be non-approvability, he couldn't have possibly read the completed reviews of the reviewing staff, because they weren't completed yet; is that right?

A The reviews were not completed at that time. As I said earlier, there had been a background package that was prepared for the Advisory Committee that would have had preliminary or draft or early versions of the reviews that are commonly submitted for the Advisory Committee's review, so the final reviews had not been

developed at that point, so no one had a chance to look at the final reviews.

Q And you knew that he wasn't in attendance at Advisory Committee meetings, because you were there yourself?

A I attended the Advisory Committee meeting, and Dr. McClellan wasn't there.

Q And you also know that he did not interface with the reviewer staff, because presumably they would have told you if he had?

A He did not interface with any of the review staff prior to the meeting, with the exception of the briefing we had in advance of the Advisory Committee meeting where some of the review staff were present.

Q So I'll go back to my prior question, which is: Did you ever obtain an explanation for how the Commissioner was able to make a determination without having read the final reviews, without having attended the Advisory Committee meetings, and without having spoken to the staff that was involved in the detailed review

of the data?

MR. WARSHAWSKY: I'm going to object to that question. Again, number one, it assumes a fact not in evidence that there was a request for some sort of explanation to the Commissioner. It also --

MR. HELLER: No. Did he ever get an explanation.

MR. WARSHAWSKY: You said "obtained an explanation." It assumes the request.

MR. HELLER: It doesn't assume anything.

MR. WARSHAWSKY: Yes, it does. And secondly, it completely glosses over any evidence of the Commissioner's interaction with Dr. Galson and Dr. Woodcock, who clearly were staff members who were involved in the loop, so again I think you're misrepresenting the record.

MR. HELLER: Neither was a medical reviewer.

BY MR. HELLER:

Q All right. So do you understand my question? Did you ever -- putting aside whether

it was requested or not, did you ever hear an explanation of how the Commissioner was able to reach a determination without doing the three things I mentioned?

A I do not recall Dr. McClellan stating at that February briefing what he had reviewed prior to the meeting. We did not specifically ask him how he had reached his conclusions about the Application earlier that had been communicated to us. That would have been a bit of an awkward question to be asking the Commissioner.

Q Because he's the head of the Agency?

A He's the head of the Agency, so subordinate staff would have been essentially questioning his actions. That would have been a bit awkward.

* * * * *

(The portion of the transcript on Page 141, Lines 1 - 16, has been marked confidential and has been redacted and included in a separate transcript called "Protected Testimony" and designated Number 11.)

* * * * *

BY MR. HELLER:

Q Did he persuade any of the staff attending that meeting that that was a, that that was an accurate concern or a valid concern?

A I don't recall that he attempted to

persuade anyone of his position. I think, as I recall, he primarily listened to the presentations that were made by the staff. He asked questions and highlighted his concerns, but I don't know that he specifically attempted to persuade the staff. It was actually, if anything, in the opposite direction; the staff were trying to persuade him that their position was the one that he should adopt.

Q During the course of that meeting did Dr. McClellan ever express that he was persuaded?

A No.

Q Did he ever indicate that he was not persuaded?

A I don't recall if he specifically stated it in those terms. I do recall that as the meeting was ending and he was leaving, I think the meeting may have run overtime or he had to leave early, I think he left the clear impression that he wanted the Center to continue to work on the issue about availability prescription for the younger age group and non-prescription for the

older age group, so that would indicate to me that he was not persuaded.

Q I also have a document that talks about a February 19th meeting that included yourself, Dr. Woodcock, Dr. Kweder, Dr. Galson and I think others, at which Dr. Woodcock stated her concern about Plan B taking on an "urban legend status" that would lead adolescents to form "sex-based cults" around the use of Plan B. You, I think, testified about something similar earlier. Is the February 19th meeting, is that where she said that?

A Yes.

Q Do you have any idea if she had evidence, scientific evidence, about sex-based cults centered around the use of Plan B?

A She did not present it as something she had scientific evidence of. She presented it as someone who had teenage daughters and she knew how teenagers behaved. She characterized it in those terms, that she knew how teenagers behaved, and we couldn't predict how this might be utilized in

that setting.

Q In January of 2005, sort of at the end of your involvement, at the point you wrote your memo in the second cycle --

A Uh-huh.

Q -- do you know if around that time Dr. Galson was planning to issue an approval of Plan B as a dual status drug?

A I know that we had drafted approval letters for his consideration, at his direction.

* * * * *

(The portion of the transcript from Page 144, Line 17, through Page 146, Line 15, has been marked confidential and has been redacted and included in a separate transcript called "Protected Testimony" and designated Number 12.)

* * * * *

BY MR. HELLER:

Q So at some point around January -- maybe December of 2004, January of 2005, Dr. Galson directed you to draft an Approval Letter for dual status?

A I believe so. Let me say, to be very

clear, I know that we were directed to draft Approval Letters during the second cycle. It's a bit fuzzy in my memory when exactly that occurred, but I know that throughout the second cycle and even up until the very end of the second cycle, we were working on Approval Letters, and we were led to believe that approval was a very possible outcome of the cycle.

Q Who led you to believe that?

A Dr. Galson.

Q And were there sort of different versions of this draft Approval Letter? When you say "Approval Letters," I'm wondering if there were sort of three different types of letters or --

A Well, we have standard templates for letters, so we would have taken the standard template for an approval letter for on OTC switch, and we would have, you know, put in the appropriate information for Plan B, the sponsor, the product, the proposal, et cetera. Any conditions of the approval we would have

incorporated into the draft. I cannot recall how many drafts might have been prepared, but I know that Approval Letters were prepared, and we were still expecting and led to believe that that was a possible Action up until Dr. Crawford made the announcement in August of 2005 about the rule-making.

Q Did Dr. Galson also direct you to draft Action Letters that would point in the other direction? In other words, did he say, oh, by the way, also draft non-approvable letter, approvable letter, non-approvable letter, sort of the whole range, or was it just an Approval Letter?

A In the second cycle it was only an Approval Letter.

Q Do you still have those draft Approval Letters?

A I personally do not have those. I can't say if they exist somewhere in the Agency. I personally do not have them, or they would have been in whatever I turned over as part of the document request. There was recently a document

request related to all e-mail correspondence, and I turned all those over. I don't recall that there was a draft Approval Letter in that stack of documents, but I could be wrong.

Q How many documents did you turn over in that, in what you just described?

A I don't have a specific number. I had -- I would guess I probably had saved less than a hundred e-mails about Plan B, but it was probably more than 50.

Q Do you know how far back those e-mails went? I mean were they just like from the last few weeks or were they going back a couple years?

A Oh, they went back into the first cycle of the review of the Application.

Q Were any of them substantive e-mails that -- they were e-mails where you say sort of I have to change the meeting for Plan B to 2:00, sort of logistical e-mails, and then there are substantive e-mails where people are discussing the science and other considerations? Were they both?

A I would not have saved them if they had not been in some way substantive in my mind, so they might have been substantive from a policy perspective or a scientific perspective. They might have been something that had attachments that were being sent around as far as draft reviews or things of that nature. I don't normally save e-mails into specific files unless I think they are important enough that I may need to look at them again in the future.

Q And do you recall approximately when you turned those over?

A The document request was within the last two or three weeks, I believe. I know my secretary printed out all the documents that I had electronically, and I went through my paper files and pulled out all the e-mails that met the document request, so I know we submitted them to the place in the Agency we were supposed to submit them probably within the last two or three weeks.

Q Okay, thank you. So around let's say -- I'm going to say in the beginning, by the

beginning of 2005, these draft approval -- that Approval Letters had been drafted by -- was it when you said "we," is it by you or you and people subordinate to you?

A Well, I need to go back and say that my memory of exactly when we drafted these Approval Letters is somewhat fuzzy, because, as you know, we missed the PDUFA goal date for the second cycle, and I think that was largely because we had not yet received feedback from the Office of Chief Counsel about their review of the Application, and so I'm fuzzy on exactly when the Approval Letter would have been drafted, but I'm certain that there were Approval Letters drafted in the second cycle.

Q Do you know if any of the e-mails and so forth that you recently provided to the person within the Agency that you're supposed to give them to, would any of those e-mails reflect sort of a timeline about those approval letters?

A I don't know. As I did my search, we had very specific criteria that we were instructed

to search for. I have a Plan B folder in my Outlook system where I store anything I want to keep for Plan B. I went to that folder and briefly opened every e-mail to see if they seemed to be relevant to the search request. I generally did not open any of the attachments, because I was just quickly trying to find what was relevant to the search. I actually found a couple of e-mails that were in the Plan B folder that should have been in a different folder, so it's kind of a housecleaning. I moved those to where they belonged, and there were a couple -- um, I don't think -- I think I provided all the e-mails that were in there that seemed relevant to Plan B, and I can't remember if there were any that didn't seem relevant to the document request.

Q Do you know if you provided also the attachments to e-mails when there were attachments?

A I very specifically instructed my secretary that she was to print the e-mail and all attachments.

Q Thank you.

A Now, I did not follow up to make sure that she did exactly that, but she was very specifically tasked with printing all the attachments to every one of the e-mails.

Q Thank you. Now, did Dr. Galson at any point in 2005 -- let's say in January, February, March or April, the first three or four months -- did he tell you that Dr. Crawford had withdrawn Dr. Galson's authority to decide the Plan B SNDA?

A I don't remember a specific time when he told me that, but I think I was clearly aware that Dr. Crawford was going to make the decision, so he must have communicated that to me.

Q After you wrote your January, I think was the date --

A Fourteenth.

Q -- 14th, 2005, memo, did you have any further -- did you do anything further with respect to Plan B?

A I don't think I did anything further substantive related to the review, because we had

completed the tasks that were assigned to us. I was aware that Dr. Galson was inclined to agree to approval of the dual marketing approach. He did not request my assistance in writing his review or his memo. He did not provide me any feedback on the one that I had submitted to the record. To a large degree I think we were kind of outside knowing what was happening with the Application through much of the early part of 2005. It was kind of in limbo, so to speak, because we knew that we were waiting for an OCC opinion, and that was at a level well above where we would have known what was happening.

Q And I think you testified earlier that you've never seen such an OCC opinion about Plan B.

A I've never seen a written review or opinion from the Office of Chief Counsel on Plan B, no.

Q Do you know if one exists?

A I am not aware that one exists. If it does exist, I have never seen it. And quite

honestly, I don't think it exists, because it was a bone of contention for many of us in the review areas that we have to meet timelines to complete our review, and it seemed that the timelines did not apply to the Office of Chief Counsel, and the need to document their review did not seem to apply, so it was a source of great frustration and in some cases anger for people in the office, that they were not being held accountable.

Q Do you know if Dr. Galson was angry that Dr. Crawford removed his authority to decide the Plan B SNDA?

A I don't recall him communicating to me that he was angry about that decision, but again I don't specifically recall him telling me at any point in time that Dr. Crawford had said that he was going to make the decision. It became clear that Dr. Crawford was going to make the decision, but as I said, things kind of went into limbo. After we completed our review in January, we kind of didn't know much about what was happening. I frequently asked Dr. Galson about any updates, but

we generally were not involved in any Plan B review activities through much of 2005.

Q Was Dr. Galson ever able to give you an update during 2005 about what was going on with Plan B?

A I think in general he shared with me that the Office of Chief Counsel was still tasked with looking at this. I think he shared with me at various times that it wasn't clear to him what the timeline was for the Office of Chief Counsel to complete their review and provide their input. I know later as we got closer to the August date when Dr. Crawford made his decision, I became aware, either through Dr. Galson or Jane Axelrad, that the idea of an ANPRM had been floated as a possible Action for the Agency, so it was only near the very end that I became aware through Dr. Galson or Jane Axelrad that that was a pathway the Agency was considering.

Q Now, Dr. Galson wrote a memo also in August of 2005, I think on the same day as Dr. Crawford announced the proposed rule-making --

A Right.
Q -- or announced the ANPRM.
A Right.
Q Had you seen any drafts of that August 26th Memo by Dr. Galson before August 26th?
A No.
Q And I think you said that he did not share with you his process in developing that Memo; is that right?
A That's correct.
Q Do you know if he had drafted, back in January of 2005, a Memo, an Approval Memo?
A I do not know that. I know that he drafted the Memo that became final in August that recommended approval for the -- I think it was over 17, if I recall, age group and non-prescription for the under 17, and he was comfortable with the dual approach, but I don't know when in the course of that time period he actually drafted the memo. I think he had help from Jane Axelrad in drafting that memo.
Q So you never had a discussion with

Dr. Galson about his August 26th, 2005, Memo, before it was filed?

A I don't know that I could say we didn't have discussion. I don't recall we had specific discussions. He didn't ask my assistance in writing the Memo, but I'm sure we had discussions about where his thinking was headed, about, you know, what his recommended Action would be on the second cycle. He had clearly articulated in the first letter, the Non-Approvable Letter, he had laid out this possible pathway for dual marketing, so he had shown that he was interested in that pathway on the first cycle. He offered it up as an option to the company, so when the company came back and provided that scenario, it seemed likely that he would find that to be an acceptable option as long as the legal issues were adequately addressed.

Q In his August 26th Memo Dr. Galson, I believe, considers and rejects the idea of an age warning on the label of the type you described earlier, you know, "shouldn't be used by children

under 12" or "should be used only with the guidance of a physician" and so forth. Do you, do you recall that in his Memo that he sort of considers and says that he doesn't think that's --

A I don't recall it specifically. I did read his Memo after it became available in August, but I don't specifically at this point recall the section where he described his thinking about whether a warning or a "not for use under 17," whatever, was appropriate or inappropriate.

Q Do you believe such a warning would be a preferable alternative to dual status marketing?

A Well, that's a difficult question to answer, because I still believe that the data are adequate to support marketing with instructions that would provide for use in post-menarchal women. It would be consistent with how we've done other over-the-counter switches for there to be -- if there were concerns about use in younger age groups, it would be consistent for the labeling to say "under age X, consult a physician" or "not for use under age Y." That would be consistent with

how we have done labeling for other over-the-counter products.

Q When you did review Dr. Galson's August 26th Memo, was there anything in it that made you -- that changed your mind and decided, well, wait a second, we shouldn't approve this without an age restriction?

A No.

Q Do you know if any of your review staff read his August 26th memo; that is, the review staff who had worked on Plan B?

A I'm sure they all read it.

Q Do you know if it changed any of their minds?

A None of them have told me that their minds were changed.

Q Do you know, do you know if those individuals continue to believe that it should be approved without an age restriction?

A To the best of my knowledge, yes.

Q After the August 26th decision was announced by Dr. Crawford, did Dr. Galson talk

with you about that and about what had happened in -- that is, that Dr. Crawford had made that announcement, and did he talk about his reaction to it?

A I don't recall specific conversations about the Dr. Crawford announcement after that with Dr. Galson. I'm sure we had general discussions, but I don't recall specific discussions. You know, I listened to Dr. Crawford's news conference that day by phone. I have never read the ANPRM.

Q I think I just have a few more questions, so I might be close to done.

A Sure.

Q Do you know someone named Pat Ronan at FDA?

A Yes.

Q Do you know what his involvement was with Plan B?

A I do not know his specific involvement. At the time that most of the Plan B issues that we're discussing were ongoing, I think he was the

head of our Office of Legislative Affairs. He now is our Chief of Staff, but I don't know what his specific involvement was in relation to Plan B, no.

Q Would the person in the position that he held typically be involved in an Over-the-counter Switch Application process?

A The answer would be no. Typically this was an Application where we had had a lot of expression of interest from members of Congress, so I guess that it would be expected that the head of the Legislative Affairs Office would be involved, if nothing else, to know what was happening and how to communicate back to members of Congress.

Q Do you have the suspicion that the entire course of the handling by the Agency of the Plan B SNDA was directed by someone outside the Agency?

A I have no knowledge to, to speculate on that. The knowledge I have is that Dr. Galson and Dr. Woodcock told me that they were instructed on

the path forward by Dr. McClellan. I have no knowledge of who Dr. McClellan and then later Dr. Crawford may have talked to outside the Agency.

Q In your considered professional judgment, do you believe that the Plan B SNDA should have been approved in May 2004?

A Yes.

Q Should it have been approved without age restriction in January 2005?

A Yes.

Q Should it have been approved without age restriction in August of 2005?

A Yes.

Q Do you believe that the failure to approve it on those three dates that I mentioned has had any consequences for the health of women in the United States?

A That I think is a difficult question to answer, because I don't have any data to derive an answer from. I have seen a lot of media reports about the Plan B controversy. I have seen that

access has been restricted in some states, liberalized in some states. I have seen debates about pharmacies that do carry it, pharmacies that don't carry it, but it's really hard for me to make an overall conclusion about what impact it's had on health of women. I've seen some information that suggests that the sales have gone up of Plan B during this time period, but I've also seen reports, and there was a recent report in the Washington Post of people who have great difficulty getting access to the product.

MR. HELLER: I have no additional questions at this time.

MR. WARSHAWSKY: And at this time we don't have any questions. Counsel for the Plaintiffs and counsel for the Government discussed this issue earlier. What we're going to do at this time is hold your deposition open, with the likelihood -- it's probably not a hundred percent, but the likelihood that we will arrange another time, given the late hour today, where someone, either myself or Mr. Amanat can ask you

some questions that we have about the case. We'll also represent on the record that between now and whenever that continuation begins, happens, that attorneys for the FDA, both in the United States Attorney's Office and in Ms. Schifter's office, will not consult with Dr. Jenkins about his testimony in Plan B or ask him further background questions in addition to the prior meeting that we've already had about Plan B. We will leave the record as it is and revisit this issue with Dr. Jenkins at that time.

MR. HELLER: And I think we also agreed, if I'm not mistaken, that whereas ordinarily if you do, I guess it's cross-examination of the deponent, and then I would do redirect, that would be limited to, in principle, to the scope of your cross, that you I think have agreed that I might go beyond that, given that we, in all likelihood, will both have transcripts of this portion of the deposition available to us that might otherwise give one or the other of us an advantage in developing additional questions. Is that fair to

say?

MR. WARSHAWSKY: Yes. I think as a practical matter, rules of scope of direct and scope of cross and so forth don't really apply in a deposition, so I think that you will be given an opportunity, of course, to ask additional follow-up questions based on whatever material that has been developed and that you want to ask. I think we can negotiate later some reasonable time limitations on this second round of depositions.

MR. HELLER: Absolutely. I want to let the witness know that we do not intend to use this as an opportunity to reconduct what we've just done and that it would be a more limited examination if much at all.

MR. WARSHAWSKY: Exactly.

MR. HELLER: So that's agreeable to us.

MR. WARSHAWSKY: Yes.

MR. HELLER: So given that the deposition is being "adjourned" rather than "concluded," I guess the issues of -- maybe issues

of --

MR. WARSHAWSKY: Reading and signing.

MR. HELLER: -- reading and signing are postponed.

MR. WARSHAWSKY: Exactly.

THE VIDEOGRAPHER: This marks the end of Volume I in the deposition of Dr. Jenkins. The total number of tapes used is two. We are going off the record. The time is 5:22 p.m.

(Signature having not been waived, the videotaped deposition of JOHN K. JENKINS, M.D., was concluded at 5:22 p.m.)

ACKNOWLEDGEMENT OF WITNESS

I, John K. Jenkins, M.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)

E R R A T A S H E E T

IN RE: TUMMINO V. VON ESCHENBACH

RETURN BY:

PAGE	LINE	CORRECTION AND REASON
____	_____	_____
____	_____	_____
____	_____	_____
____	_____	_____
____	_____	_____
____	_____	_____
____	_____	_____
____	_____	_____
____	_____	_____
____	_____	_____
____	_____	_____
____	_____	_____
____	_____	_____
____	_____	_____
____	_____	_____
_____		_____

(DATE) (SIGNATURE)

E R R A T A S H E E T

IN RE: TUMMINO V. VON ESCHENBACH

RETURN BY:

PAGE	LINE	CORRECTION AND REASON
____	_____	_____
____	_____	_____
____	_____	_____
____	_____	_____
____	_____	_____
____	_____	_____
____	_____	_____
____	_____	_____
____	_____	_____
____	_____	_____
____	_____	_____
____	_____	_____
____	_____	_____
____	_____	_____
_____		_____

(DATE) (SIGNATURE)

CERTIFICATE OF SHORTHAND REPORTER -- NOTARY PUBLIC

I, Laurie Bangart-Smith, Registered Professional Reporter, 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 _____ day of _____, 2006.

My commission expires: March 14th, 2011

_____

LAURIE BANGART-SMITH
NOTARY PUBLIC IN AND FOR
THE DISTRICT OF COLUMBIA

0172

IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

ANNIE TUMMINO, et al., Plaintiffs, vs. ANDREW C. von ESCHENBACH, as Acting Commissioner of the Food & Drug Administration, Defendant.	Civil Action No. 05-CV-366 (ERK/VVP)

CONFIDENTIAL - PROTECTED TESTIMONY

Videotaped Deposition of

JOHN K. JENKINS, M.D.

Washington, D.C.

Monday, August 14th, 2006

10:08 a.m.

Job No. 1-84238

Pages 172 - 306, Volume II

Reported by: Laurie Bangart-Smith

0173

Continued Confidential Videotaped Deposition of:
JOHN K. JENKINS, M.D.

Held at the offices of:
FOOD AND DRUG ADMINISTRATION
5600 Fishers Lane
Rockville, Maryland 20857
(888)463-6332

Taken pursuant to the Federal Rules of Civil Procedure, by notice, before Laurie Bangart-Smith, Registered Professional Reporter and Notary Public in and for the District of Columbia.

0174

A P P E A R A N C E S

ON BEHALF OF THE PLAINTIFFS:

SIMON HELLER, ESQUIRE
NAN E. STRAUSS, ESQUIRE
CENTER FOR REPRODUCTIVE RIGHTS
120 Wall Street
New York, New York 10005
Telephone: (917)637-3615

ON BEHALF OF THE DEFENDANTS:

STEVEN M. WARSHAWSKY, ESQUIRE
Assistant United States Attorney
U.S. Department of Justice
Eastern District of New York
147 Pierrepont Street
Brooklyn, New York 11201
Telephone: (718)254-6060

- and -

KAREN E. SCHIFTER, ESQUIRE
Associate Chief Counsel
U.S. Dept. of Health and Human Services
Office of the Chief Counsel
Food and Drug Administration

0175

5600 Fishers Lane, GCF-1
Rockville, Maryland 20857
Telephone: (301)827-1152

Also present:

Scott Forman, Videographer
Jessica L. Zeller, Esquire (observing)

0176

EXAMINATION INDEX

PAGE

EXAMINATION BY MR. WARSHAWSKY 178, 297

EXAMINATION BY MR. HELLER 253

E X H I B I T S

(NONE)

0177

P R O C E E D I N G S

THE VIDEOGRAPHER: Here begins Tape Number 1, Volume Number II, in the deposition of John Jenkins, M.D., in the matter of Annie Tummino, et al, versus Andrew C. von Eschenbach in his official capacity as Acting Commissioner of the Food & Drug Administration, pending in the United States District Court, the Eastern District of New York, Case Number 05-CV-366.

Today's date is August 14th, 2006. The time is 10:08 a.m. The video operator today is Scott Forman of L.A.D. Reporting. This deposition is taking place at the Food & Drug Administration, 5600 Fishers Lane, Rockville, Maryland.

Would counsel please identify themselves and state whom they represent.

MR. HELLER: Simon Heller representing plaintiffs.

MS. STRAUSS: Nan Strauss from the Center of Reproductive Rights, representing the plaintiffs.

MR. WARSHAWSKY: Steve Warshawsky,

0178

Assistant United States Attorney, representing the defendant FDA.

MS. SCHIFTER: Karen Schifter from FDA, representing the defendant.

THE VIDEOGRAPHER: The court reporter is Laurie Bangart-Smith of L.A.D. Reporting. Would the reporter please swear in the witness.

JOHN K. JENKINS, M.D.,

having been duly sworn, testified as follows:

EXAMINATION BY COUNSEL FOR DEFENDANT FDA

BY MR. WARSHAWSKY:

Q Good morning, Dr. Jenkins.

A Good morning.

Q Today we'll be continuing and completing your deposition, which began -- I don't know -- approximately what; four or five weeks ago. Let me just reiterate what Mr. Heller told you at the beginning of that deposition. I will be asking you a series of questions, and if you have any question as to the meaning of what I ask you, if you could please ask me to explain so that the transcript is as clear as we can make it.

0179

A Uh-huh.

Q Also, allow me to finish my question before giving your answer. I know sometimes the witnesses can very readily anticipate what the lawyers are asking, but again to keep a clear transcript, we need to make a clean break between your answers and my questions.

And why don't we just get started. I'd like to show you a document, please.

For the record, let me describe the document that I've handed to the witness. It is a two-page document dated December 10, 2003. At the top of the first page of the document there's the heading, "Office of the Commissioner Meeting, Executive Summary," and this document has been Bates stamped Tummino 30393 through Tummino 30394.

Dr. Jenkins, if you could please take a look at this document and first tell me if you've ever seen this document before.

A I believe I have seen it. I don't recall it in specifics, but I think I've seen this, because it would have circulated after the

0180

briefing for the Commissioner.

Q And by "the briefing for the Commissioner," you're referring to the meeting on December 10, 2003?

A Yes.

Q Did you attend this meeting?

A Uh, yes.

Q Do you have a present recollection of what took place during that meeting?

A I have a vague recollection. I remember attending the meeting to brief Dr. McClellan in advance of the Advisory Committee meeting that was scheduled a few days later. And just looking at the Agenda helps to refresh my mind that a lot of the meeting was taken up with Dr. Davis giving a background on the product in question, and the plans for the Advisory Committee were presented by Dr. Rosebraugh, and then there was discussion toward the end of that. It was only a one-hour meeting, according to the minutes of the meeting here, so yeah, that helps refresh my memory.

Q If you could please turn to the second

0181

page of this document, three paragraphs down from the top of the page there is a discussion of the Federal Food, Drug and Cosmetic Act, a quotation from a Regulation, and then a description of some criteria, all of which pertain to the decision whether to approve a drug for OTC status. Do you see where I'm looking?

A Yes.

Q Do you recall who at this meeting provided that information?

A I do not recall specifically. I would surmise it would probably have been either Dr. Davis or Dr. Rosebraugh, according to the Agenda on the first page.

Q I'd like to ask you some questions about these particular Regulations and criteria. Let's take a look, first of all, at the italicized portion on the second page, which is a quotation of 21 CFR Section 310.200(b). This Regulation provides: "Any drug limited to prescription use under Section 503(b)(1)(c) of the Act shall be exempted from prescription-dispensing requirements

0182

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, or the method of its use or the collateral measures necessary to its use, and he finds that the drug is safe and effective for use in self-medication as directed in proposed labeling."

As I understand it, this is the FDA's Regulation that implements the relevant provision of the Food, Drug and Cosmetic Act pertaining to OTC drugs; is that correct?

A That's my understanding as well.

Q And in this Regulation is the reference to "the Commissioner" a reference to the Commissioner of the FDA?

MR. HELLER: Objection.

THE WITNESS: Yes.

MR. HELLER: Sorry. It's okay.

BY MR. WARSHAWSKY:

Q And am I correct that the Commissioner of the FDA has been delegated the statutory and

0183

regulatory authority to make OTC switch decisions?
A According to this Regulation -- I'm not intimately familiar with all the Regulations related around this one. The Commissioner, in essence, has the authority for all the FDA's regulatory decision-making. Many of those are then subsequently down-delegated within the organization, because obviously one person can't take charge of all those duties on a day-to-day basis.
Q Is it correct that higher level officials in the chain of command retain the authority to displace or overrule lower level officials in the decision-making process in FDA?
A Yes.
Q Would you agree that the FDA could be described as a "hierarchal" organization rather than a "democratic" organization?
MR. HELLER: Objection.
THE WITNESS: Okay. In the last deposition you were making the objections, and I was told I could still answer, so . . .

0184

BY MR. WARSHAWSKY:
Q You can.
A I think the answer is yes.
Q Do you agree that in May of 2004 when Dr. Galson issued the Non-Approvable Letter for the Plan B OTC Switch Application, that he was acting within the scope of his regulatory authority at FDA?
MR. HELLER: Objection; leading.
THE WITNESS: Yes, I agree he was acting within his authority.
BY MR. WARSHAWSKY:
Q And do you agree that -- okay. I'd like to ask you -- let me go back. To the extent that Former Commissioner McClellan made any decisions pertaining to the Plan B OTC Switch Application, would you agree that Dr. McClellan would have been acting within the scope of his statutory and regulatory authority at FDA?
MR. HELLER: Objection; leading.
THE WITNESS: That is a bit of a hypothetical question, because it assumes what

0185

decisions he made. The reason I'm a little reluctant to answer it directly is because normally there's a process by which, you know, the people making decisions review all the pertinent information and make their decisions based on all the pertinent information. I don't have any knowledge of whether Dr. McClellan ever reviewed all the available information.

The other reason I'm reluctant to give a firm answer is that we also usually expect the people who make such decisions to document their thinking. As you know, Dr. Galson, for example, filed a memorandum to the file, as his review, to outline why he took the Action he took. I'm not aware that Dr. McClellan ever put anything in writing, but with that said, clearly the Commissioner has the authority to make regulatory decisions for the Agency.

BY MR. WARSHAWSKY:

Q Are you aware of any statutory or regulatory requirement that the Commissioner document his thinking in writing with respect to

0186

an OTC Switch Application?

A I'm not aware, no.

Q Are you aware of any statutory or regulatory requirement that the Commissioner review all relevant information before reaching a decision on an OTC switch application?

A No.

Q Let's take a look at -- I'm sorry. I want to go back. I'd like to ask you the same series of questions with respect to Dr. Crawford, Former Commissioner Crawford, who made a decision in August 2005 with respect to the Plan B OTC Switch Application, and let me just ask you again generally: To the extent that Dr. Crawford made any decisions on the Plan B OTC Switch Application, was he acting within the scope of his statutory and regulatory authority at FDA?

A I believe he was.

Q And with respect to the decision-making process that he may have undertaken, would your testimony about that process with respect to Dr. Crawford -- strike that question. Let's move

0187

on.

Now, the Regulation that's quoted here cites a number of different factors that go into the OTC switch decision process. I'd like to ask you about a few of those factors. The first one listed in the Regulation is the drug's "toxicity or other potentiality for harmful effect." Can you give a general explanation what that is intended to refer to.

MR. HELLER: Objection.

THE WITNESS: Well, all drugs have toxicity. That's by definition. So when we're looking at drugs for use over the counter where you won't have a physician or a health care provider between the patient or the consumer and the product, we're looking for drugs that have very low rates of serious toxicity so that consumers can more readily judge the balance between the toxicity of the drug and the condition that they have that they're looking to treat.

So by "toxicity" we're referring to physiologic adverse effects, pharmacologic adverse

0188

effects, and that kind of leads into the end of that phrase which talks about "potentiality for harmful effects," so we're primarily looking at the serious toxicities that may be associated with the drug, how likely those are to occur, what patient population they may occur in, various situations, so those are all things that come into play in thinking about whether a drug's toxicity or potentiality for harmful effect are such that they require that they be by prescription only.

BY MR. WARSHAWSKY:

Q Now, let me ask you just a quick, a few quick follow-up questions. You referred to the FDA looking for, quote, "low rates of serious toxicity." You also used the word "likelihood." My question to you is: With respect to let's say the idea of serious toxicity, are there any statutory or regulatory rules or guidelines that define specifically what constitutes "serious toxicity" and how to determine whether such serious toxicity exists in a given situation?

A There are regulatory definitions of what

0189

we mean when we use the word "serious" in relation to adverse events. I can't give you the specific cite in the CFR right now, but we do have specific regulations that define what we mean by "serious." I'm not aware of any regulations or statutes that define how we go about determining whether a serious effect is related to the drug or how often that may occur. That's more governed by science and reviewing the available data.

Q When you say that that's "governed by science," are you aware of any objective scientific criteria that determine whether or when there is a situation of serious toxicity?

A I'm not sure I understand the question.

Q Well, I guess I'm trying to, I'm trying to determine whether, in making a conclusion, in reaching a judgment or a conclusion that there is serious toxicity, whether that is a conclusion that can be derived from some external set of rules or guidelines such that multiple decision-makers can reach objectively the same determination as opposed to an exercise, more of

0190

an exercise of the individual scientific and, in this case, regulatory judgment for which there may be some range of opinion.

MR. HELLER: Objection; vague.

THE WITNESS: Uh-huh. Well, as I said, we do have regulatory definitions of what we mean by "serious adverse events," and clearly there's going to be some range of judgment involved as individual scientists or reviewers might look at the available data on adverse events related to a drug and decide whether or not they believe that an adverse event, number one, is causally related to the drug and, number two, whether it meets the criteria or the threshold for being serious.

Some of the components of the "serious" definition are fairly black and white, such as, you know, "result in death" is one of the definitions of "serious." Another is "result in hospitalization," but some of the lower level definitions of "serious" have a lot more room for judgment. The biggest area for judgment is considering the causality of whether the drug in

0191

question actually resulted in the adverse event or whether they just happened to occur in proximity to one another, and maybe there is no relationship.

BY MR. WARSHAWSKY:

Q Now, how about the other part of your earlier statement, the "low rates of serious toxicity"? So on the one hand, there's a question as to whether there's an incident of what would be considered serious toxicity, whether that incident is causally related, but then there's this idea of low rates. My question there is: Are there any statutory or regulatory definitions or rules or guidelines that define what would be considered, I guess, a low rate versus a high rate or an acceptable rate versus an unacceptable rate?

A I'm not aware of any statutory or regulatory definitions. We do have some guidance documents available about labeling that are primarily directed toward prescription drugs. For example, I think we have either a draft guidance or a final guidance about the adverse reaction

0192

section of the prescription drug labeling, and that guidance does comment about rates of adverse reactions. We actually generally like to try to avoid using descriptive terms about "rare," "very rare," because those aren't very well defined, but I think that document may actually go into some of, some of those ranges of definitions for adverse events.

Q Now I'd like to direct your attention to the series of bullet points that are underneath the quoted Regulation, and the heading for these bullet points reads, "Non-prescription Use Criteria." Do you see where I'm looking at?

A Yes.

Q My first question is: Where do these non-prescription use criteria come from?

A Uh-huh. My best understanding is that these were derived during the time that Carl Peck was the Director of the Center for Drugs back in the late eighties, early nineties, and they're commonly referred to as "The Peck Criteria." I think there may have been a memo or some

0193

presentation or some documentation at the time that Dr. Peck created that, laid out general criteria. I'm not aware that these are in the Regulations anywhere or in the Statute. I think these were interpretations of the Regulation that we had been discussing earlier, so these may be paraphrased to some degree from what Dr. Peck envisioned back in the early nineties, but I think that's the derivation of these.

Q And do you understand the criteria listed on this document to be the criteria or the standards that CDER applies in making OTC switch application decisions?

A Yes. These are the benchmarks. These are the questions we expect to consider when we're looking at a proposal for an over-the-counter product.

Q I'd like to ask you some more specific questions about each of these. Please look at the first bullet point, which reads, "Does the product have an acceptable margin of safety based on prior prescription marketing experience?" Can you first

0194

tell me what is meant by a "margin of safety." What is the safety issue that's being addressed in this criteria?

A Well, that term can actually have multiple meanings. For example, one meaning, when you talk about a margin of safety, can be the difference between a dose that's therapeutic and a dose that's toxic, because all drugs, as I said earlier, have toxic effects, and generally that occurs in a dose-related phenomenon. So as you go up higher and higher on the dose, your likelihood of toxicity becomes greater and greater. So some drugs have what we call a -- it's called a therapeutic index, the index between the therapeutic effect and the toxic effect, and that's a scale of dose. So some drugs are considered narrow therapeutic index drugs, meaning that the dose that gives you benefit is at or very close to the dose that gives you toxicity. Other drugs have a much wider therapeutic index, meaning that the dose that gives you therapeutic benefit is far removed from a dose where you see serious

0195

toxicity.

So that's one of the common ways that we refer to margin of safety, but "margin of safety" is somewhat of a vague term. It can also make reference to just what are the character of the adverse events that are associated with the drug, what's the seriousness of the adverse events, how likely are they to occur relative to the likelihood of the benefit that occurs with the drug.

So it's a fairly overarching concept, all related, I think, to the idea that drugs that are being moved over the counter we hope are drugs that have a very wide margin of safety, that are not narrow therapeutic index drugs in general. You want to have a safety margin, because patients and consumers are going to be dosing themselves without the intervention of a health care professional.

Q So is it, is it accurate to say then that the first criteria is referencing what you spoke about earlier, the toxicity of the drug,

0196

which you were defining as a physiological or a pharmacological type of an issue?

A In part. There can be adverse reactions related to a drug that are not necessarily physiologic or pharmacologic in their nature. They can be allergic in nature. There can be multiple mechanisms by which you can get to toxicity with a drug, but in general the answer is yes.

Q Now, my next question is -- the criteria says or asks whether the product has an "acceptable" margin of safety, and my question to you is: What is the meaning of the term "acceptable" in this context?

A That really is a term of judgment. "Acceptable," I would interpret that to mean that the benefits of the product, whatever they are, and the condition that the product is treating, when you compare it and contrast it with the risk of the product, that that balance is considered to be acceptable for something that's going to be in the non-prescription setting, meaning that the

0197

likelihood that the consumer taking the drug will get benefit is much greater than the likelihood that the consumer taking the drug according to the instruction will suffer a serious adverse reaction. We generally focus primarily on the serious adverse reactions, not so much on things like nausea or vomiting, you know, less serious reactions.

Q Are you aware of any statutory or regulatory rules or formulas or guidelines of any sort that would define or determine when a product has an acceptable margin of safety within the meaning of this criteria -- criterion?

A I'm not aware of any statutory or regulatory terminology that would go to defining what this exactly would be in every case. It's actually an area of very intense interest right now, because it essentially is the same as defining the risk-benefit profile for the drug, and there's a lot of interest in the academic and regulated industry and also in government right now in trying to have better quantifiable methods

0198

for making those decisions, but for the most part "acceptable" comes down to the judgment of the person who's making the decision.

Q Let's take a look now at the fourth bullet point, since you've already I think raised the concepts here. The fourth bullet point reads: "Do the benefits from the switch to non-prescription status clearly outweigh the risks?" So I believe that this criteria goes to this risk-benefit analysis that you were referring to.

A To a certain degree. This is actually a bit oddly worded, and I don't know again if this is exactly what Dr. Peck put forward back in the early nineties or not, because this says the benefits from the switch to non-prescription status clearly outweigh the risks, which is different from the benefits of the product outweigh the risk of the product. This is the benefits of the switch, which some could interpret to take in broader societal issues, such as easier access to medication, no need to pay to visit a

0199

doctor, so there are other factors that come into play that could be defined as benefits from the switch that are a bit separate from just the benefit-risk of the product itself.

Q Okay. Let's come back to that one then. Let's go up to the second bullet point. This criterion reads: "Does the product have low misuse and abuse potential?" Can you explain generally what is meant by "misuse and abuse potential."

A We're generally looking at, you know, is this a drug that is likely to be abused, meaning that maybe it has psychotropic effects or some effect that might be pleasurable, might lead to abuse once it's available. We would look at the prescription setting to see if there were wide-spread reports of abuse of the product for some type of gain. For example, "misuse" can be a broader terminology of just is it commonly used for some other indication that maybe would not be one that would be appropriate for a non-prescription setting.

0200

So you could have a product that has several indications. One indication might be "appropriate for non-prescription use." You would then look at is it likely that the consumers would then use that product inappropriately for things that they should be seeing a doctor about. That would be a form of misuse.

Q Now, in looking at the misuse and abuse potential of a particular drug in an OTC setting --

A Uh-huh.

Q -- how do you go about determining whether that potential is low or high or okay or too much, et cetera?

MR. HELLER: Objection; compound.

THE WITNESS: Well, we look at multiple sources of information. Almost all the products that are being considered for a switch to over-the-counter status by definition have been prescription for some period of time. So we look at the available data from the prescription use. That would include the data that were generated to

support the approval of the prescription use in the first place from the NDA, but also the post-marketing experience, the adverse reporting. There are networks of reporting systems in the country looking at reports of abuse and misuse. There's a network called the DAWN -- D-A-W-N -- System that looks at reports of patients showing up in emergency rooms abusing drugs, so we would look at all of that information.

Sometimes in the actual Switch Application there will be useful information. If there was an Actual Use Study, we would look to see if there is any evidence from the Actual Use Study that patients misused the product or abused the product. So it's a compound set of looking at all the available information.

BY MR. WARSHAWSKY:

Q And after you look at all the available information and see whatever frequency or quantity of misuse or abuse incidents may be associated with a drug, how do you then reach the further conclusion that that level of misuse and abuse is

0202

acceptably low or not?

A Uh-huh. At the end of the day, again that's a judgment that has to be made by the person who's making the decision about the Application.

Q Are you aware of any statutory or regulatory rules or formulas or guidelines that would direct the person looking at the Application to a conclusion whether the misuse and abuse potential is low or not?

A I'm not aware of any, no.

Q To cut short this line of questioning, would you agree that with respect to each of the other criteria listed here, that in determining whether those criteria are met for a particular OTC Switch Application, ultimately the person reviewing the Application is going to have to exercise his or her scientific and regulatory judgment to determine whether those criteria are met in that particular case?

A Yes, I would agree.

Q Dr. Jenkins, I'd like you please to look

0203

at the second document, which let me describe for the record. This is a five-page document. It's been Bates stamped Tummino 30421 through Tummino 30425. The title of the document is "Non-prescription Drugs Advisory Committee Meeting with the Advisory Committee for Reproductive Health Drugs," and it's dated December 16, 2003.

And let me first ask you if you've ever seen this particular document before.

A I may have. I don't have a current memory that I have seen this before. These are commonly sent around after Advisory Committee meetings by the advisors and consultant staff, so I may have seen it, but I don't recall at this moment.

Q Is -- when you say that these kind of documents are frequently sent around, is the document that we're looking at some form of an internal report summarizing what took place at the Advisory Committee meeting for Plan B?

A I believe so. I was looking at the document to see if there is any indication of who

0204

wrote the document. I don't see any signatory block at the end, but this is entirely consistent with what the advisors and consultant staff who manage the meeting prepare after the meeting as a briefing for senior staff within the Agency of what happened. These are prepared essentially for every Advisory Committee meeting.

Q Did you attend the Advisory Committee or I should say the Joint Advisory Committee meeting for Plan B?

A Yes, I did.

Q Have you read the transcript of that meeting at any time?

A No, I have not.

Q Let me ask you, please, just a few questions about the Advisory Committee process and in general to begin with. First of all, could you explain generally what the purpose of an Advisory Committee meeting is.

A It's kind of encapsulated in the title "Advisory." These are outside experts who agree to serve as advisors to the Food & Drug

0205

Administration on issues that we choose to bring to them for their input. So the Advisory Committees are constituted, as I understand it, through statutory provisions. There are Acts that relate to how the meetings are held and what the procedures are. These are experts from the field that are brought together, given background information, and they see presentations and hold discussion and then often are asked questions that the Agency would like advice on.

They are advisory in the sense that the Agency is not bound by their advice, and while we often seem to follow their advice, we essentially consider their advice very carefully, and that becomes one of the factors we weigh into regulatory decisions. So they play a very important role in helping the Agency deal with certain complex or important scientific regulatory challenges, but we don't take every scientific and regulatory decision to an Advisory Committee meeting.

Q Now, you just testified that the

0206

Advisory Committee votes are not binding on the Agency, but rather they weigh in to the Agency's decision-making process. My question is: How much weight is afforded the Advisory Committee vote?

A It's hard to answer that, because we don't have a formula that says the Advisory Committee vote counts for 50 percent of our decision. My personal experience is that I pay a lot of attention to the discussion and the comments and the exchange at the Advisory Committee. I actually pay a little bit less attention to the actual formal voting, because sometimes I've found that the voting can be swayed at times by a strong-willed member of the Committee who kind of dominates the discussion and seems to take people with him or her.

We do pay attention to the voting. We think it's important that they record their views officially. Clearly something that's more close to unanimous is going to have more weight for us than something that is a split vote. You know, an

0207

eight-to-seven vote, we're going to look much more carefully at the underlying reasons for why the vote was split in making our decision. If something is unanimous, particularly if it's unanimous and we kind of went in with a hypothesis that that's kind of where we were as well, that would probably carry more weight.

Q And do you know if you went into the Advisory Committee meeting in this case with any hypothesis with respect to your position on the Plan B OTC switch?

A My personal one or the Agency?

Q Whoever you meant by "we" in your testimony just a moment ago.

A Well, generally by the time we go to an Advisory Committee for a pending Application, at least part of the review of that Application has been completed, because we send draft or interim reviews to the Committee as part of the background package. So I think it's safe to say that at the time we went to this Advisory Committee meeting, the team involved in reviewing the Application was

0208

probably leaning toward the idea that this was a safe and effective product for over-the-counter use, and it was probably reflected in the background materials.

Q Do you recall specifically what background package was provided for the Advisory Committee members in this case?

A I don't recall the specifics. I know what we generally provide, but I can't say that I ever even saw before the meeting what we actually provided here.

Q Based on your experience, what would you -- what's generally provided to an Advisory Committee?

A We generally provide, as I said, relevant reviews. Those are either considered to be draft reviews or sometimes we call them Interim Reviews that have been provided generally by the Primary Level Reviewers, so they're -- in a Non-prescription Switch Application Advisory Committee meeting, there would probably be a primary medical review, maybe from the division

0209

that's expert in that area of medicine; in this case, the Reproductive Division may have had a primary medical review. There was probably also a primary medical review from the Non-prescription Division looking at the non- -- the Actual Use Study and the Label Comprehension Study.

So it's reviews from all the relevant disciplines. It's relatively rare that they be above the Primary Reviewer level, although there's often a transmittal memo from the Division Director or the Office Director that kind of summarizes the issues related to the Application and may actually state at the end the particular areas that we want the Committee to focus on, and we often try to send draft questions that we plan to ask the Committee to respond to.

Q Do you know if the Advisory Committee members in this case read the background materials that they were provided in advance of the December 16, 2003, hearing?

A I have no way of knowing whether each individual member read the package and to what

0210

extent they read the package. I think we know from experience that it's highly variable, that some members are very good about thoroughly going through the package. Others are, I think, much more superficial. There's sometimes the joke about reading the package on the plane as they come to the meeting.

Q In your opinion, were the members of the Joint Advisory Committee for Plan B capable of rendering an informed and thoughtful opinion with respect to whether Plan B should be made over-the-counter or not?

A In general I would say yes. We did -- by "we" I would say the Review Division and the Offices had concerns about how some of the members of the Reproductive Committee were placed on the Committee, so we had some concerns about their expertise related to the, to the issues that they would be facing, but in general we felt comfortable that the Committee, as constituted, could give useful advice to the Agency.

Q So putting aside any, any questions

0211

about individual members' qualifications to serve on the Committee, looking at a member who you believe was qualified to serve on the Committee, do you think that those members were capable of offering an informed, thoughtful opinion on December 16, 2003, as to whether or not the FDA should approve the OTC Switch Application for Plan B?

A Yes.

Q I'm done with that document.

A Okay.

Q I'd like to ask you some follow-up questions based on testimony that you gave in the first part of your deposition.

A Uh-huh.

Q I'd like to direct your attention to --

MR. WARSHAWSKY: Simon, I'm sorry. I only have one copy of the transcript. Do you have a copy?

MR. HELLER: Yeah. Do you want the witness to have a copy?

MR. WARSHAWSKY: I don't think it's

0212

necessary, but that way I can tell you what page I'm looking at.

MR. HELLER: Let me just -- well, I hope I have it. I think I have that. Do you know if it's the protected portion or the non-protected portion?

MR. WARSHAWSKY: I don't think I'm going to ask any questions about the protected portion.

MR. HELLER: Well, then I have it. Thank you.

MR. WARSHAWSKY: I'm looking, to begin with, at Page 17.

MR. HELLER: Okay.

BY MR. WARSHAWSKY:

Q Anyway, I'm sorry, Dr. Jenkins. I'd like to direct your attention to a lunch meeting that you testified you had with Dr. Woodcock, Dr. Galson and Dr. Kweder around Christmas time of 2003.

A Yes.

Q Do you recall that lunch meeting?

A Yes.

0213

Q Now, in your testimony previously you testified -- and I'm now looking at Page 18 -- "They" -- referring to Dr. Woodcock and Dr. Galson, and I'm quoting now, quote -- "described that Dr. McClellan, the Commissioner at the time, was not in favor of approving the Application and felt that the Application should not be approved on that cycle, so that's how they explained it."

Do you recall giving testimony of that type?

A Yes.

Q Let me ask you a few questions about that testimony. First of all, do you specifically recall Dr. Woodcock or Dr. Galson mentioning Dr. McClellan by name at this lunch meeting?

A Yes.

Q And did they tell you that Dr. McClellan had reached a final decision with respect to Plan B or was leaning in the direction of non-approval at that time?

A I took what they told me at that time,

0214

that it was a final decision, that the Application could not be approved on that cycle.

Q Now, if they told you a final decision had been made, why did you and the rest of CDER bother with all of the other meetings and written reviews and the remaining process that CDER went through between December 2003 and May 2004 when Dr. Galson issued the Non-Approvable Letter?

A For several reasons. One reason is that's our process, so we, we have a process where we expect Primary Reviewers to do complete reviews, and we have a process where we expect Secondary Reviewers to do their secondary reviews. We have prescription drug user fee goal dates that specify when we're supposed to complete our review, and the agreement under that Act is that we will do a complete review of the Application, meaning that we can't just send a letter saying no. We have to do a complete review and lay out all of our findings on the Application, and if the answer is no, we have to lay out the reasons why the answer is no, and we're expected to also

0215

provide how the applicant can put the Application in condition for approval.

The other reason we continued, quite honestly, was a hope that the process would play out the way the process normally plays out and that the decision would be based on the data, so, for example, I think I testified as a consequence of that lunch meeting, there was a subsequent meeting where Dr. Galson conveyed this decision or this plan to the Review Team, and at that subsequent meeting the Review Team expressed concern that the Commissioner had not had a chance to see all the data and that they would like to have an opportunity to hear his concerns and present their review of the available data.

Also I testified that subsequent to that, the Review Team spent a lot of time and effort trying to find information that would address the reasons that were articulated for not being able to approve the drug.

So some of it was process people being dedicated in doing their job, some of it was

0216

because we were directed by Dr. Galson to complete our reviews and file them into the system the way we normally do, and some of it I think was I hope that while the decision was being conveyed to us as being a final decision as far as what the Action was going to be that, that we could change that plan in a favorable manner.

Q Now, we'll take a look at your reviews a little later, but in neither of the two reviews that you wrote with respect to Plan B did you describe this lunch meeting or explain that in December 2003 Dr. McClellan had, in effect, made a decision that Plan B would not be approved, and my question is: Why was this piece of information not included in your reviews?

A Well, first of all, I had lots of conversations with my supervisors over the course of time, and I don't try to capture every one of those in my review of the Application. My review of the Application related to looking at the data that were available and rendering my judgment about whether the available data supported that it

0217

could be used safe and effectively over the counter without a physician intervention.

I think my reviews probably do make reference to the fact that Dr. Galson and Dr. McClellan have expressed alternative interpretations of the data. Probably some of the reason I didn't document it was just being polite. This was an unusual scenario to, you know, have a meeting where you're told that the Commissioner has decided that something should not be approved, and it's probably not just something you would normally put in your review.

Q Did you document this meeting in any other location?

A No.

Q In your mind is there any possibility that you misinterpreted what Dr. Woodcock and Dr. Galson told you about Dr. McClellan's views of the Application?

A No.

Q At the time of the December lunch meeting or at any time thereafter, did you

0218

understand the nature of Dr. McClellan's expressed concerns with respect to the Plan B OTC Switch Application?

A I understood the concerns that were transmitted to me by Dr. Galson and Dr. Woodcock. We also had a briefing, I think it was in February, where we went over the information in the Application with Dr. McClellan, and at that meeting he expressed primarily issues related to the amount of data available in the younger age group for the women enrolled in the trials and whether that was adequate on which to make a decision that the product could be safely used by that group of consumers.

Q Now, with respect to the last view that you just stated Dr. McClellan had about the lack of sufficient data, is it your position that that view was an unreasonable one that was outside the scope of reasonable scientific and regulatory judgment?

A Well, first I would like to say, in the meetings that I attended with Dr. McClellan, he

0219

primarily raised questions and asked for information. He never, to my knowledge, stated a particular view. I don't recall him ever stating, you know, these data seem inadequate. I think he usually put it in the form of, you know, how is this data compared to other applications, do we have any other data, those types of things.

I recall him, quite honestly, as being very careful in those meetings not to state his opinion, and in fact, I recall in one of the meetings he kind of left -- at the end of the meeting it was kind of vague what the direction was. He kind of implied that CDER would continue to work on this, but it was through other conversations that led me to know and understand that he was still continuing to believe that it could not be approved.

Back to your original question, I'm not aware that the judgments he made were inappropriate. I mean, as we talked earlier, different people can look at the same set of scientific data and reach different conclusions

0220

and different regulatory decisions.

Q Okay. I'd like to direct your attention to -- I'm looking at Page 34 now -- some testimony that you gave previously. You were asked a question -- and I don't want to quote or summarize the whole set of passages, but essentially you were asked a question about whether you or other staff members at CDER had any concerns about political interference with the Plan B process.

A Right.

Q And at one point you gave the testimony, quote, "I think many of us were very concerned that there were policy or political issues that came to play in the decision," end quote. Do you remember testimony along those lines?

A Yes.

Q I'd like to ask you just a few questions about that particular bit of testimony. In this piece of testimony you, you mentioned separately "policy or political issues," and I guess my first question is: Did you mean to make a distinction there, and if so, what distinction were you

0221

drawing?

A I can't say right now what distinction I was drawing at that point. I don't remember that in enough detail to say.

Q Well, let's start with the, with the political issues. Generally speaking or specifically speaking, what did you mean by a concern that there were political issues that came to play in the decision? What sort of political issues are you referring to here?

A The political issues that we were aware of were those related to groups that were opposed adamantly to the switch of Plan B to non-prescription status, and I recall Dr. Galson talking to me at one point in a meeting I had with him about the fact that this non-approvable decision was part of a strategy by which the Agency could take a tough stand on not approving this over-the-counter and then somehow pave the way to later compromise with some sort of an approval action for a limited subset down the road, and that was communicated to me as being to

0222

address the constituency that were very opposed to this switch.

Q Let me ask you a few follow-up questions. First of all, you referred to there being groups that were opposed to the Plan B OTC switch. Isn't it true that there were groups, including members of Congress and other high-profile individuals in this country, that were in favor of the Plan B OTC switch?

A Yes.

Q So as a general matter, the Plan B OTC switch is something which other witnesses -- would you agree -- strike that. Other witnesses have described the Plan B OTC switch as a, quote, unquote, "high-profile issue" precisely because of the public interest on both sides of the political aisle that it generated. Would you agree with that description?

A Yes. I mean this was clearly an issue that raised a lot of passion on both sides of the question of whether this should be available without a prescription. I seem to recall that we

0223

had a Citizen Petition even before we had an Application, asking the Agency to switch this over the counter.

The Advisory Committee summary transcript that you showed me earlier showed the number of outside groups who spoke during an open public hearing. At the meeting it was quite extensive, and there was quite passionate views expressed on both sides at that meeting. There were -- I don't recall if there were members of Congress who spoke. I remember there was at least one state Senator from Virginia who spoke very passionately at the open public hearing against switching this over the counter, so there is no doubt we recognize this was a high-profile controversial application, because it dealt with reproduction and sexuality.

Q Now, are you aware, or rather do you know whether any of the CDER staff members who favored making Plan B OTC, whether they were influenced or pressured by any outside individuals or organizations to reach the decision that they

0224

reached?

A I'm not aware of any beyond their interpretation and incorporating into their thought process what they heard at the Advisory Committee meeting. I'm not aware that they were influenced directly or any inappropriate adverse pressure.

Q Are you aware of any inappropriate adverse pressure placed on members of CDER or the Office of Commissioner by any outside groups or individuals who opposed the Plan B OTC switch?

A I'm not aware of any, no. I know that we got numerous letters and inquiries from members of Congress probably on both sides of the issue, but no, I don't know of any inappropriate pressure that was placed on Dr. Galson or Dr. McClellan during the process.

Q Now, you mentioned a few moments ago that Dr. Galson spoke at some point to you about a strategy for not approving the Plan B switch initially, perhaps leading, down the road, to a more limited approval, something along those

0225

lines.
A Yes.
Q Okay. Did he tell you that that strategy was a strategy -- strike that. Did he tell you where that strategy or the idea of this strategy came from?
A He told me that it came from the Office of the Commissioner.
Q Did he tell you who within the Office of Commissioner talked about this strategy?
A I can't say for certain, but I took it that he was referring to Dr. McClellan and other members of his immediate staff in the Office of the Commissioner.
Q So the implication that you took from that would be that Dr. McClellan favored some sort of limited OTC approval for Plan B?
A Let me step back for just a second and give some context. We were questioning why this had to be a Not Approvable Action versus an Approvable Action. Some of us within the Review area felt that the deficiencies that were being

0226

cited -- the lack of adequate data and the under-age group of women -- would be consistent with our interpretation of issuing an Approvable Action, saying, you know, we generally have found this to be safe and effective for the older women, we have concerns about whether you have enough data for the younger age group.

And once we learned what was going to be in the Action Letter for that first cycle, to us it looked more like an Approvable Action, not a Non-Approvable Action. So we were pressing and questioning why does this need to be a Non-Approvable Action versus an Approvable, and in that context it was explained to me that, as I said, this was a strategy that the Agency had to look like we were being tough on this issue by not approving it, but that in some way down the road that would allow for the Agency to reach a compromise, and I did get the impression that Dr. McClellan seemed to be driving things in that direction, yes.

Q Now, with respect to the compromise that

0227

you just referred to, am I correct in understanding that the compromise turned on the issue of what ages the drug would be made OTC for?

A That would be the primary issue of whether it could be safely and effectively marketed over-the-counter for the younger women versus the older, so the issues that were raised throughout the discussions were primarily those related to whether we had adequate data for that age group and whether that age group could safely and effectively use it without a prescription. So yes, I took that the compromise that was envisioned was one where it could be available non-prescription for the older women, prescription-only for the younger women, and part of the debate was where would that cutoff be.

Q Now, let me ask you a few general questions about this Approvable versus Non-Approval Letter idea.

A Right.

Q Can you give a general sense of what the definitions of those two categories are and what

0228

their distinctions are.

A They're actually spelled out in the Regulations, 21 CFR 314. I can't give you the more specific cite beyond that, but they're actually spelled out in the Regulations. The three Agency Actions that the Agency can take on a New Drug Application is we can approve it for marketing or we can decide not to approve it, and both the Approvable and Non-Approvable Letters mean that the product cannot be marketed. They are in some sense along a continuum of what the level of deficiencies are in the Application.

The strict regulatory definitions, just paraphrasing them for non-approvable, just means that the Application cannot be approved at this time and that the deficiencies are such that additional work will be needed beyond minor repairs. The approvable regulatory definition describes relatively minor outstanding issues, and I think you may even get examples such as labeling discussions that need to be completed or stability issues about the product.

0229

So the regulatory definition for Approvable generally outlines minor issues, whereas the Non-Approvable is considered to be more significant, where maybe a new study would be needed or maybe the product just doesn't work. That's the strict regulatory definition. Our actual in-practice use of those terms has evolved over time, and if you want, I can describe that in more detail, because there's a fairly complex history of why it's evolved over time.

Q Well, let me ask you these questions. As I understand your testimony a few moments ago, it was your view that the decision letter for Plan B OTC switch in May 2004 could have been characterized and fit within the definition of an Approvable Action?

A Yes.

Q Is it also your testimony that the nature of the decision was such that it did not fit within the definition of a Not Approvable Action, or could it fit within both?

A It could fit within both, yes, because

0230

again there's a lot of room for judgment in how we apply those terms. In both cases I would emphasize, and maybe emphasize it here, because the Press always gets this wrong; in both cases the drug can't be marketed. In both of those cases the drug has not been approved for marketing, but they do convey some sense of the seriousness of the deficiencies, and my view and I think other views inside the Review Divisions and Review Office was that the deficiency in the findings were such that it could easily have been an Approvable Letter, and that's why we were pressing why does this have to be a Non-Approvable Letter.

Q I'd like to direct your attention to another piece of testimony. I'm looking now at Page 51. To give you the context for your testimony here, you were describing how, as you, as you saw the development during this 2003 and 2004 period, it looked to you like Dr. Galson may initially have been on the side of disagreeing with Dr. McClellan's views about the deficiencies

0231

of the Application but then, over time, moved to his own position, agreeing that there were I guess too many deficiencies for an Approval Action to be the right position, and you were asked some questions about what, in your opinion, drove that transition.

A Uh-huh.

Q And part or one piece of testimony that you gave, you said, quote, "I got the sense that he didn't feel he had a voice." Now, I believe the transcriptionist got that wrong. It should have been "a choice."

A Right.

Q And I guess -- well, my question is: What did you mean by "he didn't have a choice," and how did you get that sense?

A I would back up for just a second and say that during the time that we were reviewing the Application before we went to the Advisory Committee, I never had any indication from either Dr. Woodcock or Dr. Galson that they felt that the product should not be available over the counter

0232

without age restriction, so nothing in their communications with me ever led me to think that they were thinking that this should not be approved or should not be available.

Over the course of the time after the lunch meeting that occurred sometime around the end of December 2003, early January 2004 that we talked about earlier and then the subsequent meeting with the Review Division in January and with Dr. McClellan in February, as we were working through the Application, getting towards the Action, there were occasions where, in conversations with Dr. Galson, that he told me that he felt he didn't have a choice, and he characterized that in a sense that he wasn't sure that he would be allowed to remain as Center Director if he didn't agree with the Action.

Q And did he make these comments to you expressly?

A Yes.

Q Now, did he give you any explanation for why he may have felt that he could not have stayed

0233
in the position of Center Director?
A I took him to mean that he felt that if he did not support the plan for Non-Approvable Action -- meaning that he shifted it up to the Commissioner's Office level to sign the Action -- that there might be some adverse impact on his position. At the time he was Acting Center Director. Dr. Woodcock was the official Center Director, but she was on detail to the Office of the Commissioner. So that's what he conveyed to me was that he wasn't sure what the impact would be on the Center, of whether he would be allowed to remain in his position if he didn't concur with the Action.
Q Did he tell you specifically if anyone in the Commissioner's Office or anyone else had actually told him directly or indirectly that his position could be in jeopardy if he didn't sign the Non-Approvable Letter?
A He did not.
Q Do you know whether the comments that Dr. Galson made to you were anything other than

0234

personal speculation on his part?

A I don't know the basis for his comment. I don't know if there was speculation on his part or whether he had some more concrete reason for making those comments. I just know that as part of our discussions and interactions about the Application during that winter and spring of 2004, on at least one occasion, possibly two occasions, he expressed to me that, that view.

Q Can you give any more specific time frame as to when these one or two occasions took place.

A Well, it was clearly before the Non-Approvable Letter was signed, which I think was in May, if I'm recalling, remembering that the -- the goal date for this Application was extended by three months from I think a goal date in February to a goal date in May, which is allowed under our Regulations. It would have been probably during the month or so leading up to the actual Action on the Application.

Q So this would have been after, for

0235
example, the staff meeting that Dr. Galson held in January of 2004?
A Yes.
Q And would it have been after the staff meeting for the Commissioner that was held in February of 2004?
A Yes.
Q I'd like to ask you some questions now about the -- I guess I would say the, the analytical process, if you will, for the, for making the OTC switch decision. Let me first ask you this: What was the intended consumer population with respect to Barr's first Application to make Plan B over-the-counter?
A As I recall, it was women in need of emergency contraception, so women who had experienced unprotected intercourse and had a desire not to become pregnant, and it had no age restriction.
Q So as a practical matter, this would apply to all females who were, who had -- of any age and of child-bearing potential?

0236

A Right.
Q And that could include females as young as say 11 or 12?
A It would include all post-menarchal females, which, you know, menarche, onset of menses can occur as early as 10 to 11 in certain females.
Q Now, my understanding is that the statutory and regulatory framework for deciding an OTC Switch Application requires the FDA to find the drug to be safe and effective for over-the-counter use by the intended population. Is that an accurate summary?
A That sounds correct.
Q So in this particular case, with respect to the first Plan B OTC Switch Application, the statutory and regulatory framework would require the FDA to reach a decision as to safe and effective OTC use by, for example, 12-year-olds?
A Correct.
Q And similarly, the FDA would have to find safe and effective OTC use by older females,

0237

18, 25, 40 and so forth?

A Correct. We would need to find that those consumers who would have the condition for which Plan B would be available could safely and effectively use that product based on the instructions that would be included with the product without intervention by a health care professional.

Q And my understanding of the Administrative Record in this case is that the primary focus of controversy, if you will, had to do with whether there was sufficient information to make this type of finding with respect to females ages 16 and under.

A That's correct. There was some debate and some issue over time of exactly what that age cutoff should be, but it was generally, you know, late teenage years and younger, of whether we had adequate data to make that judgment.

Q And again just so I know I understand this correctly, in determining -- okay, strike that. So the issue -- strike that. Hold on.

0238

So the issue, as I understand it, under the statutory and regulatory framework with respect to this younger adolescent population, was whether there was a sufficient or adequate body of data that would permit the FDA to find safe and effective OTC use for females in that younger adolescent age group.

A That's correct, but I do need to say that it's important to keep in mind that we can, and often do, extrapolate findings from older age groups to younger age groups. In fact, we now have regulations and statute on the book that give us that authority, so we don't always have to have direct data from the age group in question. We have -- we can, if appropriate, extrapolate.

Q Now, are there any statutory or regulatory rules or guidelines or formulas or any type of prescriptions that tell CDER when it can or should extrapolate from older age groups to younger age groups?

A I would have to look at the actual language of the Best Pharmaceuticals For Children

0239

Act, which is the Act that gave us the explicit authority in that area. I don't think it requires -- I think it leaves it to judgment of when to make a decision about extrapolation, and it clearly leaves to judgment a decision about whether the extrapolation is valid and whether the data are then adequate to support safe and effective use in that population.

Q I'm looking now at Page 117. I'd like to direct your attention to some testimony that you gave on this issue of the OTC standard and how it applies or applied to Plan B. You were asked the question: "Is it your view that a more demanding standard was applied by FDA to the OTC switch than for the Plan B" -- "Is it your view that a more demanding standard was applied by the FDA to the OTC switch for Plan B than other OTC switches?" And your answer was, quote: "It was certainly a different standard than we applied before, and in a sense it is more demanding, because asking for this demonstration in the younger age group is a very high hurdle, and in

0240

particular for this product it would be a very high hurdle to achieve, given some of the difficulties in conducting studies in that younger age group for an emergency contraceptive."

Do you recall giving that testimony?

A Yes.

Q Now, I'd like to ask you some questions about different parts of this particular testimony. The first question I have is: If you testified -- as you testified a few moments ago, the FDA is required to make a finding of safe and effective OTC use for the intended target population of a proposed OTC drug. And I believe you also testified that in this case the question was whether, for the younger adolescent group, there was sufficient data to make that finding. Obviously some -- many staff members thought there were, and Dr. Galson and some others thought there weren't. In what sense was this OTC standard different --

A Uh-huh.

Q -- uh, well, yeah. In what sense was

0241

the standard different as opposed to the -- strike that. In your testimony it looks to me like what you are referring to is an evidentiary hurdle as opposed to a statutory or regulatory standard, and I guess my first question is: Is that an accurate reading of your testimony, and if not, what is the different standard that was applied in Plan B's case?

A Yeah, I think what I was saying in that testimony was that the standard of evidence was different. I don't think it was a different statutory or regulatory standard. It was the standard of evidence that was being applied as far as the need for direct data from every age group that's being considered for the approval. That's not the level of evidence that we have routinely applied in other non-prescription switches. So I don't think I was saying a different standard of statutory standard, I was talking about a standard of evidence.

Q Now, when you say that the standard of evidence was different than in other OTC Switch

0242

Applications, to me that suggests a comparison.
A Uh-huh.
Q So what OTC Switch Applications do you consider sufficiently similar or analogous to Plan B to enable a comparison of that type to be made?
A I'm, I'm speaking in the general realm of the precedent of what we, as an Agency, have done historically. There have been quite a few products that have been switched over the counter in the past decade or so where direct need for data from controlled clinical trial for every age group was not expected. And the other standard I would say that is different here is that those other switches have occurred at the usual level of signoff within the Agency, which is usually at the Office of Drug Evaluation level, not at the Center Director's level or the Commissioner's Office level.
Thinking of specific applications, it's hard for me to say sitting here today, because I don't have them in front of me, to know what were the data in all the different age groups, you

0243

know. There was a switch several years ago for chromelin sodium, which is a nasal spray for allergic rhinitis. I don't recall that there was specific data, for example, from the OTC use study that covered every age range that was eventually included in the labeling. The same is probably true for Loratadine, which was switched a few years ago.

So I'm looking at from a precedent standpoint. I can't recall a situation where we have demanded that we have data from controlled clinical trials that directly address the entire span of the age range. Here we felt that we had data in the age range from the Actual Use Study, and we felt that for various reasons you could extrapolate from the data that was available for the older age range, so different evidentiary standard in the sense that others more senior to myself felt that we couldn't extrapolate and that we needed more data. That's a higher evidentiary standard that we've applied in other cases.

Q I guess I'm trying to understand -- I

0244

guess I'm trying to understand why you conclude that it was a higher standard as opposed to a difference of opinion, because it sounds to me like the issue is always whether, whatever universe of data you have, you can make an appropriate conclusion with respect to the entire intended population of users. So it seems to me that that's the standard, and what you have here is a difference of opinion as to whether the available data meets that standard.

MR. HELLER: Objection; argumentative.

THE WITNESS: I guess you could take that view. You know, a lot of what we in the Agency look at is, you know, we establish precedence. As we interpret the Regulations and set the evidentiary standard, we establish precedence. To my knowledge, there was no precedent that existed prior to Plan B that would have warranted the need to ask for data specifically in that younger age group. And beyond that, in our scientific judgment, we didn't think the data were necessary in this case and did

0245

not see presented to us a rationale that we found convincing of why this case was different than those other cases where we had not requested such levels of evidence.

So I guess you could interpret it -- I view it as a different evidentiary standard. You could argue that it's a different judgment. I'm just simply stating my own personal opinion is that it was a higher evidentiary standard, and it wasn't consistent with our long-standing practice and precedent.

BY MR. WARSHAWSKY:

Q Let me just try to understand this a little bit more, because I want to, I want to make sure I understand your position. Is it your position, with respect specifically to Plan B, that you don't believe any specific evidentiary showing should have been required for the 12-to-16 age group?

MR. HELLER: Objection --

THE WITNESS: No, that was not my position. My position --

0246

MR. HELLER: Sorry, Doctor.
Did you get my objection? Objection; argumentative.
I'm sorry for cutting you off.
THE WITNESS: My position was that we had data from the Actual Use Studies and the Label Comprehension Studies that covered a reasonable representation of the age groups that we expected the product would be used in, and I felt comfortable extrapolating data from the older age group based on comparing the data between the younger groups and the older groups and seeing no substantive differences, and also not being presented with any reason for why use of Plan B by that younger age group would raise scientific or regulatory safety and efficacy concerns that have not been raised for other products that are available that are labeled for use in that age group.
BY MR. WARSHAWSKY:
Q Is the last, the last point that you made, whether Plan B presented safety or efficacy

0247

concerns compared -- more or less safety or efficacy concerns compared to other OTC products available to younger adolescents, is that one of the regulatory or Peck factors that are to be considered in determining whether an OTC Switch Application should be approved?

A I think they go to the issue of being consistent with how you've interpreted the standard over time. It goes to the issue of precedent. There are lots of products that are available over the counter that have information on the labeling, for example, that says "under six -- under age six years, see a doctor." That, therefore, implies that we have concluded that it's safe and effective for that product to be used over-the-counter for ages six and above, but I would say it's rare, if ever, that we have had direct controlled clinical trial data about the safe and effective use of that product in the OTC setting, and that seemed to be what we were demanding in the case of Plan B. And I did not see a reason and never heard articulated to me a

0248

reason why Plan B was so different that we needed to rise -- to raise the evidentiary standard to the level of requiring direct data in that age group.

Q What sorts of OTC products do you think are sufficiently similar to Plan B that you could make the comparisons that you're making?

A I'm not sure what you mean by "similar."

Q Well, you said you didn't see anything -- you didn't hear anything that showed why Plan B was different than these other OTC products that have been treated in a different manner, so I guess my question is: What OTC products are you comparing as relevant precedence for how Plan B should be treated?

MR. HELLER: Objection. You've mischaracterized his testimony, and argumentative.

THE WITNESS: I think I'm comparing the universe of available products over the counter. I have not seen anything presented to me yet that leads to a conclusion that there is any significant new safety concern about the use of

0249

Plan B in that younger age group. The directions for use for Plan B, as I characterize in one of my reviews, are very simple and much simpler than many of the other products that are available over-the-counter that are labeled for use in this age group.

The ability of the consumer to recognize that they have the condition that the product is used for, to me, is no different and in some ways maybe easier than a lot of the other products. So I'm looking at the entire spectrum of products, because we have to regulate all the over-the-counter products, so I wouldn't point to any particular one. It's more the spectrum of how we've regulated this class of products.

BY MR. WARSHAWSKY:

Q Let me ask you a few more questions about your views on Plan B in particular. My understanding from your two reviews and from your prior testimony is that you hold the opinion that Plan B should be approved for over-the-counter use by consumers of all ages; is that correct?

0250

A I would characterize it slightly different. My professional opinion, based on my review of the data, is that the evidentiary standard that we would normally apply has been met, that there has been adequate demonstration it can be used safely and effectively for its intended use by all age groups.

Q And does that mean -- does that mean that the FDA is then bound to approve the drug, in your view, for OTC use by all age groups?

A I'm not sure I understand --

Q Well, you said that in your professional opinion, evidence had been presented to show that there could be safe and effective use by consumers of all age groups.

A Right.

Q So the further regulatory question is: Does that mean, in your view, that FDA was bound or obligated to approve Plan B for OTC use by all age groups?

A No, I don't think it means that we were bound, because whoever makes the decision -- and

0251

in this case the decision was signed by Dr. Galson -- have to make their own decision about whether the standard of evidence and the statutory standards have been met. I can tell you that had, had this followed the normal course of events within the Center for how we review these Applications, the two Office Directors were in agreement with what I just stated, and the Application would have been approved on the first cycle.

Q Right. I understand that. So Reviewers below the level of Dr. Galson were in favor of approval, and Dr. Galson obviously ultimately was not in favor of approval.

Well, let me first ask you: With respect to Dr. Galson's exercise of his scientific and regulatory judgment about Plan B, is it your opinion that his judgment was within the scope of reasonable scientific and regulatory judgment on the Plan B issue?

A I have read his reviews, and I think that they articulate what could be considered to

0252

be reasonable judgments about the scientific and regulatory issues. I do not concur with many of his lines of thinking or his analyses, but I would not say that they are unreasonable.

MR. WARSHAWSKY: Can we take a short break? I'm probably getting close to being done, but I just want to confer with Karen.

MR. HELLER: Sure. How much time would you like?

MR. WARSHAWSKY: Five, ten minutes.

THE VIDEOGRAPHER: We are going off the record. The time is 11:42 a.m.

(Whereupon, a short recess was taken.)

THE VIDEOGRAPHER: This marks the beginning of Tape 2, Volume II, in the deposition of Dr. Jenkins. We're back on the record. The time is 11:57 a.m.

MR. WARSHAWSKY: Thank you very much, Dr. Jenkins. I don't have any more questions at this time.

0253

EXAMINATION BY COUNSEL FOR PLAINTIFFS

BY MR. HELLER:

Q Dr. Jenkins, good morning again. It's only slightly morning. I have a few housekeeping questions that I need to ask you. During the time since we finished your last deposition and today, have you spoken with any of the lawyers for the Government in this case, other than for scheduling purposes?

A I have had a couple of e-mail exchanges with Ms. Schifter about scheduling, but other than that, no conversations.

Q And during that time have you reviewed any additional documents related to Plan B?

A I've seen media reports in both the lay press and the trade press. I've looked at some of those. I did scan some of the transcripts of depositions for Dr. McClellan, Dr. Houn, Dr. Rosebraugh and Dr. Griebel. I scanned them. I didn't read them in detail.

Q Let me start with something. Let me skip around a little bit, so I apologize. Please

0254

let me know if you need a time frame for my questions.

Going back to the time before the Advisory Committees met, do you recall whether there was, prior to that, suggestion within the Agency of considering an age restriction for Plan B?

A I do not recall consideration of an age restriction that was formally discussed. I think I testified at the last session that sometime in the fall we had a meeting with Dr. Woodcock where she advocated that we work with the company for them to develop what might be called a "responsible marketing plan," of how they plan to introduce Plan B into the marketplace, but that was under the presumption that it would be for all age groups, and the idea that marketing plan would be -- you know, that it would not be available in places where you might not have access to, say, a pharmacist if you had questions. So the concerns were that it not be available at the 7-11 convenience store, there with the soda pop or

0255

whatever, but I don't recall before the Advisory Committee having formal discussions about an age restriction.

Q Did you -- and I guess by "you" I mean you and your subordinate staff -- have any role in determining the composition of the Advisory Committee?

A Yes. We had a role in the sense that we decided it would be a joint committee between the Reproductive Drugs Committee and the Non-prescription Committee, which is the typical way we would do a Switch Application. There may have been some additional members who were added to the roster who were consultants or other roles, that they were not formal members of the standing committees. I think some people were brought in. We obviously also had role in selecting the majority or nominating, I should say, the majority of the members of the two committees.

Q I think you indicated in your testimony earlier today that there were concerns about placement of certain people on the Advisory

0256
Committee. Can you explain that a little bit more.
A In my time at the Agency, the way that Advisory Committee members are normally developed is it usually occurs at the division level, the Review Division for the particular area, so in the Reproductive Division they would have the responsibility for trying to maintain the expertise on the Reproductive Drugs Advisory Committee that they need for the types of applications they're expecting to come forward in the next year, two years, three years, et cetera.
So the way the process has normally worked has been that review staff and management in the Review Divisions would identify outside experts that they think have the expertise and the stature that we're looking for, and may actually even make preliminary contacts with those individuals to see if they're interested, see if they have any overarching conflicts of interest that would make them unable to serve, and then those names are forwarded to the advisors and

0257

consultant staff, who then go through the process of getting all the necessary paperwork from the nominee and submitting a package for the Advisory Committee member that then goes to the Commissioner's Office for signoff. That's the normal process that we've followed.

In the case of the Reproductive Drugs Advisory Committee, there were several members that were suggested to us from the Office of the Commissioner that we had not had any involvement in before they were suggested as new members for the Advisory Committee, and I know that the staff and the Division were concerned that some of those recommended new members did not have expertise in the areas that we felt we needed the expertise, and, quite frankly, some of them had documented records of having very opinionated views about certain areas of reproductive medicine that seemed to be outside the scope of just the science of the drug approval process, so we were concerned about whether some of those members were appropriate candidates for the Advisory Committee.

0258

Q Do you have any idea why the Office of the Commissioner became involved in nominating anyone to the Advisory Committees in the case of Plan B?

A I do not know. I mean clearly it's within their prerogative. They are the ones who actually appoint the members to the Advisory Committee, and it may have happened in the past. It just had not happened in the past in this manner, that persons were nominated essentially with the presumption that they were going to be on the Committee. It wasn't as if names were being floated for internal vetting. These names were being sent down as these are new people who will be on the Committee.

Q How did the -- well, okay. I guess while we're on the subject of the Advisory Committee, if I can find anything I have here, I wanted to show you something.

This is a document marked Tummino 7509, and on the back is 7510. It's two-sided. And at the top it indicates that Charles Ganley sent

0259

this, forwarded this to you, and it appears to be a letter to the Editor of the "New York Times" from Dr. Frank Davidoff. Do you recall seeing this letter at some point?

A Yes.

Q And Dr. Davidoff was one of the Advisory Committee members that considered Plan B?

A Yes.

Q Do you know if he was one of the ones who was -- well, at the end of the first page he -- there's this question: "What will it take for the citizens of this country to restore rational science-based decision-making to the FDA?" Do you see that?

A Yes.

Q Do you -- had you in your prior work with Advisory Committees, first let me ask, ever had a resignation from an Advisory Committee because -- as this person seems to be talking about -- the lack of "rational science-based decision-making"?

MR. WARSHAWSKY: Object to that

0260

question.

You can answer.

THE WITNESS: I would just say I don't recall an Advisory Committee member resigning, in essence, in protest of an Action that the Agency took after the Advisory Committee meeting. We had people who resigned from Advisory Committees on an occasional basis for personal reasons or career change reasons or whatever, but I don't recall, prior to this one, an advisor resigning essentially in protest.

BY MR. HELLER:

Q That was the only question I had about that. Thank you.

Also in terms of the Advisory Committee or regarding the Advisory Committee, were any of the people who were nominated I think by the Review Divisions rejected by the Commissioner's Office, that you know of?

A You'd have to be more specific. Some of the nominees from the Commissioner's Office were appointed, so I suspect -- although I don't have a

0261

correct direct memory -- that the Division probably had put forward a complete slate of candidates to fill the vacant positions, so some of those candidates must not have been appointed since there was room to appoint the ones that came from the Commissioner's Office.

Q I want to shift gears to something very recent. Are you aware that recently the Acting Commissioner of the FDA asked Barr to resubmit an Application for OTC use -- for non-prescription use of Plan B for ages 18 and above?

A Yes.

Q I have some questions about that. Was the Office of New Drugs consulted prior to that announcement to Barr?

A I personally was not consulted, and I'm not aware that anyone in the Office of New Drugs was consulted.

Q Do you know if Dr. Galson was consulted?

A I only know that I asked Dr. Galson, after the letter was sent to Barr, whether he was aware of that in advance, and he told me that he

0262

saw the letter a day or two in advance of it being sent to Barr and made some comments on the letter.

Q What were the comments he made?

A He did not tell me what the comments were.

Q In other words, he had made some comments to --

A Edits to the letter.

Q I see. Have you heard any discussion about where the age cutoff of 18 came from in that, in that letter?

A I have not. I should -- let me give you a little context. I was on vacation when the letter was sent to Barr I think now about two weeks ago, and I became aware of the fact that the letter had been sent, because I violated my own rule and took my Blackberry with me, and I happened to look at messages and saw that the letter had been shared internally so that we would not be surprised if we started seeing media reports about the letter. So I was not aware that the letter was going to be issued and have not

0263

been involved in any of the discussions about what's actually contained in the letter.

Q Are you aware that there was a meeting last week between Commissioner -- including Commissioner von Eschenbach and I believe the Chief Executive Officer of Barr?

A I know that there was a meeting last Tuesday between Barr and staff from the Review Divisions. I don't know specifically who attended that meeting. Is that the meeting you're referencing?

Q It may be. Do you know who from the Review Divisions attended that meeting?

A I do not. I did not attend that meeting, and I have not seen any, you know, meeting minutes or anything from that meeting to know exactly who attended.

Q In the course of your earlier answers, you mentioned, I believe, something with the acronym "DAWN."

A Right.

Q Can you tell me again what that is?

0264

A It's an abbreviation for Drug Abuse Warning Network, so it's basically -- it may even be -- it's either managed through the Poison Control Centers or it may be managed through a contract or some relationship to a federal government agency. I don't know the details, but it's basically a way of trying to collect information regarding emergency room visits that may be related to drug abuse or overdose, so it's one of the sources of information that are available to the Agency and others to look at abuse of drugs.

Q Do you know if that resource was used with respect to Plan B?

A I do not know if anyone in the Review Team would have actually consulted it. This would not have been the type of product that you would have expected to have been captured under that Drug Abuse Warning Network. The types of products that are normally captured there are opiates or psychotropic drugs that are abused for pleasure, for recreation, and Plan B wouldn't fit into that,

0265

that construct.

Q Were you interviewed by the Government Accountability Office in the course of its investigation of the Plan B process?

A I participated in an interview. I think there were several staff who were interviewed at the same time, kind of in a group interview.

Q Do you recall if or whether, in that group interview, you described to the GAO the lunch meeting in late 2003 or early 2004 that you've talked about today?

A I did describe it. It's actually included in their timeline in their report.

Q Okay. At the lunch meeting that we were just talking about, did either Dr. Woodcock or Dr. Galson give any explanation for what they were conveying as the Commissioner's decision?

A I don't remember specific words from that meeting. What I recall is that they were informing Dr. Kweder and myself that, you know, that Dr. McClellan, in his view, the Application could not be approved in this cycle, and it needed

0266

to be a Not Approvable Letter. I'm sure we discussed the reasons, and I think they related primarily to the issue of use in younger women and whether the data were adequate to support that use.

Q Did either of them at that time -- well, let me start with Dr. Woodcock. Did Dr. Woodcock, at that time or later, express any reservations about Dr. McClellan's decision?

A I don't recall her explicitly stating reservations or agreement or disagreement, but I clearly had the sense from the meeting that neither Dr. Woodcock nor Dr. Galson were in agreement that that was the path forward; they were communicating to us the path forward.

Q I think you said, in answer to one question about Dr. McClellan, that he was very careful not to state his opinion about Plan B at meetings that he attended with staff. Is that right?

A That's what I said, yes.

Q Do you have any idea why he would be --

0267

it seems to me that on the one hand you have his opinion being conveyed to you by Dr. Woodcock and Galson, and on the other hand, he's being very careful not to state his opinion. Do you have any idea why that would be?

MR. WARSHAWSKY: I object to the question, but you can answer.

THE WITNESS: I, I could only speculate on why he would have, not have conveyed a definitive view or definitive position in that meeting. You know, I came away from the meeting in February of 2004 feeling as if I didn't know what his position was, because he left it very vague at the end about what the path forward was, and it seemed like he was being intentionally vague, from my perspective. It wasn't like we had clear marching orders of "this is what you have to do and this is how I want you to do it." It was left very vague, and I recall being somewhat confused and frustrated by that vagueness.

BY MR. HELLER:

Q I think you've also talked about how

0268

Dr. Galson on one or two occasions expressed the view that he might -- his position in the Agency might be in jeopardy if he did not concur with the Commissioner's view about Plan B; is that right?

A I testified that he communicated to me on at least one and possibly two occasions that he didn't feel he had a choice, and he wasn't sure, you know, what would happen as far as the leadership of the Center if he did not concur.

Q Do you know if that played any role, this fact that he didn't believe he had a choice, that that played any role in the exercise of his scientific judgment?

A I really don't know. I mean he and I had a series of meetings over time. I meet with him weekly. He is my direct supervisor. And in those meetings we talk about a wide range of issues, including Plan B, and I know during that course of time I was pressing regularly on why are we taking this Action, what's the support, you know, et cetera, and he may have communicated to me what I have testified to earlier, out of

0269

frustration, that I kept pressing him on why are we doing this, why are you agreeing with the position, but I don't know if that had any impact on his eventual Review that he wrote and the conclusions that he reached.

Q You also testified about how the Non-Approvable Action, I believe, was viewed by Dr. Galson as a compromise that would pave the way toward some sort of non-prescription status later. Is that basically right?

A That's not exactly how I characterized it.

Q Okay.

A It was, it was conveyed to myself that -- and to others -- that the Not Approvable Action was necessary to address the constituents who were opposed to approval of Plan B over the counter, and that in some way down the road that hard-line position that the Agency had taken on the first cycle would in some way pave the way toward some sort of a compromise that would lead to an eventual approval that was more restricted.

0270

I have to say I never fully understood the logic of the scenario that was communicated, but that's what was communicated.

Q Did you by any chance read or look at the portion of Dr. Houn's deposition where she testified about receiving a telephone call from Dr. Woodcock around the time of the January 15th, 2004, meeting?

A I saw that in her deposition, and I was aware of the phone call, yes.

Q When did you become aware of that phone call?

A I think I may have -- Sandy Kweder and myself may have actually suggested to Dr. Woodcock that she call Dr. Houn, so I may have been aware of it before it occurred and probably was aware in reasonable proximity to when it occurred that Dr. Woodcock had actually called her.

Q Were you aware at that time -- well, were you aware at that time, around the time of January 15th, that Dr. Woodcock had conveyed to Dr. Houn that the Plan B process was occurring as

0271

it was to appease constituents of the Presidential Administration?

MR. WARSHAWSKY: I'm going to object to that question. I think that --

MR. HELLER: Let me rephrase it a little bit.

MR. WARSHAWSKY: I object to the way you phrased that, because I think we know from the record who was on that telephone call, so I think the question is more about what he was told by one of these people.

BY MR. HELLER:

Q Well, did either Dr. Houn or Dr. Woodcock tell you that during the course of that telephone call a statement was made about appeasing the constituents of the Presidential Administration?

A I have a vague memory that that's how Dr. Houn communicated back to me the substance of the call with Dr. Woodcock, that that was her interpretation of what she had heard.

Q Around the time of the phone call?

0272

A Yes.
Q Putting aside the phone call itself, just information or the proposition that, that the Agency's handling of Plan B was occurring the way it was to appease the constituents of the Presidential Administration, have you heard anyone else express that proposition or that idea?
A Well, there's been lots of speculation within the Agency that that was the reason for a lot of the events, but I think the only places that I've heard from my supervisors was in relation to the, uh, the need for the Not Approvable Letter to take a hard stance that would then later pave the way to some sort of acceptable compromise.
Q Do you remember why you asked or suggested to Dr. Woodcock around the January 15th meeting that she contact Dr. Houn?
A Yes.
Q Can you explain, tell me why.
A I knew that Dr. Houn was very upset after the meeting on -- you said January 15th? I

0273

knew that she was very upset during that meeting. She was very emotionally upset, during the conduct of the meeting, about hearing the planned Action, and I felt it was very important that either Dr. Galson or Dr. Woodcock reach out to her to try to provide her with some comfort and maybe a better understanding of how this fit into the big picture of the work that we do at the Agency. I was concerned for her individually but also concerned for her as far as the impact the Action may have had on her decisions about her career.

Q Do you -- have you been Dr. Houn's direct supervisor?

A Yes.

Q And has that been throughout your tenure at the Office of New Drugs, or --

A Yes, I've been the Director of the Office of New Drugs since January of 2002, and Dr. Houn was my direct report, I was her direct supervisor until approximately a month or so ago when she took a new position in the Center for Biologics.

0274

Q Did you have any -- during your supervision of her, did you feel that she was a qualified good scientist?

A Yes.

Q Do you know what position she took at the Center for Biologics?

A She is now the Deputy Director in the Office of Vaccines.

Q Do you know why she took that new position?

A I think she expressed that she was interested in doing new things in her career. She had been the Office of Drug Evaluation III Director for several years, and I think she was looking to do something different. Before she took the position in Biologics, she actually did a detail for about six months -- "detail" meaning a temporary assignment -- in the Office of Compliance in the Center for Drugs, so I think she was looking for something new and different, new challenges.

Q Did you review the portion of Dr. Houn's

0275

deposition transcript where she testified that she was concerned that the Agency might retaliate against her for her testimony?

A I saw the portion of her testimony where she expressed concern about her position within the Agency. I don't recall her ever using the word "retaliate" from what I recall from the transcript, but I did see that she expressed concern about the impact her testimony might have on her position.

Q Do you have any reason to believe that she's right or wrong about that?

MR. WARSHAWSKY: Objection.

BY MR. HELLER:

Q Well, let me ask you this: Do you have any reason to believe that her position at the Agency was in any way affected by her views about Plan B?

A No.

Q Your testimony you gave about Dr. Galson expressing on one or two occasions concern about what would happen if he did not concur in

0276
non-approval, did he ever -- was that ever put in writing to you as sort of an e-mail that you recall or anywhere else?
A No. As I recall, it occurred on a couple of occasions in meetings I had with him either in his office or my office in the course of routine sessions that I would have with him, and those are not captured in any formal way.

0280
BY MR. HELLER:
Q Okay. Thank you.
The next document I'm going to show you is marked Tummino 30931, and it goes through 30941, and it appears to be a Medical Officer Review from the Division of Pediatric Drug Development for Plan B, so I wanted to ask you, first of all: Do you know if you've ever seen this before?
A I do not have a specific recollection of having read this before, but I believe that it was part of the, what we call the Action Package, which means a compilation of all the reviews that would have been put together for the Second Cycle Review of the Plan B Application, and I know that I reviewed the Action Package for the second cycle before I wrote my Review in the second cycle, so it's likely that I looked at this. I just don't

0281

have a specific memory today of this document.

Q Can you tell me what is the Division of Pediatric Drug Development? Do you know what that is?

A Yes. At the time that this document was written, there was a separate office in the Center for Drugs that was called the Office of Counter-terrorism and Pediatric Drug Development, kind of a bit of a bureaucratic jumbling of issues that I won't go into the history of how that came to be, but the Division of Pediatric Drug Development was a division constituted primarily by pediatricians who were charged with various aspects of pediatric drug initiatives in the Center under the Best Pharmaceuticals For Children Act, and there's also pediatric exclusively provisions for pediatric studies, and they were also available as essentially consultants to other parts of the Center on pediatric issues.

So this looks like a Review that was written by the Division of Pediatric Drug Development related to the Application, and would

0282

have been considered essentially a consult to the reviewing divisions that had regulatory responsibility for the Application.

Q Is it fair to say then that this Division of Pediatric Drug Development is the, the office within the FDA that contains expertise on pediatrics?

A They are one of the offices in the FDA that has expertise in pediatrics. We have pediatricians who are also in other divisions within FDA. This is a concentrated division that really arose out of the need to manage the Pediatric Exclusivity Program that originally started in 1997 which offers companies additional marketing exclusivity for their product if they do certain studies that the FDA requests in writing, so the Division grew out of that responsibility but over time also, as a nidus of concentrated expertise in pediatrics, became a place where we would go to for advice on pediatric issues.

Q Do you know if this is the same place that Dr. Galson went to to get advice just prior

0283
to his May 2004 letter?
A He -- as I understand it, he sought input from Dr. Diane Murphy, who was at that time the Director of the Office of Counter-terrorism and Pediatric Products. Dr. Murphy is also a pediatrician by training, and so she was the Office Director over this Division at the time, but she was not any of the people who's listed here as the signatories on this consult.
Q If you'd turn to the page marked 30933 for a moment, and looking just at the two, the first two full paragraphs on that page, if you wouldn't mind just reading those to yourself for a moment.
A Okay.

0291
Do you know if the drug -- if there are nicotine-related drugs that are available over the counter?
A Yes, there are.
Q And are they available over the counter only for certain age ranges?
A There are restrictions on purchasing those nicotine replacement products. I believe the age cutoff is 18. I've actually been involved in the past in researching how that age restriction came about, and I believe that it was a voluntary agreement on the part of the company,

0292

the sponsor, who agreed to impose those sales restriction in the eighties or early nineties when those products were approved over-the-counter.

Q Do you know if that product or that group of products, I guess, are they kept behind the counter, or is it required by the FDA that they are kept behind the counter?

A From personal observation they seem to either be kept behind the sales counter or locked up somewhere where you have to get a clerk to garner access. That's different than what I would characterize -- when we normally talk about "behind the counter," we're usually talking about behind the pharmacy counter, and my experience just from observation is that in practice these nicotine replacement products are kept behind the sales counter such that the sales clerk has to give them to you when you ask and check your I.D., in theory.

Q Based on the research you did about where the age 18 restriction came from for these nicotine replacement products, do you know if it

0293

had anything to do with the fact that sale of cigarettes and other tobacco products is restricted to persons under 18?

A As I recall, that was part of the rationale and part of the concern about the availability of these products over the counter. As you say, the tobacco products had existing sales restrictions, and these products essentially replaced the nicotine from the tobacco, so I think there were concerns about the consistency of the message that you couldn't buy cigarettes if you were under 18, but you could buy these products and get the same pharmacologic effect as the cigarettes would provide, but also I believe that it was related to concerns about people under 18 potentially abusing these products as a way to get high.

Q Thank you.

MR. HELLER: I'd like to take a two-minute break, because I'm almost done, but I just want to confer with my colleague, and we may be done.

0294

THE VIDEOGRAPHER: We're going off the record. The time is 12:52 p.m.

(Whereupon, a short recess was taken.)

THE VIDEOGRAPHER: We're back on the record. The time is 12:57 p.m.

BY MR. HELLER:

Q Dr. Jenkins, just a couple more things. In your, in your capacity as Director of the Office of New Drugs, did you receive weekly reports from ODE III?

A Yes. We actually have a weekly report that all of the Offices submit that's then compiled to be an Office of New Drugs Weekly Report, and then we review that to some degree in a Monday morning meeting of all the Office Directors with myself to go over what are the hot topics for the week, what Actions are coming up, et cetera, so yes.

Q What role do those weekly reports play, if any, in your decision-making process?

A I would say they really don't play a role in the decision-making process per se.

0295

They're intended to keep me briefed on all the activities that are going on across the Office of New Drugs on an ongoing basis, so I instituted them when I started in my position so that I have information about those activities, and also I use it as a reference document during the week. If I get a question from someone about an Application or an issue, that's the first place I go to to see if I have any information if I don't know about it off the top of my, off the top of my mind, but it's not a decisional document. The updates often say we're planning to approve this drug on such and such date or we're planning not to approve this drug, but it's not really directly related to decisions.

Q And would those weekly reports go on -- I mean do you pass them on to someone higher up, or do they just stop with you and then you -- I mean did you -- what I mean is literally did you take those weekly reports and give them to Dr. Galson or someone higher up?

A First just to put it in context, I don't

0296

actually receive the individual weekly reports from the Offices. They come to a member of my staff who is responsible for compiling them into a document that covers all of the offices within OND, and then every Friday that compiled document is then e-mailed to a distribution list that includes myself, but it also includes people within the Office of New Drugs, people within the Center who are not in the Office of New Drugs, and it also includes distribution to someone in the Center Executive Operations staff. I do not believe that it goes directly to Dr. Galson. I don't think he's on the distribution list, but it goes to the Executive Operations staff so that they can be aware of issues that are coming up that he may need to be apprised of.

Q Do you recall the name of the person from the GAO who was at that group interview that you participated in?

A I remember one of the persons' name. I don't remember his last name. I think his first name is Marty, but I don't remember his last name,

0297
Ehrhart, maybe, or --
Q As someone from the Government Accountability Office?
A Yes.
MR. HELLER: No further questions.
MR. WARSHAWSKY: I just have one or two quick follow-ups.
FURTHER EXAMINATION BY COUNSEL FOR FDA
BY MR. WARSHAWSKY:
Q Mr. Heller asked you a few questions about whether CDER, or I should say FDA, was going to require special pediatric studies for Plan B?
A Uh-huh.
Q Within the context of the two documents that Mr. Heller discussed with you, one that he didn't show you and the consult that he did show you, my first question is: Do you know what the substantive purpose of that review process is? In other words, what is the intended purpose of these special pediatric studies?
A Okay. First I'd have to say the two documents that you're referring to seem to be on

0298

different points. The document he read from the computer was about whether we were going to issue a written request. The document that he shared with me which was the consult from the Division of Pediatrics related to the actual Application under review, so they were kind of addressing different issues.

With that, can you restate your question.

Q Sure, and they address different issues, but if I understood the two documents correctly, they both concluded that additional pediatric studies were not required for the Plan B Application; is that right?

A Right.

Q Okay. What would those additional pediatric studies -- what would the purpose of such studies have been? I'm just trying to understand what is meant by this notion of some sort of an additional pediatric study as opposed to the information in the studies that were provided in this case.

0299

A Right. As the law is set up, FDA can request studies, through these written requests, when we feel that there's information needed that would help inform the safe and effective use of that product. We generally focus on the indication that's already approved in adults, but the law does not restrict us to considering just that indication when we issue a written request, so that's a way of saying we issue the written request based on information we need to know about the molecule used in children, not just that product for that same adult indication used in children. So we're supposed to assess whether we need any additional information to help inform the safe and effective use of that drug substance in children, and if we feel we do, then we issue the written request, hoping to obtain that information.

The ultimate goal is to allow us to include that information in the labeling of the product to instruct physicians on how to safely and effectively use it in children. In the case

0300
for Plan B, it's my understanding that the Review Division, Dr. Shames being the Division Director, concluded that we did not need additional studies for Plan B, that the labeling in place already adequately addressed the safe and effective use in children, but I would say that was as a prescription drug.

Q Now, with respect to the pediatric consultation document that you were shown, I believe that document was dated November of 2004. Do you know who, if anyone, within CDER that document would have been provided to?

A It would have gone to the Review Division, either the Reproductive Division or the Over-the-counter Division or both at the time, because they would have been the ones who requested the consultation, so I think the document was actually directed to the file. That's the way we officially capture those. So it was directed to the file for that Application, but it would have been shared directly with the Reproductive Drugs Division and the

0301

Non-prescription Division.

Q Do you know if Dr. Galson or anyone else within the, within CDER or the Office of New Drugs had supervisory authority over the folks who issued that consult in November 2004?

A At that time Dr. Galson would have been Dr. Murphy's supervisor, so Dr. Murphy was the Office Director for Counter-terrorism and Pediatrics. I don't recall at the time who was the Division Director for Pediatrics, but Dr. Murphy, so Dr. Galson was clearly in the supervisory chain for that division. That division was not part of the Office of New Drugs, so myself, Dr. Houn, or anyone else in the Office of New Drugs would not have been in the supervisory chain.

Q Do you know if Dr. Galson specifically reviewed that document from November 2004?

A I have no way of knowing.

Q Do you recall that in, I believe it was February of 2004, after the presentation to the Commissioner, that Dr. Griebel sent a letter to

0302

Barr asking them to provide additional adolescent data in connection with their Application?

A I remember we made that request. I didn't recall that it was Dr. Griebel who signed the letter.

Q I could be wrong on that. That's what I recall.

MR. WARSHAWSKY: Okay. No further questions.

THE WITNESS: Okay.

MR. WARSHAWSKY: Thank you.

MR. HELLER: Thank you very much.

THE VIDEOGRAPHER: This marks the end of the deposition of Dr. Jenkins. The number of tapes used was two. We're going off the record. The time is 1:07 p.m.

(Signature having not been waived, the confidential videotaped deposition of JOHN K. JENKINS, M.D., was concluded at 1:07 p.m.)

0303

ACKNOWLEDGEMENT OF WITNESS

I, John K. Jenkins, M.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)

0304

E R R A T A S H E E T

IN RE: TUMMINO V. VON ESCHENBACH

RETURN BY:

PAGE	LINE	CORRECTION AND REASON
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

(DATE) (SIGNATURE)

0305

E R R A T A S H E E T

IN RE: TUMMINO V. VON ESCHENBACH

RETURN BY:

PAGE	LINE	CORRECTION AND REASON
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

(DATE) (SIGNATURE)

0306

CERTIFICATE OF SHORTHAND REPORTER -- NOTARY PUBLIC

I, Laurie Bangart-Smith, Registered Professional Reporter, 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 _____ day of _____, 2006.

My commission expires: March 14th, 2011

_____

LAURIE BANGART-SMITH
NOTARY PUBLIC IN AND FOR
THE DISTRICT OF COLUMBIA