IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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

Videotaped Deposition of
SUSAN WOOD, Ph.D.
Washington, D.C.
Monday, July 31st, 2006
12:02 p.m.

Job No. 1-83315
Pages 1 - 186
Reported by: Laurie Bangart-Smith

Videotaped Deposition of

SUSAN WOOD, Ph.D.

Held at the offices of:

ARNOLD AND PORTER

555 12th Street, Northwest

Washington, D.C. 20004

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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.

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EXAMINATION INDEX



Question Marked

Page 69 Line 21

"Q Do you have a party affiliation?"

E X H I B I T S

(Attached to the Transcript)

| DEPOSITION EXHIBIT | | PAGE |
|---|---|---|
| No. 1 | Curriculum Vitae | (Premarked) |
| No. 2 | Letter of Resignation 8/31/05 | (Premarked) |
| No. 3 | E-mail string, 8/31/05 | (Premarked) |
| No. 4 | E-mail, 9/1/05 | (Premarked) |
| No. 5 | E-mail string | (Premarked) |
| No. 6 | Nightline transcript | 89 |
| No. 7 | "Science Magazine" article | 129 |
| No. 8 | "New Eng. Jrnl. of Med." article | 131 |
| No. 9 | "Washington Post" article | 137 |
| No. 10 | Power Point presentation | 143 |
| No. 11 | Postcard | 144 |
| No. 12 | Prescribing Information | 146 |
| No. 13 | E-mail string | 157 |
| No. 14 | Letter to Wood, 6/13/06 | 161 |
| No. 15 | Document WOOD 051 thru 053 | 171 |

P R O C E E D I N G S

THE VIDEOGRAPHER: Here begins videotape Number 1 in the deposition of Susan Wood, M.D., (sic) 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. In the U.S. District Court for the Eastern District of New York, Case Number 05-CV-366 (ERK/VVP).

Today's date is July 31, 2006. The time on the video monitor is 12:02 p.m. The video operator today is Will Freburger. This video deposition is taking place at Arnold and Porter, 555 12th Street, Northwest, Washington, D.C.

Counsel, please voice-identify yourselves and state whom you represent.

MS. LABATON: Vivien Labaton for the plaintiffs.

MS. JONES: Bonnie Scott Jones for the plaintiffs.

MS. POULSON: Zoe Poulson from Williams & Connolly for Duramed Research, Inc., and Barr

Pharmaceutical, Inc.

MR. AMANAT: Franklin Amanat, Assistant U.S. Attorney, Eastern District of New York, on behalf of the defendant.

MR. TRISTER: Michael Trister for the witness.

THE VIDEOGRAPHER: The court reporter today is Laurie Bangart-Smith of L.A.D. Reporting.

Would the reporter please swear in the witness.

SUSAN WOOD, PhD.,

having been duly sworn, testified as follows:

EXAMINATION BY COUNSEL FOR PLAINTIFFS

BY MS. LABATON:

Q Hi, Dr. Wood. My name is Vivien Labaton, and I'm going to be taking your deposition today. I just want to first establish a few grounds rules so we understand each other during the course of this deposition.

If at any point you don't understand any of my questions or you find a question ambiguous, please just let me know so I can clarify or

rephrase it. If you don't ask me to rephrase my question, I'm going to assume that you understand it. Is that acceptable to you?

A Yes.

Q And if you want to take a break at any time, please just let me know, and we'll finish the question we're on and move on to a break as soon as we can.

Please answer each question verbally so that the court reporter can record your answer. And your lawyer may object to questions, but unless he instructs you not to answer a question or unless I withdraw the question, please answer the question.

A Okay.

Q I'm going to start by just going over a few definitions so I can make sure we're on the same page.

You're familiar with the Citizen's Petition filed February 14th, 2001, seeking to make FDA-approved emergency contraceptive products available over the counter?

A Yes.

Q I'll refer to that as "the Citizen's Petition."

A Okay.

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

A Yes.

Q I'll refer to that as "Plan B SNDA."

A Okay.

Q I'm going to hand you what has been marked as Exhibit 1.

A Can I make a correction? On the announcement of the tape it was I was an MD, and I'm not an MD. I'm a Ph.D., so correct that for the record.

MR. AMANAT: Do you have her CV?

MS. JONES: Yeah, I have it.

MR. AMANAT: Is it the same one that you got for Mr. Trister?

MS. JONES: Yes.

MR. AMANAT: Okay, I have it.

BY MS. LABATON:

Q Is this one of the documents you produced today in response to the subpoena?

A Yes.

Q What is this document?

A It's a CV.

Q And it's your CV?

A My CV, yes.

Q And who prepared that document?

A I prepared this document.

Q Okay. Is that document an accurate representation of your educational background and your professional experience?

A Yes.

Q Okay. Did you ever work at the FDA?

A Yes.

Q When was that?

A From fall of 2000 to August of 2005.

Q Okay. And did you work at the FDA for that entire time?

A Yes.

Q And what was your position at the FDA?
A Assistant Commissioner for Women's Health and Director of the FDA Office of Women's Health.
Q What were your responsibilities in that position?
A Um, managed and directed the Office of Women's Health, which was part of the Office of the Commissioner, and the budget and the programs therein. I was also to be involved in relevant policy discussions within the Office of the Commissioner on behalf of women's health issues across the Agency.
Q Okay. And do you currently work at the FDA?
A No, I do not.
Q When do you leave the FDA?
A August 31st, 2005.
Q Okay. I'm handing you what has been marked Exhibit 2.
A Yes. Did I get the date right? Good.
Q What is that document?

A That's the Letter of Resignation I submitted on August 31st of 2005.

Q And did you prepare that letter?

A I did.

Q And who did you give that letter to?

A Dr. Woodcock.

Q So that's a true and accurate copy of the letter you gave to Dr. Woodcock?

A Yes, it is.

Q Okay. Why did you leave the FDA?

A It was in response to the decision announced the few days before to not approve Plan B emergency contraception over-the-counter, due to the stated need to put it into rule-making, and I disagreed with that and felt that I could not continue on in my position as head of Women's Health, and so I resigned.

Q And have you been working since you left the FDA?

A Yes.

Q What type of work have you been doing?

A Well, currently I'm on the faculty of

George Washington University School of Public Health, where I'm a Research Professor. For -- taken a range of, uh, short-term consulting positions.

(Phone rings.)

MS. LABATON: Can we go off the record.

THE VIDEOGRAPHER: Going off the record, the time is 12:08 p.m.

(Whereupon, a short recess was taken.)

THE VIDEOGRAPHER: We're back on the record, the time is 12:10 p.m.

MR. AMANAT: Would you please read back the witness's last answer, ma'am.

(Whereupon, reporter reads requested material.)

BY MS. LABATON:

Q So you got cut off. Do you want to finish your answer to the question of where you have been working since you left the FDA?

A I ask again to explain how much detail you would like on that.

Q Perhaps you could start with the work

you began doing as soon as you left the FDA.

A Um, well, I was, um, had not lined up any subsequent employment prior to my departure, do I was essentially unemployed for a couple of months, although I took a couple of, um, consulting positions with, um, a couple of companies, and, uh, and with some nonprofit organizations. Um, beginning in November of 2005 for six months, I became a Senior Policy Advisor for the Reproductive Health Technologies project, that, you know -- and through that was doing a lot of traveling and speaking, um, to universities, women's organizations, family planning groups. Then that position ended on May 1st of this year, and, um, I started my position, uh, with, uh, George Washington University on July 1st. And I still do some consulting to different organizations, all -- yeah.

Q In your capacity as the Assistant Commissioner for Women's Health and the Director of the Office of Women's Health, were you aware of the Agency's decision-making process with respect

to Plan B?

A Can you specify as to sort of what point during -- what point in time? At some points I was; at other points I was not.

Q Let's start with upon Barr's submission of the SNDA.

A I mean I was aware of the process that it was going through, yes.

Q Were you involved in any way in the Agency's handling of the Plan B SNDA?

A Only in the capacity of the Office of Women's Health as part of the Office of the Commissioner. We're not part of the chain of command on a decision, but we were aware, um, and in contact with, um, different levels of review of this product.

Q And while you were not involved in the decision-making process, did you have knowledge of it?

A Yes.

Q Did you speak with any of the people involved in the decision-making of the Plan B SNDA

about the Application?

A Yes.

Q Who did you speak with?

A Um, and this is for the Application that -- of the decision in 2004, that stage of the Application?

Q Uh-huh.

A Um, I spoke with, um, some of the reviewers. I spoke with, um -- I'm trying to remember. I -- probably others within that, the, the review chain, um, and I also spoke with, um, Dr. Woodcock and also with Dr. Galson.

Q And what did you speak with, with the reviewers about?

A Um, well, this was sort of during the general review time in the preparation for the Advisory Committee meeting, sometimes after the Advisory Committee meeting, and it was just conversation about is it, you know, is it moving along, the stage of the Application, where it was in the process, and, um, and what was happening in the review process.

Q Did you attend any meetings related to Plan B within the FDA?

A I did. I remember, um -- one meeting early on, I believe, was actually prior to the submission of the Application, um, where with a large number of people there from Women's Capital Corporation as well as the Review Division and so forth. Um, there may have been another internal FDA meeting that I attended. It may have been a briefing of Dr. McClellan of it, of -- by the Review Team that I attended, I think. Uh, I then, uh, prior to the '04 decision, I met with Dr. Woodcock and with Dr. Galson.

Q Where were you -- where were you working in May 2004?

A Where was I working in May 2004? I was working in Rockville.

Q In Rockville? And are you aware that in May 2004 Dr. Galson signed a Non-Approvable Letter regarding the Barr SNDA?

A Yes.

Q And did you agree with the Agency's

decision to issue a Non-Approvable Letter on the Barr SNDA?

A No. In 2004?

Q Uh-huh.

A Correct. No.

Q Are you familiar with the Plan B SNDA and the scientific evidence provided in support of it?

A Yes, I'm familiar with it.

Q In your professional opinion, did the scientific evidence support the Agency's decision?

MR. AMANAT: Objection.

You can answer the question.

THE WITNESS: Um, I rely on the reviews done by the professional staff, um, on, on their assessment of the Application.

BY MS. LABATON:

Q And based on that reliance, you did not agree with the Agency's decision?

A Correct.

MR. AMANAT: Would you mind reading back not the last answer where she said "correct," but

the one before that, please.

(Whereupon, reporter reads requested material.)

MR. AMANAT: Okay. Thank you.

BY MS. LABATON:

Q Why did you disagree with the Agency's decision?

A Again the decision in 2004?

Q Yes, the decision to issue a Non-Approvable Letter.

A Non-Approvable Letter. Um, because again I agreed with the, uh, reviewers and the Division Directors and the Office Directors that it should have been approved over-the-counter for all women of child-bearing potential.

Q Did others within the FDA express concerns similar to yours about the handling of the Plan B Application?

A Yes.

Q Was the expression of those concerns wide-spread?

A It seemed to me --

MR. AMANAT: Objection.

THE WITNESS: It seemed to me to be wide-spread.

BY MS. LABATON:

Q Did, did Dr. Steven Galson ever discuss with you the basis for his decision to issue a Non-Approvable Letter?

A Yes.

Q Did that occur in a conversation by phone?

A No.

Q In person?

A In person.

Q And who initiated that conversation?

A Dr. Galson.

Q When did that conversation take place?

A Either the day -- I believe it was the day before or a couple of days before the, um, issuing of the Non-Approvable Letter.

Q And where did that conversation take place?

A In Dr. Galson's Office.

Q And what did Dr. Galson say about the basis for his decision?

A Um, he said that he, um, had reached conclusions about concerns regarding the use by younger teens, um, and he also, uh, said, uh, that he was, um, felt it important to be an effective leader of the Center for Drugs, and that issuing this Non-Approvable Letter was, um, necessary if he was going to be able to be an effective leader of the Center for Drug Evaluation and Research.

Q Did Dr. Galson ever indicate that issuance of the Non-Approvable Letter in May of 2004 might lead to some favorable action related to Plan B in the future?

A Yes.

Q And what did he indicate?

A Well, he really thought that this was a path forward towards approval, at least for older teens and adults.

Q And did Dr. Galson express that in that same conversation with you?

A Yes.

Q Do you have any understanding of why Dr. Galson thought that denial of the SNDA was, was necessary to be an effective leader?

MR. AMANAT: Objection.

You can answer the question.

THE WITNESS: Can you ask that question again.

BY MS. LABATON:

Q Sure. Do you have any understanding of why Dr. Galson thought that denial of the SNDA was necessary to be an effective leader?

A I don't remember the exact words that he said, but my understanding of it was that he felt that he would not be able to work with the leadership of the Agency in an effective manner if this letter -- if this denial did not go through. My understanding from that meeting was that he, he felt that this was necessary if he was going to be, um, an integral part of the leadership of the Agency in terms of being able to work with, um, uh, his supervisors, uh, in, in managing, uh, the Center for Drugs.

Q Uh-huh. Did you ever speak with Dr. Woodcock about the decision-making process regarding the May 2004 Non-Approvable Letter?

A Yes, I did.

Q And when did that conversation take place?

A That took place a few days before the meeting with Dr. Galson. No, maybe a week before, maybe just a few days before. I don't remember exactly.

Q And did that conversation take place in person?

A It did.

Q And who initiated that conversation?

A Dr. Woodcock initiated that conversation.

Q And what did she say during that conversation?

A Well, she was -- she had wanted to let me know, uh, that, um, the decision on Plan B was going to be this Non-Approvable Letter, and requesting this, uh, keeping it prescription

status for young teens.

Q And who did she say was making the final decision about the Plan B Application?

MR. AMANAT: Objection.

THE WITNESS: She didn't say exactly. It was just that this was what the decision was going to be, and she wanted to make sure that I knew about it ahead of time and, um, so that I would be properly prepared for the announcement, um, and so that when Dr. Galson called me to let me know, I already knew what the decision was going to be, but she didn't say exactly who.

BY MS. LABATON:

Q Did you ask Dr. Woodcock if there was any way that the decision to issue a Non-Approvable Letter could be reconsidered?

A Yes, I did. We discussed whether there was a chance of revising that decision or changing it before it was announced.

Q And who did Dr. Woodcock say was the person to speak with about whether or not the decision could be reconsidered?

A She suggested that perhaps we could have a meeting with Dr. Crawford and that she would look into that to discuss changing the decision, although she was not very optimistic.

Q So did she indicate that the decision to issue a Non-Approvable Letter was Dr. Crawford's?

MR. AMANAT: Objection.

THE WITNESS: I said that was, that was -- well, like I said, she didn't say who was making the decision, whether it was Dr. Crawford or anyone else. She just said that perhaps we could get a meeting with Dr. Crawford to, um, discuss it once again to see if, if there was a chance of the decision not going forward as planned at that point.

BY MS. LABATON:

Q And did Dr. Woodcock say why the SNDA was going to be denied?

A Well, it was the issue of the young teens again. I mean there was -- that was what was going to be the decision. It wasn't a real why, so to speak; it was just that that was the,

the, um, nature of the decision, was to, uh, request an Application that would keep it prescription for young teens, and otherwise it would be non-approvable.

Q Did you have a conversation with Dr. Galson in December of 2004 or early January of 2005 about the Plan B SNDA?

MR. AMANAT: Objection.

THE WITNESS: I'm sorry. Say that again.

BY MS. LABATON:

Q Did you have a conversation with Dr. Galson in December of '04 or early January of '05 about the Plan B SNDA?

A Yes.

Q And was that conversation on the phone or in person?

A It was on the phone.

Q And who initiated that conversation?

A Well, the conversation was, uh, started was about -- and so I don't know who initiated it. Probably I placed the call, but the conversation

was, was happening, because, um, I was asking Dr. Galson about a completely unrelated matter, and at the end of the conversation I asked him about what was the status of the Plan B Application, since it was approaching its PDUFA deadline.

Q Uh-huh, and what did Dr. Galson tell you during that conversation?

A He said it was going to be approved for those 17 and older, over-the-counter.

Q And did he, did he predict that, um, he would take action on the SNDA during a particular time frame?

A He said to me, um, that it would be a matter of a few days, maybe a week or two, that he thought it would go out and that it would be an approval letter, not an approvable, and so all the, um, t's had to be crossed and the i's dotted, but that it should be coming out very soon. It might miss the PDUFA deadline but not by much.

Q And do you know when Dr. Galson first wrote the memo that was released on August 26,

2005?

MR. AMANAT: Objection.

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

BY MS. LABATON:

Q Are you aware that the FDA made a decision in August of '05 to postpone action on the Plan B SNDA and issued a Notice of Proposed Rule-Making regarding whether Plan B could be both prescription and over-the-counter based on the age of the individual using the drug?

A Am I aware of that?

Q Yes.

A Yes, I am.

Q And in your opinion, why did the FDA take that action?

MR. AMANAT: Objection.

THE WITNESS: In my opinion?

BY MS. LABATON:

Q In your opinion.

A I can't think of a good reason to issue that, to issue that decision. There's -- I don't,

I don't know why, and it doesn't fit any normal process that, that I can explain in terms of why it happened. I don't know why it happened. It didn't make sense.

Q When you resigned to Dr. Woodcock, did she say anything about her own feelings about staying at the Agency?

MR. AMANAT: Objection.

THE WITNESS: Yes.

BY MS. LABATON:

Q And what did she tell you?

A I, I, I really don't feel comfortable speaking on behalf of someone else in terms of their professional duties.

Q To your knowledge, did Dr. McClellan, in his tenure as FDA Commissioner, use e-mail regularly to communicate with FDA staff?

MR. AMANAT: Objection.

THE WITNESS: Yes, he did, a lot.

BY MS. LABATON:

Q A lot?

A A lot.

Q And what did he e-mail about?

A Everything. It was a, you know, almost to -- you know, it was one of the, um, uh, humorous and friendly commentaries that these people would make in meetings that they had got in a meeting, an e-mail that had been sent at 2:00 in the morning from Dr. McClellan, because he was very engaged and very hands-on.

Q Then did he e-mail about substantive issues?

A Oh, yeah, the whole range of issues, everything.

Q Uh-huh. I am handing you what's been marked as Exhibit 3. Is this one of the documents that you produced today in response to the subpoena?

A Yes, it is.

Q And what is this document?

A This is an e-mail from Dr. Bob Temple in response to my e-mail which I sent out to, you know, a bunch of FDA staff, announcing my resignation.

Q And you were -- you are the recipient of this e-mail?

A Yes. He responded back to me.

Q And you said that Robert Temple sent it?

A Yes.

Q Can you please tell me who Robert Temple is.

A Bob Temple is -- let's see. What's his title? He's the Director of Medical Policy for the Center for Drugs. I believe he's also an Office Director of one of the Office of Drug Evaluations.

Q And can you please read his e-mail, the portion of the e-mail that he sent to you, for us now.

MR. AMANAT: Objection.

THE WITNESS: He says, "We're pretty uniformly horrified, and I'm sorry it drove you away. We all have to deal with decisions we dislike, and it's easy to understand your inability to continue to serve as Director of OWH under the circumstances. Best wishes in what you

do next."

BY MS. LABATON:

Q And to what is he referring when he says "we're pretty uniformly horrified"?

MR. AMANAT: Objection.

THE WITNESS: Um, I read it to be he's horrified -- he was horrified at the decision to not approve emergency contraception over the counter.

BY MS. LABATON:

Q And what is his reputation within the Agency?

MR. AMANAT: Objection.

THE WITNESS: He has a -- he's an extremely influential and highly respected member of the FDA senior staff. He's been a long-time and very knowledgable and again highly respected member of FDA, and is, is a very important part of the FDA professional staff.

BY MS. LABATON:

Q I'm going to hand you what's been marked as Exhibit 4.

MR. AMANAT: Ms. Labaton, are you going to have all these exhibits attached to the transcript when the transcript is made?

MS. JONES: Yeah, they've all been marked, what she's identifying as having been marked.

MR. AMANAT: Thank you. I would ask that they be attached to the transcript, please.

BY MS. LABATON:

Q Is this one of the documents that you produced today in response to the subpoena?

A Yes.

Q And what is this document?

A This is one of the e-mails that were sent to me after my resignation to my FDA e-mail account from someone at FDA, um, in response to my resignation.

Q So you were a recipient of this e-mail?

A Yes.

Q Without stating the author's name, could you tell me whether you know who the author of the e-mail is.

A I actually don't remember. I got quite a few like this.

Q And can you read that e-mail.

A "I admire your decision to highlight this administration's politicalization of Plan B.

Q I'm going to hand you what's been marked as Exhibit 5.

THE VIDEOGRAPHER: Can we go off for one moment. Something's wrong with the microphones. We're going off the record. The time is 12:37 p.m.

(Whereupon, a short recess was taken.)

THE VIDEOGRAPHER: We're back on the record. The time is 12:38 p.m.

BY MS. LABATON:

Q To go back to Exhibit 4 for a moment, is it possible for you to, to tell me who -- to tell me the title of the person who sent that e-mail, or their level within the FDA?

A Um, I think I remember who wrote this, but I really prefer not to give any indication of where they were. This person was fairly senior,

but I prefer -- they're not in the approval chain of Plan B, so I prefer not to, um, state anything more about where they are.

MR. AMANAT: Object to the witness's answer as non-responsive to the question posed. Move to strike it as such.

You may proceed.

BY MS. LABATON:

Q I handed you a document marked as Exhibit 5.

A Yes.

Q Would you please identify that document.

A It's another e-mail sent to me actually very shortly after I resigned, um, from, um, someone at the Center for Drug Evaluation Research.

Q And you were a recipient of that e-mail?

A Yes.

Q And do you know who sent that e-mail?

A I do. I remember his name, yes.

Q And what is that person's title?

A I, I, I'm sorry. I really still don't

want to tell people's name. It's a very senior person at the FDA.

MR. AMANAT: Object to the witness's answer. Move to strike as non-responsive to the question posed.

MS. LABATON: We'd like to take a break, a ten-minute break.

THE VIDEOGRAPHER: We're going off the record. The time is 12:41 p.m.

(Whereupon, a short recess was taken.)

THE VIDEOGRAPHER: We're back on the record. The time is 12:53 p.m.

BY MS. LABATON:

Q Dr. Wood, you, you expressed earlier that Dr. Galson indicated to you that issuance of a Non-Approvable Letter in May of 2004 might lead to some later favorable action related to Plan B?

A Yes.

Q And what exactly did he explain to you about that?

A I think it's actually stated in his -- the Non-Approvable Letter itself, was that if,

um -- that if the company came back in with a Dual Status Application, that the Agency would be interested in looking at that, and I think he was very optimistic at that time that that type of Application could be approved if it came in.

Q I have one final question for you. I asked you earlier, when you resigned to Dr. Woodcock, whether she said anything to you about her own feelings about staying at the Agency. Unless your lawyer instructs you not to answer, I'd like you to answer the question.

MR. TRISTER: Can we consult?

MS. LABATON: Uh-huh.

MR. TRISTER: Okay.

THE VIDEOGRAPHER: We're going off the record. The time is 12:54 p.m.

(Whereupon, a short recess was taken.)

THE VIDEOGRAPHER: We're back on the record. The time is 12:57 p.m.

THE WITNESS: Okay. You want to restate that question for me.

BY MS. LABATON:

Q Sure. When you resigned to Dr. Woodcock, what did she tell you about her own feelings about staying at the Agency?

A Um, she said that she, um, was actually very understanding as to why I felt I needed to resign in order to maintain my credibility as someone working in women's health policy and women's health science and research. She was just very, um -- she was very understanding. She asked me if I would reconsider, and she said that she understood the need to maintain your credibility in the outside world and that, um, she, um, wasn't sure, um -- and I have to say I'm very uncomfortable in revealing private conversations of this nature. She wasn't sure how long, you know, that she would be able to feel credible at the FDA herself, and -- but she was certainly understanding how I had reached that point.

MS. LABATON: Thank you, Dr. Wood. I have no further questions.

CROSS-EXAMINATION BY COUNSEL FOR DEFENDANT

BY MR. AMANAT:

Q Dr. Wood, good afternoon. As you know, I'm Frank Amanat. I'm counsel for the Food & Drug Administration in this case. I do have a few questions for you, and before I begin my questions I'll reiterate some of the, couple of basic ground rules that Ms. Labaton mentioned.

In particular, if I ask you a question and you don't understand the question, I would ask that you inform me of that fact and that you ask me to restate my question or to further elaborate. And if you don't ask for that clarification, I'm going to assume that you understood my question as asked.

Let me, let me first start with some aspects of your, your biography on your CV which I think the plaintiffs have marked as Exhibit 1 to this deposition. I knew you indicated on a number of occasions during the course of this that you are not a physician; is that correct?

A That's correct.

Q Am I correct in understanding from your CV that your primary academic training was in marine biology?

A Um, no. My primary -- it was at the Marine Biological Laboratory in Woods Hole, but my primary training was -- my degree is from the Department of Biology, and my work was in the area of neuroscience and cell biology on marine organisms, but that's just the model system that we worked with.

Q So -- and I know I saw that you -- that a good portion of your research was in cellular mechanisms of sensory transduction, right?

A That's correct.

Q And among other things I saw that you had, you had studied the vision of squids, right? Is that right?

A Yes, as the model system of vision, yes.

Q And I saw you also had done some research in the olfactory systems of certain --

A Invertebrates, yes.

Q -- invertebrates as well. Now, I looked

at your CV in some detail, and there are -- there are some things that I didn't see there, and I wanted to kind of ask if maybe I was missing something or maybe there was a kind of training or background that you may have actually had, but I'm not seeing how it's reflected in your CV, so I want to ask you about different types of backgrounds --

A Sure.

Q -- and you tell me whether you did, in fact, have some kind of training or experience in that area and where I would find that in your CV.

Do you have any training in pediatric or adolescent medicine?

A No.

Q Do you have any training in the field of in statistics or statistical demographics?

A I took statistics in graduate school.

Q How about in the field of demographics?

A No.

Q Do you have any formal training in psychology?

A Well, one of my -- my undergraduate degree was in biology and psychology, but I wouldn't -- it's not advanced training in psychology, no.

Q How about in sociology?

A Only at the undergraduate level.

Q Anthropology?

A No.

Q Social anthropology?

A No.

Q Social psychology?

A No.

Q Epistemology?

A No.

Q Social economics?

A No.

Q Do you have any training in adolescent psychology?

A No.

Q Adolescent psychiatry?

A No.

Q Adolescent behavioral psychology?

A No.

Q Pharmacology?

A Yes.

Q And what is your training in pharmacology?

A In the Department of Neuroscience I was working in the field of pharmacology in terms of with Dr. Snyder there, as my post-doctoral training in neuroscience included the -- we were essentially doing a lot of pharmacology at the cellular level.

Q Okay. Would you describe biology and I guess cell biology in particular -- which you indicated as being your, one of your focus -- as being a hard science, a science that lends itself to more or less black-and-white answers to scientific questions?

A I think I'll need you to rephrase that, because --

Q Okay. Well, let me ask you this way: Would you -- as a biologist, you study living organisms, right?

A Correct.

Q And the, um, systems within those organisms which allow those organisms to remain alive; is that correct?

A That's certainly part of it.

Q And the cellular structures which make up those organisms and which allow them to procreate and eat and grow and --

A Yeah.

Q -- right? So would you say that, that as a biologist, most of your -- most of the empirical process that a biologist undertakes involves, um, setting a hypothesis and then testing a hypothesis in some kind of empirical testing system, right?

MS. LABATON: Objection.

THE WITNESS: That is a scientific method I think that applies to most science, all of science. That's how science is done.

BY MR. AMANAT:

Q And those kind of empirical testing systems can, in the biological field, can often

give you a concrete yes-or-no answer in terms of whether the hypothesis that you were testing holds or does not hold?

A It can. It can. Not always. I mean I think it's much more complex than that. It always generates new questions. That's the nature of science.

Q And am I correct in my understanding -- and forgive me, I'm a lawyer. I'm not a scientist. I don't pretend to be a scientist, but I've been fortunate to know many brilliant scientists over the course of my life, and I'm pleased to make your acquaintance as well in that regard. Am I correct in my understanding that the, the process of testing a scientific hypothesis through some kind of, um, empirical testing system ultimately requires a scientist to evaluate evidence; is that correct?

A Yes.

Q Okay. You do tests, you do studies, you see what the results are, you evaluate them, you extrapolate, and then you draw a conclusion as to

whether the original hypothesis which is under discussion is true or not; is that -- I know I'm generalizing, but is that a fair statement of how the empirical process works?

A I think that's a general statement of the scientific method, but yeah, go ahead.

Q So when -- now, do all scientists, um, interpret evidence the same way? In other words, let's say you did -- you started with a hypothesis, and you came up with a system to test the veracity or validity of that hypothesis, and you do that test and it generates results. Okay. So now you've got your raw data, your raw empirical data. If you put 5,000 scientists in the room, have all of them look at that data, are all of them going to interpret that data the same way?

A It depends on the quality of the data. It depends on the nature of it, if it's very clear, and then I would say -- and it depends on what type of interpretation you ask for, if it's a quantitative one or if it's a -- but again it

depends on the quality of the data. If there's good science that's been done on the whole, the scientific community or those with expertise in a particular area will come to some general agreement as to what the conclusion is. If the data is poor or if, in fact, comes up with contradictory information, or there are alternate explanations of whatever, you know, that people feel they still need to test, then there will not be agreement. It really depends on the nature of the question and the quality and the nature of the data that's generated.

Q Do scientists always agree as to what, as to what that quality is? I mean if you put those same 5,000 scientists in the room, are they all going to have the exact same opinion as to whether the data are good quality or bad quality, in your experience?

A In my experience, if there's really good data, there will be general agreement. Will there likely be someone who disagrees? I can't say that there never would be, but if there is good quality

data and there's a, you know, a good design, then they will come to some general -- there are always points of contention, but they're not -- it really depends on what you're -- what the question is and the nature of the data and the nature of what you're asking, what type of, you know, answer you're trying to get to, whether or not there will be a discussion point or a real conflict or a general agreement.

Q Fair enough. So do all -- now, you in the course of your, um, what is it; about 20 years, 25 years that you've been --

A Am I that old?

Q That you've been a biologist? I think --

A No, I got my degree in '89.

Q So 17 years.

A As a Ph.D.

Q In the 17 years since you've been a Ph.D. in biology, I assume you have had occasion to work with scientists from a wide range of scientific disciplines; is that correct?

A Well, yes, because I stopped working in the lab about 15 years ago and worked in other fields.

Q And so particularly during your time as a public official, you've certainly worked with scientists from a wide range of different disciplines; is that correct?

A That's correct.

Q Okay. In your experience, do, do um, scientists from different disciplines have the same, um, standards or expectations in terms of the quantum of evidence that they accept as sufficient to support a particular conclusion, or have you noticed variations, that some scientists may be willing to go out on a limb and draw a conclusion from a smaller quantum of evidence, while other scientists may be more risk-averse, so to speak, and may expect or demand a higher level of evidence before they're prepared to draw a conclusion from that evidence?

MS. LABATON: Object to form.

BY MR. AMANAT:

Q You can answer the question.

A And you're -- I mean you're saying this would vary by field so that some fields are more risk-taking versus other fields?

Q Before we get there, let's ask just more generally: Have you observed that some scientists, regardless of their discipline, may be more risk-averse than others in terms of the amount of evidence that they're willing to accept as sufficient to draw a scientific conclusion?

MS. LABATON: Object to form.

THE WITNESS: I guess I'm still not -- I don't know that that question really -- I'm not really understanding what you're looking for, because, um, scientists have different personalities, but I think in terms of -- and scientists have different levels of expertise in different fields, so I just don't think I fully understand your question.

BY MR. AMANAT:

Q Okay. Well, let me ask you -- let me

try to ask you the question this way then. Let me kind of go into kind of the different fields.

A Okay.

Q Would you say that a psychologist, for example, somebody trained with a Ph.D. in psychology, would approach a body of data in precisely the same way as a cellular biologist would?

A I think they would be approaching data in their field in a very similar way that a cell biologist would approach the data in their field, I would assume. They would not approach data that they're not familiar with in the same way that a cell biologist would approach that data, but they would, they would hopefully have, you know, a qualitatively similar approach to what they think is good science.

Q Okay. Very good. So something you said prompted a question in my mind. Is it -- you know, if a person is trying to kind of assess whether a scientist's opinion or conclusion with regard to a particular hypothesis or particular

body of evidence has validity, is it a relevant question to ask what their background is and whether their particular scientific training makes them best suited to interpret this particular body of data?

MS. LABATON: Objection to form.

THE WITNESS: If they're, you know, being an expert in that field and drawing a conclusion based on their own expertise, but if they're just evaluating the general science or the, the, the, you know, the general nature of the work, uh, but they're evaluating the individual data points, they need expertise in that particular field; but if they're reviewing generally whether it's good science and the quality of the, um, data generally, um, they need scientific training, et cetera, as well, but we all would assume that they have expertise in the field if they're going to be drawing -- you know, if they're going to be -- if they're going to be evaluating the data itself.

BY MR. AMANAT:

Q Okay. So in other words, if I understand the last part of your answer, you're saying if it's just a matter of kind of evaluating the strength of the data, that's something that really any trained scientist should be able to do competently, right?

A Well, I mean it really again depends on the field. I don't, you know -- quantum physics I can't look at, you know, but there are, there are types of -- you know, it depends on the question, it depends on the nature of the data, it depends on the nature of the question at hand.

Q Well, how about adolescent psychology; what, if anything, qualifies you to draw conclusions with regard to a body of data about adolescent psychology as opposed to conclusions that a specialist in that field might draw?

MS. LABATON: Objection to form.

BY MR. AMANAT:

Q You can answer the question.

A I rely on the reviewers' expertise, who

do have that expertise.

Q Now, at some point in your -- your CV indicates that at some point after you had completed your Ph.D., you spent a few years as a researcher. At some point you left that scientific research and you went to work for the Congressional Caucus for Women's Issues; is that correct?

A That's correct.

Q Okay. And what exactly were you doing -- it's not entirely clear to me from the way you've described it in your CV. What exactly were you doing for the Congressional Caucus for Women's Issues?

A The first year of my work at the Caucus, I was a Fellow sponsored by the American Association for the Advancement of Science and the Biophysical Society, which is my professional society, which sponsored me to go to there for a year. This is a program to bring scientists to work on Capitol Hill, to provide them with people with a scientific background when they're working

in various legislative or policy proposals that could benefit from someone with some sort of scientific expertise.

So I took that Fellowship and then, through a placement process, ended up working with the Congressional Caucus for Women's Issues, because they were just launching their focus on research on women's health and the need for -- funded by the NIH primarily, but then looking at other women's health research and services, and so since I had experience in biomedical research and this made, you know, a good placement for me, that ended up shifting my focus in my career for the next 15 years, so at the Caucus I helped them develop policy proposals and legislative proposals around women's health research prevention and services, and that extended the Fellowship that ended after a year, and they offered me a regular job there as Congressional Staff, and I stayed there until 1995, I think.

Q Was one of the things you were working on there, Dr. Wood, legislative proposals dealing

with family planning and family planning initiatives?

A Yes.

Q Okay. Is Congress a scientific organization or a political organization?

MS. LABATON: Objection to form.

BY MR. AMANAT:

Q You can answer the question.

A Well, I mean it's not a scientific organization, and it's a branch of government. You can name it whatever you like, but it certainly involves politics and policy and law and everything else that Congress does.

Q Okay. So is it fair to say that as a Congressional Staffer you were working with members of Congress to set policy, national policy on --

(Phone rings.)

THE VIDEOGRAPHER: We're going off the record. The time is 1:18 p.m.

(Whereupon, a short recess was taken.)

THE VIDEOGRAPHER: We're back on the

record. The time is 1:26 p.m.

BY MR. AMANAT:

Q So is it fair to say that when you were working as a Congressional Staffer you were participating in a process by which Congress was setting policy or at least considering setting policy for women's health-related issues?

A Yes.

Q And is it fair to say that part of your role, you were working with Congress to try to obtain changes in family planning policies through the legislative process; is that correct?

A That's correct.

Q Okay. Did you see it as being appropriate for Congress to have a role in setting family planning policies for the United States or changing those policy setting?

MS. LABATON: Object to form.

THE WITNESS: Congress does have an appropriate role in setting law and policy in this country.

BY MR. AMANAT:

Q Okay. So let's say hypothetically that Congress were to consider legislation which by, through the legislative process, were to determine that emergency contraceptives should be available over-the-counter. In other words, let's say that Congress were to draft an amendment to the Food, Drug and Cosmetics Act which says, "We hereby pass this bill," and submit it to the President for his signature, and the bill provides that, notwithstanding any other provision of the Food, Drug and Cosmetics Act, emergency contraceptives shall be available without a prescription; would that be appropriate for Congress to, to do that, in your view?

A In my opinion, not as a lawyer, but in my opinion, it's not Congress's role to make decisions on individual products. It is the FDA's role to evaluate the data and make recommendations and make the decisions about the safety and efficacy of products.

Q So if that's the case, then what was the

point of you working for Congress to try to get them to make changes through the legislative process in family planning policies if that was not part of Congress's role to do that?

A The nature of the family planning policies that Congress is appropriately involved in is setting the funding levels for family planning clinics to assure that FDA-approved drugs and devices are available in family planning clinics, whether other health insurance programs, whether there is research supported by the National Institutes of Health in the areas of contraception and infertility. This is not making decisions on the safety and efficacy of individual products, but rather -- which do need to be based on the evidence, but rather saying, you know, what sort of funding level and authorization of programs that have to do with family planning.

Q Okay.

A At least that's the parts that, you know, I was at all involved with.

Q Okay. Well, let's go beyond then --

let's go beyond emergency contraceptives, and just let me ask you a broader question.

A Uh-huh.

Q If Congress were to pass legislation saying, for example, notwithstanding any other provision of the Federal Food, Drug and Cosmetics Act, all non-steroidal anti-inflammatory drugs shall be available without a prescription in the United States, regardless of their dosage and indication, removing it, um, removing the prescription requirement carte blanche for NSAIDs; is that something that you think would be inappropriate for Congress to do as a matter of legislation?

A If I understand your question correctly, you're saying Congress would bring a whole class of drugs over-the-counter regardless of FDA's determinations.

Q Correct.

A I would agree that that's -- I don't know whether it's legal or they are able to do that, but in my view, I would not recommend that,

no.

Q Why?

A Because FDA is -- and the medical and scientific community need to be the ones who evaluate the data on NSAIDs, as well as again the safety net for the product is available for the FDA to be evaluating.

Q Now, let me follow up with you on that, because I've read a number of your speeches and your writings and your articles, and in a number of places you refer to FDA as an "independent agency." Do you recall having made statements along those lines in a number of your public statements?

A Well, that it should be able to make its decisions independently, based on the science and medical evidence.

Q Okay. And you, in some of your articles -- and we'll look at a couple of them in a few minutes -- you can criticize FDA for having, as you perceive it, gone away from this independence, and you kind of urge FDA to become

independent. Is that a fair characterization of some of your statements that you've made publicly?

A Well, I'd like to see those if you have those.

Q Yeah, we'll look at a couple of them.

Is FDA part of the Executive Branch of the United States Government?

A It is, indeed.

Q It's not an independent agency like, for example, the -- I don't know -- the Securities and Exchange Commission that's outside the Executive Branch, is it?

A No.

Q In fact, it's part of the Department of Health and Human Services, is it not?

A It is indeed.

Q Isn't it true that in the Food, Drug and Cosmetics Act, Congress assigned the responsibility -- well, let me ask you. I mean to whom did Congress assign the responsibility to approve drug applications in the FECA?

A Not being a lawyer, but I believe it's

the Secretary.

Q Secretary of HHS?

A Yes.

Q Who's, of course, outside of the FDA?

A Yes.

Q And the Secretary of HHS has, in turn delegated, that to the Commissioner of the FDA; is that not correct?

A That's my understanding.

Q And both of those officials are members of the Executive Branch, appointed by the President, confirmed by the Senate; is that correct?

THE REPORTER: You need to slow down. Both of those --

BY MR. AMANAT:

Q Individuals, those officials, are members of the Executive Branch, appointed by the President and confirmed by the Senate; is that correct?

A That's correct.

Q Now, you, after you left Congress, if

I'm not mistaken, went to work in the Office of the Secretary at HHS; is that correct?

A That's correct.

Q And what was your position there?

A Um, I was, uh, Director of the Division of Policy and Program Development within the Office of women's health at the FDA. Sorry. Within the Office of the Secretary.

Q And was that a position that was, um, occupied by career scientists, or was that a position that was typically occupied by political appointees?

MS. LABATON: Objection as to form.

THE WITNESS: It's a career position.

BY MR. AMANAT:

Q But you had not theretofore served in the Executive Branch; is that correct?

A No.

Q That was your first employment in the Executive Branch?

A Right.

Q But that Policy Director position in the

Office of Women's Health is a career position?

A Yes.

Q Okay. Um, and in what year did you, uh, were you appointed to that position? Was that '95?

A I believe it was '95 when I started that job.

Q And then at some point in time -- who appointed you to that position?

A It wasn't an appointment; it was just a job.

Q Well, who hired you?

A Who hired me? It was -- Dr. Susan Blumenthal was the head of that office at that time.

Q Okay. Did Secretary Shalala have any role in your selection for that position at all?

A No, not that I'm aware of.

Q And then at some point in time you left the Office of the Secretary and you moved to the Office of the Commissioner at FDA; is that correct?

A That's correct.

Q Am I correct in understanding that that happened during the waning days of the Clinton Administration?

A They posted the job in the summer of 2000, and so I applied then.

Q Was that a politically appointed position or a career position?

A Career.

Q Okay. And who hired you for that position?

A Sharon Smith Holston.

Q Who is she?

A She was at the time a Deputy Commissioner for -- they kept changing the title of that office about three times. "International" and something. I can't remember her official title, but she was a long-time career FDA employee.

Q Okay. And may I ask you, please, what is your, what is your party affiliation, your political party affiliation, if any, if you have

one? You can answer the question.

A Do I have to answer that question?

MR. TRISTER: What's that got to do with this case?

MR. AMANAT: Relevance is not a basis for objecting to a question at deposition, Mr. Trister. May I ask, please, for you to state what your --

MR. TRISTER: I will instruct her not to answer until I have a good reason.

MR. AMANAT: On what basis?

MR. TRISTER: It's private. The First Amendment still applies.

THE WITNESS: I'm a career employee.

MR. TRISTER: I instruct her not to answer.

MR. AMANAT: That's not a basis to instruct the witness not to answer the question.

MR. TRISTER: There we are.

BY MR. AMANAT:

Q Do you have a party affiliation?

A I'm -- I don't -- I'm not going to

answer any questions.

MR. TRISTER: Don't answer that either.

THE WITNESS: I'm not going to answer any questions about that.

MR. AMANAT: Well, okay. Would you please mark that question, please.

If I need to file a Motion to Compel, I'll file a Motion to Compel, and we can come back here and answer the question another day.

BY MR. AMANAT:

Q You didn't have any role, any direct role in the process of reviewing the Drug Application that Women's Capital Corporation filed, did you?

A That's correct.

Q That's because the Office of Women's Health, I believe you testified, was outside the chain of command for the review process for drug application; is that correct?

A Generally speaking, that's true, yes.

Q Give me a little bit of a sense of what, what the Office of Women's Health does at FDA.

A The Office of Women's Health is to advise the Commissioner on women's health issues. It's also to -- has programs promoting women's health across the Agency. It's also involved in policy development, um, again across the Agency in multiple centers, often around the issues of inclusion of women in clinical studies to ensure that the analysis -- both that the data is available on, uh, by sex and other demographic variables, and also that it can be evaluated properly by the reviewers in looking for sex differences and safety and efficacy.

We also have a research program that was funded, um, funded research in women's health ranging from, um, medications used in pregnancy in terms of proper dosing as well as looking at again sex differences and different types of medications and devices. We also had an outreach program involved in getting good information to women about products that they might use, ranging from safe medication use to hormone therapy and menopause to diabetes and heart disease in women's

health, and we created educational materials and distributed them to the public. So we had a multifaceted role in the Agency.

Q Okay. Thank you.

A We also were, depending on -- we worked with the different centers, depending on either they invited us to help with different products or different policy development or we invited ourselves to sometimes provide consults. Some of the members of the staff would provide consults to the review teams or would serve on working groups in the centers on things ranging from breast implants to aspirin and heart disease and so forth, so . . .

Q Okay. Did you supervise any of the scientists who did the scientific reviews of Plan B?

A No.

Q Did you review or study any of their reviews or reports?

A I reviewed -- not in the review chain. Careful how I use the word "review." I saw their

reviews, read their reviews, um . . .

Q At what point in time did you see the reviews and read the reviews?

A Actually, it was after the decisions I had spoken with them and with different, at different times, but the review is left to the reviewers. It's not the role of, of the Office of Women's Health or of me to participate in the actual review itself, in the normal process of things.

Q When you say that you spoke with them, with whom in particular did you speak?

A I honestly can't -- some of the reviewers -- it was more likely -- it was in the Reproductive Health Division where we had a closer contact with the Reproductive Health Division, so some of the reviewers, Division Director, Office Director, in that chain.

Q Would that have included Dr. Griebel?

A I have spoken with Dr. Griebel on a number of different occasions, and I honestly cannot remember whether I spoke with her or if

some of the other reviewers at the time of the actual Plan B review. I don't remember speaking with Dr. Griebel.

Q How about Dr. Rosebraugh?

A No, I don't think I spoke to Dr. Rosebraugh.

Q How about Dr. Bull?

A About the Plan B Application?

Q Yeah.

A I don't believe I spoke to Jonca about it.

Q She was your predecessor in your position as --

A She was, so I know Jonca.

Q How about Dr. Houn?

A I think I spoke to Dr. Houn about it.

Q What conversation did you have with Dr. Houn about Plan B?

A I don't remember a specific conversation with her, but she would have been -- oh, that's not true. Hold on. After -- in the summer of 2005 I spoke with Dr. Houn.

Q What was the substance of that conversation?

A I asked her -- I was asking her about different things. We were talking about a whole host of different things, but when we talked about Plan B, I was asking her what, um, what she knew -- when and why and what was happening with the Plan B Application in the summer of 2005 such that it was supposed to have been approved in January of 2005, and here it was summer and it hadn't happened. And so I asked her what she knew about it, and she said she didn't know anything about it, because they hadn't been asked for further information or asked to do anything or, or consulted on anything, and she knew nothing about it at that time.

Q How about Dr. Beitz?

A No, I don't think I ever talked to Dr. Beitz about it.

Q How about Dr. Kweder?

A Dr. Kweder? Did I ever talk to Dr. Kweder? Not that I remember.

Q How about Dr. Jenkins?

A Certainly I've been in the room with Dr. Jenkins when Plan B has been discussed, but I don't know that I spoke to him directly about it.

Q Do you recall any of the other reviewers with whom you do have a recollection of having had a conversation about Plan B?

A I may have spoken to Dan Davis or Dan Shames or Scott Monroe, because they presented some of the data, and I probably would have discussed them around the Advisory Committee or preparing for the Advisory Committee.

Q You, you mentioned that you had occasion to read or look at some of their scientific reviews after, after the fact. I don't mean to put words in your mouth, but did you read anything other than their, you know, their final reports?

A I read some of the papers by Dr. Raines and by -- oh, I'm so bad on names. Dr. Glaser and Dr. Bear, I've read some of those papers, I've read those papers on the use of emergency contraception.

Q Would you say that you read the entire body of scientific literature on which the reviewers based their conclusion?

A No.

Q Did you actually review any aspects of the SNDA itself?

A I was not part of the review process.

Q So, for example, would you have actually read the Label Comprehension Study that Barr submitted?

A I did not have -- I did not have access to all those data.

MS. POULSON: This we need to mark as confidential, the past two questions and answers about information submitted by Barr.

BY MR. AMANAT:

Q Were you privy to any of the information that Barr itself had submitted in support of its Application?

A Well, I was again -- well, not that Barr submitted. I was at the meeting that the Women's Capital Corporation held, and they presented information at that meeting and, of course, the information presented by both Barr and by, uh, the reviewers at the Advisory Committee meeting.

Q But other than that, you weren't privy to and didn't have access to any of the information Barr submitted in support of its --

A That was not my role as Director of the Office of Women's Health.

Q Did you review any of the materials that were submitted in support of the Citizen Petition, either by the Petitioners themselves or by the various public commenters who commented on the Citizen's Petitions?

A No.

Q And why not? Why did you not take the time to review those?

A Because the majority role of the Office of Women's Health was around very broad issues in women's health, around heart disease and hormone therapy and menopause and gender differences and drug safety and efficacy, and review of any specific product was not the role of the Office of Women's Health. We did not -- we engaged on occasion when we felt that the Reviewers could benefit from the expertise in the Office of Women's Health in different subject matters. In the case of the Plan B Application, I felt quite confident in the expertise in the Review Division and in the review chain. They did not need our assistance. It was not a difficult Application. It was not one where they needed to consult with our office, and we had our hands full with lots of other things.

Q Okay. Now, during Ms. Labaton's questioning --

MR. AMANAT: Am I pronouncing your name

right, by the way?

MS. LABATON: Uh-huh.

MR. AMANAT: I never thought to ask you before.

BY MR. AMANAT:

Q During Ms. Labaton's questioning you described some conversations that you had along the way with Dr. Galson and Dr. Woodcock, and I want to come back to those later and ask about those in a little more detail, but one thing that you did not mention in response to her questioning was any conversations about Plan B that you may have had with Dr. McClellan or Dr. Crawford, and so let me ask you that. Did you ever have any conversations with Dr. McClellan about Plan B?

A Not directly. I'm trying to remember the meetings that were held where data was presented on Plan B, and I believe there was one where he was there and he was asking questions, but I'm -- but I can't be certain of that.

Q But other than that kind of formal meeting that you may have attended, you never had

any --

A I never had a private conversation with Dr. McClellan on this.

Q You reported directly to Dr. McClellan, did you not?

A No, I did not.

Q Who did you report to?

A Well, there was usually one person in between me and Dr. McClellan or Dr. Crawford. It was Sharon Smith Holston or Alderson or Linda Suydam. My supervisors kept retiring or moving on, and I had several during those years, but it was always someone else.

Q But you were in the Office of the Commissioner, right?

A Correct.

Q That was the component of FDA within which OWH was situated, correct?

A Correct.

Q So did you have occasion from time to time to have interaction with the Commissioner?

A Not on a one-to-one basis.

Q You never did?

A No. When Dr. McClellan came to -- actually, it was probably when Dr. Crawford was first acting they stopped having the weekly meetings at the Office of the Commissioner level where all of the Office Directors inside the Office of the Commissioner would be part of the weekly meeting with the Commissioner, that it previously -- certainly for the first year that I was at FDA, I believe about a year, where we would have these regular meetings, but that got changed, I believe, when Dr. Crawford came on board when he was Acting Commissioner the first time, and, uh, we were no longer allowed to be attending those meetings. They became much smaller, so I did not have opportunity to see him on a regular basis, see the Commissioner, either Dr. Crawford or Dr. McClellan, on a regular basis.

Q Did you ever have any conversations with Dr. Crawford about Plan B?

A No, I did not.

Q So --

A I tried -- I -- I tried to set up a meeting to discuss it and was informed that it was not possible to have the meeting.

Q When you say you tried to set up a meeting, couldn't you just pop your head into his Office and say, you know, Les, why don't you talk to with me about this?

A No, I was not able to do.

Q I met Dr. McClellan. He's a fairly straightforward guy.

A Yeah, I know, but no, on this subject, the meeting with Dr. Woodcock, she said she would try and set up a meeting with Dr. Crawford to discuss Plan B and to discuss the decision that was being made in 2004. I then got word back that we were not going to have that meeting. That meeting was not able to be set up.

Q And did you follow up with an e-mail to Dr. Crawford saying I'm very disappointed by this, by this decision, you know, I talked to Janet about it, is there any way that I can get some time to talk to you about it as well?

MS. LABATON: Objection to form.

THE WITNESS: No.

BY MR. AMANAT:

Q Why not?

A Because the message I had gotten back from Janet was that, that this was -- the decision was final and there would be no point, that Dr. Crawford felt there would be no benefit to having such a meeting.

Q When you tendered your resignation, why did you send your resignation memo to Dr. Woodcock instead of to Dr. Crawford?

A It's addressed to both of them. The reason I met with Dr. Woodcock is because Dr. Crawford was on vacation. He left. He was on vacation that week. The announcement had been on a Friday afternoon, and he was on vacation the entire following week, so the only person -- she was acting at the time as Deputy Commissioner, so she was the senior-most person there.

Q Would you please identify for me, Dr. Wood, all contacts that you have had with Barr

Pharmaceuticals and any of its subsidiaries on the subject of Plan B.

A I don't know that there have been any. You mean anytime?

Q At any point in time, yes.

A I think I ran into some people from Barr at some conference, and they -- and that was probably -- and that was it. I don't have any contacts or really know anybody at Barr or have had any communication with them or anything.

Q Did you have any contact or communication with Women's Capital Corporation when that company was, was in existence?

A Well, when -- I met them when came to the agency. I don't think I've had any other meetings with anyone from Women's Capital Corporation.

Q Did you have any relationship with Planned Parenthood historically?

A They're one of the, you know, big organizations. We are in communication with all women's groups, have been in touch with all of

them over the years, and certainly over the last year I've given presentations at several Planned Parenthoods around the country, along with all the other presentations to organizations.

Q Did you ever serve on a Board for Planned Parenthood or anything like that?

A Planned Parenthood? No.

Q Do you own any stock in Barr Pharmaceuticals or any of its subsidiaries?

A No.

Q Have they, have they contributed -- since your departure from FDA, to the best of your knowledge, have you received any financial support from Barr Pharmaceuticals?

A Not that I know of, no.

Q Has Reproductive Health Technology's project received any, to the best of your knowledge, received any financial support from Barr or its subsidiaries?

A No.

MR. AMANAT: Mr. Trister, did you bring a copy of the documents that you produced to me?

Because I have some copies, but I don't know that I have enough copies to go around. Well, we can make do. I tried to pack light. So I didn't bring a huge -- but we'll proceed this way.

BY MR. AMANAT:

Q Dr. Wood, at some point did you -- do you recall having given an interview to Ted Koppel --

A Yes.

Q -- for a segment that appeared on Nightline?

A Yes.

Q And you produced a transcript of that Nightline segment as part of the documents that you produced in response to the subpoena?

A Uh-huh.

Q I'd like to ask you, if I may, just a few questions about that Nightline segment. Do y'all have that transcript in hand?

MS. LABATON: Uh-huh.

MR. AMANAT: Because I don't have a whole lot of extra copies.

BY MR. AMANAT:

Q Now, just for the record, upon receiving the documents from Mr. Trister in response to our subpoena duces tecum, I had our office number the documents in the exact order in which they were received, so you guys don't have our numbering, but I will tell you what they are, but I'm going to state for the record, when I refer to a document, what its numbers are, since they did not come with numbers on them already.

So I'm going to hand you some pages of a -- what you produced to us as the transcript of the Nightline interview.

MR. AMANAT: And I'd like to have this marked -- what was the last number; 5? Let's call this Wood 6, please. Would you hand this to the reporter to mark, and then the witness can take hold of the marked copy, and these are pages which we have numbered Wood 78 to 91. It's a 14-page transcript of a Nightline segment from September 27, 2005.

(Exhibit No. 6 was marked for identification and attached to the deposition transcript.)

BY MR. AMANAT:

Q Now, this, this Nightline interview took place, I suppose, less than a month after you resigned from the Agency; is that correct?

A That's correct.

Q And do you recall how it happened that you ended up being a, not a panelist, but a guess I guest I questions guess you would call it on that show?

A Not specifically. A guest, I guess.

Q Now, in response to Mr. Koppel's questioning, you made a number of statements, and I want to ask you about a few of them. I'd like to ask you first to turn to what's there in front of you as Page 83, which for those of you who don't have the numbered set, is the sixth page of the interview.

MS. LABATON: Can you read the first

line.

MR. AMANAT: Top of the page FDA has shown that it's sensitive to the concerns of our society.

BY MR. AMANAT:

Q Now, you state down at the bottom of the page there -- Mr. Koppel asks you, he says, "You're saying science was being overruled. By whose definition?" And you responded, "I think by the definition of all the ways we've always done business at FDA, where science and the scientists and medical professionals at FDA are the ones who review the evidence and make a decision about whether a drug should be approved or not approved."

Do you recall having made that statement to Mr. Koppel?

A Yes.

Q So isn't Dr. Galson a scientist and a medical professional himself?

A This was referring to the 2005 decision, which Dr. Galson was not a part of.

Q Okay. And to the best of your understanding, whose decision was that?

A Well, it was certainly announced by Dr. Crawford.

Q Okay. And you don't consider Dr. Crawford to be a scientist and a medical professional?

A I believe he overruled all the scientists and medical professions below him.

Q When you say "overruled," wasn't it his decision to make?

A Yes. I never questioned that it was not his decision.

Q Okay. And do you have any reason to believe that he didn't review the evidence before making what you understood to be his decision?

A I have no information to believe that he reviewed it or didn't review it. I don't -- I wouldn't have expected him to have reviewed all the evidence, because it's a -- it's thousands of pages of evidence, and he has a lot more on his plate than one product approval, but, um, but I

believe he overruled all of the Reviewers and the scientists below him, who had reviewed all the evidence in great detail.

Q Okay. Now, lower on down on Page 84 there, that same page that we were just looking at the carry-over quote, you refer in a couple of places to "consen -- you used word "consensus." You do that -- there's a quote from you, the first full quote from you on that page where it says, in part, "And has been caught up in delay after delay, even though there's consensus at the -- amongst the scientists and health professionals there that it should be approved."

And then Mr. Koppel asks you, "What would you say are the main reasons that you -- and you call it the 'consensus.' So clearly there were some scientists who did not agree, but the preponderance of scientists who voted on this did agree." And then you responded, "I would actually still call it a consensus, because the scientists you're referring to who didn't agree were part -- were a few of the Advisory Committee meeting made

up of outside experts. They voted, a preponderance, to bring it over-the-counter and that it was safe and effective for women to use over-the-counter."

Now, is -- I have a couple of questions about these comments that you ask here. Is the Food & Drug Administration a democracy?

A Uh, the Food & Drug Administration is a government agency, you know. It's -- there's -- never thought it would be a democracy. It doesn't vote the way individuals vote. It's not -- that question doesn't really make sense to me.

Q So let me follow up with that. So does the FDA make policy by taking a vote among the career scientists at the Agency to see whether a preponderance or a consensus among them agrees on a certain course of action?

A No. It reviews the data as teams, who then evaluate it and come to some decision-making, using the decision-making process. If there is a question about the quality of the data or the safety or efficacy of a product, individuals have

the role and responsibility to bring that to the attention of other members of their team in their division to the Division Directors, and in this case, um, those -- that didn't happen, and it just happened -- so if there is disagreement, there are ways of handling disagreement, and if there is agreement, it makes life simple in terms of how products goes through.

Q You say that when there are disagreements, there are ways of handling that disagreement. Let me follow up with you on a couple aspects of that. Is it fair to say that FDA is a hierarchal organization?

A Yes.

Q There is a chain of command with superiors and subordinates, correct?

A Right.

Q When there is a difference of opinion between a superior and a subordinate about science and about what conclusions can be drawn from a certain body of scientific data, how is that kind of a dispute resolved?

A Usually we're talking about disagreements within people who are the Reviewers, who have different views of the evaluation of the data, and it would be resolved by their superior.

Q But what if there is a difference of opinion between the superior and the subordinate; how is that kind of difference --

A The superior overrules or makes a determination.

Q So now, that's an important distinction, because you say "overrule," but --

A Or makes the determination.

Q Makes the determination in the first instance, right? Okay.

Now, you also make reference in this passage that we just looked at to the Advisory Committee, and you talk about how -- the scientists who didn't agree with a few of the Advisory Committee made up of outside experts. The Advisory Committee's votes are not binding, are they?

A No.

Q They're only advice?

A Correct. Yeah, go ahead.

Q And in fact, FDA does, uh, does -- it's not uncommon for the FDA to make a decision that is not consistent with what the Advisory Committee recommended; is that correct?

A Absolutely, and I always make that clear.

Q And in fact, you do on the very next page, I believe, on Page 85, where you state at the top, "FDA does overturn its advisory committees on occasion," but you use the word "overturn" there, and that word kind of struck me, because that implies -- your use of the word "overturn" suggests to me that you believe the Advisory Committee actually makes the decision, and then somebody in the Agency decides to overturn it. Is that, is that how you see it?

A No. I mean the Advisory Committee is advisory. I think many people in the public see the Advisory Committee as making a decision, and they see it as overturning, but I'm quite clear

that the Advisory Committees provide the advice to the Agency upon which they make their determination, using the advice and the discussion as well as the votes in the Advisory Committee.

Q Okay. Now, later on in that same paragraph you make the following statement. You say, "In this case the FDA staff, at every level within the Agency, multiple levels, agreed that it should be approved for over-the-counter status." Do you see where you make that statement?

A Uh-huh.

Q Now, that's not entirely true, is it, because --

A Clarify. I'm not sure --

Q Well, because Dr. Galson, at the level of the Center Director -- that is a level within the Agency, correct?

A Yes. I was speaking about the 2005 decision of which Dr. Galson was not a part.

Q So here you're talking specifically about the decision to invoke the ANPRM in August of '05, right?

A Let me -- I believe that's the only thing I'm referring to. Certainly in thinking of my resignation, that was all around the '05 decision, and I assume that that's what I was speaking to at that time.

Q Because I was a little puzzled by that, because you make reference to overturning the Advisory Committee. The Advisory Committee's recommendation was in December of '03, and Dr. Galson's issuance of the Non-Approvable Letter was in May of '04 was the first significant Agency Action after the Advisory Committee meeting, and then -- but you're saying that, in fact, you were referring to the August '05 Action, not the May of '04 Action?

A Yeah, I honestly don't remember, even reading this, whether I was referring specifically to the '04 or the -- or both the '04 and '05 decision. It's -- I just can't remember, but certainly that statement is true for the '05 decision, which is what I'm -- in September was primarily responding to.

Q But it's not true for the '04 decision; is that correct?

A Not in terms of Dr. Galson, although I disagreed with Dr. Galson's decision at that time.

Q Now, Dr. Galson, if I'm not mistaken, is a career scientist at FDA, right?

A Yes.

Q He's not a political appointee?

A That's correct.

Q In fact, he's a uniform public health official; is that correct?

A That's correct.

Q Um, now, lower down on this page 85 you make the following statement. This is in the second quote from you on this same page that we're looking at. You say, "The question that was raised by a very small part of the Agency was whether or not they" -- meaning the younger girls -- "could understand the label and use it properly. But we've never asked that question about any other product. We don't ask it about pain medication. We don't ask it about condoms or

any other contraceptive method that's available over the over-the-counter."

I have a couple of questions for you based on that statement. Does FDA make policy based on precedent?

A Often it seems to, yes.

Q So the way something was handled in the past for another drug is -- or in your view, should be dispositive of how the Agency handles a new drug?

MS. LABATON: Objection to form.

THE WITNESS: You have to explain that to me, because I don't understand all the legal terms.

BY MR. AMANAT:

Q Well, I'm asking you about your own statement here in response to Mr. Koppel's question. You seem to be complaining about the fact that -- forgive me if I'm mischaracterizing your statement, but this is how it comes across in the transcript to me. You seem to be complaining about the fact that the Agency requested

information about this drug that in your view it had not previously requested for other drugs.

A That's correct.

Q Okay. So my question to you is: In deciding what information to request from a manufacturer, from a drug sponsor, in connection with a pending Drug Application, is FDA bound by the scope of information it asked from other manufacturers relating to other drugs?

A Not in all cases, no.

Q Um, if I were to make the statement that each drug that is considered for approval by the Agency is sui generis, would you agree with that statement or disagree with that statement?

MS. LABATON: Objection as to form.

THE WITNESS: Can you rephrase the question.

BY MR. AMANAT:

Q Do you consider each drug to be sui generis, or do you consider drugs to be -- do you consider that the Agency can treat all drugs essentially the same way?

MS. LABATON: Object to form.

THE WITNESS: They can treat drugs differently based on the questions about safety or efficacy about a product. I have no problem with drugs being treated differently depending on the different circumstances, including the safety data and the efficacy of a product and what the Agency, through its Reviewers or through the review chain, feel that they need to ask of a company.

BY MR. AMANAT:

Q So am I understanding you correctly that if the Reviewers determine that a particular drug raises safety and efficacy issues that other drugs did not raise or safety and efficacy issues that are unique to that drug, that it would be appropriate for the Agency to then call upon the sponsor to produce data that respond to that unique concern; is that what you're saying?

A If that is indeed the case.

MS. POULSON: We just need to mark the preceding two questions and answers confidential.

BY MR. AMANAT:

Q You seem very careful in your last answer to say "any further information." Do you know whether the Staff Reviewers called for that

kind of information in the first instance?

A Well, they were looking -- if I'm remembering correctly, they were -- in response to questions that had been raised from higher up in FDA, they were compiling information from the sponsors and from outside researchers, uh, to, to address some of the concerns that others were raising, so they compiled information to address these concerns and, and presented it within the Agency, but I don't -- they were not calling for a, a Non-Approvable Letter pending further research or pending further data collection.

Q So have you reviewed any of the documents or the correspondence that were exchanged between the review staff and, um, representatives of Women's Capital Corporation prior to the filing of the SNDA?

A No.

Q So you don't know whether those, in those initial memos, whether some of the scientific reviewers themselves may have, in fact, on their own, um, called upon the sponsor to

include that information as part of their actual use --

A Again, thinking back on the pre-meeting that was held with Women's Capital Corporation and the discussions that the Reviewers were having at that time and later, they were trying to ensure that all the data was, I believe even unpublished data was, by different researchers around the country and around the world, was included to address some of the questions about -- and again I believe that was -- whether it was compiled early on or later on, I'm not, not certain when it came in, but it was looked at.

Q In your view, was it inappropriate for FDA to have even raised the issue of the impact of -- the impact of making this drug available over-the-counter would have on the behavior of adolescent consumers?

A Well, I guess at which point? At the end of -- to raise it at the end of the process or at any point?

Q At any point.

A No, it's not inappropriate.

Q So it was a valid, it was a valid, um, aspect of the scientific inquiry relevant to the OTC switch decision; is that correct?

A To the extent that it doesn't need, you know, a separate series of studies, but to the extent that looking at the question if there was evidence to suggest that it would create a problem, you should look at that evidence, and if there's evidence to suggest that it would not create a problem, you should look at that evidence. It should be part of the, the picture, and that's a reasonable part of the picture is to look at that evidence.

Q Okay. So that's what I was driving at. So getting back to your statement here on Page 85; this is, um -- what I don't understand about your statement in response to Mr. Koppel's question is it strikes me is it doesn't mesh with what you just testified to, because your question here -- your statement here to Mr. Koppel seems to be saying that because we have never asked -- because

we have never explored the question of what would happen to the behavior of adolescent consumers if a particular drug were to be made available OTC, because we've never asked that question before for other drugs, it was inappropriate for us to ask it for this drug.

MS. LABATON: Objection as to form.

THE WITNESS: Um, in this case I'm quite sure I'm speaking specifically about the Non-Approvable Letter, which was going to require additional studies of either the Actual Use or Label Comprehension Studies, which is not actually getting at the question which we were just talking about, the question of whether it would increase risk or risky behavior or have an impact on adolescent behavior for which there is data that had been reviewed by the Agency.

In the 2004 Non-Approvable Letter it was asking that there be separate subpopulations studies done on actual use and label comprehension on a very young population, and that is the type of question we've never required, you know. We

didn't ever require that level of subpopulation analysis and data, specific study data to be presented for any other OTC product that I'm aware of.

Q Well, how do you know that it hadn't been produced in the first instance by this sponsor of other drugs so that it wasn't necessary to ask for follow-up?

A It's my understanding that they hadn't, and I believe even Dr. Galson has stated and agreed that they've never asked this question of other products, and he says maybe we should in future products, maybe we should look at these questions, but I would argue we have not asked for it since.

Q And where did Dr. Galson say that, to your recollection?

A Where did I read that or hear that? It may have been at the, when he did the, um, teleconference press call on the announcement of the 2004 decision --

Q Okay.

A -- but I have heard him discuss that point.

Q Okay. Why don't you turn the page, please, to the next page which is labeled Wood 86, the page that says at the top, "The worst thing that can happen is that you would have an unintended pregnancy."

Do you have that page there?

A Yes.

Q Um. Now, here --

MS. JONES: Can we take a break?

MR. AMANAT: Yeah, we've got to take a break in a couple of minutes to change the tapes.

MS. JONES: I'll wait for that break then.

MR. AMANAT: Let me just ask a couple of questions.

BY MR. AMANAT:

Q Down at the bottom of this page Mr. Koppel asks you or he says, "There are political consequences to making this drug available over-the-counter." I get the sense

political pressure may have been behind what happened or at least that you perceive it that way. And then they take a break and come back after the commercial, and at the top of the page he asks you, "Would it be fair to say that you felt that the decision the FDA made was not on the basis of science but made on the basis of political pressure?" And then you give -- it's the beginning of a lengthy discussion.

MR. AMANAT: Um, actually, how many more minutes do we have on the tape?

THE VIDEOGRAPHER: About one and a half right now.

MR. AMANAT: Why don't we actually take a break now. I'll resume this line of questioning when we come back from the break.

THE VIDEOGRAPHER: We're going off the record. The time is 2:24 p.m.

(Whereupon, a short recess was taken.)

THE VIDEOGRAPHER: Here begins Tape Number 2 in the deposition of Susan Wood, Ph.D. We're back on the record. The time is 2:34 p.m.

BY MR. AMANAT:

Q Dr. Wood, thank you. We were looking at Page 87 here of this interview with Nightline, and Mr. Koppel asks you on the top of this page, "Would it be fair to say that you felt that the decision the FDA made was not on the basis of science but made on the basis of political pressure," to which you respond, "I have to agree with the first half of your sentence."

What -- well, let me make sure I properly understand what you're saying. When you say "the first half of the sentence," are you referring to the portion of the sentence that stated that the decision was not on the basis of science?

A That's correct.

Q And then you go on and you say, "I can only tell you what I observed, and that was it was not made on the basis of the scientific and medical evidence."

Now, let me ask you: Do you -- you

didn't really answer his question about the second half of his question, about the basis of political pressure. Do you believe that the Agency's decision was made on the basis of political pressure?

A I don't know on the basis that it was, and so I don't have any -- and I try very hard not to speculate as to how it was made.

Q And that's because you're a scientist and you make your statements based on your empirical observations?

A Well, I'm just trying -- you know, people ask me this all the time as if I have some special knowledge, which I don't, so again I try very hard to say that I don't think it was made on the basis of the science and medical evidence and the usual process of the recommendations of the professional staff and stop there, because honestly I don't know upon which basis it was made.

Q So is that another way of saying that you really don't have any evidence that there was

political pressure brought to bear?

A I do not have any evidence. All I talk about is how -- as far as I could see, how it was not made. It was not made based on the evidence. It was made on some other basis, and I don't know what that basis is. I don't have any other evidence on what that other basis is.

Q You weren't privy to any communications that the Commissioner might have had with other individuals about Plan B, were you?

A That's correct.

Q And you never became aware of any actual communications or instructions from outside FDA to the Office of the Commissioner directing a particular outcome with regard to Plan B?

A That's correct.

Q Now, let me explore your statement, "It was not made on the basis of the scientific and medical evidence." How do you know that it was -- how do you know that?

A I am relying on again the Reviewers and all those in the review chain up to the 2005

Division, and again I spoke to -- in late summer I spoke to different people, asking them what was happening with the decision, and no one seemed to know what it was. And that was deeply concerning to me, because they were the people who knew this evidence most closely, and they also are normally part of the review chain or they are very senior people in the Agency who should be aware of the outcome.

Q How do you know that these, that these career staffers were right and that the Commissioner was wrong?

A Because I respect their expertise in the particular fields that they are reviewing.

Q And you didn't respect the Commissioner's expertise?

A Not in this particular field. He has plenty of expertise that I respect.

Q When you say it was not made on the basis of scientific and medical evidence, are you the final arbiter of what evidence is sufficient to support a conclusion?

A No, and as I said several times, I'm relying on the Reviewers and the review chain to -- in this particular case, where there was little to no disagreement on the safety and efficacy and the appropriateness of it going over-the-counter from people who have the expertise, and I will -- I rely on their evaluation and their expertise.

Q Now, earlier you testified that FDA is a hierarchal organization.

A That's correct.

Q And that when there are disputes between a superior and a subordinate about the conclusions that can be drawn from a particular body of science, the way that that kind of dispute, that species of dispute is resolved is the superior has the prerogative to make the call; is that correct?

A That's correct.

Q Okay. So how do you know that that's not what happened here, that a superior and a subordinate have a legitimate scientific dispute over what conclusions could be drawn from the body

of scientific data, and the superior -- in this case, the Commissioner himself -- exercised his prerogative to make the call based on what his interpretation of the science was?

A I think the -- I'm not -- I don't know the law or technical legal authority that the Commissioner has to overrule the Center in an approval. I just point out that it's extremely unusual, and particularly when there is such strong agreement amongst all the people who actually been evaluating the data for years, there is strong agreement, and it is overturned at the very highest levels. It is very, very unusual.

And not saying that he's not authorized to do that, but I disagreed with it, because I felt that the weight of the evidence, the number and senior level and expertise amongst all the people in the Center for Drugs who were in agreement, this was not a controversial decision as are other products that come up that a more senior individual needs to, you know, be the arbiter between different opinions. This was --

there was agreement, and this was a, in my view, a complete overturning of that very strong agreement of the scientific staff and medical staff who do know these fields very well and whom I rely on their expertise in this situation more than any other senior official in the government.

Q Do you know the reason why Dr. Crawford took the action that he did in August of 2005?

A No, I don't.

Q You never -- you never took the time to read his rationale and explanation for it?

A Oh, no, I read his rationale, and again, I didn't agree with it.

Q What aspect of his rationale did you not agree with? Well, why don't you tell me what you believe his rationale was, and then tell me what aspect you didn't agree with.

A From my understanding, he was putting it into Advance Notice of Proposed Rule-Making, which I now understand has been announced it's not necessary to do, so I feel vindicated at the moment. And the need for a Proposed Rule-Making

was on the basis of how would the FDA implement a dual status marketing situation, that this was a complex and novel situation that needed, potentially, a Federal regulation to ensure that it was implemented properly, both in terms of enforcing it to keep it out of the hands of young teens, but also in terms of whether it needed to have different packaging, whether it would be confusing to people, and whether it was -- you know, whether having it available in this dual marketing status was, was allowable to do.

Q Did you believe that the FDA's authority to approve this kind of dual marketing approach was well-established as of August of '05?

A I'm not a lawyer, but it's my understanding that -- I know that FDA does have other products in different kinds of dual marketing status or in age-restricted status, and therefore -- and that the, uh, FDA had not, itself, by putting it out for rule-making, clearly had not determined that it did not have the legal authority to do that; else, it would have just

said no, we don't have the legal authority to do it. And therefore, putting it out into rule-making to my mind was a method of delay that in my mind was not credible.

Q Later on in that same paragraph on Page 87 that we were looking at, you say, "And not just me, but all of the scientific and professional staff who normally are the part of the decision-making at the Agency, because they are the ones who review the evidence and evaluate it and make the recommendations. They also were cut out of the decision." What do you mean by that statement? Who was cut out of the decision?

A This was referring to the 2005 decision, when, up until apparently just a couple of days prior to the decision, none of the folks in CDER nor other senior people inside FDA were aware of this decision, or at least they weren't telling me that they were aware of the decision, and I believe them, and therefore they were cut out, they were not part of it. If they weren't aware of it, they couldn't have been part of it.

Q And who in particular are you referring to?

A I spoke to the Division Director, Dr. Shames. I spoke to Dr. Houn. I spoke to Dr. Woodcock. I spoke to Dr. Lumpkin. I was trying to meet with Dr. Galson, but he was unavailable. He later informed me that he had not been aware of the decision until a day or so before it was announced publicly. And all of them told me they were not aware of the decision up until shortly before the announcement.

Q So that's what you were referring to in that paragraph?

A That's correct.

Q Let me back up a minute. I was asking you earlier about, you know, what knowledge and evidence you had about, you know, what the August of '05 decision was based on. Am I wrong in understanding that during much of the period of time in between the May 2004 issuance of the Non-Approvable Letter and the August 2005 issuance of the letter invoking the ANPRM process, that

during much of that time you were actually out of the country?

A That's correct.

Q And that was because you were on a detail to Great Britain?

A Yeah, a Fellowship, but like a detail, yes.

Q Fellowship, okay, and that was something that, that Dr. Crawford approved in his capacity as Acting Commissioner; is that correct?

A That's correct.

Q Um, and so during the time that you were in London -- how many months were you in London, approximately?

A About eight months.

Q Okay. And so that would be roughly, roughly half the period of time between May of '04 and August of '05?

A Could be.

Q During that time were you, were you in regular contact with, uh, with Rockville?

A Yes, I was.

Q And who, who in Rockville were you interacting with?

A I had my FDA e-mail. I checked my FDA e-mail daily and had conference calls or calls with my office, although we had an Acting Director, Marsha Henderson, at the time, but was in contact with the office quite regularly by telephone and in communication with CDER on different issues as well during, during that year; as well as with my supervisor, um, handling budget issues, you know, documents that had to be provided, you know, usual process type work that had to be maintained.

Q Did you have any interaction or communication with Dr. Crawford during that period of time that you were in London?

A Well, with his Office, not with him permanently. I gave a presentation to an international conference that he was supposed to be at that he couldn't attend, so I actually spoke on his behalf at this conference, so during that period of time I was in close communication with

his office.

Q Did you have a good working relationship with Dr. Crawford?

A I did.

Q Do you respect him personally?

A Uh-huh, I do.

Q And he, himself, was by and large -- obviously, as Commissioner, it's a political appointee, but he wasn't new to the FDA, was he?

A No.

Q He, in fact, had served in the FDA on and off in various career scientist capacity for more than 20 years; no?

A I don't know exactly his career. I don't know.

Q He had been there longer than you had been there, right?

A Oh, yeah, off and on, in and out.

Q Now, continuing on in this interview with Nightline, on the bottom of that Page 87 Mr. Koppel asks you, "What other possible reason can there have been then that someone brought

pressure to bear, which I describe as 'political' but if you have some other description, tell me what it is." And you answer, "Well, I won't disagree with you on that point, because I honestly don't know where it came from either. And so it must have come from somewhere."

What does that mean?

A Well, it didn't come from below. It didn't come from the recommendations of the professional staff or the, again up the review chain. The recommendation from CDER was to approve it for those 17 or older. That recommendation had been pending since January. I don't know. It didn't come from the usual places it comes from, so I don't know where it came from, but somebody made the decision.

Q Going down lower on that Page 88, you state -- in the last full paragraph that has a quotation from you, you state, "But I would argue that the decision to delay approval of this product over-the-counter is, in fact, a denial." Do you see that?

A Uh-huh.

Q "And this is, again, in part why I resigned, because by couching it as a delay and a non-decision, in fact, denied women of all ages not just teens, but women of all ages access to timely use of this product."

So why, why did you believe that the decision to delay the approval was a denial?

A It is not technically a denial, as I think I make clear, but by putting something into rule-making, which takes usually many years, if it's, in fact, going to go through rule-making, and, you know, many, many months at best, that for that period of time we are denying women access, timely access to this important product. And we're not just denying the young women who the concerns are being raised about, but we're denying all women during that time period, however long that time period is. It's telling women they can't have access to this product when they need it.

Q Well, but they can, with a prescription.

A Timely access.

Q Now, but I mean the decision to undertake the rule-making proceeding was just a continuation of the status quo that had been in place before that. In other words --

A It's not changing its status. I mean they were prepared to approve it. It's putting it in an entirely new status, which is rule-making.

Q Well, but it had not previously been approved for OTC for any age group; is that correct?

A That's correct, but it was -- CDER has been prepared to approve it since January of '05.

Q But the Commissioner's decision to issue the Advanced Notice of Proposed Rule-Making did not result in anybody having less access to the drug than they did before, did it?

A No.

Q On Page 89 Mr. Koppel asks you toward the middle of the page, "Insofar as the impact of this physically and psychologically is concerned, there's no difference between this and a rubber

condom?" You see where he asks you that?

A Uh-huh.

Q And you respond, "I would have to compare it to oral contraceptives or, in terms of its availability, to a condom or spermicides or the Today Sponge."

A Uh-huh.

Q What does that statement mean?

A Well, he's talking about physiologically. I don't know about psychologically, but physiologically it's a hormonal contraceptive, so it's more similar to oral contraceptives than to a condom; however, in terms of availability, we would be making it available in the same fashion that a condom or spermicides or the Today Sponge are available, which is over-the-counter. It would just be adding one more contraceptive option over-the-counter, so it would not change dramatically our concept of contraception. We have other contraceptives that are over-the-counter. This would just be one more

contraceptive over-the-counter.

Q Have there ever been any other systemically-absorbed hormonal contraceptives available without prescription to any consumers of any age in the United States?

A Other than some of the dietary supplemental type products, certainly, certainly not, not as contraceptives or hormone, you know, drug products, there are no -- not that I'm aware of, there are no drug products.

Q And going beyond contraceptives, have there -- to your knowledge, have there ever been any systemically absorbed estrogenous product available?

A Estrogenous?

Q I'm sorry. I meant -- I don't know the adjective. Progesterone? Progesterone-based drug product available over-the-counter for consumers of any age group.

A Again I think some of them come up in some of the natural progesterone products, but not ones that are regulated by CDER, that I'm aware

of.

Q Okay. You also produced in response to our subpoena an article that appeared in science magazine that's entitled "Plan B: A Collision of Science and Politics." Do you recall having produced that?

A Yep.

MR. AMANAT: I'll give you a copy of it and ask that it be marked Exhibit 7, please.

(Exhibit No. 7 was marked for identification and attached to the deposition transcript.)

(Discussion was held off the record.)

BY MR. AMANAT:

Q I just have a couple questions about this article, and I want to direct your attention to the very tail end of this article, the one on -- we have numbered it Wood 95, but the magazine page number is Page 39. The third paragraph from the end says, "The FDA official who signed off on the delay -- Steven Galson, head of the Center for Drug Evaluation and Research --

declined through the press office to be interviewed." Do you see that paragraph?

A Yes.

Q Then he goes on to say, "Susan Wood, who quit over Plan B last month, says she spoke with people below and above Galson prior to the August announcement, and 'no one seemed to know what the answer was going to be . . . the scientific staff were shut out of this decision,' including members of the Commissioner's office and the reviewing staff."

A Uh-huh.

Q Whom did you speak with below and above Dr. Galson prior to the August announcement? Who were you referring to?

A That's what I told you a few minutes ago, which was I spoke with Dr. Shames, with Dr. Houn, with Dr. Woodcock, with Dr. Lumpkin, so those would be above and below.

Q Tell me about your conversation with Dr. Woodcock in that regard.

A Um, I asked for a meeting with

Dr. Woodcock to ask her what she, you know, what was going on, because this was now August at some point, and the deadline for an Action was September 1st, and she said that she didn't know what the answer was going to be. She said Les was still waiting on the answer.

Q Okay. That's all I have with this exhibit.

You published a -- I guess you would call it an opinion piece, an article, whatever you want to call it, in the "New England Journal of Medicine"?

A I call it a perspective piece.

Q I see. You call it perspective. You published a perspective piece in the "New England Journal of Medicine" that was published October 20, 2005?

A That's correct.

MR. AMANAT: I'd like to have this marked, please, Exhibit 8, I guess.

(Exhibit No. 8 was marked for identification and attached to the deposition

transcript.)

BY MR. AMANAT:

Q Okay. Is this the piece that you wrote for publication in the "New England Journal of Medicine"?

A It is.

Q It is -- was this piece published substantially as you wrote it, or did the "Journal" edit it very much before --

A Substantially as I wrote it.

Q Okay. I want to focus your attention on just a couple of passages in this article that were of interest to me. You -- let me direct your attention first to the page that's marked Wood 97, and it's -- the "Journal" page is 1650. The right-hand column on that page has a passage in the second paragraph that says, "But women's health has meant more at the FDA than just reproductive health or women-specific health concerns." Do you see that?

A Yes.

Q You go on to say as follows: "The key

focus since 1993 on including women in all phases of clinical studies and evaluating the resultant data for differences according to sex and other demographic variables has affected all the products that come before the FDA, ensuring that studies explore the potential for sex differences in safety and efficacy and that data are collected rigorously enough to permit such evaluation. This issue was the primary reason for the formation . . . of the Office of Women's Health."

My question to you is this: If it's important for FDA to ensure that studies explore the potential for sex differences in safety and efficacy and that data are collected rigorously enough to permit such evaluation, is it also important for FDA to ensure that studies explore the potential for age differences in safety and efficacy?

A As a general rule, that would be true. In the case of contraception, FDA has looked at the question historically, or the Division, in answering questions about whether or not young

women, young teens who are of child-bearing potential should be treated differently or in such as pediatrics, as if they were pediatric, and had reached the determination that in the case of oral contraceptives, and that women, females of child-bearing potential, regardless of age, should be treated the same, looking at data and evaluating it for any kind of potential risks or differences, but on the general rule of contraception, that question actually has been looked at by the Reproductive Health Division about age difference.

Now, if you're talking like before menstruation, you know, pre-pubescent girls or boys, they would be treated as children, and therefore that age looking at, but that's not relevant to issues around contraception but certainly would be relevant to issues around other drug products, which children, pre-pubescent children, do, in fact, take.

Q Okay. So let me just make sure I understood your answer. You're saying that as a

general proposition, you believe that it is appropriate to -- for FDA to take steps to ensure that studies explore potential for age differences in safety and efficacy and that data are collected rigorously enough to permit such evaluation. Would you agree with that statement?

A As a general rule.

Q And do you believe that that rule does not apply in the case of studies regarding contraceptive usage?

A In the case -- yes, this has already been evaluated. This question has been looked at by the Reproductive Health Division about all contraceptions, in that should extra studies on young teens, in the case of sort of the -- be treated in the same way as other products for the pediatric rule, and they determined that in terms of the physiologic response, safety and efficacy issues for females of child-bearing potential, that there is no rationale to do separate pediatric-style studies.

MS. POULSON: Please mark that question and answer confidential.

BY MR. AMANAT:

Q Let me direct your attention to the next

article immediately after this. It's a "Washington Post" article.

MR. AMANAT: Have that marked Exhibit 9.

(Exhibit No. 9 was marked for identification and attached to the deposition transcript.)

MR. AMANAT: And what's being marked, Counsel, there's actually five pages -- four pages, two pages that are listed as "The Washington Post," "When Politics Defeats Science," and then two additional pages which have handwritten in the top corner, "As Submitted."

MS. JONES: How many pages is the "Post" article?

MR. AMANAT: Two. Two-page article in the "Post," followed by two more pages that says "as submitted" on the top.

(Discussion was held off the record.)

BY MR. AMANAT:

Q So the first question I have for you, Dr. Wood -- as it was produced to us, this two-age article as published in the "Washington Post"

Dated March 1, 2006, with you listed in the byline, and then immediately following that is another two pages that are -- that say "as submitted" --

A Uh-huh.

Q -- which are -- which have some overlap with the article but are, frankly, substantially different. Can you tell me, is -- I mean what the relationship between these --

A Oh, wait. No, it's not -- hold on.

Q They were produced sequentially?

A No, I made an error here. The second one is just a draft, it's not s submitted -- it didn't get submitted like that.

Q Because I was wondering, the way it was produced --

A Yeah, and I thought I was printing out the "As Submitted" version, but apparently this is an earlier draft.

Q That clarifies it, because it gave the impression that you had submitted --

A And they totally rewrote it.

Q Yeah, and they totally rewrote it, that you had submitted a second version, and the "Post" totally rewrote it and simply credited it different.

A No. My mistake there. That was not "as submitted." That was an earlier draft.

Q So these were both drafted by you?

A Yes. There were some changes the "Post" made, very small, but this is not "as submitted."

Q So the version that was published in the "Post," is it fair to say that that's essentially your work, and the "Post" didn't modify it very much from what you drafted?

A They added a headline, and they made one or two small edits.

Q Okay. I want to direct your attention to just a few passages in this article. You start in the first paragraph, and you say toward the end of the first paragraph, "I have shared my concerns that our federal health agencies seem increasingly unable to operate independently and that this lack of independence compromises their mission of

promoting public health and welfare."

I touched on this earlier a while back, but what do you mean by this? What do you mean that federal agencies seem increasingly unable to operate independently?

A Well, in this case I'm talking about the fact that, that the science can be the primary driver of -- and the medical evidence can be the primary driver of the decision for an Agency like FDA when, in their mission and in their statute, that's supposed to be the driving force of their decisions, and it didn't appear that FDA was able to do that. And I used word "independently" not in a perhaps legal term of being independent of the Executive Branch, but independently as in making its decisions based on a fair and open and independent scientific evaluation of the evidence.

Q Okay. Fine. Later on in the third paragraph of that first page you describe some testimony that Dr. Von Eschenbach gave to the House Subcommittee, and you state at the end of that paragraph, "This exchange confirmed my

suspicion that, like his predecessor, von Eschenbach is unable or unwilling to let the science and the scientists guide FDA policy and decisions, and that the real answer as to whether the FDA will allow Plan B over the counter for those 17 and older is no." What is the basis for that statement that you published in the "Washington Post"?

A What do you mean by that? It's my opinion.

Q Does -- do you have a factual basis for offering and publishing that opinion?

A I'm sorry. I don't understand the question.

Q Well, you say the exchange confirmed your suspicion that, "like his predecessor, von Eschenbach is unable or unwilling to let science and scientists guide FDA policies and decisions." How do you know that? What makes you suspect that that's the case?

A That is what I've said earlier, that I believe that science was not the underlying driver

of the decision on Plan B, that the Reviewers, the recommendations, the general agreement that this should be made over-the-counter by those who know the data best, that was not allowed -- for whatever reason, that decision was not allowed out of FDA when Dr. Von Eschenbach at that time said that it was, there was still a whole host of issues that had to be addressed, this was concurring with the previous decision, and therefore it confirmed my concerns about the science not driving the decision-making.

Q And do you still believe that the real answer as to whether the FDA will allow Plan B over-the-counter for those 17 and older in no -- do you still believe that?

A Well, if the announcement made today is true, perhaps there's an opportunity for approval, but as long as it remains within rule-making or under continual review, we're -- when I say the decision is no, it means that in real time, right now, women do not have timely -- adult women do not even have timely access to emergency

contraception when they need it.

MR. AMANAT: Okay. Next I'd like to hand you -- please mark this Exhibit 10. It's a three-page document consisting of a slide show, Power Point presentation.

(Exhibit No. 10 was marked for identification and attached to the deposition transcript.)

BY MR. AMANAT:

Q What is this document, Dr. Wood?

A This is a Power Point presentation that I've used speaking to academic audiences, women's groups around the country.

Q Is this the Power Point presentation that you've used -- I think you said that after you resigned, there were a period of about six months where you were on a speaking tour with Reproductive Health Technologies Project.

A Well, before and after that and continuing that, this is the basic slide presentation that I've continually used, with minor changes depending on the audience.

Q Okay. And did anybody participate in the drafting or preparation of this slide show other than yourself?

A Someone assisted with like animating it and formatting it and the colors and things, but in terms of the content, I did this.

(Exhibit No. 11 was marked for identification and attached to the deposition transcript.)

BY MR. AMANAT:

Q Included in your production was a postcard, and the version I've given you, the front of the postcard is is on top, in color, and the bottom of the postcard is on the bottom.

A Yes.

Q Okay. What is this postcard?

A It's a cartoon called "The FDA's Plan B Approval Process," and on the back is a note from me, because I -- it was sent to people who had sent me sort of as a -- several hundred people who had sent me letters of support, and this was a response.

Q Who created this postcard?
A The Reproductive Health Technologies Project created this postcard.
Q Okay, and they paid for it as well?
A I believe so, yes.
Q And why, why did they do that? Why did they send it out?
A Well, because this is during the time that I was senior advisor to them, and, uh, thought it was, um -- I had been contacted, had all these letters sent to me and felt this was something to respond back to people.
Q Do you have any evidence that FDA's actions with regard to Plan B were influenced by pharmaceutical lobbyists?
A No, this is, this is a joke. This is a cartoon. It's funny.
Q And so the last little, I guess Item 6 in the cartoon, I guess it's meant to be a picture of you there, where it says, "Shuffle staff until no one remembers what Plan B is," is there any staff that was shuffled at FDA, that you know of,

other than your --

A No. I think they're talking about me. I think they were talking about my departure, and again it's making light of the situation.

MR. AMANAT: Okay. One of the documents that you produced to us is a ten-page document. It says "Prescribing Information" on top of it.

(Exhibit No. 12 was marked for identification and attached to the deposition transcript.)

MS. POULSON: Without being able to see the exhibit, I'm going to need to mark the exhibit and the questions about it and the answers as confidential.

MR. AMANAT: You can see the exhibit. I don't care.

MS. POULSON: I'm happy to take a look at the transcript and the exhibit when they become available and determine whether we need to keep that a confidential designation or not.

BY MR. AMANAT:

Q There are a couple -- do you remember what, if any, use you made of this document?

A No.

Q A couple of statements in here I want to draw your attention to. For the record, we have numbered this Wood 6 to 15, so the first page is 6, so let me direct your attention to Wood 8, which is the third page of the document.

A Okay.

Q Towards the very bottom or at the very bottom, it said, "Emergency contraceptives are not as effective as routine contraception, since their failure rate, white low based on a single use, would accumulate over time with repeated use." What, if any, conclusion do you draw from that statement by the manufacturer about the propriety of FDA's examination of whether adolescents are likely to use Plan B as a routine contraceptive?

A I'm sorry. Rephrase that question.

Q That was a little bit convoluted.

A Yes.

Q I apologize.

A I see the sentence you've identified.

Q One of the areas of inquiry that, um -- let me back up, lay the foundation this way. Is it your understanding that part of Dr. Galson's concerns in his May 2004 Non-Approvable Letter was that there wasn't sufficient evidence as to whether younger adolescents would attempt to use Plan B as a regular contraceptive in the event that it were made available over-the-counter?

A I don't know that that was one of his concerns. In the letter I believe he was identifying Label Comprehension and Actual Use Studies not having enough data on the younger population. Um, in any case, the studies that I've seen and that were reviewed by the Reviewers and in their, their reviews identify the fact that there's no evidence to suggest that there would be any change in regular contraceptive behavior or any increased risky sexual behavior or increased unprotected sex in any age group, including younger teens, so this, to me, doesn't speak to the issues of younger teens.

Q Okay. Who is Jim Dickinson?

A Who is Jim Dickinson? Remind me. I don't know.

Q You don't recall that name?

A Well, I'm very -- I'm sometimes very bad with names.

Q Do you recall whether he's a reporter?

A Could be. I honestly don't remember.

Q You --

A Oh, oh, okay. Is he the one who kept e-mailing me?

Q Yes.

A Yes. Yeah, okay. He was this fellow who kept e-mailing me after my resignation.

Q Did you ever respond to him?

A I think I had one phone conversation where he was rather -- he was -- I had not received his e-mails at that time, and he was thinking that I had been avoiding his communications, and I explained to him I had not received any of the e-mails at that time, but by then he had already published whatever he was

going to publish without my input.

Q Did you ever give him an interview?

A I don't recall one way or the other. I really -- I may have, but I don't remember, but most of what he wrote was apparently before we ever spoke.

Q Um, let me direct your attention back to Exhibit 3 that the plaintiffs gave you, which was your Memorandum of Resignation that you sent to Dr. Woodcock and Dr. Crawford.

A Uh-huh.

Q I want to ask you about one thing in this document. You make the statement towards the end of the first paragraph, "Indeed, this only limits access to something that can reduce unintended pregnancy and therefore reduce abortions in the U.S., something I think that we all agree promotes the health of women and their families." Do you see that statement?

A Uh-huh, I do.

Q In your view, is the Food & Drug Administration obliged to approve all products

that reduce unintended pregnancy, regardless of efficacy or other potentiality for harmful effect?

A No. They approve products based on safety and efficacy.

Q And only those products, right?

A That's correct.

Q So if the Agency were to determine that a particular product were not safe or efficacious, it should not approve the drug even if it reduces unintended pregnancies; is that correct?

A That's correct. That was not the case in the August of '05 decision. Safety or efficacy was never raised.

Q Now, let me ask you similarly: Is FDA obliged to approve all products that reduce abortions, regardless of their efficacy or other potentiality for harmful effect?

A All products are supposed to be evaluated for safety and efficacy for approval.

Q So in that case why is it relevant then to your decision to resign, that the drug reduces unintended pregnancies and reduces abortions? Why

was that relevant?

A Because it's part of the mission of the Agency to promote the public health and the health of individuals, and I would say that when we have a product that is clearly, as I say in the sentence before that, "clearly established as safe and effective," it is an additional public health benefit and individual health benefit if we can reduce unintended pregnancies and have the potential to reduce the need for abortions. This is a positive good that is not controversial, I would hope, regardless of one's position on abortion.

As someone who is there as the, one of the job descriptions, "champion for women's health inside and outside the Agency," this is something I would hope that FDA could be -- as it is pleased when we're able to put out a drug that can treat cancer or heart disease, we should be pleased when FDA is able to approve, based on the data, a product that can reduce unintended pregnancy and reduce the need for abortion.

Q Okay.

A And when we can't and it's not based on the efficacy or the safety or the evidence, that's not fulfilling what I think is the positive benefit of FDA.

Q You produced to us in response to our subpoena a number of e-mail correspondence that you had with various individuals.

A Yes.

Q And for a great many of the e-mails that you produced, the name of the author of the e-mail was redacted.

A That's correct.

Q Why did you, why did you direct -- well, did you direct your attorney to redact those names?

A No. I redacted them.

Q And why did you do that?

A Um, because the people sent them to me as private communications. They are not involved in the decision, and I don't think their names need to be brought into this case. You can have

the content, but I, I don't want to provide their names.

Q One of the e-mails that you produced was shown to you by the plaintiffs. It was marked as Exhibit 3, an e-mail from Robert Temple. Do you recall that e-mail?

A Yes.

Q His name is not redacted. Why not?

A Because he is a very senior FDA official and is someone who's very involved in many decisions as Director of Medical Policy, and I didn't think I had the same rationale to not reveal his name that I had for the other staff at FDA and in HHS who are not in such a position.

Q Can you tell me who Eric Colman is?

A I believe I know who Eric Colman is.

Q Who is he?

A The Division Director within FDA, or is that someone else? I'm very bad with names.

Q You tell me.

A I'm very bad with names.

Q I want you to take a look at the e-mails

that the plaintiffs gave you that was marked as Exhibit 4 earlier.

A Yeah.

Q September 1, 2005, 8:03 a.m.

A Yeah.

Q You declined to identify earlier in response to Ms. Labaton's questions who the author of this e-mail was.

A Yep.

Q Is it fair to say that the author of this e-mail was Eric Colman, C-O-L-M-A-N?

A Colman? I'm, I can't -- first of all, I'd ask you how you would know that from this e-mail, but -- it could be his name, but I don't recall for sure.

Q What about on Exhibit 5 that the plaintiffs showed you earlier? With regard to that e-mail, you indicated that you did know who the author was, but you declined to identify the person on the record. Is it fair to say that this comes from Warren Rumble?

A He's into my e-mail systems now. Um,

that would be fair to say.

Q Can you tell me who Warren Rumble is?

A He's the Ombudsman of FDA.

Q What contact have you had with him since your departure from the Agency?

A None at all.

Q Other than this e-mail?

A Other than this e-mail.

Q Did you respond to his e-mail?

A I don't think so.

MR. AMANAT: Bear with me one second, please.

You produced two separate collections of e-mails to us. The first collection we have numbered with 39 to 46.

And Counsel, these were the last documents before the divider that says "Requests 3 and 4." There was about seven or eight pages of e-mails. Do you have those?

MS. LABATON: Uh-huh.

(Exhibit No. 13 was marked for identification and attached to the deposition

transcript.)

BY MR. AMANAT:

Q I'll ask you about a few of these e-mails. The first one down at the bottom of that first page, Page 39, where it says, um, "While sorry that someone of your strength and character and determination will no longer serve as the conscience for women's health issues at the Agency," do you see yourself as the conscience for women's health issues at the Agency?

A No. Someone was being very nice.

Q Can you tell me who wrote this.

A I honestly don't remember who wrote this.

Q Now, you haven't disclosed who were the authors of these e-mails in this collection. Let me ask you first: Do you know who any of these authors are?

A Right now?

Q Yes.

A On these e-mails?

Q Yeah.

A No, I can't remember.

Q Have you had -- do you know whether you have had any contact with any of the authors of these e-mails since you received them?

A No. I don't -- no. I mean it's possible I sent -- oh, no, because this came to my FDA e-mails, and so I would not have been able to reply --

Q After you left?

A -- after I left the Agency, so I highly doubt I contacted any of them by reply e-mail, and I haven't contacted them by any other means either.

Q Okay.

A I mean I don't know. I've run into numerous people since my resignation, and I may have run into some of these people, but I don't remember.

Q I'll give you a quick list of names, and I'd like to tell me whether you have had contact with any of these individuals since you left Agency.

Aleta, A-L-E-T-A, Flores?

A Have any other information on her, like where she's from?

Q No.

A The name's familiar, but I mean I doubt it.

Q Douglas Throckmorton, T-H-R-O-C-K-M-O-R-T-O-N?

A No.

Q Norman Marks, M-A-R-K-S?

A No.

Q Freyja Lynn, F-R-E-Y-J-A, L-Y-N-N?

A No, not that I remember.

Q Evelyn DeNike, D-E-N-I-K-E?

A No.

Q Michael Owen?

A No.

Q Mary Ong, O-N-G?

A No.

Q Gary Masters?

A No.

Q Laurie Brown?

A No.

Q Patricia Delaney?

A No.

Q Marlene Bourke, B-O-U-R-K-E?

A No.

MR. AMANAT: I'm going to give you a two-page document. This is the letter from Sarah White with the check attached to it.

Mark that, please, Exhibit 14, I guess.

(Exhibit No. 14 was marked for identification and attached to the deposition transcript.)

BY MR. AMANAT:

Q I ask you to take a moment to look at that document. Do you recognize it?

A Yep.

Q Appears to be a two-page document. The first page is a letter dated June 13, 2006, from Sarah White at the Center for Reproductive Rights, addressed to you --

A Yep.

Q -- care of your counsel, and it attaches

a check in the sum of $800.20. What was the purpose of this check?

A It was to pay travel expenses from wherever I was in the country at that time to New York and -- going to New York, travel expenses.

Q Why was the Center for Reproductive Rights paying for your travel to New York?

A Because I was going for a meeting and a presentation up there, and they covered the travel expenses.

Q Who were you meeting with, please?

A Simon Heller and Nan Strauss.

Q And what was the day of that meeting?

A I don't recall the date.

Q Do you recall what month it took place in?

A It says April, so I'll go with April.

Q Okay. Did anybody accompany you to that meeting?

A No.

Q What was the purpose of the meeting?

A For me to present my -- the information

I have on what happened with Plan B within FDA.

Q Did they ask you to -- did they invite you to come, or did you suggest to them that you make this presentation?

A I think they invited me to come.

Q What?

A I think they invited me to come.

Q Okay. And what was exactly the nature of your presentation that you gave there?

A Well, uh, talk about many -- the, the, what happened, what I observed during the approval process and what led to my resignation.

Q Did they ask you questions?

A I suppose so.

Q Who asked you questions?

A Well, it was more of a discussion and presentation rather than questions, question-and-answer type setting.

Q So they didn't like interview you or ask you questions about specific factual details that they wanted information about?

A Well, I talked about things, and if they

wanted more clarification or information, they would ask such questions.

Q Did they show you any documents?

A No.

Q Did you take any documents with you to this presentation?

A No.

Q Who was in attendance at this presentation, to the best of your recollection?

A Simon Heller. Nan Strauss. Bonnie I believe was on the phone, and there were several other people, whose names I forget, who were also present.

Q Did you -- when you made a presentation, when you made a presentation there, did you use a slide show or a Power Point?

A No, not at that time.

Q When you were there at Center for Reproductive Rights, did you discuss any matters there with them that you have not testified to today?

A I don't think so.

Q Take a moment to think about it.

A I'm thinking, I'm thinking.

Q Is there anything you told them, any piece of information, any detail that you may have given at that meeting that you have not revealed today?

A Not about my -- I mean it was all about my experience at FDA, and we discussed, uh, any conversations or impressions or -- with the other staff at FDA, including Dr. McClellan and Dr. Crawford and Dr. Woodcock, and any -- no, so that was basically it.

Q Did you give them any information about, for lack of a better word, the personalities or the personal styles of any of those individuals you just mentioned?

A Sure. I mean I would in any conversation, sure.

Q What did you tell them, for example, about Dr. McClellan's personality?

A I told them that he was very engaged, was very smart, uh, is a person who takes a lot of

notes, writes a lot of e-mails, had, you know, seemed to be very interested in, you know, in all-around Plan B and was listening at that time but was gone by the time of the decision.

Q Okay. What, if anything, did you tell them about Dr. Crawford's personality?

A That he's very charming, that he's very outgoing, that, that again, as I told you earlier, that I don't think he -- that I don't think he had a particular strong opposition that I could detect against emergency contraception, and like . . .

Q What did you tell them about Dr. Woodcock and her personality, if anything?

A If I did, it would have been that she's very smart, very -- she's tough, and that she, she knows a great deal about FDA, and I can't think of anything else.

Q What about Dr. Galson? What, if anything, did you tell them about, uh, about him?

A I would have said -- what would I have said? I would have said that he's very -- that he thought at the time of the '04 decision that he

was laying a path forward and that he was very disappointed in what had happened in the '05 decision, and that -- these are again all things I've already said about conversations I had with him and Dr. Woodcock.

Q Did you tell the folks at the Center for Reproductive Rights anything about Dr. Galson's family that you may have known about?

A Well, I met Dr. Galson's family, and Dr. Galson told me that I was going to run into his family in Syracuse when I was going up for, uh, presentations up there, and I indeed met Dr. Galson's father and his mother at that time. And I probably mentioned that I told all the, you know, all the, all of my experiences, as I've been telling around the country all of my experiences. They heard the same stories.

Q Other than this presentation that you gave in April to -- at the Center for Reproductive Rights, please provide me with a complete catalog of all other contacts which you have had with the Center for Reproductive Rights or the attorneys

who work there.

A I'm sorry. What --

Q What other meetings, communications, e-mails, correspondence --

A I think I gave you any correspondence that I had.

Q Telephone conversations, any kind of interaction with them.

A There were meetings -- uh, there was a meeting at the Reproductive Health Technologies Project at some point last year. I have had occasional telephone conversations, mainly logistical -- and e-mail, mainly logistical either to set up this meeting or at the time when trying to do the subpoena and like that.

I was on a panel with Nan Strauss on Capitol Hill, um, back in the fall of 2005, I believe. I can't remember who sponsored that. It was a briefing, a Hill briefing, and she happened to be one of the other panelists.

Q And that was a Hill briefing for whom?

A Well, it was a public -- it was

organizations and Hill staff came. It was sort of a public briefing on -- I think maybe reproductive health generally, but I can't remember the specifics. About emergency contraception in specific, probably.

Q Did you meet with counsel for the plaintiffs to prepare yourself for this deposition?

A No, I did not.

Q Did you review any documents that they may have sent you at any point in time?

MS. LABATON: Objection to form.

BY MR. AMANAT:

Q Did the plaintiff's counsel ever send you any documents?

A Back in the, back in the fall or at some point I got documents which were the Reviewers' reviews that I guess had been part of -- that I think I gave you as part of the subpoena, but I think those are the only documents that they sent me.

Q Who sent you those documents?

A Somebody in the Center for Reproductive Rights. I can't remember who.

Q Why did they send them to you?

A I think, you know, in part I may have requested them, because -- you know, anything that was public so that I could read them. I was interested in seeing the memos and the reviews.

Q Why did you need to read them at that juncture after you left the Agency?

A I was interested in the subject. People were asking me questions as I spoke. You know, this is a subject that -- again, since I had spent most of my career in much broader issues in women's health and had not anticipated resigning around this subject, this helped me understand what had happened in a more specific way.

Q You produced an e-mail from Nan Strauss to you at your personal e-mail address, dated Friday, May 12, 2006. Simon Heller also listed as addressee. And it says, "Let's shoot for a call on Tuesday, at 2:00 p.m. We can always postpone it if your schedule requires it. Talk to you

then. Nan."

Did you, in fact, have a phone conversation with Ms. Strauss on that Tuesday, May 16?

A I don't remember. I assumed this was a call about logistics, so I don't, don't remember.

Q You also produced a request -- well, I can give it to you. A three-page document we've numbered 51, 52, 53. The first page says, "ARHP Expenses for Susan F. Wood," and it has a quarter page of information, and then the second page is an e-mail from Wayne Shields, dated February 1 --

A Uh-huh.

Q -- which then goes on to the third page. Do you recall having produced that?

A Yes.

THE REPORTER: Did you want that marked as an exhibit, or --

MR. AMANAT: Yeah, might as well mark it.

(Exhibit No. 15 was marked for identification and attached to the deposition

transcript.)

BY MR. AMANAT:

Q Let me first ask you: What is your relationship with the Association for Reproductive Health Professionals?

A No, I have no formal relationship. I don't have a relationship with ARHP, other than we crossed paths.

Q Can you explain why ARHP was -- why you were calling upon them to reimburse you for $122.25?

A Because they had invited me to come to their annual meeting in September, and I did that and gave a presentation there, and then this was the total sum of costs that they then reimbursed me.

Q What, if any, relationship do you have with Wayne Shields?

A A friend and colleague.

Q Have you talked to him specifically about Plan B?

A Well, in the time around my

resignation -- and my presentation was about Plan B, and he was there, so yes, I spoke to him at that time, generally, on -- generally speaking, not a lot, no, not about this case at all.

Q How about with Felicia Stewart prior to her passing?

A You know, I never talked to her. I feel kind of sad about that, but I never spoke to Felicia after my resignation.

Q How about prior to your resignation; did you have much of a -- much interaction with her?

A Not in recent years, because she had been out in California, but when she was in Washington I would have interactions with her, but that was some years ago.

Q Other than this $122 here, what, if any, other money has the Center for Reproductive Professionals paid you over the last year?

A None.

Q Have you -- when you produced documents to us in response to our subpoena, the production was covered by a letter from your counsel. Are

you familiar with that letter? Have you seen it?

A Yes.

Q There's one statement in his letter I would like to ask you about. There is a -- in response to our first and second requests in our subpoena, Mr. Trister writes in part, "In addition, Dr. Wood has a small number of e-mail communications with Congressional staff that may be covered by these requests. Dr. Wood objects to the production of these communications on the ground that they constitute lobbying communications protected by the First Amendment."

I must ask you, Dr. Wood: What, what Congressional staffers have you had e-mail communications with about Plan B since your resignation from the Agency?

A Well -- go ahead.

MR. TRISTER: I instruct her not to answer.

MR. AMANAT: On what basis, Counsel?

MR. TRISTER: Same on what's in my letter.

MR. AMANAT: Do you believe that's a valid basis to instruct the witness not to answer?

MR. TRISTER: I definitely believe it.

BY MR. AMANAT:

Q Have you had communications with members of Congress as opposed to staffers relating to Plan B since your resignation from the Agency?

A Yes, I have.

Q What has been the nature of those communications?

A The general nature has been to provide information about what happened in the review and approval process for Plan B emergency contraception. In response to their queries, they have been of bipartisan nature to both committee and personal staff who are -- and to members who are interested in learning about -- for the process and what actually occurred, and to the best of my ability I provided that information.

Q Mr. Trister's letter says that the "objection to disclosures on the ground that they constitute lobbying communications protected by

the First Amendment." What you just described a moment ago doesn't strike me as lobbying communications; it strikes me as being a response to Congressional inquiries, which strikes me as a different animal. Have you, in fact, lobbied Congress and members of Congress since your departure from the Agency on the subject of Plan B?

A What do you mean by "lobby"?

Q I mean actively attempted to persuade members of Congress or their staffers to take a particular position with regard to Plan B.

A With that definition of actively trying to -- I don't know about persuade, but provide the information on a particular, you know, on my particular point of view on Plan B, I would say that that would be then considered lobbying, because I'm trying to provide information, in my mind, accurate and complete information to them so that they can then make appropriate determinations about their role in responding -- their appropriate oversight role in responding to what

happened at FDA, but sometimes it was they were inquiring of me directly. It depended on the situation.

Q And when they inquired of you, in what manner did they make those inquiries?

A Well, I have to point out I have had no contact with anybody in Congress -- staff, members or otherwise -- prior to my resignation at all on the subject.

Q I'm focusing on subsequent.

A Which is -- which I don't necessarily see the relevance of, but in any case, subsequent the first call I got was from a Majority Committee staff who were considering doing an investigation, and they asked me to -- they wanted to interview me on, on what happened and my resignation, and that occurred. And then other -- you know, other times I've contacted or other aspects of communications with Congress have been on things unrelated to Plan B.

I have to point out I've worked as a consultant in a couple of different capacities

where we contacted the Hill and different Congress people or senators who are interested in women's health broadly, and I was communicating with them on those subjects, and then other communications were about Plan B specifically.

Q When you were getting these requests for information from members of Congress or their staffers when they wanted to get information from you about Plan B, were they requesting this information from you by sending you e-mails, by writing you letters, by faxing you? How did they --

A Sometimes they sent e-mails, sometimes they called me, sometimes, um -- I don't think I got any faxes or letters, although I got one -- that's not true. I got one thing sent to me by mail, but otherwise it's, you know, just routine types of contacts.

Q And when you provided this information to them, did you typically provide it in writing or did you pick up the phone and call or did you testify, or --

A I typically spoke on the phone or went to their offices and met with them in person.

Q And how many -- so how many such meetings would you say took place since you've left the Agency?

A Specifically about Plan B?

Q Yes.

A Roughly 15 or 20.

MS. JONES: Can we take a short break?

MR. AMANAT: Yeah.

THE VIDEOGRAPHER: Going off the record, the time is 4:02 p.m.

(Whereupon, a short recess was taken.)

THE VIDEOGRAPHER: We're back on the record. The time is 4:16 p.m.

BY MR. AMANAT:

Q Dr. Wood, I appreciate your patience with me. I have had a lot of questions for you. I apologize for having so many. I just have a couple more.

We were talking before the break about any contacts or communications you may have had

with members of Congress or their staff. As a corollary to that, I want to ask you whether you had any contact or communication with the government accountability office with regard to the, uh, their examination of the Agency's decision-making process with regard to Plan B.

A This is for the report that came out in November of 2005?

Q Yes.

A Yes. I was on the interview list provided by FDA or to the GAO, and so the GAO -- or I don't know how many -- anyway, I was one of the people who was interviewed by the GAO when they were doing their investigation.

Q Do you recall approximately when that interview took place?

A Um, winter 2005, something like that.

Q Did you give them any documents?

A No.

Q And do you recall what exactly you told the investigators?

A Not specifically, no.

Q Did you tell the investigators anything that you haven't testified to today, to the best of your recollection?

A Not that I can think of, no.

MR. AMANAT: I have no further questions. Thank you for your time, Doctor.

MR. TRISTER: We get to read and sign.

MS. JONES: We have a couple more questions before you do that. Just a couple. Just a couple.

REDIRECT EXAMINATION

BY MS. LABATON:

Q We really just have a couple of questions. Dr. Wood, you testified earlier that you asked Dr. Woodcock what was going on with the Plan B Application in 2005, and you stated that she said Les was waiting for an answer. Who was he waiting for an answer from? And I'm assuming you were referring to Dr. Crawford.

A Yes, I was referring to Dr. Crawford, and I don't know who he was waiting for an answer from. I --

Q You've referred a couple times in your answers today to a decision by the FDA that was announced today. Is it your understanding that the FDA reached some decision with regard to the Plan B Application today?

A Um, only what I read in the AP story that was, um, being passed around, that, that Dr. Von Eschenbach has indicated, through a letter to the company, that rule-making is not necessary and they've asked Barr to come back in with a new Application, but I don't have any details or know anything really about it. It's entirely secondhand at this point.

MS. LABATON: Okay. I have no further questions. Thank you, do Wood.

THE VIDEOGRAPHER: This marks the end of the deposition of Susan Wood, Ph.D. The total number of tapes used is two. We're going off the record. The time is 4:20 p.m.

(Signature having not been waived, the videotaped deposition of SUSAN WOOD, Ph.D., was concluded at 4:20 p.m.)

ACKNOWLEDGEMENT OF WITNESS

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

_____ _____

(DATE) (SIGNATURE)

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IN RE: TUMMINO VS. VON ESCHENBACH

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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 9th day of August, 2006.

My commission expires: March 14th, 2011

_____

LAURIE BANGART-SMITH

NOTARY PUBLIC IN AND FOR

THE DISTRICT OF COLUMBIA