

1 UNITED STATES DISTRICT COURT
2 EASTERN DISTRICT OF NEW YORK

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4 ANNIE TUMMINO, et al., :
5 Plaintiffs, :
6 v. : No. 05-CV-366 (ERK/VVP)
7 ANDREW C. VON ESCHENBACH, : (Korman, C.J.)
8 as Acting Commissioner of : (Pohorelsky, M.J.)
9 the Food & Drug :
10 Administration, :
11 Defendant. :

12 - - - - - X

13 Videotaped Deposition Of Janet Woodcock, M.D.
14 Volume 2
15 Rockville, Maryland
16 Thursday, April 27, 2006
17 11:03 a.m.

18
19 Job No.: 1-77268
20 Pages 117-180
21 Reported by: Cynthia R. Simmons Ott, RMR, CRR
22

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

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9 Pursuant to agreement, before Cynthia R.
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11 Realtime Reporter, and Notary Public of the State of
12 Maryland.

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9 E X H I B I T S

10 (None.)

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1 P R O C E E D I N G S

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3 THE VIDEOGRAPHER: Here begins tape number
4 1, volume 2, in the deposition of Janet Woodcock MD,
5 in the matter of Annie Tummino, et al. versus Andrew
6 C. Von Eschenbach as Acting Commissioner of the Food
7 and Drug Administration. Today's date is April 27th,
8 2006, the time is 11:03 a.m.

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

11 EXAMINATION BY COUNSEL FOR PLAINTIFFS (RESUMED)

12 BY MS. JONES:

13 Q Good morning, Dr. Woodcock.

14 A Good morning.

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

22 MR. AMANAT: Your question was at any

1 point in time, as far as she knows.

2 MS. JONES: Yes.

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

4 BY MS. JONES:

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

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

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

18 A I don't know of such an instance.

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

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

3 A No, I don't.

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

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

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

13 A Have health consequences, correct.

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

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

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

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

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

16 A I believe so, yes.

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

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

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

1 MR. AMANAT: Okay.

2 BY MS. JONES:

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

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

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

12 A Yes, uh-huh.

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

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

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

1 A No.

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

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

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

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17 (This concludes the "PROTECTED TESTIMONY".)

18 BY MS. JONES:

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

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

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

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

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

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

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

21 A They had recommended that.

22 Q And did he express anything to you about

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

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

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

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

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

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

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

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

22 BY MS. JONES:

1 Q That's quite all right.

2 A I've been at the FDA a long time.

3 Q I understand.

4 A Could you restate the question?

5 THE REPORTER: "Question: Other than in
6 the case of Plan B, is there any other time during
7 your time in the Commissioner's office where the
8 Commissioner refused to share his decision making
9 process with you on a matter that you had worked on?"

10 THE WITNESS: In the time I've been in the
11 Commissioner's office, okay, well that's a shorter
12 time. I believe so. However, I'm not able to recall
13 specific instances. Maybe if you gave me an hour, I
14 could think about them. But I believe there have
15 been other cases, since the time I've been in the
16 Commissioner's office, where I've not, where I've
17 been involved in contributing to an issue and then
18 was not involved in the final decision making or --

19 BY MS. JONES:

20 Q Okay. Has there ever been such an
21 instance where not only were you not involved in the
22 final decision making, but you weren't kept informed

1 about what the decision making process was for the
2 Commissioner?

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

6 Q But you can't recall?

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

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

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

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

19 A No.

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

22 A No.

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

5 A No.

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

8 A No.

9 Q Have you asked him to explain?

10 A No.

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

18 A No.

19 Q Do you know anything about an e-mail from
20 Gold, I don't know if it's a Ms. or a Mr. or a
21 Doctor, from this author to the FDA on February 13th,
22 2004?

1 A No.

2 Q Do you know who this author is?

3 A Doesn't come to mind.

4 Q Do you know if you had any contact with
5 this person?

6 A Not to my recollection.

7 Q Do you have any documents related to Plan
8 B within your personal control that you have not yet
9 produced to the defense attorneys in this case in
10 connection with our discovery requests?

11 A Only the recent e-mails scheduling this
12 deposition.

13 Q Nothing other than that?

14 A And maybe an e-mail about the Plan B GAO
15 report that was released. But, no, no other kind of
16 documents.

17 Q Who would the email about the GAO report
18 release be from?

19 A Zach telling me that it was released,
20 something like that.

21 Q Is that something you would have in your
22 personal control outside of your work computer, or

1 would that be in your work computer?

2 A Everything's on my work computer.

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

6 A No. No.

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

9 A It says a letter to Mr. Enzi.

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

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

17 Q This letter states that Michael Leavitt
18 spoke to someone in the FDA, and based on the
19 feedback he received, that he could state that the
20 FDA would act on the Plan B application by September
21 1st, 2005.

22 Do you have any idea who he spoke to

1 within the FDA about this?

2 A None.

3 Q It was not you?

4 A It was not me.

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

7 A I don't.

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

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

15 Q CDER?

16 A That's correct, uh-huh.

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

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

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

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

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

11 A Correct. In many, many cases.

12 Q Okay.

13 A Yes.

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

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

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

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

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

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

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

22 As far as appropriate use and whether

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

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

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

19 Q Anything else?

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

1 various age groups as drug regulation has evolved.

2 And so I don't think the policies of the
3 1950s, for example, when we approved -- we just had
4 some warnings on phenergan, where it was just
5 approved sort of globally for children. And now we
6 realize that -- we just put out some warnings in the
7 two and under age group, it may cause respiratory
8 depression and harm. We're becoming more -- try to
9 become more precise, and really understand the impact
10 in the different age groups.

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

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

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

22 (Recess.)

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

3 BY MS. JONES:

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

7 MR. AMANAT: Go ahead.

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

11 BY MS. JONES:

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

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

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

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

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

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

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

12 BY MS. JONES:

13 Q Okay.

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

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

3 A No reason related to Plan B.

4 Q Any reason at all?

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

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

11 A No.

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

15 A I have no knowledge of that.

16 Q Has anyone told you that?

17 A No.

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

21 A No.

22 MS. JONES: I have no further questions,

1 thank you very much for your time.

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

4 EXAMINATION BY COUNSEL FOR DEFENDANT

5 BY MR. AMANAT:

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

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

1 decision that may have been before the center?

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

4 Q Could you give some examples, please?

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

12 Q Can you think of any other examples?

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

22 And that was, you know, a very upsetting

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

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

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

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

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

1 center director?

2 A Yes.

3 Q And that reached your personal
4 consideration as center director?

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

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

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

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

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

22 And again, most of her questions in that

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

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

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

1 mifepristone. And there are numerous other examples.

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

7 A That's correct.

8 Q And this is a chemical abortifacient,
9 right?

10 A Yes.

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

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

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

1 States?

2 A Yes.

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

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

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

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

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

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

7 A I saw the letter from Dr. Hager yesterday.

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

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

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

22 A Yes.

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

3 A I do.

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

10 A Yes.

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

13 A Yes.

14 Q Involving Plan B?

15 A Yes.

16 Q And were you part of that meeting?

17 A I believe so.

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

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

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

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

11 A No.

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

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

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

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

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

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

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

7 A No.

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

11 A Yes.

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

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

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

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

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

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

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

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

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

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

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

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

3 A Okay.

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

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

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

13 BY MS. JONES:

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

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

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

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

22 Q That's the first time you saw this

1 document.

2 A Uh-huh.

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

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

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

16 A Oh, okay, uh-huh.

17 Q And what are the signatures there?

18 A Curt Rosebraugh and Jonca Bull.

19 Q And who are they?

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

1 director that oversaw that division.

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

5 A When I was head of CDER?

6 Q Yeah.

7 A Or now?

8 Q When you were head of CDER?

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

11 Q Four levels below?

12 A Depending how you count.

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

15 A That's right.

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

18 A It says 3/30/04.

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

22 A It would have been that much time after

1 the February 19th meeting.

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

9 A Okay.

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

14 A Yes.

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

22 A They do.

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

4 A Well, certainly a highly incomplete
5 characterization.

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

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

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

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

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

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

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

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

4 Q Was your -- go ahead, please.

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

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

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

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

3 A Right.

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

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

16 Q Well --

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

1 things into account.

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

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

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

20 A Could you go through those adjectives
21 again?

22 Q Ideological, is there any ideological

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

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

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

14 A Moral. I think --

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

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

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

1 over the counter?

2 A No.

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

5 A I don't think so.

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

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

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

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

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

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

1 that a correct statement?

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

4 BY MR. AMANAT:

5 Q Please answer the question.

6 A Can you repeat it?

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

8 A Yes.

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

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

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

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

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

1 (Recess.)

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

4 EXAMINATION BY COUNSEL FOR PLAINTIFFS (RESUMED)

5 BY MS. JONES:

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

9 A Yes.

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

12 A No.

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

16 A No, I don't know.

17 Q Is OxyContin a prescription drug?

18 A Yes.

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

22 A Allegedly both.

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

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18 (This concludes the "PROTECTED TESTIMONY".)

19 BY MS. JONES:

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

1 status?

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

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

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4 (This concludes the "PROTECTED TESTIMONY".)

5 BY MS. JONES:

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

9 A You're correct, yes.

10 Q It was?

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

13 Q You're referring to Tina Raines?

14 A Yes.

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

17 A I believe not.

18 Q Is Plan B an addictive drug?

19 A There is no evidence that it is.

20 Q Is OxyContin an addictive drug?

21 A OxyContin is a narcotic, yes.

22 Q And as a narcotic, it is addictive, is

1 that right?

2 A Yes, uh-huh.

3 Q Is dextromethorphan an addictive drug?

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

8 Q But it is a form of a narcotic?

9 A It is related to narcotics.

10 Q Are methamphetamines addictive?

11 A Yes.

12 (The following testimony was designated
13 "PROTECTED TESTIMONY" and is bound separately.)
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VIDEOTAPED DEPOSITION OF JANET WOODCOCK, M.D., VOLUME 2
CONDUCTED ON THURSDAY, APRIL 27, 2006

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3 (This concludes the "PROTECTED TESTIMONY".)

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

7 EXAMINATION BY COUNSEL FOR DEFENDANT (RESUMED)

8 BY MR. AMANAT:

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

13 A I don't know.

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

21 A Yes.

22 Q The reference to other potentiality for

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

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

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

9 MS. JONES: My objection stands.

10 BY MR. AMANAT:

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

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

22 And the example used was cholesterol

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

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

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

22 Q Okay. And do you believe there are such

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

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

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

9 EXAMINATION BY COUNSEL FOR PLAINTIFFS (RESUMED)

10 BY MS. JONES:

11 Q Are any cholesterol lowering drugs
12 available over the counter?

13 A No.

14 MS. JONES: No further questions.

15 MR. AMANAT: Thank you, Dr. Woodcock.

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

20 (Signature having been not waived, the
21 deposition of JANET WOODCOCK, M.D., was concluded at
22 12:33 p.m.)

1 ACKNOWLEDGMENT OF DEPONENT.

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

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9 _____

10 (DATE)

(SIGNATURE)

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1 CERTIFICATE OF SHORTHAND REPORTER - NOTARY PUBLIC.

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

13 IN WITNESS WHEREOF, I have hereunto
14 set my hand and affixed my notarial seal this
15 2nd day of May 2006.

16 My commission expires:

17 August 1, 2006

18 _____

19 NOTARY PUBLIC IN AND FOR

20 THE STATE OF MARYLAND

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