UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF NEW YORK

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ANNIE TUMMINO, et al., :

Plaintiffs, :

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

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

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

the Food & Drug :

Administration, :

Defendant. :

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Videotaped Deposition Of Janet Woodcock, M.D.

Volume 2

Rockville, Maryland

Thursday, April 27, 2006

11:03 a.m.

Job No.: 1-77268

Pages 117-180

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

Videotaped deposition of Janet Woodcock, M.D., held at the offices of:

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

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C O N T E N T S

E X H I B I T S

(None.)

P R O C E E D I N G S

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THE VIDEOGRAPHER: Here begins tape number 1, volume 2, in the deposition of Janet Woodcock MD, in the matter of Annie Tummino, et al. versus Andrew C. Von Eschenbach as Acting Commissioner of the Food and Drug Administration. Today's date is April 27th, 2006, the time is 11:03 a.m.

I would like to remind the witness that she is still sworn in from yesterday. You may begin.

EXAMINATION BY COUNSEL FOR PLAINTIFFS (RESUMED)

BY MS. JONES:

Q Good morning, Dr. Woodcock.

A Good morning.

Q I'm going to ask you a couple follow up questions from yesterday to start us off. First of all, we talked a bit yesterday about over the counter switches that were not directly requested by a manufacturer. Do you know of any drug that the FDA has switched to over the counter status, where the manufacturer itself did not request the switch?

MR. AMANAT: Your question was at any

point in time, as far as she knows.

MS. JONES: Yes.

THE WITNESS: No, I don't know of any.

BY MS. JONES:

Q Does that mean you know that there aren't any or that you just don't know?

A I don't know. Switch is a term of art, which means the drug is in prescription status and then is moved over to the OTC status. And as we discussed yesterday, that requires certain showings in the OTC setting. And ordinarily, that would be by a sponsor.

Q So you don't know of any instance, for example, where there was a citizen's petition filed for an OTC switch, and it was granted despite the fact that the manufacturer itself didn't ask for the switch?

A I don't know of such an instance.

Q Or I suppose there could also be an instance where the FDA sort of on its own, on its own decision based on the evidence that was available to it made a switch of a drug despite the fact that the

manufacturer hadn't asked for a switch. You don't know of any instance that that's happened?

A No, I don't.

Q Dr. Galson, in at least one of his memos, and perhaps other places, expressed a concern that adolescents might face certain risks if they used Plan B incorrectly. Do you share that concern?

A I share the concern that the availability of Plan B might lead to certain ill-advised health behaviors, potentially.

Q So it might lead to changes in adolescent behavior that would be harmful?

A Have health consequences, correct.

Q If it didn't cause changes in behavior but an adolescent simply used it incorrectly, does that pose risk to the adolescent?

A Well, it depends on the degree of the use or misuse or incorrect use. Most drugs are -- most drugs can cause harm or side effects when they're used incorrectly, and sometimes even if they're safe and effective when they're used correctly, they can rarely cause harm.

Q Let's say an adolescent used Plan B as their regular form of contraception, so every time they had intercourse, they used Plan B. Does that pose risks, health risk to that adolescent?

A Well, it would depend on how frequently the intercourse happened. Obviously, this is a higher dose than would be recommended for ordinary oral contraceptives and therefore regular use might put someone at the same type of risks, but perhaps because of a dose related phenomena, slightly higher risk than taking oral contraception which is a prescription drug because of certain rare side effects that can occur.

Q What are the risks of taking -- this is a progesterone only product, is that right, Plan B?

A I believe so, yes.

Q It's my understanding also. What are the risks?

MR. AMANAT: I think it's an estrogen only product.

MS. JONES: No, it's not. It doesn't have any estrogen in it.

MR. AMANAT: Okay.

BY MS. JONES:

Q What are the risks of taking a progesterone only birth control product every day?

A Well, there aren't any such that are used for regular oral contraception, to my knowledge. And therefore, I think some of those might be unknown. Obviously, a high dose estrogenic oral contraceptive is associated with a measurable incidence of thromboembolic phenomena.

Q That's for a product with estrogen in it?

A Yes, uh-huh.

Q But there -- am I correct that there are no known risks of just taking a progesterone only birth control product daily?

A Yeah, I'm not an expert in this area, all right? But I would say that those risks are unknown rather than to say there are no known. The absence of evidence is not evidence of absence.

Q Do you know if -- what risks are listed on the packaging for progesterone only birth control pills?

A No.

Q Would the risks that a woman would face if she took Plan B on a daily basis be similar to the risks you would face if she took regular progesterone only birth control pills on a daily basis?

A It would depend on the magnitude of the dose, comparative dose. Most side effects are dose related.

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

(This concludes the "PROTECTED TESTIMONY".)

BY MS. JONES:

Q Do you know if you met with Drs. Galson and McClellan in the, let's say month to two months following the advisory committee hearing to discuss the advisory committee hearing and what had occurred?

A I met with Dr. Galson and McClellan on a variety of issues. And the follow-up to the advisory committee was discussed during those meetings, it was not the sole subject of the meetings to my recollection.

Q Do you recall what Dr. Galson or Dr. McClellan said to you about the advisory committee hearing after it had taken place and the votes had been made?

A I do not recall specifically any specific comments by either of those individuals.

Q Do you remember generally what sort of -- what generally they were expressing to you about the advisory committee outcome?

A Dr. McClellan expressed his continuing concern about the adolescent data and adolescent age group.

Q And the advisory committee had met and considered those concerns and had decided it should be made over the counter anyway, is that right?

A They had recommended that.

Q And did he express anything to you about

his response to the fact that that had taken place at the advisory committee?

A No, I don't believe so. He reiterated his concern based on his review of the data.

Q And do you recall anything about what generally Dr. Galson expressed to you on this matter?

A Dr. Galson responded that he was also reviewing the data, and would look at the data within the light of Dr. McClellan's concerns, particularly the adolescent data.

Q Other than in the case of Plan B, is there any other time during your time in the Commissioner's office where the Commissioner refused to share his decision making process with you on a matter that you had worked on?

MR. AMANAT: Are you referring to a specific Commissioner, or the incumbent Commissioner, whoever it may have been.

MS. JONES: The Commissioner at the moment, the relevant moment.

THE WITNESS: I'm sorry to take so long.

BY MS. JONES:

Q That's quite all right.
A I've been at the FDA a long time.
Q I understand.
A Could you restate the question?
THE REPORTER: "Question: Other than in the case of Plan B, is there any other time during your time in the Commissioner's office where the Commissioner refused to share his decision making process with you on a matter that you had worked on?"
THE WITNESS: In the time I've been in the Commissioner's office, okay, well that's a shorter time. I believe so. However, I'm not able to recall specific instances. Maybe if you gave me an hour, I could think about them. But I believe there have been other cases, since the time I've been in the Commissioner's office, where I've not, where I've been involved in contributing to an issue and then was not involved in the final decision making or --
BY MS. JONES:
Q Okay. Has there ever been such an instance where not only were you not involved in the final decision making, but you weren't kept informed

about what the decision making process was for the Commissioner?

A Again, I believe so. However, the instances cannot come to mind right now, but I believe that has been the case in some other issues.

Q But you can't recall?

A Since I've been in the Commissioner's office.

Q But you can't recall any instance sitting here now?

A It's hard. Maybe you could clarify, are you talking about an approval decision of a product or any type of decision that the agency might take?

Q Well, maybe if I narrow it, it'll make it easier. Can you recall any such instance where the Commissioner sort of excluded you from his decision making process on a matter that you had worked on and the matter was a drug, either an NDA or an SNDA?

A No.

Q Or the approval of any sort of drug or device?

A No.

Q After Dr. Crawford made his decision in August of 2005, and announced it publicly, did he at that point explain his decision making process to you?

A No.

Q So to date, has he explained his decision making process to you?

A No.

Q Have you asked him to explain?

A No.

Q Do you know anything about a teleconference call that was held January 22nd, 2004 between someone in the FDA and a person named -- initials MA, and whose last name is Gold? She's the coauthor of a study called The Effects of Advanced Provision of Emergency Contraception on Adolescent Women's Sexual and Contraceptive Behavior?

A No.

Q Do you know anything about an e-mail from Gold, I don't know if it's a Ms. or a Mr. or a Doctor, from this author to the FDA on February 13th, 2004?

A No.
Q Do you know who this author is?
A Doesn't come to mind.
Q Do you know if you had any contact with this person?
A Not to my recollection.
Q Do you have any documents related to Plan B within your personal control that you have not yet produced to the defense attorneys in this case in connection with our discovery requests?
A Only the recent e-mails scheduling this deposition.
Q Nothing other than that?
A And maybe an e-mail about the Plan B GAO report that was released. But, no, no other kind of documents.
Q Who would the email about the GAO report release be from?
A Zach telling me that it was released, something like that.
Q Is that something you would have in your personal control outside of your work computer, or

would that be in your work computer?

A Everything's on my work computer.

Q So you don't have any documents, electronic or paper, related to Plan B that are outside of your office and work computer?

A No. No.

Q Could you take a look at the document marked D81, Tummino 81?

A It says a letter to Mr. Enzi.

Q Yes, from Michael Leavitt. Could you take a look at that, and let me know if you are familiar with that letter?

A I'm not familiar with the letter, but I knew -- I heard, somebody told me that the letter had been sent, I think after the fact, told me that. But I had never seen this letter.

Q This letter states that Michael Leavitt spoke to someone in the FDA, and based on the feedback he received, that he could state that the FDA would act on the Plan B application by September 1st, 2005.

Do you have any idea who he spoke to

within the FDA about this?

A None.

Q It was not you?

A It was not me.

Q And you do not know if it was someone in the Commissioner's office?

A I don't.

Q During your time at CDER, that office approved some number of drugs to be switched from prescription to over the counter status, is that right?

A The Office of Over the Counter Drugs, the Division of Over the Counter Drugs -- or CDER, you're talking about?

Q CDER?

A That's correct, uh-huh.

Q And I think as we discussed yesterday, those switches were made without the agency requiring data on adolescent use, is that right?

A To my knowledge. However, I must point out that in many cases, because these were switches from prescription to over the counter, various

instances of exposure of various age groups had occurred prior to the switch. That's part of the safety and efficacy review that goes on.

So when you have a prescription drug in wide use, for many years often, and most of these have a very long track record of use in the United States before they're switched, then there's a long history of exposure of all age groups.

Q So in other words, you would have data on adolescent use in the prescription setting?

A Correct. In many, many cases.

Q Okay.

A Yes.

Q I guess I should have been more clear. What I meant to say was that those switches were made without requiring data on adolescent use in the OTC setting?

A To my knowledge, that is the case. However, some of the actual use studies may have included a broad population, I don't actually know. It depends. What is needed for an over the counter switch depends on the scientific questions that arise

about the use in the OTC setting versus under the care of a learned intermediary.

And so we have an obligation to see how the use would change, and what the health consequences would be in the OTC setting. And that requires a number of different inquiries.

There have been a number of OTC -- of prescription products where people have desired to switch them, but have not been able to satisfy satisfactorily the issues about consequences of OTC use. And these have remained prescription drugs.

Q Okay. Where the office, CDER, has approved OTC switches without significant OTC like trials with adolescents, does it do so by extrapolating the data it has on adults or older adolescents to the younger populations?

A There's a variety -- it depends on what issue. It would not usually extrapolate data on safety or efficacy, the actual pharmacologic effects, all right, of the agent. As I said, we would usually have data on the pharmacologic effects.

As far as appropriate use and whether

people can understand the label and won't misinterpret the label and so forth, that was a case by case basis. And I can not tell you, sitting right here, how much data we had on label comprehension by adolescents for any given switch that was done for other products.

Q Well, let's just talk in general terms, then. Where a switch is approved, where an OTC switch is approved, and there is little or no data on adolescents submitted in connection with the switch, what are the possible, what are the possible bases for that decision apart from extrapolating the adult data to adolescents?

A The basis would be that the comprehension which would be based more on various literacy levels and so forth could be extrapolated down into the younger age groups who actually might go into a drugstore and purchase this product.

Q Anything else?

A Generally, as I said yesterday, we've become more and more aware, from a scientific standpoint, of the need for additional data in

various age groups as drug regulation has evolved.

And so I don't think the policies of the 1950s, for example, when we approved -- we just had some warnings on phenergan, where it was just approved sort of globally for children. And now we realize that -- we just put out some warnings in the two and under age group, it may cause respiratory depression and harm. We're becoming more -- try to become more precise, and really understand the impact in the different age groups.

So what I'm telling you is because in the past we have taken a sort of global attitude does not necessarily mean we'll do that in the future, as we have more scientific knowledge about how different age groups either may react pharmacologically or how their behaviors may be different.

Q Okay. We're going to take a five minute break now, and then I think we probably only have five more minutes.

THE VIDEOGRAPHER: We are going off the record. The time is 11:26 a.m.

(Recess.)

THE VIDEOGRAPHER: We are back on the record. The time is 11:30 a.m.

BY MS. JONES:

Q Dr. Woodcock, do you have any idea why Dr. Crawford resigned two months after being confirmed by the Senate?

MR. AMANAT: Go ahead.

THE WITNESS: I have no definitive information, all right? I have been told various things which I'm reluctant to talk about.

BY MS. JONES:

Q I'm sorry to tell you that you have to answer unless your counsel instructs you not to.

MR. AMANAT: Well, I would object to the question. I would not object to your asking her whether she is aware, whether she is aware if Plan B or the agency's process with regard to Plan B contributed, as far as she knows, to his decision to retire from the agency in September. But to the extent that the question --

MS. JONES: Frank, unless you're going to instruct her not to answer the question, could you

just let her answer? It doesn't seem to me that you have an objection that you need to make at a deposition.

MR. AMANAT: Well, I stated my objection on the record.

MS. JONES: Okay, thank you. You can go ahead and answer the question.

THE WITNESS: As I said, I have no direct knowledge. And I did not talk to Dr. Crawford after he announced his resignation, and he did not share with me prior to that that he was going to resign.

BY MS. JONES:

Q Okay.

A So I have no knowledge at all from Dr. Crawford. I read various accounts about -- well, he said that in his e-mail that it was time for him to move on, that was one reason. And he sent that e-mail around to the FDA. Number two, various accounts said that Dr. Crawford had stock that there was a dispute over. They were public accounts and I don't know, I don't have any substantive knowledge of that.

Q Did anyone indicate to you any other reason that Dr. Crawford may have resigned?

A No reason related to Plan B.

Q Any reason at all?

A People felt that various allegations that had previously been made about a relationship with a staffer in his office may have contributed to this, that's another reason that was raised.

Q Were any other reasons raised to you or that you heard about?

A No.

Q Do you have any knowledge of whether Dr. Crawford is the subject of a criminal investigation that relates in any way to Plan B?

A I have no knowledge of that.

Q Has anyone told you that?

A No.

Q Do you have any knowledge of any criminal investigation related in any way to Plan B, regardless of whether it has to do with Dr. Crawford?

A No.

MS. JONES: I have no further questions,

thank you very much for your time.

MR. AMANAT: I do have some questions for the witness.

EXAMINATION BY COUNSEL FOR DEFENDANT

BY MR. AMANAT:

Q Dr. Woodcock, yesterday Ms. Jones asked you a series of questions about whether, to your recollection, the director of CDER had made a decision that was contrary to, or overruled the views and recommendations of staffers. And she was very careful to limit her question specifically to OTC switch applications. And I believe you testified in response to her question that you were not aware of any OTC switch applications in which a center director had made -- had taken an action of that nature.

Let me take her questions and broaden those, okay? Going beyond the circumstances of an OTC switch application, are you aware of any type of circumstance in which a center director has overruled the recommendations of subordinate staffers with regard to any type of policy decision or application

decision that may have been before the center?

A Yes. I was involved in several of these activities personally.

Q Could you give some examples, please?

A The name Plan B was not accepted by the staffers of the center as an appropriate name for this particular product. That was appealed all the way up to me, and I overruled those objections and said that a name of the product could be Plan B. And that, you know, was against all the recommendations up the line about this particular product.

Q Can you think of any other examples?

A I overruled both the reproductive division, as well as the entire generic drug division, as well as my deputy, on the matter of whether there could be a generic equivalent of Premarin -- that decision is well documented in the record -- based on the fact that the proposed generic copies of Premarin did not have the same active ingredients as the conjugated estrogen product that was the reference listed drug.

And that was, you know, a very upsetting

overruling of what -- a path that the generic drug division, reproductive division had been on for quite a long time. They had written a guidance and so forth.

And I overruled that on the basis of the science, and I believe that the subsequent scientific developments in estrogen receptors and so forth have shown that that was the correct thing to do.

Q And can you think of one more example, perhaps?

A Well, the approval of thalidomide which was done in the mid-'90s was done over the objection of many of the staff at that time. And I don't think I had to sign that one because one of the office directors was willing to sign a letter. However, we had very public objections about approving thalidomide for leprosy, by the division director and a number of the staff, who spoke up at the advisory committee. And also of course, wrote memos opposing the approval of thalidomide.

Q So is it fair to say that these, all three of these were decisions that rose to the level of the

center director?

A Yes.

Q And that reached your personal consideration as center director?

A Yes, and I was the one who actually made those decisions.

Q In your view, was it inappropriate for you to have made those decisions?

A I regard that as my responsibility. I'm the person, along with the Commissioner -- when I was head of the Center for Drugs, I'm the person along with the Commissioner who is accountable for the consequences of regulatory decisions.

Q Yesterday there was also some questioning about high profile decisions, I believe in response to questions that you -- that Ms. Jones asked you.

You testified that when a matter is what you described as high profile, it is more typically a matter which is likely to rise to the attention of the center director, or even above that to the Office of the Commissioner.

And again, most of her questions in that

regard were directed specifically and narrowly to the context of OTC switches. So let me once again take her question and broaden it, okay? Beyond the realm of OTC switches, and going to the more general universe of policy decisions and drug application decisions which fall under FDA's programmatic responsibility, can you think of any other circumstances in which what you would call a high profile decision rose to the level of the center director or the Office of the Commissioner?

A Certainly many, many. I've been personally involved in almost every withdrawal of a drug from the market, and made many decisions to withdraw those drugs from the market myself when I was center director.

The approval of mifepristone, which happened in the '90s, was obviously a high profile action that I was personally involved in, and that the FDA Commissioner at the time, Jane Haney, also was briefed on extremely frequently, and was kept aware and actually participated in some of the, you know, evaluations of the safety program around

mifepristone. And there are numerous other examples.

Q Now, when you refer to mifepristone, just to make sure the record is clear, is that the drug which is known in the United States by the trade name Mifeprex, and more commonly known in the public vernacular by its French trade name, RU486?

A That's correct.

Q And this is a chemical abortifacient, right?

A Yes.

Q Would you please state for the record what involvement, if any, you had in approving mifepristone for dispensing in the United States?

A I was the head of the Center for Drugs at the time. I was very directly involved in all aspects of basically the risk management program, how the drug would be distributed and dispensed. There were numerous aspects that I was directly involved in, including obviously the announcement and subsequent follow-up and so forth.

Q Were you directly involved in the decision to approve mifepristone for marketing in the United

States?

A Yes.

Q Now, there was some question yesterday from counsel for the plaintiffs as to whether the drug at issue in this case, Plan B, is an abortifacient. Do you believe that Plan B is an abortifacient?

A No, but I think you can't rule out a rare instance where it would prevent implantation, given the current scientific data that are available.

Q If you did believe that it were an abortifacient, would that have factored into your decision making process as to whether this drug should be approved for OTC purposes?

A No, it would have perhaps, depending on the strength of the evidence, might have changed the way the label was written.

Q Now, there were some -- there was reference to one or two documents yesterday. In particular, there was a letter I believe from this guy, what was his name, Dr. Hager. And I think there was also a letter from some members of Congress, who

appeared to have taken their position in their communications to the agency that they believed this drug was or may well have been an abortifacient. And they articulated that as being one of the reasons why the agency should deny OTC status for the drug. Do you recall having seen those documents?

A I saw the letter from Dr. Hager yesterday.

Q In your view, Dr. Woodcock, was -- did these opinions that this drug was an abortifacient, and that the agency should reject the OTC switch application because it was an alleged abortifacient, did those opinions factor into either your views or Dr. Galson's views on the drug?

A No, we had done, as is reflected in this record, a very careful review of all the scientific evidence on this matter. And we'd found no evidence that that was the mechanism of action.

Q Let me direct your attention, Dr. Woodcock, to a document you saw yesterday. It's in your book in front of you, document 3108. Back towards the beginning.

A Yes.

Q Do you recall you were questioned about this document yesterday?

A I do.

Q And for the record, this is a document carrying Bates numbers 21030719 to 30744. And do you recall that you testified yesterday about your recollection of this meeting that took place on February 18th of '04 with the Office of the Commissioner relating to Plan B?

A Yes.

Q Do you recall whether there was a meeting the following day on February 19th of '04?

A Yes.

Q Involving Plan B?

A Yes.

Q And were you part of that meeting?

A I believe so.

Q Now describe, to the best of your recollection, Dr. Woodcock, what you recall about the meeting which took place on February 19th of 2004?

A We were discussing the issues that had been raised at this meeting the prior day about

whether or not there was need for further data in adolescents. And we were having some discussion about the degree to which one could extrapolate from the adult data and how much was actually known about the behavior of young teenagers with respect to this medication, based on the data that had been submitted by the sponsor or based on the ability to extrapolate from what we know in older teenagers or adults.

Q Do you recall who had requested that this meeting take place?

A No.

Q Who was present at this meeting to the best of your recollection?

A The review staff, which would constitute the over the counter review staff, as well as the reproductive division review staff, as well as Dr. Galson and myself.

Q And what -- to the best of your recollection, were any formal official minutes of that meeting taken?

A I don't know. I don't believe I ever saw any minutes of that meeting.

Q Is that the kind of meeting at which minutes normally would be taken?

A We try to take minutes of all our meetings, yes.

Q But you haven't seen any minutes of that particular --

A No.

Q Do you have any recollection of any statements which you may personally have made at that meeting?

A Yes.

Q Would you please state what your recollection is in that regard?

A I was discussing with the staff the fact that we did not have much data in the younger adolescent age group on over the counter use of this product, that all the data that we had really was in settings where they had already come in contact or under a health care practitioner.

And I discussed with them our inability as basically middle-aged health professionals, our inability to really get into the minds of young

teenagers and their behaviors. For example, we have very proudly approved many drugs in the past that have become cult drugs in certain populations, for example, OxyContin, that staff had approved that, felt very good about that approval for cancer patients who suffer from severe pain. And they thought it was a wonderful new option.

They -- although that obviously had abuse potential. They never imagined it would reach this cult status of abuse and misuse in rural areas, which is actually what happened to OxyContin. Similarly, dextromethorphan, which is an ingredient in over the counter cough and cold remedies is particularly used as a recreational drug in the 13 to 16-year-old age group. And I, in my wildest dreams, could not imagine misusing cough and cold medicines, but these young teenagers call them skittles, they use the internet to disseminate this sort of cult status of using, misusing this drug.

And I was telling them, you know, we don't have any data and we really need to think about these behavior al consequences, because we do not have

data. And our experiences show that we have difficulty extrapolating from the behavior of older people into the younger age group.

Q So in offering these examples to the group, were you -- I mean, were you suggesting that you thought that Plan B definitely would become a cult drug of some kind of that same nature that OxyContin and dextromethorphan had been?

A No, I was reflecting the fact that we had no data on what it would become, that there could be a risk. And we are poorly prepared to extrapolate the health consequences. Everything we know about young teenagers is that their risk taking behavior and their cognitive processes are different than the older adolescent age group or adults.

Q Let me ask you to turn to the next document in your book, Dr. Woodcock, it's document number 3109. For the record, this is a document which is labeled with Bates numbers 30745 to 30783.

And let me ask you to, for the sake of my question, why don't you take a moment to read just the portion of this document prior to the word

background on the second page, so the whole first page and the first full paragraph on the second page.

A Okay.

Q Now, despite Mr. Heller's having promised the news media that plaintiffs plan to grill you about this document at your deposition, they of course didn't ask you about this document at your deposition today, is that correct?

MR. HELLER: Did I promise the news media that?

MR. AMANAT: You were quoted in Newsday as having promised that, sir.

BY MS. JONES:

Q Now, Dr. Woodcock, have you seen this document before?

A I hadn't seen it -- well, I saw it last week.

Q You saw it in the context of our meeting to prepare you for this deposition; is that correct?

A That's correct. That's the first time I saw it.

Q That's the first time you saw this

document.

A Uh-huh.

Q Now, let me ask you, are these official minutes of FDA meetings as far as you can tell?

A This says at the top it's an addendum to the division director memo. Division directors write a memo covering their review of an action, and they're called division director memos. And there would be two. One would be in the over the counter division and one would have been from the reproductive division. I can't tell from this which one it is.

Q Well, look at the very last page of this document, if you don't mind, the 30783, which has a signature on it.

A Oh, okay, uh-huh.

Q And what are the signatures there?

A Curt Rosebraugh and Jonca Bull.

Q And who are they?

A Curt was a medical officer, maybe the deputy director within the OTC division. And Jonca was his supervisor, head of the -- the office

director that oversaw that division.

Q So is it fair to say that Dr. Rosebraugh is, what, five levels below you in the chain of command at FDA?

A When I was head of CDER?

Q Yeah.

A Or now?

Q When you were head of CDER?

A All right. Let me count on my fingers, one, two, three, four levels.

Q Four levels below?

A Depending how you count.

Q And Dr. Bull would have been three levels below you?

A That's right.

Q And I see that this document, what is the date on this document?

A It says 3/30/04.

Q So this would have been, what, about seven weeks after the February 19th meeting; is that correct?

A It would have been that much time after

the February 19th meeting.

Q So let me direct your attention, then, to the first page of this document on 30745 to 30746. The very bottom paragraph that starts on the bottom of 30745. And goes on, continues on and concludes on the top of 30746. Let me just ask you to reread that one paragraph because I have a couple questions for you about it.

A Okay.

Q Okay. Is it fair to say that that paragraph purports to summarize the author's recollection of this meeting that had taken place six or seven weeks prior, is that correct?

A Yes.

Q Now, he attributes in that paragraph -- by he, I'm referring to Dr. Rosebraugh, who's the first signatory of this document. I'm assuming the document originates -- I should say "they" perhaps, because it's signed by two people. So they attribute certain comments to you in particular in this, in this paragraph, do they not?

A They do.

Q To the best of your recollection, are the comments attributed to you a fair and correct characterization of your statements at that meeting?

A Well, certainly a highly incomplete characterization.

Q Could you elaborate on that? Explain what you mean by that?

A I went through, as I did here, a number of examples of the fact that we have great difficulty in understanding consequences of behavior in the absence of data. And as I said earlier in this deposition, that has led us to refuse to switch or discourage sponsors from switching quite a few over the counter potential switches, because we were concerned about adverse health consequences of the OTC availability of the product.

We had data that was fairly good on OTC availability and the consequences of OTC availability for the older age groups. But what I was talking about in this meeting or what could be various health consequences of the availability in the younger age group for which we did not have data. And of course,

of particular concern is failure to be under proper health care for women who are sexually active at a young age.

Q Now, at the very bottom line of this, it says, "as an example, she stated that we could not anticipate or prevent extreme promiscuous behaviors." To what extent did you comment on a fear about extreme promiscuous behaviors?

A I think, to my recollection, I shared with the group the fact that I was the mother of two teenage girls. And that they had shared with me a number of behaviors of their classmates or colleagues. And some of that, you know, would alarm most health professionals, although I think they're aware of it as a statistic. And some of it involves sexual activity.

And I said that I was -- we could not predict that. I wasn't trying to imply that Plan B would cause this, okay? I was concerned that it would get caught up in this type of behavior that is already occurring out there in some pockets, especially of the early adolescence. And if that

were to occur, I was saying then we would have a terrible problem on our hands as far as availability of this product at all which --

Q Was your -- go ahead, please.

A Well, we have countered that with other products that are extremely desirable products for a certain part of the population. But if abuse occurs in a subpopulation, the pressure to make those products unavailable becomes very strong. And so we have to balance the ability to make sure that the product remains, you know, an overall positive benefit/risk ratio, and we can't simply focus on the good it's going to do. For example, the OxyContin example is a very good example.

I mean, for people with cancer, that is a really important drug. All the long acting narcotics are. But there's a countervailing force that would like us to remove that drug from the market because of the harm that is being caused by abuse of the drug.

Q Now, when you were thinking about the, when you were thinking about the possible

relationship between OTC availability of Plan B and the sexual behavior of adolescents?

A Right.

Q Was that, were your thoughts affected to any extent by a moral opposition to adolescent sexual activity?

A No, I think most people have a public health or parental concern about adolescent sexual activity, which I share, all right? But, no, I wasn't trying to imply, as I said, that the availability of Plan B would cause this. This is already going on, people should know. And if a over the counter product became involved in something like that, then there would be, as I said, an extreme jeopardy of the product.

Q Well --

A And we've seen this time and time again. We just have had to take Sudafed, all right, behind the counter. You know, there have had to be different actions taken on Sudafed because people who want to make meth will buy the Sudafed and turn it into a different use. And we have to take these

things into account.

Q You mentioned a moment ago, briefly you made reference to a public health concern about adolescent sexual activity. Could you elaborate on that, please? What is the public health concern about teenagers having sex?

A A very strong one, and one of the reasons we're here today, is, of course, unwanted pregnancy is a very negative consequence of adolescent sexual behavior, sexually transmitted diseases, some of which, especially not under health care supervision that can lead to infertility later in life, currently can perhaps lead to cervical cancer and so forth. So there are a lot of concerns about the spread of infectious diseases and so forth.

Q Is there any ideological, political, moral, philosophical component to your views with regard to whether Plan B should be made available over the counter?

A Could you go through those adjectives again?

Q Ideological, is there any ideological

component to your views as to whether Plan B should be made available over the counter?

A No, I should probably just make my views clear. I view contraception and family planning as the most important issue that faces our species, all right? So I think that we have to do things right. We have to recognize that although I don't have any of those objections, other people may. And we must be based on data and scientific evidence, and do the right thing.

Q Is there a moral component to your views as to whether Plan B should be made available over the counter?

A Moral. I think --

Q Or religious, if you want to look at it that way.

A No, I think we have an ethical imperative to make it available as widely -- that would keep the benefit/risk ratio in balance, because of its potential to prevent unwanted pregnancy.

Q Is there a political component to your views as to whether Plan B should be made available

over the counter?

A No.

Q Are you a member of a vast right wing conspiracy?

A I don't think so.

Q Do you -- now, the plaintiffs have raised a number of allegations in their complaint about Plan B, and the FDA's actions with regard to Plan B. They allege, for example, in paragraph 83 of their third amended complaint, "the FDA applied a different and higher standard to Plan B's OTC switch than it has applied to OTC switches of other drugs." Is that a correct statement?

A We try to apply the current scientific knowledge that we have at the time. It may be true that in the 1950s, we had a different standard of OTC switches, but we've learned a lot of science and we have gained a lot of experience since then. And I think that it's our obligation as regulators to keep our science up to date. We don't -- we're not like the law, we don't have to just follow what's been done before. We incorporate current scientific

knowledge and experience into our standards of both safety and efficacy, and we would be wrong to do anything else.

Q So they go on to allege in paragraph 84 of their complaint that "there is no medical or scientific basis for the FDA's application of a different and higher standard to Plan B's OTC switch." Is that a statement with which you agree?

A Well, I don't agree that we applied a different and higher standard, all right? So I believe that the rules, the law and regulation that regard OTC availability are very clear on everything, including misuse and other health consequences, which is we make a benefit/risk analysis. At the end of the day, we have to measure the demonstrated benefits against the foreseeable risks. And we try to do that based on data, and I believe we made the right recommendation in this case.

Q Thank you. And the plaintiffs go on to allege in paragraph 85 of their complaint, "the FDA's failure to approve Plan B for OTC use is based in part on outmoded stereotypes of women and girls." Is

that a correct statement?

MS. JONES: Objection, outside the scope of direct.

BY MR. AMANAT:

Q Please answer the question.

A Can you repeat it?

Q Their allegation -- I can show it to you.

A Yes.

Q Paragraph 85, "the FDA's failure to approve Plan B for OTC use is based in part on outmoded stereotypes of women and girls."

A I would say, actually in opposition to that, it's based on really emerging modern understanding of the behavior of teenagers, young teenagers and the cognitive differences and behavioral differences in the different age groups.

MR. AMANAT: Thank you, Dr. Woodcock, I have no further questions.

MS. JONES: Let's take a five minute break, and then we'll do redirect.

THE VIDEOGRAPHER: We're going off the record. The time is 12:07 p.m.

(Recess.)

THE VIDEOGRAPHER: We're back on the record. The time is 12:20 p.m.

EXAMINATION BY COUNSEL FOR PLAINTIFFS (RESUMED)

BY MS. JONES:

Q Dr. Woodcock, do you still have your notebook open to the memorandum that starts at Tummino 30745.

A Yes.

Q You don't know when Drs. Rosebraugh and Bull drafted that memo, do you?

A No.

Q And you don't know whether either of them took notes at that meeting that's described in it, do you?

A No, I don't know.

Q Is OxyContin a prescription drug?

A Yes.

Q Is the -- so is the abuse that's going on about prescribing physicians abusing that drug or by illegal abuse?

A Allegedly both.

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

(This concludes the "PROTECTED TESTIMONY".)

BY MS. JONES:

Q If the actual use study had had a larger number of younger adolescent subjects, would it have been able to show whether the drug would gain cult

status?

A I would like to make it clear that this sentence in this memo was only a very small part of the discussion that I raised at this particular meeting.

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

(This concludes the "PROTECTED TESTIMONY".)

BY MS. JONES:

Q I thought that the trend that you're talking about right now was in the Tina Raines study rather than in the actual use study?

A You're correct, yes.

Q It was?

A I wasn't referring to the actual use study.

Q You're referring to Tina Raines?

A Yes.

Q According to the FDA, is the prevention of implantation of a fertilized egg an abortion?

A I believe not.

Q Is Plan B an addictive drug?

A There is no evidence that it is.

Q Is OxyContin an addictive drug?

A OxyContin is a narcotic, yes.

Q And as a narcotic, it is addictive, is

that right?

A Yes, uh-huh.

Q Is dextromethorphan an addictive drug?

A It is an analog of the narcotic class of drugs. I don't know, it wouldn't be over the counter if it were felt to have a lot of addictive properties.

Q But it is a form of a narcotic?

A It is related to narcotics.

Q Are methamphetamines addictive?

A Yes.

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

(This concludes the "PROTECTED TESTIMONY".)

MR. AMANAT: I have one question that's inspired by some questions Ms. Jones just asked you, Dr. Woodcock.

EXAMINATION BY COUNSEL FOR DEFENDANT (RESUMED)

BY MR. AMANAT:

Q The agency's regulations, namely 21 CFR section 310.200(b), with regard to -- is that the regulation that applies to OTC switches as far as you know?

A I don't know.

Q Are you aware of the regulation which talks about "any drug limited to prescription use shall be exempted from prescription dispensing requirements when the Commissioner finds such requirements are not necessary for the protection of the public health by reason of the drug's toxicity or other potentiality for harmful effect"?

A Yes.

Q The reference to other potentiality for

harmful effect, to your knowledge, is that limited to addictive properties that a drug may have?

MS. JONES: Objection, outside the scope of redirect.

MR. AMANAT: You asked numerous questions about whether the various examples she gave were addictive or not. It is within the scope of what you had asked. Does --

MS. JONES: My objection stands.

BY MR. AMANAT:

Q Please answer the question. The term other potentiality for other harmful effect, is that limited to the consideration of whether the drug has addictive properties?

A No. In fact, when we did our part 15 hearing in 2000, we specifically asked about preventives in general. And we asked, could the presence in the OTC market without a learned intermediary of a preventive lead to ill-advised actions, behavioral actions by people who are taking the over the counter product.

And the example used was cholesterol

lowering drug, which then the ill-advised behaviors we mentioned in the notice included continuing smoking, continuing having improper diet, failure to exercise, all the interventions that presumably a learned intermediary would advise a patient who had high cholesterol to have as their first steps.

Q Okay. And so those types of behavioral changes would, in your view, be subsumed within the term other potentiality for harmful effect?

A Yes, that is not the only -- we had many examples of this, all right? Where potential switches were floated by different companies to the agency. And the concern really was not about the pharmacologic safety of the agent, but about the consequences of the consumer self-medicating, especially in a preventive mode. And then perhaps they would progress to a cancer or they wouldn't have the health care professional oversight, and they would perhaps engage in other health related activities that were negative as a consequence of having the OTC availability.

Q Okay. And do you believe there are such

potentialities for harmful effect of that nature that are implicated with the Plan B OTC switch application?

A Well, the specific concern is about health related behaviors around sexual activity, and the availability in the younger age group.

MR. AMANAT: Thank you very much, Dr. Woodcock.

EXAMINATION BY COUNSEL FOR PLAINTIFFS (RESUMED)

BY MS. JONES:

Q Are any cholesterol lowering drugs available over the counter?

A No.

MS. JONES: No further questions.

MR. AMANAT: Thank you, Dr. Woodcock.

THE VIDEOGRAPHER: This marks the end of the deposition of Dr. Woodcock. The total number of tapes used today was one. We are going off the record. The time is 12:33 p.m.

(Signature having been not waived, the deposition of JANET WOODCOCK, M.D., was concluded at 12:33 p.m.)

ACKNOWLEDGMENT OF DEPONENT.

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

_____ _____

(DATE) (SIGNATURE)

CERTIFICATE OF SHORTHAND REPORTER - NOTARY PUBLIC.

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

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my notarial seal this 2nd day of May 2006.

My commission expires:

August 1, 2006

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