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1 UNITED STATES DISTRICT COURT
2 EASTERN DISTRICT OF NEW YORK

3
4 ANNIE TUMMINO, et al., *
5 Plaintiffs, *
6 V. *
7 ANDREW C. Von ESCHENBACH, *
8 as Acting Commissioner of *
9 the Food and Drug *
Administration, *
Defendant. *

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

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13 Videotaped Deposition of FLORENCE HOUN, M.D.
14 Rockville, Maryland
15 Thursday, July 20, 2006
16 9:43 a.m.

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20 Job No.: 1-82114
21 Pages 1 - 235
22 Reported by: Nancy K. Barker, CSR

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1 Videotaped Deposition of FLORENCE HOUN,
2 M.D., held at the offices of:

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4 FOOD AND DRUG ADMINISTRATION
5 Office of the Chief Counsel
6 5600 Fishers Lane, GCF-1
7 Rockville, Maryland 20857

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11 Pursuant to notice, before Nancy K.
12 Barker, Certified Shorthand Reporter and Notary
13 Public in and for the State of Maryland.
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A P P E A R A N C E S

ON BEHALF OF THE PLAINTIFFS:
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ON BEHALF OF THE DEFENDANT AND WITNESS:
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A P P E A R A N C E S

(CONTINUED)

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ALSO PRESENT:
William Schurmann, Intern, Dept. of Justice
Santiago Murillo, Videographer

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(NONE MARKED)

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P R O C E E D I N G S

THE VIDEOGRAPHER: Here begins videotape number one in the deposition of Dr. Florence Houn in the matter of Annie Tummino, et al., versus Andrew C. von Eschenbach, as Acting Commissioner of the Food and Drug Administration, in the U.S. District Court, Eastern District of New York, Case Number 05-CV-366.

Today's date is July 20th, 2006. The time on the video monitor is 9:43 a.m. The video operator today is Santiago Murillo. This video deposition is taking place at the Food and Drug Administration located at 5600 Fishers Lane in Rockville, Maryland.

Counsel, would you please voice identify yourselves and state whom you represent?

MR. HELLER: Simon Heller, Center for Reproductive Rights, representing the plaintiffs.

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

MR. AMANAT: F. Franklin Amanat, Assistant U.S. Attorney, Eastern District of New York, representing the witness and representing the

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1 defendant.

2 MR. WARSHAWSKY: Steven Warshawsky,
3 Assistant United States Attorney, Eastern District of
4 New York, representing the defendant.

5 MS. SCHIFTER: Karen Schifter from FDA
6 representing the defendant.

7 THE VIDEOGRAPHER: The court reporter today
8 is Nancy Barker of LAD Reporting. Would the reporter
9 please swear in the witness?

10 FLORENCE HOUN, M.D.,
11 having been duly sworn, testified as follows:

12 THE VIDEOGRAPHER: Thank you. You may begin.

13 EXAMINATION BY COUNSEL FOR PLAINTIFFS

14 BY MR. HELLER:

15 Q Good morning, Dr. Houn.

16 A Good morning.

17 Q As you may have heard, my name is Simon
18 Heller. I'm one of the lawyers for the plaintiffs in
19 this case. Have you ever had your deposition taken
20 before?

21 A Yes.

22 Q You have? Do you feel familiar with the

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1 process?

2 A Please explain.

3 Q Sure. I'm going to ask you a series of
4 questions which I'd like you to answer as completely
5 as you can. If you don't understand a question I
6 ask, please let me know and I'll try to clarify what
7 I meant. If you need to take a break at any time,
8 let me know and we'll try to take a break shortly
9 after that.

10 Sometimes there are objections that the
11 other lawyers might make to a question I ask. And in
12 general, if an objection is made, it's a good idea
13 for you to not answer the question immediately but --
14 because there might be some discussion of the
15 objection. Once the discussion is over, if there is
16 a discussion, usually you can go ahead and answer the
17 question unless one of the lawyers for the FDA
18 instructs you not to answer a question. They might
19 do that.

20 It's also important to answer questions
21 verbally, using words, as opposed to sort of what
22 people tend to do in conversations, sort of say

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1 uh-huh or uhn-uhn, because that makes it easier for

2 the court reporter to transcribe responses.

3 You can also, you know, if I ask you a
4 question and then 15 minutes later you remember
5 something else that you would like to have said, you
6 can also say, oh, I remember something I'd like to
7 add to what I said before. Feel free to do that as
8 well. Does that process make sense?

9 A Yes. Thank you.

10 Q And what's going to happen after I finish
11 asking questions is then Mr. Warshawsky might have
12 some questions for you, then I might have some
13 questions after that. There's a little bit of back
14 and forth afterwards, but to start with me.

15 Let me start with some background stuff.
16 What did you do to prepare yourself to participate in
17 today's deposition?

18 A I reviewed internal memos that were part of
19 the Administrative Record. I participated in the
20 search of documents. There were two searches that
21 were required of me. So I went through those data
22 sources to generate response to those requests. I

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1 met with Frank, Steve, Karen -- and I'm sorry, I
2 forgot your name.

3 MR. SCHURRMAN: It's Bill Schurrman.

4 A -- on June 9th to prepare. And then I
5 thought hard about the questions that they had posed
6 to me during the June 9th meeting and thought about
7 the events that had transpired.

8 Q Okay. Thank you. Tell me a little bit, if
9 you would, about your work experience here at FDA,
10 sort of when did you start working here, what
11 positions have you held?

12 A I started at FDA in December of 1993 as a
13 Division Director for the Division of Mammography
14 Quality and Radiation Programs in the Center for
15 Radiologic Health and Devices. And I was responsible
16 for establishing the national quality standards
17 program, inspection program, and FDA certification
18 program of mammography facilities.

19 I then transferred to the Center For
20 Drugs -- Drug Evaluation and Research in May of 1998
21 where I was Deputy Office Director in the Office of
22 Drug Evaluation 2. In April of 1999 I became Office

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1 Director for the Office of Drug Evaluation 3. And on
2 June 11th, 2006 I became Deputy Office Director for
3 the Office of Vaccines and Review and Research in the

4 Center for Biologic Review, Evaluation and Research.

5 Q Okay. Thank you. Prior to coming to the
6 FDA -- well, maybe I'll start the other way. Can you
7 tell me about your post high school educational
8 background, if you would?

9 A I went to Harvard University. I graduated
10 with honors in biology. I was a pre-med major. I
11 was very active with minority student organizations.
12 And I went into medical school at Albert Einstein
13 College of Medicine. I did an international
14 fellowship in rural health in the Philippines. I was
15 accepted to internship and residency at what was then
16 called the Columbia-Presbyterian Medical Center in
17 New York.

18 I then fulfilled my National Health Service
19 Corps obligation in the manpower health shortage area
20 in east Baltimore where I was an attending at Johns
21 Hopkins Hospital. I then did a fellowship at the
22 National Cancer Institute in preventive oncology and

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1 obtained a Master's of Public Health at the then
2 Johns Hopkins School of Hygiene and Public Health. I
3 conducted research on mammography screening, and that
4 led me to FDA's job opportunity as Division Director
5 for Mammography.

6 Q Do you have board certifications in certain
7 specialty areas?

8 A I'm board certified in internal medicine.

9 Q For -- most of the questions I'm going to
10 ask you today are going to involve the period, I
11 think, when you were Director of ODE-3 between, I
12 think you said about April of 1999 and June of this
13 year. Is that --

14 A Well, I didn't have responsibilities for
15 ODE-3 after June -- after January 17th of 2006.

16 Q Oh, even then, still most of my questions
17 are going to be about your time as Director of ODE-3.
18 Can you tell me a little bit about what that
19 position, what job duties that position entailed?

20 A Office of Drug Evaluation 3 had three review
21 divisions that received applications for marketing as
22 well as applications for investigation of new drugs.

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1 The division that oversaw application for Plan B is
2 the Division of Reproductive and Urologic Drug
3 Products. And my responsibility was to oversee their
4 scientific and regulatory decision-making and
5 processes, and ensuring that our responsibilities as

6 outlined under the drug regulations and guidances as
7 well as other mandates are fulfilled.

8 Q Without going into -- I'm not going to -- I
9 don't want to list all the possible reviewers within
10 ODE-3 that you might have supervised. But as a
11 general matter, did you find their reviews to be or
12 the work that they conducted on Plan B to be good
13 scientific work?

14 MR. AMANAT: Objection. You can answer the
15 question.

16 A Yes.

17 BY MR. HELLER:

18 Q Did you identify any shortcomings in the
19 analysis and reviews they conducted regarding Plan B?

20 MR. AMANAT: Objection. You can answer the
21 question.

22 A No.

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1 BY MR. HELLER:

2 Q Who do you -- who was your supervisor within
3 FDA at the time that you were Director of ODE-3?

4 A Dr. John Jenkins.

5 Q And during --

6 A That was the latter part. Initially it was
7 Dr. Murray Lumpkin.

8 Q During the time that you were supervising
9 work on the Plan B OTC switch application, were you
10 consistently reporting about that process to Dr.
11 Jenkins?

12 A Yes.

13 MR. AMANAT: I'm just going to object.

14 MR. HELLER: To consistently or what --

15 MR. AMANAT: No, reporting as in -- that's
16 subject to at least two different interpretations --

17 MR. HELLER: I'll clarify it.

18 MR. AMANAT: -- in the sense that you report
19 to a supervisor or you actually give updates.

20 MR. HELLER: I meant report to as a
21 supervisor.

22 A Both.

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1 BY MR. HELLER:

2 Q So it was both?

3 A Both.

4 Q Thank you. Are you aware that in addition
5 to the Plan B OTC switch application submitted by
6 Barr, there was also a citizen petition requesting a
7 switch?

8 A Yes.
9 Q Effectively requesting a switch of Plan B to
10 OTC status?

11 A Yes, I'm aware.

12 Q Did you have any involvement in review or
13 analysis of that application -- of that petition
14 rather?

15 A Yes.

16 Q Can you tell me about your involvement with
17 that?

18 A The petition is received in the Center in
19 our Office of Regulatory Policy. It is reviewed
20 there, and the scientific issues relating to a
21 petitioner's arguments or requests are then consulted
22 to the Review Division for draft input responses.

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1 And in addition, I do recall that this
2 petition was the subject of meetings beyond the
3 Review Division and myself in terms of timing of
4 response, what else we need to do on the petition,
5 whether there were information or processes needed to
6 occur relating to being responsive to the petition.

7 Q Are you aware that the FDA has recently
8 issued a letter stating that it denies the citizen
9 petition?

10 A No.

11 Q You had not heard about that? You haven't
12 heard about that?

13 A That's correct.

14 Q Thank you. Do you -- the meetings you just
15 described that went -- I think you said sort of went
16 beyond the review division?

17 A (Witness nods.)

18 Q Who were those meetings -- who did those
19 meetings involve?

20 A I do recall they involved Jane Axelrad,
21 Steve Galson, and executive secretary -- I'm sorry,
22 Executive Operations Officer for the Center Director,

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1 Ms. Maureen Hess. Those folks and perhaps others.

2 Q Were there several such meetings or was
3 it -- do you know roughly sort of -- what I'm trying
4 to get a sense of is sort of when those types of
5 meetings occur and how many --

6 A Usually in the context of discussing the
7 Plan B OTC switch, there was also in addition we have
8 to, if we're doing an action, we must consider the
9 petition.

10 Q So sort of that in most -- in some of the
11 meetings in which the Barr application was being
12 considered, the citizen petition would also be
13 mentioned?

14 A Yes.

15 Q I've reviewed big portions of the
16 Administrative Record that's been provided by the
17 Agency, and I did not find myself review memos,
18 medical review memos, that you yourself wrote. Is
19 that correct that you yourself didn't write some sort
20 of even a summary review of -- related to the Plan B?

21 A That's correct.

22 Q Was there someone who would have been sort

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1 of the highest level person that you supervised who
2 would have written such reviews, if there was
3 somebody?

4 A The Deputy Director for Office of Drug
5 Evaluation 3, Julie Beitz, took on that
6 responsibility on my discussions with her. We knew
7 that we had to generate an office memo, office level
8 memo. And she worked closely with the review team on
9 Plan B as part of our arrangement in terms of Deputy
10 and Director on workload and sharing responsibility,
11 offering her opportunities to have domains in which
12 she can grow and learn. So this was a responsibility
13 that we mutually agreed that she could take on.

14 MR. AMANAT: For the record, Beitz is
15 B-E-I-T-Z.

16 BY MR. HELLER:

17 Q Would there -- I think you said that you
18 knew that you had to generate an office level memo.
19 Why did you have to generate such a memo?

20 A Well, it was normal practice that in the
21 Office of Drug Evaluation 3 for Office Directors on
22 an OTC switch application or anything that required

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1 office level sign-off, that a memo be generated. And
2 so in this case not only did memo generation fall
3 within the usual practice of my office, but we also
4 knew that we needed to ensure the Administrative
5 Record had enough details.

6 Q Why wouldn't you -- I mean wouldn't that be
7 what you would always do to try to ensure that the
8 Administrative Record had enough details? Was there
9 some other -- what was the -- why did you feel that
10 it was also necessary for that reason?

11 A I think for my part, I wanted to leave open

12 the opportunity that should Barr Research,
13 Incorporated, have objections to the actions, that
14 they had a complete Administrative Record to pursue
15 their options.

16 Q In the course of the Agency's process
17 regarding Plan B, did you observe any departures from
18 normal practice?

19 MR. AMANAT: Objection. You can answer the
20 question.

21 BY MR. HELLER:

22 Q You can answer.

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1 A Yes.

2 Q Can you tell me -- I don't know if there
3 were one or many, but can you tell me whichever --
4 whatever things that were departures that you recall?

5 A Well, I think that there were a number of
6 events that I felt were questionable. And I think
7 the most striking event was related to our January
8 15th meeting with Steven Galson in which he conveyed
9 that the data for age group 14 to 16 was insufficient
10 to support approval for OTC switch; that either the
11 company would have to conduct a study in that age
12 group or they could propose restricted marketing to
13 18-year-olds or older. And he described this
14 decision as sincere, not ideologic. But that begged
15 the question of should we complete our reviews or
16 not.

17 And so I asked that question at the meeting.
18 And we were instructed to complete our reviews. But
19 I think that by conveying that this decision was a
20 concern of the Commissioner's, it might have made our
21 further evaluation superfluous. So I do know that
22 some of the reviewers finished their reviews soon

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1 after that meeting. But in the Office of Drug
2 Evaluation 3, in order to try to capture all the data
3 that the reviewers were aware of that supported the
4 OTC switch, they continued working with the principal
5 investigators, Melanie Gold and others to obtain the
6 data and document it for the record.

7 Q At that January 15th meeting did Dr. Galson
8 convey that the Commissioner's Office believed that
9 the SNDA could not be approved?

10 MR. AMANAT: Objection. You can answer the
11 question.

12 A I believe so.

13 BY MR. HELLER:

14 Q Why was what Dr. Galson said at that meeting
15 or -- why was it as you said sort of the most
16 striking of the questionable things you noticed?

17 MR. AMANAT: Object to the form of the
18 question. You can answer the question.

19 THE WITNESS: Could you repeat it?

20 BY MR. HELLER:

21 Q Yes. Let me ask it a little bit
22 differently. Why was it striking at all that the

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1 head of CDER was coming to tell people that the data
2 was insufficient? Why would that be striking?

3 A Well, I think what was very unusual is that
4 we had not finished the evaluation process, and we
5 were in the middle of getting data on the question of
6 adolescent use of emergency contraception. So if we
7 were to continue an evidence-based approach, we would
8 hope to have all the evidence in hand before an
9 evaluation and decision was made.

10 Q So was it your sense that at that meeting a
11 decision had been made, in essence?

12 MR. AMANAT: Objection. You can answer the
13 question.

14 A It was my sense that a decision had been
15 made, and that I also sensed within the room and then
16 subsequent discussions that we should meet with Dr.
17 McClellan, present him with new information and
18 perhaps it could be altered. Some people had that
19 view.

20 BY MR. HELLER:

21 Q Did you have that view?

22 A I think I had that hope.

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1 Q Wouldn't it be sort of standard that if
2 there was additional evidence that could be presented
3 to alter someone's view, that you would be, of course
4 that could alter that view? Isn't that -- let me
5 rephrase the question, because I don't know if that
6 was even a question.

7 There was a January 15th meeting, and then
8 some people believed that they might be able to
9 present additional evidence to the Commissioner that
10 might alter his view, is that right?

11 A Yes.

12 Q And some people didn't have that view?

13 A Right.

14 Q Does that mean that there were some people
15 who thought it's not going to do any good to present

16 the Commissioner with additional evidence?

17 A Right.

18 Q There were some people who felt that way?

19 A Yes.

20 Q And it sounds like you had a hope, but you
21 weren't exactly sure that it was going to be
22 successful either?

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1 MR. AMANAT: Objection.

2 A That's correct. Oh --

3 MR. AMANAT: Go ahead. You can answer that.

4 A That's correct.

5 BY MR. HELLER:

6 Q Why -- it seems to me that why would it be
7 that people wouldn't sort of all feel, oh, of course
8 if we have additional evidence, that could be
9 persuasive to the Commissioner, who's a scientist and
10 so forth?

11 A I think --

12 MR. AMANAT: I object. You can answer the
13 question.

14 A I think since at least in 2000, we are -- we
15 in HHS, Health and Human Services, are aware that
16 then Secretary Tommy Thompson's goals and strategic
17 objectives for the Department, when they involved
18 unintended pregnancies, was the -- was the advocacy
19 of abstinence. And under the president's management
20 agenda, the Department's strategic plans and goals
21 are cascaded down to agencies, to supervisory heads
22 in our performance evaluation.

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1 So I think that the availability of Plan B
2 over-the-counter raised concerns on whether this was
3 counter to the strategic goals of the Department.

4 MR. AMANAT: I object. I want to move to
5 strike as nonresponsive to the question posed.

6 MR. HELLER: I thought it was very
7 responsive. Thank you. And moving to strike it from
8 the deposition, what does that even mean?

9 MR. AMANAT: It's preserving my right to
10 move to strike the answer from the deposition as
11 nonresponsive to the question posed.

12 MR. HELLER: Did you want to say something?

13 MR. WARSHAWSKY: Can I just ask the witness
14 to speak a little more loudly, please?

15 THE WITNESS: Yes. Sorry.

16 MR. HELLER: Speak however you want.

17 MR. AMANAT: You may proceed.

18 BY MR. HELLER:
19 Q The strategic goals that you describe, are
20 those written out somewhere --
21 A Uh-huh.
22 Q -- and sort of passed around to people?
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1 A Uh-huh.
2 MR. AMANAT: You have to verbalize.
3 A Oh. Yes. And you can find them on the Web.
4 BY MR. HELLER:
5 Q You were describing, sort of giving me an
6 overview of questionable events that occurred during
7 the Plan B process, and you began with a January 15th
8 meeting. And I wanted to get back to sort of the
9 general overview, if there are other things that
10 occurred that you viewed as questionable?
11 MR. AMANAT: I'm going to object to the use
12 of the word "questionable".
13 MR. HELLER: I'm just using her word.
14 MR. AMANAT: The witness can answer the
15 question. That was not her word but --
16 MR. HELLER: It was her word.
17 MR. AMANAT: The witness can answer the
18 question if she understands it.
19 MR. HELLER: I guess you can't really search
20 -- can you search on this? Can you search for the
21 first occurrence of the word "questionable", please?
22 (Discussion off the record.)

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1 BY MR. HELLER:
2 Q I forgot my question. No, I remember what
3 it was. So after the January 15th meeting or in
4 addition to the January 15th meeting, what other
5 things occurred in the Plan B process that you
6 thought were questionable?
7 MR. AMANAT: Object to the word
8 "questionable". The witness can answer the question
9 if she understands the question.

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12 BY MR. HELLER:

13 Q Why -- well, first of all, was this
14 information which was to be conveyed to Barr
15 communicated to you by Dr. Woodcock or by someone
16 else?

17 A I -- I know I heard about this. I know that
18 Dan worked directly with Dr. Woodcock probably via
19 e-mail to craft that. And the Division, so that's
20 Dan Shames and the review group, conveyed that
21 information to Barr in a teleconference.

22 Q Did you inquire of anyone within the Agency

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1 why this was being done?

2 A No.

3 Q Why did you -- why did you mention this as
4 an example of something that might be questionable?

5 MR. AMANAT: Objection. You can answer the
6 question.

7 A Well, first, usually the concerns of an
8 application arise from the primary reviewers. And if
9 they're not resolved in the Division level, the
10 Office gets involved to assist in evaluating the
11 problem and can it be resolved. If it can't be
12 resolved or we need more assistance, it's elevated.
13 So usually it goes from the review scientists up for
14 management input and approval or direction.

15 This came down, and we did not -- I think
16 we -- I cannot recall if Dr. Woodcock conveyed that
17 this was her plan versus what she was told to do. I
18 don't recall that aspect.

19 BY MR. HELLER:

20 Q Do you know whether it was her plan or
21 someone -- or the plan of someone above her?

22 A I do not know.

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1 Q Continuing on with other things that may
2 have occurred that you viewed as questionable, are
3 there any others that come to mind?

4 MR. AMANAT: Object to the word
5 "questionable" once again. You can answer the
6 question.

7 A Well, going back further, I guess the
8 December -- let me get the dates right -- it was
9 December 2002, appointments of the Reproductive
10 Health Drugs Advisory Committee members was also very
11 unusual.

12 BY MR. HELLER:

13 Q In what way?

14 A Usually nominations received from the
15 Division, received by the Division from different
16 sources, Division members put together a panel of
17 nominees and send those names up for clearance. In
18 this case names were sent down, and this was in 2002,
19 because we were --

20 MR. WARSHAWSKY: I'm sorry, can I ask you to
21 speak up? I'm having a hard time hearing you.

22 A Okay. This was in 2002 because I remember

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1 we wanted to try to constitute the Advisory Committee
2 to discuss the findings with estrogen and
3 hydroxyprogesterone acetate on cardiovascular risks
4 that became known in July 2002, because we wanted to
5 hold an Advisory Committee in the fall of 2002 to
6 deal with the cardiovascular risks of the
7 post-menopausal estrogen agents.

8 And so in trying to constitute that
9 committee, a compromise was reached which some of the
10 members were names that the Division had put forward
11 and others were not. And that --

12 MR. AMANAT: Go ahead.

13 A And that full committee was signed off by
14 Associate Commissioner Linda Skladany late December
15 in 2002.

16 MR. AMANAT: I'm going to object and move to
17 strike the entire answer as being nonresponsive to
18 the question posed.

19 MR. HELLER: I thought it was completely
20 responsive.

21 MR. AMANAT: Well, it doesn't have anything
22 to do with Plan B, which is why it was not

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1 responsive.

2 A Well, I think that in --

3 BY MR. HELLER:

4 Q Please explain further.

5 A I think that everybody knew the application
6 would be coming in either late 2002, which I think
7 the company made public announcements. The
8 Washington Post -- or was it the New York Times had a
9 summer article about the impending application.

10 Q And certainly within the Agency you knew
11 that the application was coming?

12 A Yes. Yes. And so I think that the
13 constitution of the panel was important, and that
14 these OTC switch applications are heard before
15 advisory committees. So I thought it was irrelevant.

16 MR. AMANAT: I'm going to renew my objection
17 and my motion. You may proceed.

18 BY MR. HELLER:

19 Q Have you -- have there been other times
20 during your tenure at the FDA where you have been
21 involved in the formation of an Advisory Committee?

22 MR. AMANAT: Objection. You can answer the

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1 question.

2 A Yes.

3 BY MR. HELLER:

4 Q Have you ever in any of those other
5 instances had nominations come from above down?

6 MR. AMANAT: Objection. You can answer the
7 question.

8 A In my experience in constituting Advisory
9 Committee members, this has not happened.

10 BY MR. HELLER:

11 Q Do you -- I'm just sort of wondering how
12 this happened. Did you at some point receive a list
13 of proposed -- of the individuals who were proposed
14 to be put on the Advisory Committee for in, I guess,
15 late 2002?

16 MR. AMANAT: I'm going to object to this
17 whole line of questioning. The witness can answer
18 the question.

19 A Yes. I believe we received a list of names
20 in July or August of 2002. And of particular
21 contention was who would be the chair of that
22 committee. And I do know that there was a lot of

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1 discussion with Dr. Sandy Kweder, who was the Deputy
2 Director for Office of New Drugs under John Jenkins.

3 She had a lot of discussions with the Associate
4 Commissioner on the constitution of the panel and who
5 would be chair.

6 And we received an e-mail, I believe it was
7 in October of 2002, stating that Dr. Skladany had
8 asked Dr. W. David Hager to be chair and he had
9 accepted. And when I got that e-mail, I called Dr.
10 Woodcock asking her to see if this issue could be
11 revisited. And I believe she was able to intervene,
12 and Dr. Hager became a member of the Committee but
13 not the chair.

14 BY MR. HELLER:

15 Q Was Dr. Hager --

16 MR. AMANAT: I'm going to object again to
17 the answer and move to strike as nonresponsive.

18 BY MR. HELLER:

19 Q Was Dr. Hager one of the names of
20 individuals to be put on the Committee that was
21 received from higher up in the Agency?

22 MR. AMANAT: Objection.

0035

1 BY MR. HELLER:

2 Q You can answer.

3 A Yes.

4 Q Do you recall any of the other names of
5 individuals who people higher up in the Agency wanted
6 to have put on the Committee?

7 MR. AMANAT: Objection. You can answer
8 question.

9 A I recall a couple of names. Yes.

10 BY MR. HELLER:

11 Q Can you tell me what they were, who they
12 were rather?

13 MR. AMANAT: Objection. You can answer the
14 question.

15 A Dr. Susan Crockett, Dr. Joseph Stanford, I
16 recall those.

17 MR. WARSHAWSKY: Can you please speak up?

18 A Dr. Joseph Stanford and Dr. Susan Crawford
19 (sic), I recall those names, as well as Dr. Hager's
20 name.

21 MR. AMANAT: Actually, Dr. Houn, it might be
22 helpful if you face the camera when you testify

0036

1 instead of facing Mr. Heller, because that way the
2 camera will get you and all sides of the table can
3 hear you better perhaps.

4 THE WITNESS: Okay.

5 BY MR. HELLER:

6 Q Did you keep any -- do you have any written
7 records of the sort of proposed names that were given
8 from higher up in the agency?

9 MR. AMANAT: Objection. You can answer the
10 question.

11 A I have a -- I have an e-mail -- I think I
12 have e-mails related to that. And I think I did
13 produce them in response to -- yeah, I think I did
14 respond to your first request for records.

15 BY MR. HELLER:

16 Q Were there any members -- well, were there
17 any nominees for the Advisory Committee -- and just
18 to be clear, which Advisory Committee are we talking
19 about throughout this whole --

20 A Reproductive Health Drugs Advisory
21 Committee.

22 Q Were there any nominations for that

0037

1 committee from within the office, your office, that
2 were rejected by people higher up in the agency?

3 MR. AMANAT: Objection. Object to the form
4 of the question. And I also object to this
5 continuing line of questioning.

6 BY MR. HELLER:

7 Q You can go ahead and answer.

8 MR. AMANAT: You can answer the question.

9 A Your question was whether there were
10 nominees put forward by the Office or the Division
11 that were not signed on as members?

12 BY MR. HELLER:

13 Q Let me ask a different question because
14 yesterday I did -- no, I guess my colleague conducted
15 the deposition of Dr. Griebel, who you know. And she
16 talked about there being contention around the
17 composition of this Advisory Committee.

18 And what I'm trying to get a sense of is,
19 was the contention about some of the names that were
20 nominated from higher up in the Agency, or was the
21 contention also about people who were nominated from
22 sort of the more normal process for nominations?

0038

1 MR. AMANAT: I'm going to object to the word
2 "contention" and object to the characterization of
3 the testimony of the witness who testified yesterday,
4 and object to the form of the question as compound,
5 vague and ambiguous.

6 BY MR. HELLER:

7 Q You can answer the question.

8 A Well, from my perspective, the contention
9 was over the constitution of the panel, the type of
10 experts needed, and the lack of expertise in some of
11 the nominees relevant to the function of the
12 Reproductive Health Drugs Advisory Committee.

13 MR. AMANAT: Object to the response. Move
14 to strike as nonresponsive to the question posed.

15 BY MR. HELLER:

16 Q Which of the nominees did you view as having
17 a lack of expertise relevant to the function of the
18 Committee?

19 A Well, I was concerned that the appointment
20 of Dr. Susan Crawford -- Crockett was not reflective
21 of the desire to have expertise recognized on a --

22 MR. WARSHAWSKY: I'm sorry, expertise what?

0039

1 A Expertise recognized on a regional or
2 national level or specialty field that would help our
3 deliberations.

4 BY MR. HELLER:

5 Q Anyone else you were concerned about?

6 A I was concerned about the expertise of
7 Dr. Joseph Stanford, being that of natural family
8 planning as you don't have any drugs being developed
9 in that area, and we don't use natural family
10 planning as a control arm in our trials. So I wasn't
11 sure about his expertise being, again, relevant to
12 the functions of the Advisory Committee.

13 Q Do you know who makes the final decision
14 about the composition of the Advisory Committee?

15 A The Secretary or Assistant Secretary or
16 delegate.

17 Q In this case, in the case of the composition
18 of the Committee that you're talking about in 2002,
19 do you know who made -- was there someone --

20 A The deciding official was Dr. Linda Skladany
21 in this case.

22 MR. WARSHAWSKY: I'm sorry?

0040

1 MR. AMANAT: Dr. Linda Skladany, Assistant
2 Secretary of the Agency.

3 THE WITNESS: No, she is the Associate
4 Commissioner.

5 BY MR. HELLER:

6 Q How long do people serve on the Advisory
7 Committee? Is it sort of constituted when it's
8 needed or do people get appointed for ten years? How

9 is that done?

10 A Four-year -- maximum membership is four-year
11 and would have to be renewed. And then you can have
12 shorter membership appointments. So I think in this
13 case we tried to come up with a compromise that Dr.
14 Kweder and Dr. Skladany negotiate in terms of length
15 of time, who would be on it.

16 Q And so Dr. Kweder might know even more about
17 these negotiations and the constitution of the
18 Committee than you do?

19 A Dr. Kweder would know more, and Dr. Igor
20 Cerny, who's head of the Advisory Committee staff for
21 CDER, also has knowledge.

22 Q Do you know if Dr. Crockett -- I hope I have
0041
1 the name right -- Dr. Susan Crockett, wound up being
2 on the Committee?

3 A Yes.

4 Q She was on the Committee?

5 A Yes.

6 Q And what about Dr. Stanford?

7 A Yes.

8 Q And Dr. Hager?

9 A Dr. Hager, yes.

10 Q Were there any other names that were
11 proposed from higher up in the Agency that you can
12 recall, or was it just those three?

13 MR. AMANAT: I object to the question. You
14 can answer.

15 A I don't recall, but like I said, they were
16 in e-mails responsive to your request.

17 BY MR. HELLER:

18 Q Do you know who outside the Office was
19 communicating these proposed nominees or conveying
20 that these people were proposed for the Committee?

21 MR. AMANAT: Objection. You can answer.

22 A Well, we interacted with the Advisory
0042

1 Committee staff, and they provided us with the latest
2 news. We interacted with Dr. Kweder and she would
3 provide us with feedback. So we were not the direct
4 recipients of interactions. We were the recipients
5 of names. And our job was to look at the name,
6 research their credentials, their publications. And
7 we felt if there was a question of qualification, we
8 should raise it with our senior managers, which we
9 did.

10 BY MR. HELLER:

11 Q Do you recall receiving or seeing the names
12 of any individuals proposed for the Advisory
13 Committee from outside the Office, like sort of in
14 the way you saw Dr. Hager, Dr. Stanford and Dr.
15 Crockett's names? Do you recall seeing any other
16 names of individuals whose expertise you didn't
17 question or didn't doubt?

18 MR. AMANAT: Objection. You can answer the
19 question. I'm going to object. I want to make clear
20 I object that your question assumes facts not in
21 evidence because not all of the names -- the witness
22 did not testify that she questioned the expertise of

0043
1 all the names that you mentioned. But your question
2 is objectionable for other reasons as well.

3 BY MR. HELLER:

4 Q Didn't you say that you questioned the
5 expertise of Dr. Hager, Dr. -- I'm sorry, maybe you
6 didn't -- did you question the expertise of Dr.
7 Hager?

8 A No, I did not. I questioned whether he was
9 the -- well, no, I didn't actually tell you why.

10 Q Well, go ahead.

11 MR. AMANAT: My objection was well taken.

12 A I think Dr. Hager got his training in the
13 Center for Disease Control, Sexually Transmitted
14 Disease. Drugs that treat, prevent sexually
15 transmitted disease are not handled in the
16 Reproductive Drugs Advisory Committee. They're
17 handled in the anti-infectives or antiviral drugs
18 committee. And they approve like vaginal
19 antifungals, STD treatments for chlamydia.

20 But so that's why I objected for his
21 appointment as chair. I thought it was not the right
22 expertise.

0044

1 BY MR. HELLER:

2 Q Putting aside Dr. Hager, Dr. Crockett and
3 Dr. Stanford --

4 A And I didn't tell you about Dr. Crockett. I
5 just said I was concerned that I think in the last
6 maybe four or three and a half out of five years
7 prior to her appointment, she had not been in active
8 practice. It might have been even longer. And that
9 was unusual.

10 Q So putting aside those three individuals,
11 were there other individuals whose names were
12 communicated as coming from outside the Office who

13 you thought, well, this is an appropriate person for
14 the Committee?

15 A Well, I think in the end we heard in
16 December that Dr. Linda Guidice from Stanford, a
17 fertility expert, was being asked to be chair. And
18 we were very pleased to have her be considered. And
19 so that is an example of where I think we were
20 satisfied.

21 MR. AMANAT: Do you know how to spell that
22 name?

0045

1 THE WITNESS: G-U-I-D-I-C-E. She was the
2 co -- she was present at the December 2003 Advisory
3 Committee Meeting.

4 BY MR. HELLER:

5 Q Were you present at the December 2003
6 Advisory Committee Meeting?

7 A Yes.

8 Q Do you recall -- there were votes -- were
9 there votes taken at that meeting or were the votes
10 taken after the meeting was over?

11 A No, at the meeting.

12 Q Do you recall there were -- there were a
13 number of votes taken. For example, I think one of
14 them was 28 to zero, and another one might have been
15 24 to 3 --

16 A Zero to 28.

17 Q -- or something like that?

18 A Yes.

19 Q So there were some votes on which there was
20 a minority --

21 A Right.

22 Q -- a small minority --

0046

1 A Right.

2 Q -- voting the opposite way from the
3 majority?

4 A Right.

5 Q Do you know if Dr. Hager was among the
6 minority voters on any of the votes?

7 A I would have to look at my document. I have
8 it.

9 Q That shows that. Oh, you have it here?

10 A Yes.

11 Q Go ahead. Actually, why don't we -- we'll
12 take a break later and you can look for that maybe
13 during the break. Let me go on to some other things.
14 I think that's probably in a record somewhere anyway

15 who voted which way.

16 A That's correct. It's all in the record on
17 the public transcript.

18 Q Okay. Now I'm going to return to the
19 overview. So you've talked about the January 15th
20 meeting. Did you -- please, is there something you
21 want to add?

22 A (Witness shakes head.)

0047

1 Q I had a question about what you said about
2 the January 15th meeting. I think you said that Dr.
3 Galson had viewed data about 14-to-16-year-olds as
4 inadequate in some manner?

5 A That's correct.

6 Q But that what he proposed was a restriction,
7 I think you said, that was sort of pegged to the age
8 of 18?

9 A That's correct.

10 Q Did anyone at the meeting ask him, well, if
11 it's 14 to 16, why are you talking about 18 then?

12 A I don't recall.

13 Q Do you have any idea why he -- why he would
14 be using 18 as a relevant age when his concerns were
15 about 14 to 16?

16 A It doesn't seem logical, and you would have
17 to ask him.

18 Q Are there other events that occurred in the
19 Plan B process that you view as questionable?

20 MR. AMANAT: Objection. You can answer the
21 question.

22 A Well, I think what was also a concern was

0048

1 that -- that our ability to provide -- our ability,
2 meaning the Office or the Division's ability to
3 provide guidance to Barr was severely hampered. And
4 we looked toward -- for direction either on helping
5 them pursue a restricted plan that was conveyed to us
6 as the approach out of our quandary or having them do
7 something else to continue the viability of their OTC
8 application.

9 And in order to provide them with advice,
10 we -- we encountered a concern that the legality of a
11 dual marketing situation where you have a
12 prescription product and a nonprescription product
13 had to be addressed. And yet we were not able to get
14 a response on that particular legal matter as it was
15 framed to us.

16 MR. AMANAT: Could you please read back the

17 question to which that answer was made, please?

18 (Record read.)

19 MR. AMANAT: I object to the answer and move
20 to strike as nonresponsive to the question posed.

21 MR. WARSHAWSKY: Could I ask you to read
22 back the last part of the answer? I didn't catch it.

0049

1 MR. AMANAT: The very tail end, like the
2 last two sentences.

3 (Record read.)

4 MR. AMANAT: I remind you again, please try
5 to speak up if you can.

6 THE WITNESS: Okay. I'm so bad.

7 MR. AMANAT: I know you're a little bit
8 nervous perhaps, but try to speak up.

9 BY MR. HELLER:

10 Q If there's anything I can do to help you be
11 less nervous, please let me know.

12 Do you remember after the January 15th
13 meeting that Dr. Galson chaired or ran, there was a
14 subsequent meeting with Dr. McClellan where you
15 actually did try to present information to him that
16 might -- in the hope that it would change his
17 position? Do you recall that?

18 A Yes, I recall that meeting.

19 Q And were you at that meeting, also?

20 A Yes.

21 Q I recall someone testifying that during the
22 course of that meeting Dr. McClellan left for a

0050

1 little while.

2 A Yes. He was called away on a telephone
3 call.

4 Q Do you know how long he was gone from the
5 meeting?

6 A Maybe five minutes. Maybe longer. I -- I
7 do know it was not an in-and-out absence.

8 Q Was that a successful meeting from your
9 viewpoint?

10 A It was informative.

11 Q In what way was it informative?

12 A I personally got from the meeting that it
13 would be unlikely that we would get -- that we,
14 meaning myself or the Division, would get any
15 specific answers resolved with Dr. McClellan at that
16 time. I think I felt at that meeting he was
17 distracted, and that these matters would have to be
18 then resolved promptly without -- without hearing

19 resolution at that meeting.

20 Q After -- well, did you come away from that
21 meeting believing that you had persuaded Dr.
22 McClellan to change his view on the view

0051
1 on-the-counter switch application?

2 A No.

3 Q Did you come away with the opposite view,
4 that you had not persuaded him?

5 A Yes.

6 Q Did you come away with the view that he
7 continued to believe that the application should not
8 be approved?

9 MR. AMANAT: Objection. It assumes a fact
10 not in evidence.

11 THE WITNESS: If I'm to answer that, can you
12 repeat that?

13 BY MR. HELLER:

14 Q Sure. Did you come away from that meeting
15 believing that Dr. McClellan had the view that the
16 OTC switch application should not be approved?

17 MR. AMANAT: That's not the same question
18 you asked before. The witness can answer it.

19 A I think for a younger age strata, that would
20 be the case, that it would not be able to be
21 approved.

22 BY MR. HELLER:

0052
1 Q Did Dr. McClellan at that meeting state any
2 specific scientific concerns about the application?

3 A He stated a statistical concern relative to
4 findings that were small -- the numbers of subjects
5 studied were small.

6 Q Was that the only scientific concern you
7 recall that he stated at that meeting?

8 A He raised, I think, concern in terms of a --
9 I think it was a finding in the Gold study relative
10 to maybe sexually transmitted disease, that there
11 might be, I think -- I can't recall if it was 5 or 6
12 percent. I would have to look up the slide to tell
13 you what the actual number was, difference between
14 younger and older users.

15 Q Okay. Was there anything unusual about this
16 February meeting with Dr. McClellan?

17 MR. AMANAT: Object to the word "unusual".

18 A Well, the circumstances of the meeting were
19 unusual in that I believe this meeting was offered to
20 the review staff when Dr. Galson conveyed that the

21 application could not be approved on January 15th,
22 and that Dr. McClellan was offering to meet with we
0053

1 all. And that -- that's unusual.

2 I think usually we approach a briefing of
3 the Commissioner as informative, and we do look for
4 decision and direction. Here it was somewhat more --
5 it was somewhat more -- I would characterize it as
6 trying to provide information to him in hopes that he
7 would see the data supported a position that he did
8 not hold. I think that's unusual for the staff for
9 myself.

10 BY MR. HELLER:

11 Q After that February meeting, did anything
12 else happen in the Plan B process that you felt was
13 or you believe was questionable?

14 MR. AMANAT: Objection. You can answer the
15 question.

16 A We received in March as part of general
17 correspondence Barr's proposal to restrict the
18 application to -- I can't recall their exact proposal
19 but it wasn't age 18. It might have been to those
20 less than 16. And we sent that for legal review, but
21 I understood it was never really reviewed.

22 And I had thought that was unusual because I
0054

1 thought we wanted to get a reading on whether this
2 was something we would be putting in our -- in the
3 Agency's deficiency letter to Barr that as an option
4 to resolve this deficiency of concern for use under
5 age 16 or 17, you could pursue a dual marketing
6 status as one option. We were -- it was my
7 impression that if we were to make that as an option
8 to pursue, that it should be a option that was
9 viable.

10 MR. AMANAT: I'm going to object to the
11 answer and move to strike as nonresponsive to the
12 question posed.

13 BY MR. HELLER:

14 Q Prior to May of 2004, did there come a point
15 where the medical reviews within your office were
16 completed?

17 A Yes.

18 Q Did you review -- did you review or read
19 those medical reviews and make your own determination
20 about the OTC switch application?

21 A I read them. I provided comments and edits
22 to them. I provided advice to them, and I know Julie

0055

1 did the same for Donna's reviews, so.

2 Q After your review of the reviews that had
3 been done, did you -- was it your opinion that the
4 OTC switch application should be approved?

5 A Yes.

6 Q Did you think it was sort of a close case
7 scientifically, that this was, you know, well, if we
8 approve this, it's sort of on the border, or was it a
9 clear case that it should be approved?

10 MR. AMANAT: Object to the form of the
11 question.

12 A I thought it should be approved.

13 BY MR. HELLER:

14 Q I -- sorry.

15 A I think the concerns raised were well
16 handled by the data provided in the reviews as
17 evidence for meeting 310.200.

18 Q At what point did you instantly -- would you
19 -- ordinarily would you have been involved in signing
20 an approval letter if there had been an approval?

21 MR. AMANAT: Objection. Object to the form
22 of the question.

0056

1 A I would have had Julie sign.

2 BY MR. HELLER:

3 Q You would have had Julie sign?

4 A Uh-huh.

5 Q And there would have been someone from
6 the --

7 A ODE-5.

8 Q ODE-5. They're in charge of OTC?

9 A (Witness nods.)

10 Q Someone from there would have signed?

11 A Uh-huh. Yes.

12 Q When did it become clear to you that you
13 were not going to be able to just have Julie sign?

14 MR. AMANAT: Objection. You can answer the
15 question.

16 BY MR. HELLER:

17 Q Would that have happened already back in
18 January when Dr. Galson --

19 A Yes.

20 Q So at that point you sort of knew this isn't
21 going to be decided by us?

22 A That's correct. And we told Barr that as

0057

1 well.

2 Q Did you at any point engage in discussions
3 either -- let me say with Dr. Galson or with --

4 (Mr. Blumberg entered the room.)

5 THE WITNESS: Who is he?

6 MR. HELLER: He, I believe, is --

7 MR. AMANAT: It's Rick Blumberg from OCC.

8 MR. BLUMBERG: FDA litigation deputy.

9 MR. HELLER: He works with Karen.

10 MR. AMANAT: It's Karen's boss.

11 THE WITNESS: Okay.

12 MR. AMANAT: He's here to make sure that she
13 doesn't get out of hand.

14 MR. HELLER: So far, Karen, you're well in
15 hand.

16 THE WITNESS: She's very calm.

17 BY MR. HELLER:

18 Q So after -- well, first, was the January
19 15th meeting the first occasion on which you realized
20 that this decision was not going to be -- that this
21 decision was not going to be made by your office in
22 ODE-5 or would that have happened earlier?

0058

1 MR. AMANAT: Objection. You can answer the
2 question.

3 A I think I got a -- I think I got knowledge
4 that this was going to be a problem maybe a week or
5 so before the January 15th meeting.

6 BY MR. HELLER:

7 Q Do you know where you got that knowledge
8 from?

9 A Yes.

10 Q Where did you get it from?

11 A I do know that Dr. Mark Goldberger, the
12 Acting Center Director at that time, conveyed that to
13 me. And probably I'm thinking Dr. Kweder might have
14 also conveyed to me that this application may not be
15 approved and wouldn't -- the decision was not going
16 to rest with the Office of Drug Evaluation 3 and Drug
17 Evaluation 5.

18 Q Between that time when you sort of first
19 learned of that and May of 2004, when the
20 non-approvable letter was issued, did you engage in
21 any discussions with Dr. Galson to try to understand
22 why ODE-3 and ODE-5 were not going to make the

0059

1 decision about the application?

2 MR. AMANAT: I'm sorry. What were the dates
3 in your question?

4 MR. HELLER: Between the dates when she
5 first learned that ODE-3 and ODE-5 would not be
6 making the decision, and May of 2004 when Dr. Galson
7 issued the letter.

8 A I didn't talk with Dr. Galson.

9 BY MR. HELLER:

10 Q Was there anyone else you did talk to about
11 that subject?

12 A I talked to Dr. Woodcock. She called me at
13 home, either the afternoon of the 15th, or more
14 likely the afternoon of the 16th of January, 2004, to
15 review the impact of the January 15th meeting with
16 me, to find out what did the -- what was the reaction
17 to the team. And she conveyed to me her assurance
18 that this was the only way to go to issue a non-
19 approval letter to appease the administration's
20 constituents, and then later this could be approved.

21 Q Which administration, the Food and Drug
22 Administration?

0060

1 A I didn't take it as that.

2 Q So she told you, if I understand you
3 correctly, that this was the only action that could
4 be taken to appease the constituents of the
5 presidential administration?

6 A That's what was conveyed.

7 Q And this was a call you received at home?

8 A Yes.

9 Q May I ask where you reside, just the town or
10 city where you reside?

11 A Potomac, Maryland.

12 Q Do you know where Dr. Woodcock was calling
13 you from?

14 A No.

15 Q Was there anyone else on the phone call?

16 A No.

17 Q Did you keep any notes about that phone call
18 or write anything down about it?

19 A No, I don't think I wrote anything down.
20 But I do know, I recall this very well because we had
21 to discuss another controversial issue that was
22 happening the next day, Friday. And so I took that

0061

1 opportunity to ask her about that issue. So it was a
2 substantive conversation.

3 Q Do you know how long the call lasted,
4 roughly?

5 A I think ten minutes.

6 Q Did Dr. Woodcock say anything about her own
7 view about the non-approvability of Plan B, of the
8 Plan B application?

9 MR. AMANAT: Objection. You can answer the
10 question.

11 A Her own view about the approvability?

12 BY MR. HELLER:

13 Q Yeah. Well, I mean, here she was telling
14 you that this is the only thing we can do to appease
15 the administration's constituents. I'm wondering
16 whether she said something like, "and I think that's
17 the right thing to do" or "it's unfortunate, but
18 that's the way things are," or something else?

19 A No. I don't recall her at that time giving
20 me any other embellishment on what she felt needed to
21 happen.

22 Q Did she at a later time do that?

0062

1 A Yes. I do recall her voicing concerns about
2 the availability of Plan B OTC with respect to her
3 own children. She gave an example relating to her
4 own inquiry to her daughter.

5 Q Aside from this conversation in which the
6 presidential administration was mentioned, do you
7 recall other people within FDA talking about the
8 presidential administration having a connection in
9 any way to the Plan B OTC switch?

10 MR. AMANAT: Object to the form of the
11 question.

12 A I recall in the briefing to Dr. McClellan
13 prior to the Advisory Committee, that I believe the
14 only question that came from that briefing arose
15 from the political appointee at that time, Scott
16 Gottlieb, relative to the issue of are there
17 sufficient data in the younger age strata.

18 MR. AMANAT: I object to that answer as
19 nonresponsive to the question posed.

20 BY MR. HELLER:

21 Q So at that meeting prior -- the sort of
22 preparatory meeting for the Advisory Committee

0063

1 Meeting, the question came from Scott Gottlieb about
2 the adequacy of data?

3 A I recall it that way, yes.

4 Q Do you know if Scott Gottlieb, is he still
5 at the Agency, Scott Gottlieb?

6 A Yes, he's the Deputy Commissioner for
7 Medical and Scientific Affairs.

8 Q Is he a doctor himself, do you know?

9 A Yes.

10 Q But he's a political appointee?

11 A At this time I don't know.

12 Q In the telephone conversation you mentioned
13 with Dr. Woodcock -- incidentally, this comment she
14 made about appealing the administration's
15 constituents, did you convey that comment to anyone
16 else at your office?

17 A I believe I did.

18 MR. AMANAT: I object to the question. The
19 witness did not use the word "appease".

20 MR. HELLER: She did use the word "appease".

21 MR. AMANAT: She did not.

22 BY MR. HELLER:

0064

1 Q Did you use the word "appease"?

2 MR. AMANAT: She most certainly did not.

3 BY MR. HELLER:

4 Q Well, we'll check the transcript again, in
5 any case. In that conversation did she talk about
6 this as the only way that could lead to approval?

7 A Eventually.

8 Q Did she -- did she talk about it -- I mean,
9 was she talking about this process leading to
10 approval without an age restriction or approval with
11 an age restriction?

12 A She wasn't -- I don't recall her specifying
13 that.

14 Q Okay. So going back to the prior question I
15 asked. Who did you talk with within FDA about the
16 conversation you had with Dr. Woodcock that day?

17 A I believe I shared it with many members of
18 the review team, such as Dr. Beitz, Dr. Griebel and
19 others.

20 Q And you would have done that within a couple
21 of days or a week of the conversation, or was it --
22 would it be much later?

0065

1 A No, within probably the next day. I had
2 asked Dr. Woodcock in that conversation to call Dr.
3 Griebel because I know she was upset and I thought if
4 she heard Dr. Woodcock's explanation, she would at
5 least have some questions answered and could talk
6 with Dr. Woodcock more if she had additional
7 questions. But I went to Dr. Griebel and asked her,
8 "Did Dr. Woodcock call you? I asked her to call
9 you." And she stated no.

10 Q Do you know if Dr. Griebel ever got that --
11 had that conversation with Dr. Woodcock?

12 A I don't know.

13 Q Was that phone call unusual?

14 MR. AMANAT: Objection.

15 BY MR. HELLER:

16 Q Had you ever gotten a phone call or a --
17 have you ever had a conversation with someone above
18 you in the Agency where they informed you that an
19 action or a course of action was necessary to appease
20 or placate the presidential administration's
21 constituents?

22 MR. AMANAT: I'm going to object to that

0066

1 question. The witness neither used the word
2 "appease" or "placate".

3 MR. HELLER: Well, that's my question.

4 MR. AMANAT: Well, your question assumes a
5 fact that the witness did not testify to.

6 MR. HELLER: Let's try to figure this out.
7 I'm sorry to bother you again. Can you look for the
8 word "appease"?

9 MR. AMANAT: It will appear in your question
10 that you asked a few minutes ago.

11 MR. HELLER: It definitely will. I know
12 that.

13 (Discussion off the record.)

14 (Record read.)

15 MR. HELLER: So it was in her answer, her
16 initial answer to my question about the phone call.

17 Now I can't remember my last question.
18 Well, you had asked for a break, I believe, and you
19 had also asked about what to do with objections. Let
20 me just tell you -- go over that. If the lawyers for
21 the FDA object to a question, generally once they've
22 stated their objection, you can just go ahead and

0067

1 answer my question, unless if you have a problem
2 understanding my question, you should let me know.
3 But if you understand my question, you can just
4 answer it.

5 The one exception to that would be if they
6 tell you "don't answer the question, we instruct you
7 not to answer the question." But in general it's
8 just an opportunity for them to comment and state
9 sort of for the record that they think there was some
10 problem with the question I asked. But in general
11 you can just go ahead and answer the question.

12 And you would like a break?
13 THE WITNESS: Yes.
14 MR. HELLER: Tell me how long you'd like so
15 we don't give you too little time or hold you up.
16 THE WITNESS: Ten minutes?
17 MR. HELLER: Sure. That's fine.
18 MR. AMANAT: Can we change the tape during
19 the break so that we don't have to take another break
20 in 15 minutes?
21 THE VIDEOGRAPHER: No problem.
22 MR. HELLER: Sure. So we'll go off the

0068

1 record then.
2 THE VIDEOGRAPHER: Going off the record.
3 The time is 11:16 a.m.
4 (Recess.)
5 THE VIDEOGRAPHER: Here marks the beginning
6 of videotape tape number two in the deposition of Dr.
7 Florence Houn. We're back on the record. The time
8 is 11:29 a.m.
9 BY MR. HELLER:

10 Q Hello, Dr. Houn. I'm going to hand you a
11 packet of documents. And I'm sort of switching
12 gears. We might return to what we were doing
13 earlier, but I want to get some things out of the
14 way. And there's a lot of pages in here. I believe
15 the first page is marked Tummino 1740 at the bottom.

16 A Yes.

17 Q And the last page is marked Tummino 1921.
18 And there may be some numbers that fall between there
19 that aren't included here. I'm not going to ask you
20 about all these pages, but I do have a few questions
21 about some of them, so I want to sort of take care of
22 that.

0069

1 If you would turn to the second page here,
2 and maybe even actually look at the second and third
3 pages. There is on Page 1744 and 1745, there's an
4 e-mail that appears to be from Tom O'Brien to a whole
5 large group of people. And I assume you are
6 somewhere on this list, although at the moment I
7 don't see your name. But in any event, this was one
8 of the documents that was produced to us by the
9 government as one of the things you had provided to
10 them and they gave it to us.

11 And so my question about this is, the date
12 on the Tom O'Brien e-mail is March 2nd, 2006. And
13 under -- when you get to whatever there is of the

14 text of the e-mail, it says, "The purpose of this
15 message is to request your assistance in preparing
16 Dr. von Eschenbach for the Senate Agriculture
17 Appropriations Subcommittee Hearing on March 14."
18 Then there's the Number 10, Plan B time frame CDER.

19 Do you have any recollection what this
20 e-mail was about, anything else about this e-mail?

21 A I believe I did get a forwarded version of
22 this original e-mail. And the request was to provide

0070

1 information to help prepare Dr. von Eschenbach for
2 this subcommittee hearing. And this may be related
3 to a timeline that was put together really based on
4 the publicly available GAO report and asking for
5 input on revisions or corrections. I believe that
6 this is related to that.

7 Q So it may have been -- okay. Then above the
8 Tom O'Brien e-mail there's some blanks where things
9 have been taken out. I'm wondering did you sort of
10 then make comments about this e-mail and send them on
11 to other people or anything like that? What was
12 contained on this blank page?

13 MR. AMANAT: Object to the question.

14 A I would have to go back to my original
15 documents in which it isn't redacted to look.

16 BY MR. HELLER:

17 Q Okay. Then if you would turn to Page 1753.

18 MR. AMANAT: It's a very informative page.

19 BY MR. HELLER:

20 Q And if you'd also look at Pages 1754 and 55.
21 This seems to be a chain of e-mails in which you were
22 one of the -- you were -- some of them, they were

0071

1 sent to you, I guess, regarding the Government
2 Accountability Office investigation or study, I
3 think, related to Plan B?

4 A Uh-huh. Yes.

5 Q And, again, there's this page of sort of
6 stuff that's been taken out. Do you have any idea
7 what was taken out, or you would have to look at your
8 original?

9 MR. AMANAT: I object to the question.

10 A Yes, I don't recall what was taken out.

11 BY MR. HELLER:

12 Q And then on the page marked 1755, there's
13 sort of at the end of the chain of e-mails, it looks
14 like there's a Microsoft Word attachment of a
15 briefing paper on Plan B that was requested by HHS,

16 at the very end. On page 1755, are you?

17 A Oh.

18 Q Sort of at the bottom there. There's this
19 e-mail, "Diane, I'm sending the promised briefing
20 paper on Plan B requested by HHS yesterday." And
21 then it looks like there was an attachment of a Word
22 document. Do you know what the briefing paper -- was

0072

1 there a briefing paper on Plan B done for HHS?

2 A Yes. It might have been -- there's a
3 standard name for such informational -- informational
4 documents that HHS asks for. And I believe this was
5 that type of request, kind of a summary including a
6 little bit of timelines about what were the issues.

7 Q Then if you would turn to Page 1786. And
8 this is a series -- all the way to the end is a
9 series of documents that I believe all say ODE-3,
10 basically are headed with this ODE-3 heading, and
11 then there's blank spaces and then notes about Plan B
12 on some of them.

13 A Right.

14 Q And are these --

15 A These are the reports. You had asked me, do
16 I report to Dr. Jenkins.

17 Q These are the reports you make to John -- to
18 Dr. Jenkins?

19 A Yes.

20 Q Are they sort of handed to him by hand or
21 e-mailed to him or --

22 A E-mailed to him.

0073

1 Q And are they done on --

2 A It may not actually be him. It may be to
3 his project manager who's in charge of compiling
4 these reports from the other offices every week on
5 issues.

6 Q But essentially it goes to his office?

7 A Yes.

8 Q And are these prepared or would these be
9 prepared on a weekly basis, daily basis or as needed?

10 A Weekly report. This is the CDER OND weekly
11 report.

12 Q When I looked through these reports, there
13 were -- a lot has been removed from them because it
14 had nothing to do with Plan B, as I understand it,
15 but what does relate to Plan B I believe has been
16 left in the reports, is that correct?

17 MR. AMANAT: That is correct, yes.

18 MS. SCHIFTER: There is nothing on these
19 pages that's been redacted that relates to Plan B.
20 There are some pages that have been withheld if they
21 had some substantive explanation that I thought was
22 deliberative process.

0074

1 MR. HELLER: So some things have been
2 withheld based on deliberative process?

3 MS. SCHIFTER: And they will show up in a
4 log, and that would be missing pages in the sequence
5 of the numbers. But all the redactions you see are
6 subjects unrelated to this lawsuit.

7 BY MR. HELLER:

8 Q Okay. When I was -- as I looked through
9 these pages, I did not see a report, for example,
10 that reflected -- and there might not be one -- but a
11 report that reflected the January 15th, 2004 meeting
12 that Dr. Galson ran at which various things were
13 discussed. Would there have been a report about that
14 meeting?

15 A Yes.

16 Q I also did not see a report generated
17 related to the February 18th meeting or presentation
18 to Dr. McClellan. Would there have been a report
19 about that?

20 A Yes.

21 Q Would you have made a report about the
22 phone call with Dr. Woodcock that you testified about

0075

1 earlier?

2 A I don't recall that I had written anything
3 down, but I do recall conveying the substance of that
4 phone conversation with the review staff.

5 Q Do you recall conveying the substance of
6 that conversation to Dr. Jenkins at any time?

7 A Yes.

8 MR. HELLER: I guess I'll ask you, Karen.
9 Do you know if the two --

10 A Actually, let me say I'm not sure.

11 BY MR. HELLER:

12 Q About Dr. Jenkins?

13 A About Dr. Jenkins.

14 Q Okay. That's fine.

15 A I would have assumed I did, but I cannot
16 recall specifically.

17 Q Did you convey the substance of the
18 conversation with Dr. Woodcock to Dr. Kweder?

19 A I can't recall specifically, but I would

20 assume I did because I usually am communicative with
21 my supervisors.

22 MR. HELLER: Karen, I'm going to ask you
0076

1 because I think maybe you know the answer to this.
2 Do you know if the two reports that I believe aren't
3 in here and that she testified exist are among the
4 ones that were withheld until the request?

5 MS. SCHIFTER: I don't recall and I also
6 don't recall what the dates were or I didn't go
7 through to try and figure out whether it was
8 comprehensive. I just took the documents that she
9 gave me and -- but I can't tell you off the top of my
10 head.

11 MR. HELLER: Okay.

12 BY MR. HELLER:

13 Q Would there have also been a report
14 generated after the Advisory Committee votes? Would
15 that have been reflected in one of these reports?

16 A Yes.

17 Q Okay. I think I'm done with this stack of
18 materials if you don't want -- I can take it back so
19 it doesn't clutter up your part of the table.

20 MR. AMANAT: Do you mind if we hold onto our
21 copy?

22 MR. HELLER: Sure, you can have it. And if
0077

1 in looking through it, you find that I'm wrong about
2 those reports not being in there, I'd like to --

3 MR. AMANAT: Yeah, I haven't studied these
4 documents.

5 BY MR. HELLER:

6 Q Let me show you another document.

7 (Discussion off the record.)

8 BY MR. HELLER:

9 Q This is a document marked Tummino 30909
10 through 30911. And if you'd like to take a moment to
11 look it over. At the very top it seems to be an
12 e-mail from you to Bronwyn --

13 A Collier.

14 Q -- Collier. And at the very top it says,
15 "Bronnie, please put this into DFS for archival
16 purposes under the Plan B OTC NDA. Thanks, F," which
17 I assume is your first initial?

18 A Yes.

19 Q Do you recall why you asked Ms. -- is it a
20 woman?

21 A (Witness nods.)

22 Q -- Ms. Collier to put this e-mail exchange
0078

1 into DFS for archival purposes?

2 A DFS refers to the Document Filing System.
3 It is for official record-keeping related to the NDA.
4 It's electronic. I asked her to put this in for the
5 Administrative Record.

6 Q I guess my question is, why this as opposed
7 to, let's say, other e-mail exchanges that occurred
8 about Plan B?

9 A Because prior to Dr. Galson issuing his May
10 non-approval letter, he telephoned -- well, he
11 conveyed to the review staff that he had consulted
12 the Office of Pediatric -- it's the Office of
13 Counter-Terrorism and Pediatric -- and Pediatrics,
14 for their advice relating to the concern about could
15 adolescent information from the -- could
16 adolescents understand the benefits and risks of this
17 product if it was over-the-counter.

18 And this was a surprise to me that a
19 consultation had been asked for and I thought
20 generated. And so I asked him over the e-mail
21 systems to provide that consultation, their formal
22 request documents for archival purposes for the

0079
1 Administrative Record. And I wanted to archive the
2 pediatric consultation he obtained as it was material
3 to his decision-making.

4 So I -- so the e-mail that you don't have is
5 me asking Steve, you conveyed to us that the Office
6 of Counter-Terrorism and Pediatrics was consulted,
7 please provide me that consultation so we can put it
8 into the archival system. And he responded by
9 forwarding me these e-mails. And so this is his
10 response to me, "Hi Flo, this is the documentation."

11 Q Is this sort of written record of a
12 pediatric consultation typical of the written record
13 of a consultation?

14 MR. AMANAT: I'm going to object to the
15 question. You can answer.

16 A No.

17 BY MR. HELLER:

18 Q In what way?

19 A Well, they later on, the Office of
20 Counter-Terrorism and Pediatrics and its Division of
21 Pediatrics provided a formal consult on the Plan B
22 OTC NDA switch. And that consultation is reflective

0080

1 of the usual consultation a division provides in
2 terms of response to a request for their opinion and
3 their expertise.

4 Q Do you know what that later consultation
5 concluded or what it stated?

6 A It stated that the Plan B OTC NDA data
7 submitted meet the requirements of the Pediatric
8 Research and Equity Act, and that no further studies
9 were needed in any age group.

10 Q Do you recall who wrote -- was there a
11 written memorandum of some sort?

12 A Of course.

13 Q Do you recall who wrote that one?

14 A I have it here.

15 Q Okay. Well, if you could look and tell me
16 who wrote it, that would be helpful.

17 A (Witness referring to document.) The
18 reviewer is Hari Sachs, S-A-C-H-S. And it was signed
19 off through the Acting Team Leader and the Acting
20 Division Director.

21 Q Who is the Acting Division Director? Does
22 it say there?

0081

1 A Dr. Lisa Mathis, M-A-T-H-I-S.

2 MR. AMANAT: What's the date of that
3 document, Dr. Houn?

4 THE WITNESS: This is signed off as
5 11/12/04.

6 BY MR. HELLER:

7 Q May I look at that document?

8 MR. HELLER: Do you want to look at it
9 first? Certainly we don't want to take anything
10 that's attorney-client.

11 BY MR. HELLER:

12 Q Dr. Houn, while they're looking over the
13 document, is that a copy of it or is that your
14 original?

15 A It's a copy -- it's a copy.

16 Q So you have your own copy, another copy?

17 A The original, I believe, is the electronic
18 version that exists in that system. The medical
19 officer probably generated it in Word and may have a
20 copy.

21 Q I'm wondering if it's your only copy of it?

22 A You can have it, or they can have it.

0082

1 MR. AMANAT: Or we can have it and we can
2 decide if --

3 THE WITNESS: You all can have it.

4 MR. AMANAT: We're going to have to review
5 this document further.

6 MR. HELLER: I'd like to have it marked as
7 an exhibit for the deposition. You could review it
8 over a break.

9 MR. AMANAT: Yeah, we have to -- I mean --

10 MR. HELLER: If you're going to assert a
11 privilege, I'd like to contact the magistrate about
12 it because I don't think it's in the Administrative
13 Record that you produced. We're going to check --

14 MR. AMANAT: How do you know? You haven't
15 seen the document.

16 MR. HELLER: We're going to check if there
17 was a document with that date docketed in the record
18 from the -- that reflects what she described. Maybe
19 it is. Then there shouldn't be any problem with
20 using it as an exhibit.

21 MR. AMANAT: Let me just check.

22 MR. HELLER: Sure. We'll check it, too. Or

0083

1 we're trying to check. Our computer is a little
2 slow.

3 (Discussion off the record.)

4 MR. AMANAT: Would you please read back the
5 last question that Mr. Heller asked before the
6 witness gave her last response, please?

7 (Record read.)

8 MR. HELLER: Frank, do you want me to stop
9 in my question while you look at this or should I --

10 MR. AMANAT: You can keep going.

11 MR. HELLER: I don't want to pull you in too
12 many directions at the same time.

13 MR. AMANAT: That's fine.

14 BY MR. HELLER:

15 Q Dr. Houn, aside from the document you just
16 testified about, what other documents did you bring
17 with you today? I mean, I know there's a lot in
18 front of you.

19 A Right.

20 Q There's probably some that are published
21 documents, like the books you have.

22 A Yes.

0084

1 Q But are there -- what other internal FDA
2 documents have you brought with you?

3 A Internal. In terms of obtaining documents
4 from the Document Filing System, DFS, I obtained the

5 reviews done by the ODE-3 reviewers, Dr. Julie Beitz
6 and Dr. Donna Griebel, for both cycles of the NDA.

7 I think I also retrieved meeting minutes
8 that you discussed on January 15th, 2004. And I
9 retrieved from DFS Steve Galson's memo.

10 MR. AMANAT: Yeah, it appears that the
11 document in question was produced as part of the
12 Administrative Record. It was the document that the
13 witness was testifying about earlier. Her copy here
14 is not Bates numbered, so I can't give you the Bates
15 numbers. But the first three pages is a document
16 dated August 11, 2004, which we have labeled Tummino
17 30923 to 30925. That was a request for consultation
18 from Karen Kirchberg to the Office of Pediatrics
19 asking whether the PREA requirements had been met for
20 Plan B.

21 The remaining documents in the document that
22 the witness handed me are a eleven-page document

0085

1 dated November 12, 2004, from Hari, H-A-R-I, Sachs,
2 S-A-C-H-S, from the Office of Pediatrics. And that
3 was produced to you at Bates number 30931 to 30941.

4 MR. HELLER: Can I see this document?

5 MR. AMANAT: You may, of course. Yes.

6 MR. HELLER: Thank you.

7 MR. AMANAT: Well, actually, yeah, let me
8 have that back if you don't mind because I see on the
9 log that in the version that we produced to you, we
10 had redacted certain confidential commercial
11 information, certain IMS data which was listed on the
12 log.

13 MR. HELLER: What's IMS data?

14 MS. SCHIFTER: It's sales data. And it's a
15 company that we contract with that gives us
16 information on sales. And we have a contract with
17 them that we can't disclose the information because
18 that's what they -- that's their business is to sell
19 information that they gather about sales numbers.

20 MR. AMANAT: So and I don't know what was --
21 I don't have the redacted version here, so I can't
22 tell.

0086

1 MR. HELLER: If we can ever get our computer
2 to work, we'll be able to look at the redacted
3 version.

4 MR. AMANAT: Yeah, and I would prefer to do
5 that because I just can't guarantee that this version
6 has not -- it does not appear to be redacted from

7 this copy.

8 THE WITNESS: It's not redacted. The IMS
9 data is there.

10 MR. AMANAT: So I would prefer that we work
11 with the version of the document that was produced to
12 you as part of the Administrative Record --

13 MR. HELLER: That's fine.

14 MR. AMANAT: -- which contains the
15 redactions.

16 MR. HELLER: So regarding this IMS sales
17 data, is that -- am I saying that right?

18 MR. AMANAT: Yes.

19 MR. HELLER: Is that data about -- sales
20 about of what?

21 MS. SCHIFTER: For example, how many units
22 of Plan B were sold in a particular time period.

0087

1 THE WITNESS: And to what age group.

2 MR. HELLER: And is the data that they
3 provided sort of how much was sold to a particular
4 age group, is that confidential?

5 MS. SCHIFTER: Yes, because that's what IMS
6 does is they collect data about sales and they sell
7 it to people who want the data. But you have to
8 enter into a contract that you're not going to give
9 the data to anyone else without their permission.

10 THE WITNESS: You have to seek their
11 permission, and that takes some time.

12 MR. HELLER: Does the data contained in this
13 document that's been redacted reflect sales of Plan B
14 to different age groups?

15 MR. AMANAT: It appears. I see actually the
16 page where this information exists. And there is a
17 notation on the document which says, "source IMS
18 Health, National Disease and Therapeutic Index.
19 Note, data not to be shared outside of FDA or with
20 non-FDA staff without prior clearance by IMS Health.
21 Clearance must be requested from IMS Health through
22 the FDA Office of Drug Safety." And the document in

0088

1 question does, I can see on this page, contain data
2 which appears to have been drawn from them.

3 So I have no objection to you using the
4 redacted version of the document that was produced as
5 part of the Administrative Record and asking the
6 witness about it, but --

7 MR. HELLER: Let me say this about the
8 redacted data. It seems to me that given the

9 importance ascribed by the defendant to data about
10 Plan B use by younger adolescents or maybe older
11 adolescents also, information that the FDA has about
12 such use is highly relevant to our ability to present
13 our claims. So we would like to explore with you
14 obtaining that redacted information under some sort
15 of protective order if necessary. Are you willing to
16 do that?

17 MR. AMANAT: Well, we'd have to think about
18 that and confer with IMS. I mean, if you want to ask
19 the magistrate judge for leave to issue a subpoena to
20 IMS, I suppose you could do that, but --

21 MR. HELLER: No, I mean you already have it.
22 We don't need to get it from them. The question is

0089

1 sort of would you be willing to engage in a
2 protective order under which we're not going to
3 release this information?

4 MR. AMANAT: Let's have that discussion off
5 line perhaps, because we need to think about it and
6 confer and we'll get back to you.

7 MR. HELLER: Okay. Thank you.

8 BY MR. HELLER:

9 Q You were in the course of describing to me
10 the documents you had brought. And I don't remember
11 exactly where we stopped with that. And you were
12 telling me about DFS documents that you --

13 A Right.

14 Q -- brought with you.

15 A You should have them because they're in the
16 Administrative Record.

17 Q But -- I'm sorry. Go ahead. So the reviews
18 within your office?

19 A Right. Dr. Galson's memo.

20 Q Anything else?

21 A I brought with me some documents I gave to,
22 I guess, Karen as well as the first -- the first set

0090

1 of documents went to Chris Bechtel responsive to your
2 request.

3 Q And what -- what do those documents consist
4 of?

5 MR. AMANAT: Before you answer that
6 question, I would just like to state for the record
7 that I had previously instructed this witness not to
8 bring any documents with her to the deposition. And
9 she chose to bring the documents of her own decision,
10 you know, contrary to our instructions. I just

11 wanted to make sure I stated that on the record.

12 THE WITNESS: You told me not to bring any
13 documents?

14 MR. AMANAT: I did.

15 THE WITNESS: You told me I did not need to
16 bring any. You did not say "do not bring any".

17 MR. AMANAT: Actually, I did. But that's
18 okay. I just wanted to --

19 MR. HELLER: Well, there's been some
20 disputes about what people said but -- so your view
21 is that the deponent violated your instructions?

22 MR. AMANAT: I just wanted to make it, you

0091

1 know, just in case any questions get asked at some
2 point in the future, I wanted to make it clear on the
3 record that I had instructed the witness not to bring
4 any documents with her to her deposition, and her
5 decision to do so was her own decision.

6 BY MR. HELLER:

7 Q It certainly wasn't -- we didn't request you
8 to bring any documents but -- the documents you were
9 just describing, the ones that you had provided to
10 Karen or someone named Chris, I think, what did those
11 consist of?

12 A They consist of writings relating to Plan B.

13 Q Things that you wrote or other people wrote?

14 A Yeah, both.

15 Q Do any of them -- what sort of things are
16 included that you wrote yourself?

17 A What do you mean?

18 Q What I mean is sort of, are they memos that
19 you wrote or e-mails or letters among the things you
20 wrote?

21 A Among the things I wrote are drafts of
22 minutes to meetings. I have notes on the Advisory

0092

1 Committee vote. I have notes on -- let's see --
2 different aspects of the review that the data were in
3 question, such as was there an impact of use of Plan
4 B in the younger age group for more risky behavior.

5 Q The drafts of minutes you mentioned, I
6 didn't see any minutes of -- were these drafts you
7 wrote of minutes?

8 A They might have been early drafts that
9 didn't become finalized or parts of it didn't become
10 finalized.

11 Q Because when -- and I may have missed things
12 easily. I didn't see any meeting minutes that you

13 wrote in the Administrative Record, sort of final
14 versions of meeting minutes. Do you recall if there
15 were those?

16 A Well, for example, the meeting minutes that
17 relate to our conversation and our face-to-face
18 meeting with Barr Incorporated following January
19 15th, I generated the first draft of what should be
20 conveyed at that meeting, the review team took it and
21 edited further. And what was conveyed at that
22 meeting was captured by the project manager and then

0093

1 put into minutes.

2 Q Okay. So that you worked on it at some
3 stage, and then the final product was actually
4 associated with someone else's name other than yours?

5 A Right.

6 Q Okay. Anything else you brought with you
7 today that you have left out among the -- that is
8 among the non sort of public stuff that you have
9 there?

10 A I have -- well, I have from other NDAs
11 copied the pharm-tox, pharmacology-toxicology reviews
12 relating to levonorgestrel.

13 Q So those would be reports about the compound
14 that is in Plan B?

15 A That's correct.

16 Q Anything else?

17 A I have notes to myself and, you know, things
18 that can be found on the Web.

19 Q That's fine. Can you tell me in general
20 what your understanding is of what the lawsuit is
21 about that you're here being deposed for?

22 MR. AMANAT: Objection. You can answer the

0094

1 question. But I would instruct you that to the
2 extent that your answer to the question would require
3 you to divulge communications that you have had with
4 the Agency's lawyers, including with Mr. Warshawsky
5 and myself, that you not answer the question to the
6 extent that your answer would require you to disclose
7 or divulge the content of such communications.

8 BY MR. HELLER:

9 Q So to maybe -- and Frank, please tell me if
10 I'm wrong -- all I want you to answer about is what
11 you know about the nature of the lawsuit from sources
12 other than your conversations with the lawyers for
13 the FDA, sort of from reading public documents or
14 internal FDA documents and so forth.

15 MR. AMANAT: Same objection.

16 A I understand it that the plaintiff would
17 like the application to be approved for
18 over-the-counter use.

19 BY MR. HELLER:

20 Q This is again sort of switching gears a
21 little bit. I apologize. Are you a member of any
22 professional organizations that you know of?

0095

1 A I am a member of the American College of
2 Physicians.

3 Q Any others that come to mind that you're a
4 member of?

5 A No.

6 Q All right. Did you ever hear that in the
7 early part of 2004, January or February or even
8 December of 2003, around that time period, did you
9 ever hear anyone talking about approval letters being
10 drafted for Plan B?

11 A What was the time frame?

12 Q Around December 2003 to February of 2004.

13 A No, not during that time frame.

14 Q Did you hear about it at some other time?

15 MR. AMANAT: Hear about what exactly? What
16 is the "it" that is the --

17 BY MR. HELLER:

18 Q I'm sorry. I'm giving you the wrong time
19 frame. December 2004 to February of 2005.

20 A Yes.

21 Q What did you hear?

22 A That I think Dr. Galson was prepared to

0096

1 approve Plan B over-the-counter for an older age
2 group and proceed with restrictions in a younger age
3 group.

4 Q Do you recall who you heard that from or
5 what sources that came from?

6 A I can't recall the individuals.

7 Q Do you recall seeing any drafts of approval
8 letters?

9 A No. I think we might have gotten an inquiry
10 to send the Office of the Center Director an approval
11 letter template.

12 Q After the May 2004 non-approvable letter was
13 issued, did you have involvement after that as well
14 with the Plan B review process?

15 A Yes, on the resubmission.

16 Q During that time, after May of 2004, were

17 there any things that occurred that you thought were
18 questionable?

19 MR. AMANAT: Objection.

20 A You'd have to be more specific.

21 BY MR. HELLER:

22 Q Did any events occur that you thought were
0097

1 unusual?

2 MR. AMANAT: Objection.

3 A Relating to Plan B?

4 BY MR. HELLER:

5 Q Yes.

6 MR. AMANAT: Objection. You can answer the
7 question.

8 A Well, it was unusual to have GAO come
9 investigate.

10 BY MR. HELLER:

11 Q Did the Government Accountability Office
12 interview you?

13 A Yes.

14 Q Did you -- was that on one occasion or
15 several occasions?

16 A I recall two occasions.

17 Q Did they ask you about the phone call with
18 Dr. Woodcock that you told me about today or did that
19 phone call come up, do you recall?

20 A Yes, I believe I conveyed that information
21 to them.

22 Q Do you recall if you ever sent an e-mail
0098

1 that conveyed the content of the call with Dr.
2 Woodcock?

3 A I don't recall.

4 Q Am I right that Dr. Beitz wrote two review
5 memoranda regarding Plan B, one in the sort of first
6 cycle and one in the second cycle?

7 A That's correct.

8 Q Do you concur in what she wrote in those
9 memoranda?

10 MR. AMANAT: Objection. The memoranda are
11 very long and they're not in front of the witness.

12 MR. HELLER: Well, I don't want to --

13 MR. AMANAT: You say what she wrote.

14 MR. HELLER: Let me ask a different

15 question.

16 BY MR. HELLER:

17 Q Do you recall or are you aware of any
18 disagreement you had with her memoranda?

19 A No. She showed me her earlier drafts. I
20 provided comments, I provided advice in terms of
21 where I thought she needed additional information and
22 where she was doing very well in, just as any

0099

1 supervisor would. And I agreed with her overall
2 outline of her thinking about the evidence and her
3 conclusions.

4 Q I'm about to show you a document, if I can
5 find enough copies of it, which is marked Tummino
6 30912 through 30914.

7 A Let me give you back --

8 Q Thank you. And it's entitled
9 "teleconference minutes" and it's signed. It has the
10 electronic signature of Dr. Galson. And you are
11 listed on this document as the meeting recorder.

12 A Yes.

13 Q Do you recall this teleconference?

14 A Yes.

15 Q What does it mean to be the meeting
16 recorder?

17 A I took notes.

18 Q Okay. And do you know if this document
19 reflects the notes you took?

20 MR. AMANAT: Take a moment to read the whole
21 document.

22 A (Witness reading document.) Yes, I think

0100

1 this captures what was said.

2 BY MR. HELLER:

3 Q I want to call your attention to the second
4 page of the document 30913. And there's bullet
5 points at the top. And the fourth one says
6 "Non-medical or political views about the drug and
7 sexual behavior did not factor into the decision."

8 And I think this is referring to the
9 decision to issue a non-approvable letter. Do you
10 recall or do you know why that was conveyed in the
11 teleconference?

12 A It was conveyed in the teleconference. It
13 was also conveyed in January 15th, when he said that
14 his -- the decision for non-approval was not
15 ideologic.

16 Q But do you know why he was conveying that?

17 A I can only speculate as to why.

18 Q Tell me your speculation.

19 MR. AMANAT: Objection. You can answer the
20 question.

21 A I speculate that he states these reasons
22 because he's concerned that his staff views the

0101
1 non-approval for the opposite reason.

2 Q Was there staff or is there staff in CDER
3 that views the Agency's process regarding Plan B as
4 involving or as having factors that are non-medical
5 or political?

6 MR. AMANAT: As of the date of this document
7 you're asking?

8 BY MR. HELLER:

9 Q Let's start with as of the date of this
10 document, were there people within CDER who believed
11 that there were non-medical and political views that
12 factored into the Agency's decision?

13 MR. AMANAT: Objection.

14 BY MR. HELLER:

15 Q You can answer.

16 A Yes.

17 Q How widespread was that view?

18 MR. AMANAT: Objection. You can answer the
19 question.

20 A I think it was fairly widespread.

21 Q Is it still a widespread view within CDER?

22 MR. AMANAT: Objection.

0102
1 A I think so.

2 BY MR. HELLER:

3 Q Were Dr. Galson's statements disavowing
4 non-medical and political factors persuasive to you?

5 A No.

6 Q Can you tell me why not?

7 A I think at the time there was concern on --
8 there was concern about if Dr. Galson did not issue a
9 non-approval letter, the leadership of CDER would be
10 placed in a difficult position and may not be in the
11 interest of CDER.

12 Q Can you --

13 MR. AMANAT: I object and move to strike as
14 not responsive to the question posed.

15 BY MR. HELLER:

16 Q Can you explain that a little bit more? In
17 what way would an action other than non-approvable
18 have affected the leadership of CDER?

19 A It was told to me that perhaps if there was
20 a contrary decision, meaning if it was an approval
21 decision, that the leadership that was involved in
22 that decision may not be able to stay on.

0103

1 Q Who conveyed that to you?

2 A I heard it from Dr. Jenkins as well as from
3 Jane Axelrad.

4 MR. AMANAT: I wasn't given the opportunity.
5 I'm going to object to the previous response of the
6 witness as nonresponsive to the question posed.

7 BY MR. HELLER:

8 Q Anyone else who conveyed that to you that
9 you can recall?

10 A I think Dr. Kweder might have been involved
11 in discussions with Dr. Jenkins when that was
12 conveyed to me.

13 Q So she might have been present or --

14 A Yes.

15 MR. HELLER: I'm going to propose a lunch
16 break at this point. Is that suitable for you,
17 Doctor?

18 THE WITNESS: Yes.

19 MR. AMANAT: How much more questions do you
20 think you have?

21 MR. HELLER: I don't know.

22 MR. AMANAT: Hour, two hours, three hours?

0104

1 MR. HELLER: Well, not three hours, but it
2 might be another hour, roughly, I would say. We
3 could continue now, but I would prefer to take a
4 lunch break now.

5 MR. AMANAT: Can we come back at 1:10?

6 MR. HELLER: That's fine with me. Is that
7 sufficient time for you, Dr. Houn, to have some
8 actual lunch if you --

9 THE WITNESS: No, I don't eat lunch.

10 MR. HELLER: Oh, you don't? Often I don't
11 either but --

12 THE WITNESS: I give the public all my time.

13 MR. HELLER: Would that be a suitable break
14 for you?

15 THE WITNESS: That's fine. Shorter is fine,
16 too.

17 MR. HELLER: So let's reconvene at 1:10. Is
18 that good? Okay, we'll go off the record.

19 THE VIDEOGRAPHER: We're going off the
20 record. The time is 12:26 p.m.

21 (Luncheon recess.)

22 THE VIDEOGRAPHER: We're back on the record.

0105

1 The time is 1:15 p.m.

2 BY MR. HELLER:

3 Q Good afternoon, Dr. Houn. I want to ask you
4 some questions, and I apologize in advance if these
5 are difficult for you. We had a conversation during
6 the lunch break, is that right?

7 A (Witness nods.)

8 MR. AMANAT: You and the witness did?

9 MR. HELLER: Yes. That's why I'm putting
10 this on the record.

11 BY MR. HELLER:

12 Q Is that right?

13 A Yes.

14 MR. AMANAT: Outside the presence of her
15 counsel?

16 MR. HELLER: Yeah, that's why I'm putting it
17 on the record.

18 BY MR. HELLER:

19 Q And I initiated that conversation with you
20 because I observed that you were upset, is that
21 right?

22 A Yes.

0106

1 Q I asked you, I think I asked you essentially
2 why you were upset, is that right?

3 A Yes.

4 Q And -- well, maybe that's not exactly how it
5 happened. I think you asked me sort of what was
6 going to happen after I was done with my questions,
7 what was going to happen next, and I told you that
8 the lawyers for the other side would probably ask you
9 questions. Is that right?

10 A Yes.

11 Q Okay. And then I think you became a little
12 bit upset, is that right?

13 A Yes.

14 Q And I think you became -- I think you
15 indicated to me that you became upset because you
16 were concerned or worried about their questioning of
17 you, is that right?

18 A Yes.

19 Q And I asked you a little bit more about why
20 that would be. And I think you indicated to me that
21 you were concerned about the effect your testimony
22 today might have upon your position at FDA. Is that

0107

1 basically correct?

2 A Yes.

3 Q And I, when you said that, I said to you

4 something to the effect of, "Do you want to have your
5 own attorney represent you?" "Do you want to have
6 your own attorney representing you at this
7 deposition?" Is that right?

8 A Yes.

9 Q And I don't think you answered that
10 question, is that right?

11 A Right.

12 Q Other than what I've just summarized, is
13 that essentially the conversations we had -- the
14 conversation we had over the break?

15 A Yes.

16 Q I think I also mentioned to you that I might
17 feel that it was appropriate, first of all, to sort
18 of disclose this conversation?

19 A Yes.

20 Q And that I might need to disclose it to the
21 Court as well, is that right?

22 A Yes.

0108

1 MR. AMANAT: Let me just say on the record
2 that regardless of the on-the-record disclosure of
3 the conversation, the fact that the conversation took
4 place in the first place, I consider to have been
5 grossly inappropriate and arguably a violation of the
6 ethical rules against contact with represented
7 individuals, not to mention potential tampering of a
8 witness.

9 I just think that, notwithstanding the fact
10 that the conversation was retroactively disclosed on
11 the record, the fact that it took place in the first
12 place was inappropriate in the extreme. It should
13 have terminated as soon as it started and/or counsel
14 for the government who was, you know, footsteps away
15 should have been alerted to the fact that it was
16 taking place so that counsel for the government could
17 participate in the discussion.

18 MR. HELLER: I understand. And I have
19 concern as well about the -- I'm also concerned about
20 having conversations with deponents outside the
21 presence of counsel. And that's my motivation for
22 disclosing it.

0109

1 MR. AMANAT: And I appreciate that.

2 MR. HELLER: And I actually would propose if
3 you would like that we contact the magistrate judge
4 now, and that I can disclose it on the record to the
5 magistrate because I think the magistrate -- I would

6 like the magistrate's guidance about how to proceed
7 given what the deponent told me.

8 MR. AMANAT: I think it's not necessary, to
9 be honest with you. But if that's how you want to
10 proceed, that's your prerogative. But I don't think
11 it's necessary. I mean, the witness is here. We can
12 go forward with her testimony.

13 MR. HELLER: Okay.

14 MR. AMANAT: I can tell you that after the
15 witness was -- after you provided us with your notice
16 of intention to depose her, my co-counsel and I when
17 we met with the witness, we did inform her of her
18 right to obtain counsel of her own choosing should
19 that be her preference. She indicated she did not
20 feel that was necessary and that she would go forward
21 as the other witnesses in this case with one
22 exception; she would go forward with having the

0110
1 Justice Department represent her in her capacity as a
2 witness in this case as the Justice Department does
3 whenever any government official is deposed --

4 MR. HELLER: Of course.

5 MR. AMANAT: -- in a lawsuit to which the
6 government is a party.

7 MR. HELLER: I'm sure you did and I --

8 MR. WARSHAWSKY: How long did this
9 conversation last?

10 MR. HELLER: Three minutes, something like
11 that. I don't know. I didn't actually time it.
12 Part of the reason, also, that I would want to
13 contact the magistrate is because if I did do
14 something ethically inappropriate, I want to disclose
15 that to the Court.

16 MR. AMANAT: That's your prerogative. I
17 have no objection to your doing that. I don't think
18 it's necessary, but if that's what -- I'm not going
19 to object to your doing that if --

20 MR. HELLER: Let me -- can I just say one
21 more thing? I want to assure you that I did not -- I
22 mean, first, the witness initiated the conversation

0111
1 with me.

2 MR. AMANAT: I understand.

3 MR. HELLER: And I didn't initiate my
4 question about "Are you all right? What's wrong?"
5 in an attempt to elicit any information in any way
6 related to the case.

7 MR. AMANAT: You were being compassionate.

8 MR. HELLER: Exactly. And on the other
9 hand, I also felt that based on what the witness did
10 tell me in response to that question, that at first
11 blush it seemed to me there might be a conflict in
12 some manner between your representation of the
13 witness and your representation of the Agency -- and
14 I'm not sure if there is, frankly -- but that I
15 wanted to raise with you as well.

16 Understanding that of course you did advise
17 her of her right to have her own attorney, this
18 conversation sort of concerned me in that respect as
19 well. Did you want to ask me a question, Steve?

20 MR. AMANAT: Do you want to ask -- you said
21 you asked the witness a question about -- about
22 whether she wanted to obtain her own counsel to

0112
1 represent her, and she had declined to answer. Do
2 you want to ask her now?

3 MR. HELLER: Well, I mean, it wasn't a
4 formal question.

5 BY MR. HELLER:

6 Q Dr. Houn, would you like your own lawyer to
7 be representing you at this deposition? If you -- I
8 mean, obviously you wouldn't be able to have such a
9 lawyer immediately. They don't sort of appear
10 magically. We would have to adjourn the deposition
11 and continue later. But would you like that, or
12 would you like time to think about that, as an
13 alternative, I suppose?

14 MR. AMANAT: You also have the opportunity
15 to confer with us off the record before you answer
16 that question, if that's what you prefer to do.

17 THE WITNESS: Yeah, I'd prefer to do that.

18 MR. AMANAT: Okay.

19 MR. HELLER: So let's go off the record and
20 you can confer with them, and then we can talk some
21 more about this. Thank you.

22 THE VIDEOGRAPHER: We're going off the

0113
1 record. The time is 1:23 p.m.

2 (Recess.)

3 THE VIDEOGRAPHER: We are back on the
4 record. The time is 1:51 p.m.

5 MR. AMANAT: Let the record reflect that
6 counsel for defendant had a prolonged off-the-record
7 discussion with the witness arising out of the events
8 that took place on the record shortly before we went
9 off the record.

10 MR. HELLER: Thank you.

11 BY MR. HELLER:

12 Q Dr. Houn, I just -- I think I only have a
13 few more questions for you. Let me know if you need
14 a break at any point.

15 A Okay.

16 Q We had talked earlier about the, I think,
17 February 18th meeting at which scientists in the
18 Agency were given an opportunity to present
19 information to Dr. McClellan in the hope that it
20 might affect his view of the Plan B OTC application.
21 Do you remember that?

22 A Yes.

0114

1 Q Sometime after that, I believe in maybe
2 March or April of 2004, Dr. McClellan left the Agency
3 and Dr. Crawford became the Acting Commissioner of
4 the FDA?

5 A Yes.

6 Q Was there any similar opportunity afforded
7 to you or your -- your office to present scientific
8 information to Dr. Crawford in the hope that he might
9 have a different view of the OTC application than Dr.
10 McClellan's view?

11 A No such opportunity arose.

12 Q Do you know anything about what Dr.
13 Crawford's view of the OTC application for Plan B
14 was?

15 A I recall being informed that to the --
16 something to the effect that Dr. Crawford would be
17 carrying out the similar views of Dr. McClellan.

18 Q Do you recall who informed you about that?

19 A Not specifically.

20 Q Would it have been someone sort of higher up
21 in the Agency?

22 A Oh, yes.

0115

1 Q Do you know roughly when you might have been
2 informed about that?

3 A Probably around the April time frame.

4 MR. WARSHAWSKY: Could I just clarify?
5 April 2004?

6 THE WITNESS: Yes.

7 BY MR. HELLER:

8 Q One moment, please. I -- in the sort of
9 second cycle for Plan B after the May 2004
10 non-approvable letter was issued, there was a second
11 memo from Julie Beitz in about -- I think in January

12 of 2005. Does that seem right to you?

13 A Right.

14 Q After that memo was finalized, did you have
15 any further involvement in the Agency's Plan B -- the
16 Agency's process regarding Plan B?

17 A No, not substantively. We responded to
18 requests from general external inquiries. Like if
19 there were press requests, if the press office
20 couldn't handle them, they may ask us for a piece of
21 information that we would supply them.

22 When GAO came to investigate, we were not

0116

1 part of the entry or exit conference, but they
2 interviewed us and we released our documents that
3 they wanted relating to Plan B. I believe there
4 might be -- might have been Congressional requests
5 for information as well.

6 So providing documents and searching files
7 and providing that information to upper management
8 was our role at that point.

9 Q Do you know of a letter sent by the
10 Secretary of HHS to United States Senator Enzi
11 stating that the Agency would take action on the
12 Plan B application by September 1st, 2005?

13 A Only from reports of the press.

14 Q Do you believe in your professional
15 scientific judgment that the Agency should have
16 approved the Plan B OTC switch in May of 2004?

17 MR. AMANAT: Objection. You can answer the
18 question.

19 A I believe that the application submitted by
20 Barr Incorporated met the requirements of 310.200.

21 BY MR. HELLER:

22 Q And is that the provision that governs OTC

0117

1 switch applications, among other things maybe?

2 A That's correct.

3 MR. HELLER: I have no further questions,
4 Doctor, at this time. After the government's
5 questions, it's possible I may have a few questions,
6 but I might not.

7 THE WITNESS: Okay.

8 MR. AMANAT: Mr. Heller, when we came back
9 on the record after the last break, I neglected to
10 mention that it was my understanding that the witness
11 had elected to proceed with the deposition with us
12 continuing in the same capacity in which we had been
13 proceeding prior to the break.

14 MR. HELLER: I had sort of understood that.
15 MR. AMANAT: Yeah, I just wanted to clarify
16 and make sure that was on the record that that was
17 the case.
18 MR. HELLER: Okay. Thank you.
19 MR. AMANAT: We would like a very short
20 break so that we can confer as to questioning that we
21 may wish to posit to the witness. And if we can come
22 back maybe at 2:05. Is that too much time?

0118
1 MR. WARSHAWSKY: I'm going to need a little
2 more time because I have to pull the documents.
3 MR. AMANAT: Why don't we come back at 2:10,
4 if that works. Is that good?
5 MR. HELLER: Whatever you want. I --
6 MR. WARSHAWSKY: Yeah, let's shoot for 2:10.
7 MR. HELLER: How much time do we have left
8 on the tape?
9 THE VIDEOGRAPHER: 45 minutes.
10 MR. HELLER: So we can continue with that
11 tape.
12 MR. AMANAT: So we'll come back at ten after
13 two.
14 MR. HELLER: If possible. And if you're not
15 back by then, we'll just wait for you. Thank you.
16 THE VIDEOGRAPHER: We're going off the
17 record. The time is 1:58 p.m.

18 (Recess.)
19 VIDEOGRAPHER: We're back on the record.
20 The time is 2:17 p.m.
21 EXAMINATION BY COUNSEL FOR DEFENDANT
22 BY MR. WARSHAWSKY:

0119
1 Q Good afternoon, Dr. Houn. Let me begin by
2 once again assuring you on the record, first of all,
3 that it's FDA and DOJ's -- I want to assure you in my
4 capacity to the extent I represent DOJ and FDA that
5 you should not fear any repercussions or retaliation
6 having anything to do with the testimony you may give
7 in this case about Plan B. And that I want to assure
8 you that whether in response to the plaintiff's
9 questioning or our questioning, all both sides want
10 and all both sides expect is a complete truthful
11 answer.

12 Now, having said that, I also want to
13 confirm that we have advised you that if you're
14 uncomfortable with the representational arrangements,
15 that you always have the right to adjourn this

16 deposition to seek individual legal counsel. Do you
17 understand that?

18 A Yes.

19 Q Okay. And I just want to also further
20 confirm that at this time you wish to proceed with
21 the deposition and not adjourn it at this point for
22 purposes of seeking your own individual counsel, is

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1 that correct?

2 A Yes.

3 Q Okay. I'd like to begin with the last bit
4 of testimony that you gave the plaintiffs. Mr.
5 Heller asked you a question along the lines of in
6 your professional scientific judgment, did you
7 believe that the OTC application for Plan B should
8 have been approved in May 2004.

9 And your answer, as I recall it, was to
10 the -- was along the lines of, yes, the application
11 submitted by the sponsor met the requirements for
12 approval. Is that a fair characterization of your
13 last bit of testimony?

14 A Yes.

15 Q I'd like to begin by asking you what those
16 requirements for approval of an OTC switch
17 application are?

18 A First, we must look at toxicity. With
19 reference to toxicity, this is levonorgestrel 0.75
20 milligrams, approved for decades, and which the
21 Agency doesn't require any pharmacologic or
22 toxicological studies for new drug applications.

0121

1 Second, with respect to toxicity, there is
2 no established cardiovascular risk with progesterone-
3 only contraception. And this is also documented in
4 the post-marketing review of over a million and a
5 half uses of Plan B.

6 Also, with respect to toxicity, the Advisory
7 Committee had over -- had seven clinical
8 pharmacologists at the meeting, including Dr.
9 Benowitz, who is a clinical pharmacologist with
10 expertise in the third or fourth leading Poison
11 Control Center. And there was no concern raised in
12 the discussion about toxicity with levonorgestrel.
13 In fact, during the vote on whether there was any
14 safety concern, it was unanimous that there wasn't a
15 safety concern. So toxicity is one aspect that the
16 regulations require us to review. And there is not a
17 concern for toxicity.

18 The second concern -- the second part of the
19 regulation requires us to look at other potential
20 harm. Dr. Galson raised two concerns about other
21 potential harm. The first concern he raised was that
22 it may be taken incorrectly. I don't know if -- I'm

0122
1 sorry, he was not convinced that younger adolescents

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9

10 Q That's okay.

11 A With respect to potential harm in taking it
12 wrong, there's actually some benefits for taking
13 it -- taking the two tablets together in terms of
14 more efficacy. And that was raised during the review
15 by the scientists. And publications in 2002 from
16 Contraception and Lancet show there is more efficacy
17 if you take two pills together as soon as possible
18 after unprotected coitus.

19 So the other aspect of taking it incorrectly
20 might refer to taking it after 72 hours, whether it's
21 less effectiveness. But we're not talking about
22 harm. We're talking about less effectiveness. So

0123
1 taking it incorrectly might have more efficacy or
2 less, but I'm not sure there is any harm.

3 I think the second thing Dr. Galson was
4 concerned about relates to the substitution of Plan B
5 inappropriately for either regular contraception or
6 barrier methods of contraception which protect
7 against sexually transmitted diseases. So in the
8 effort to try to address that concern, the reviewers
9 presented data from the Actual Use Study, Dr. Melanie
10 Gold's study, Dr. Raine's study, which looked at
11 outcomes of unprotected sex with respect to access
12 for emergency contraception, as well as other
13 outcomes such as STDs.

14 And, in fact, Dr. Gold was at the Advisory
15 Committee during the open public hearing and
16 presented her data to the Committee members. And she
17 gave us permission for her unpublished study at that
18 time to reference the findings in the reviews of
19 staff from Drug Evaluation 3.

20 So finally with respect to potential harm
21 and substitution, there was a vote in the Advisory
22 Committee on was there evidence that substitution,

0124

1 that this was a concern, and it was unanimous that
2 this was not a concern.

3 So that I believe was his concerns with
4 other potential harm. I think the regulation also
5 requires us to look at the route of administration.
6 This is an oral tablet. It's not injected. It
7 doesn't require professional administration such as a
8 non-oral method might require. And there are many
9 tablets on the market over-the-counter. Also, the
10 regulation requires us to look at collateral measures
11 necessary. I don't believe there are any stated
12 collateral measures necessary for this drug.

13 And finally we're to look at self-
14 medication. That speaks to the issue of self-
15 selection and will patients, consumers know that they
16 need to take Plan B as emergency contraception. And
17 I don't think there were any concerns raised that
18 girls or women would not know that they had
19 unprotected sex or an accident relating to barrier
20 methods, or if they had sex that could result in a
21 pregnancy, that they needed Plan B.

22 So those were the requirements in the

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1 regulation to look at. But also Dr. Griebel talks in
2 her review that the Agency looks at overall benefit
3 versus risk. And the benefits of the drug, as Dr.
4 Clapp, one of three pediatricians at the Advisory
5 Committee, stated, is that Plan B could be looked at
6 in the context of preventing the considerable teenage
7 mortality and morbidity associated with pregnancy.
8 And if you're not familiar with those figures, I can
9 give them to you.

10 Q No. I don't need the figures.

11 A So the benefit in terms of saving young
12 girls' lives, because the under-15-year-old has twice
13 the rate of mortality as the age strata with the
14 lowest rate, in avoiding abortions, as the
15 under-15-year-old group and the 15-to-19-year-old
16 group have the highest abortion to live birth rates
17 in the U.S. And then avoiding pregnancy-related
18 hospitalization and antenatal hospitalization for
19 girls under 20 being the highest among any age group.

20 Those were with benefits that Public Health
21 officials consider. So, again, weighing the

22 benefit/risks ratio, benefit/risk ratio, that is why
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1 I think members of the review team recommended that
2 it be approved over-the-counter.

3 Q Does that complete your answer?

4 A Yes.

5 Q Let me ask you some questions about various
6 aspects of your answer. The first factor which you
7 indicated went into the analysis for an OTC switch
8 was the proposed drug's toxicity, is that right?

9 A Right.

10 Q And as I understood your explanation, that
11 referred to the risk of adverse physical effects to
12 someone taking the drug? Is that a fair
13 characterization?

14 A Right.

15 Q Now, you made the statement, quote -- well,
16 you made the statement that there was, quote, not a
17 concern for toxicity, end quote, with respect to Plan
18 B. Did you mean by that that there have been no
19 reported cases of an adverse physical effect
20 resulting from Plan B or a product containing the
21 same hormone?

22 MR. HELLER: Objection. Compound. But you
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1 can answer it.

2 A There are adverse events reported for the
3 Plan B NDA post-marketing. I can review them with
4 you. They are, by my judgment, incredibly
5 unremarkable.

6 BY MR. WARSHAWSKY:

7 Q What do you mean by incredibly unremarkable?

8 A For a drug with that much use and especially
9 -- for a drug with that much use, the types of
10 reports that were received, including nausea,
11 dizziness, are very mild. There are no deaths
12 reported with this.

13 Q Now, in evaluating whether the adverse
14 events associated with Plan B or any other drug are,
15 quote, incredibly unremarkable, end quote, or
16 something else, what standard or measure do you apply
17 to reach that, as you called it, judgment?

18 A Well, you look at adverse events as they
19 happen in the general population. You compare that
20 background rate to what is reported, and you also
21 anticipate an under-reporting. And then you see if
22 there's a concern, a signal raised in the

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1 post-marketing reports. And there are none.

2 Q Now, when you say that you look at the
3 background rates of adverse events, rates can mean
4 anything from zero to a hundred, correct, or perhaps
5 a different number?

6 A Or more, yeah.

7 Q So my question then is, in looking at those
8 rates, how do you decide whether a particular rate is
9 a high rate, a low rate, an in-between rate or
10 something else?

11 A The comparison is to background, to general
12 population that doesn't take the drug, and then you
13 look at what happens with drug.

14 Q So you're saying --

15 A If there is no difference, that doesn't --
16 if there is no difference versus if there is a
17 difference, that is what we were looking at.

18 Q Okay. I understand now. So you're
19 comparing the adverse events reported for a
20 particular drug to the -- or I should say you're
21 comparing the rates or incidence of adverse events
22 reported for a particular drug to the rates or

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1 incidence of those adverse events in the general
2 population?

3 A Well, in the post-marketing arena you are
4 looking at reporting rates, so you're not looking at
5 incidence.

6 Q So reported rates?

7 A Uh-huh.

8 Q And you're making a comparison to see if
9 there's a difference between those two rates, is that
10 correct?

11 A Yes.

12 Q And do you know whether -- did you
13 perform -- did you perform that comparison in the
14 case of Plan B?

15 A I know Dr. Griebel looked at it, and she
16 probably asked the Office of Drug Safety as well as
17 the review team asked the Office of Drug Safety to
18 provide us data.

19 Q And was there any difference at all in the
20 reported rates of adverse events with respect to
21 Plan B compared to the background rates?

22 A There was no concern raised. The

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1 differences --

2 Q Hold on. That's not my question. It's not

3 whether the question -- whether a concern was raised.
4 My question is a numerical question or a statistical
5 question.

6 A It's not a statistical question because
7 there's no hypothesis testing.

8 Q Then it's a numerical question, quantifiable
9 question. Was there a difference in the figures of
10 the two rates, one for Plan B and one for the
11 background rate?

12 A Yes.

13 Q And that difference was of a certain
14 magnitude, is that correct?

15 A Yes.

16 Q And in looking at that magnitude, it sounds
17 like you and others --

18 A Right.

19 Q -- drew the conclusion that the magnitude
20 did not create a concern in your mind about Plan B,
21 is that correct?

22 A Right. This was with respect to ectopic

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1 pregnancies. It was a hundred times less than the
2 anticipated rate in the compared -- this time not to
3 the general population but to a more controlled
4 setting of clinical trials of pre -- of other
5 hormonal drugs. So the comparison --

6 Q That's fine. That's not my question. My
7 question is, in drawing the conclusion that the
8 difference shown did not raise a concern --

9 A Right.

10 Q -- what standard or measure did you or
11 others apply to reach that conclusion?

12 A We used the standard of the clinical trial
13 population of what is the ectopic pregnancy rate
14 there. And we compared it to what was the reporting
15 rate in Plan B. That was what was looked at, and
16 there was less with Plan B. So it did not signal a
17 problem.

18 Q So you're saying there were fewer adverse
19 events in this particular --

20 A With respect to that particular -- that
21 particular adverse event, yeah.

22 Q So fewer adverse events for Plan B than for

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1 the background population with respect to ectopic
2 pregnancies?

3 A In the clinical trial comparison.

4 Q Okay. Well, let me go back to my first

5 question, because I thought we established something
6 a little differently. Was -- let me first ask you,
7 was ectopic pregnancy the only adverse event that's
8 relevant in the consideration of Plan B?

9 A No.

10 Q Is ectopic pregnancy the only adverse event
11 that's ever been reported in connection with Plan B?

12 A With respect to serious adverse events, I
13 would have to actually take some time to find it.
14 But I think that may be so.

15 Q I didn't ask you about serious adverse
16 events. I just simply said, was that the only
17 adverse event?

18 A Well, the other adverse event -- the other
19 adverse events known with levonorgestrel related to
20 nausea and vomiting and some of the -- and so those
21 kinds of symptoms, nausea and vomiting, which people
22 frequently get with other medicines.

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1 Q And so did you ever compare the rates of
2 those adverse events to the background rates that you
3 referred to before?

4 A Nausea and vomiting?

5 Q Sure.

6 A Nausea and vomiting, because they're so
7 common -- they're common for not only taking drugs
8 but not taking drugs -- was looked at very carefully
9 in the controlled trial setting with Plan B when it
10 was first submitted for prescription use. And so
11 it's well described, it's in labeling, nausea and
12 vomiting, and there was nothing serious.

13 And so did we expect OTC use to have
14 different nausea and vomiting? No. We think it
15 didn't -- the formulation didn't change. It would
16 still be a labeled side effect that could be put in
17 the OTC prescription label and box so that people
18 would be aware.

19 Q Let me just ask one clarification question
20 and then we can move on. Is it your testimony that
21 the only adverse events associated with Plan B are
22 nausea, vomiting and ectopic pregnancy?

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1 A Well, Dr. Griebel here in her review brings
2 out that the Office of Drug Safety identified three
3 spontaneous abortions, one missed abortion, one
4 inevitable abortion, three European cases of
5 congenital anomalies in women who have used
6 levonorgestrel for emergency contraception. And she

7 states that this Division has previously reviewed
8 these teratogenic effects of contraceptive hormones
9 in early pregnancy and have concluded there is no
10 association between accidental use of these hormones
11 and adverse fetal outcomes.

12 Q So is your testimony then that the only
13 adverse events associated with Plan B are nausea,
14 vomiting and ectopic pregnancy?

15 A That's described in the post-marketing
16 safety database. There was an additional, one
17 foreign report of phlebitis. There was no evidence
18 of thrombotic events. That's what the written record
19 shows from Dr. Griebel.

20 Q All right. Well, let's move on to the next
21 element. You said the next element for requirements
22 for OTC switch were other potential harm. And the

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1 first concern under that element that you discussed
2 was whether Plan B would be taken correctly or
3 incorrectly, is that right?

4 A Right.

5 Q Now, as I understand it, both the Rx form of
6 Plan B and the proposed OTC form of Plan B has a
7 specific prescribed regimen for how to take the drug,
8 is that right?

9 A Right.

10 Q And that regimen is the first pill should be
11 taken as soon after the unprotected intercourse and
12 earlier than 72 hours, and that the second pill
13 should be taken 12 hours after the first pill, is
14 that correct?

15 A Right.

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19 MR. HELLER: Yeah, maybe we should try that
20 now. And Dr. Houn, I mean, do you want her to stay
21 in the room while we make the call or not? As far as
22 I'm concerned, she's welcome to be here, particularly

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1 if the magistrate might want to ask her something.

2 MR. WARSHAWSKY: Correct. You're right.
3 She should stay.

4 MR. HELLER: So let's go off the
5 videographer record and we will keep the -- we will
6 try to make the call now.

7 THE VIDEOGRAPHER: This marks the end of
8 videotape number two in the deposition of Dr.
9 Florence Houn. We're going off the record. The time
10 is 2:46 p.m.

11 (Discussion off the record.)

12 (The following testimony is a telephone
13 conference between counsel and the magistrate judge.)

14 MR. HELLER: Your Honor, this is Simon
15 Heller. I also wanted to let you know that the court
16 reporter who we have for the deposition we're
17 conducting is transcribing the call, if that's
18 acceptable.

19 THE COURT: That's fine.

20 MR. HELLER: And we also have present in the
21 room Dr. Florence Houn, H-O-U-N, who is the deponent.

22 THE COURT: Whose deposition?

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1 MR. HELLER: It's the deposition of
2 Florence --

3 THE COURT: No, who noticed it?

4 MR. HELLER: The plaintiffs did. And we're
5 at the moment in the midst of the defendant's
6 examination. I had completed my initial examination.
7 The reason we're calling is that during the lunch
8 break, or at the lunch break, as I was preparing to
9 leave the room, Dr. Houn asked me what was going to
10 happen after I concluded my examination of her,

11 essentially. I mean, I'm paraphrasing.

12 And I responded that the government, the
13 lawyers for the government would then possibly ask
14 her questions unless we ran out of time today for
15 that. And she became visibly upset to me. And I
16 inquired of her what was upsetting her. And she
17 indicated to me that she was, in essence, worried
18 about the government's examination of her.

19 Since the government is representing both
20 the defendant, that is the Agency, the FDA and its
21 Commissioner as well as the deponent, I became
22 somewhat concerned because it's quite unusual, I

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1 think, to have a witness concerned about her own
2 lawyers' examination of her. And let's see, what
3 else.

4 I think she indicated to me that she was
5 concerned that the testimony she was providing might
6 affect her future at FDA in some respect. She's
7 still an employee of the Agency. And at that point I
8 suggested to her that she might want to consider
9 having her own attorney.

10 That was the basic essence of the
11 conversation. I disclosed that on the record after
12 we returned from lunch. Mr. Amanat -- and Mr.
13 Warshawsky may correct me -- expressed his concern
14 that I may have violated professional ethics in
15 having this conversation outside the presence of
16 counsel. I informed him that I didn't initiate it,
17 and that it was not conducted for the purpose of
18 discovering information outside the presence of
19 counsel, but out of compassion for the witness who
20 seemed quite upset.

21 And I wanted to contact the Court and
22 disclose it to the court as well because I feel that

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1 if I have engaged in an ethical breach, I want to
2 inform the Court of that immediately. And that's in
3 essence what I wanted to do, and I wanted to do it
4 sooner rather than later.

5 I will also say just for the record that
6 also after we returned from lunch, the counsel for
7 the defendant conferred privately with the deponent.
8 And she at this point, at least as I understand it,
9 has decided to proceed with the government's lawyers
10 continuing to represent her.

11 THE COURT: Okay. And so are you still in
12 the middle of the examination?

13 MR. HELLER: Yes. The government -- we're
14 in the middle of the government's examination at this
15 point. And I just thought I wanted to get this to
16 the Court quickly because if there are ethical
17 concerns, I wanted to disclose them sooner rather
18 than later.

19 THE COURT: Well, is there any action you
20 want me to take?

21 MR. HELLER: Well, I mean, I will say that
22 initially when I had this conversation, I was

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1 concerned about a possible -- about some sort of
2 possible conflict in the representation of Dr. Houn,
3 given her being upset. And I -- certainly my concern
4 about that is somewhat allayed by her statement that
5 she wishes to proceed with government's counsel, with
6 the government as her counsel rather.

7 But I don't want any -- I don't think
8 there's any other actions I'm requesting. I just
9 wanted to make this disclosure because I think it
10 was, for me at least, a very unusual circumstance.

11 THE COURT: So you're not asking me to do
12 anything?

13 MR. HELLER: I'm not asking you to do
14 anything, but I guess I want to give the government
15 also an opportunity to ask the Court to do something
16 if the government wants.

17 THE COURT: Okay. Mr. Warshawsky?

18 MR. WARSHAWSKY: No, Your Honor, we don't --
19 Mr. Amanat made an objection on the record to the
20 conversation, but we also respect that Mr. Heller
21 raised this immediately and put it on the record as
22 well. We had a 20-, 25-minute conversation, we being

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1 Mr. Amanat and myself and Karen Schifter, had a 20-
2 to 25-minute conversation with the witness to explain
3 the nature of the representation, to explain her
4 various options, to assure her that if she wished to
5 adjourn the deposition for purposes of seeking
6 independent counsel or some further advice, that she
7 certainly was welcome to do that, and is still
8 welcome to do that.

9 We confirmed that understanding on the
10 record when we resumed. And our understanding of the
11 purpose of this call really was just to bring the
12 issue to the Court's attention so it wouldn't, I
13 guess, potentially fester and become an issue later
14 on.

15 THE COURT: Okay. All right. I will note
16 the conference and note that this was disclosed. And
17 that's about all, I guess, we need to do right now.

18 MR. HELLER: Thank you, Your Honor. We
19 appreciate your time.

20 MR. WARSHAWSKY: Thank you.

21 (The above telephone conference was
22 concluded at 2:56 p.m.)

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1 THE VIDEOGRAPHER: Here marks the beginning
2 of videotape number three in the deposition of Dr.
3 Florence Houn. We are back on the record, and the
4 time is 2:59 p.m.

5 BY MR. WARSHAWSKY:

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15 characteristic refutes concerns.

16 Q Let me follow up on that because I want to
17 try to clarify what I think one of your arguments is.
18 I'm going to put it very bluntly, and maybe that's
19 not fair. But it sounds to me with respect to the
20 issue of whether the dosing regimen for Plan B is
21 followed, that your argument is it doesn't really
22 matter?

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1 MR. HELLER: Objection. It characterizes
2 the witness's testimony as argument.
3 BY MR. WARSHAWSKY:

4 Q But your testimony is that it actually
5 doesn't really matter when a user takes the two
6 drug -- takes the two pills, and that the current
7 prescribed regimen as placed on the Rx label and as
8 proposed by the sponsor of the Plan B OTC switch is
9 not terribly relevant; is that what your testimony
10 is?

11 A No.

12 MR. HELLER: Objection. Argumentative.
13 BY MR. WARSHAWSKY:

14 Q Well, let me go back to the earlier point.
15 I believe that the issue that you've testified -- I
16 believe that you've testified previously today that
17 one of the concerns that Dr. Galson expressed was a
18 lack of data about younger adolescents, is that
19 correct?

20 A Yes.

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17 Q Correct. We're not talking about the --
18 we're talking about this trial, we're not talking
19 about other types of trials or other types of
20 products. Would three test subjects from the ages of
21 17 and under be a sufficient or adequate number to
22 draw meaningful conclusions about that age group?

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1 A The reason why I'm hesitating is I'm just
2 considering other precedents the Agency has had where
3 we don't require studies in under 17-year-olds
4 specifically related to, let's say, the recently
5 approved preventative vaccine for HPV, where again
6 it's very difficult to conduct trials relating to
7 enrolling minors and outcomes related to sexual
8 intercourse. One, it's hard to get informed consent
9 and you would need parental informed consent.

10 And so in some trials we don't, for
11 approval, we don't require these age group breakdowns
12 or a sufficient number of, for example, young boys
13 had to test whether they could correctly put on
14 condoms or not.

15 So I am thinking relating to Plan B in the
16 hypothetical situation where they could only enroll
17 three subjects under 17, and this is -- and we were
18 looking at the Actual Use Study in terms of use
19 correctly, and there were only three subjects to
20 evaluate. And would we be concerned that a
21 15-year-old would not be able to follow instructions
22 on the packaging to take it now and then in 12 hours.

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1 I think by and large, we would probably not
2 have major concerns. Since these indications are
3 discussed before an Advisory Committee, we also ask

4 the Advisory Committee their view on this. And so I
5 hope I've responded.

6 Q Well, I think you have, but let me clarify
7 because the question that I asked wasn't about other
8 trial designs or other products. But I believe at
9 the end of your answer your testimony is that, yes,
10 in fact, had there only been three test subjects ages
11 17 and below, you in your professional judgment would
12 consider that a sufficient number of test subjects to
13 be able to evaluate whether potential Plan B users in
14 that age group would be able to follow the prescribed
15 regimen?

16 MR. HELLER: Objection. Mischaracterizes
17 the witness's testimony.

18 BY MR. WARSHAWSKY:

19 Q Is that your testimony?

20 A In looking at the entire application, yes.

21 Q What does that mean, "in looking at the
22 entire application, yes"? Well, let me short-circuit

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1 that. You mean -- well -- no, let me ask you. What
2 do you mean "in looking at the entire application,
3 yes"?

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7 Q Let me ask a slightly different question.
8 In your professional opinion, would the Plan B OTC
9 switch application be approvable even in the complete
10 absence of the Actual Use Study submitted by Barr?

11 MR. HELLER: Objection. It calls for
12 speculation.

13 A Well, back in 2001 perhaps, there was an
14 agreement reached between the Agency that they would
15 conduct two studies to support this application. And
16 so I would have to carefully look at what those
17 agreements were, and if they submitted something
18 different, evaluate whether the absence of this study
19 and the inclusion of other studies was acceptable. I
20 don't -- I don't recall all those agreements and
21 how -- and how, you know, and I guess I would
22 actually defer to the Over-the-Counter Divisions and

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1 Office to help determine the acceptability of an
2 application that did not have that particular study,
3 which is really part of what the Office of the
4 Over-the-Counter Products and their division wanted
5 as part of the NDA submission.

6 BY MR. WARSHAWSKY:

7 Q I really didn't mean to ask you whether
8 Barr's failure to submit an Actual Use Study would
9 contravene some sort of obligation on their behalf,
10 thereby requiring the Agency to disapprove their
11 application.

12 But let me ask the question a little
13 differently. You testified a few moments ago that
14 you look at the entire application and you look at
15 the totality of the data. So my question then is, in
16 reaching your judgment that the Plan B application
17 should have been approved, was there any piece of
18 that application, let's say any of those different
19 studies, either by Gold or Raine or whoever, that you
20 could take away from that application and you'd still
21 believe that the application should be approved, or
22 was it all necessary to reach a final conclusion of

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1 approvability?

2 A I think the review team --

3 Q I'm just asking your opinion here.

4 MR. HELLER: I'm just going to interpose an
5 objection. The application, at least as far as I'm
6 aware, had something like over 80 volumes of
7 material, and you're asking her to decide on the spot

8 whether some little piece of that could be taken away
9 and still be approvable? If you want to show her the
10 full application submitted by Barr and have her look
11 through it, it's --

12 A I rely on the scientific staff to bring
13 their evaluation to their superiors. And in this
14 process that was defined, the Division makes a
15 recommendation to the Office. And I'm certain that
16 if the Division had major concerns about the
17 application or that they found something was missing
18 that they needed, they would let -- they would
19 reflect that in their evaluation.

20 They were prepared to -- I believe that they
21 were prepared to render favorable recommendations
22 even without Dr. Raine's or Dr. Gold's study or the

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1 Dial EC study. And I think the Advisory Committee
2 saw data that was reflective of the studies conducted
3 by Barr Incorporated, as well as the summary data
4 that Dr. Gold presented during the open public
5 hearing. And they voted on what they would recommend
6 in terms of looking at those data.

7 But in these reviews that the Division did,
8 there is more data than the December 2003 Advisory
9 Committee Meeting to try to address concerns that
10 senior management raised.

11 BY MR. WARSHAWSKY:

12 Q Let me ask you, in going through the Plan B
13 review process, did you reach an independent judgment
14 and conclusion as to whether the indication should be
15 approved, or are you in essence simply concurring
16 with Dr. Beitz and Dr. Griebel's and perhaps other
17 reviewers' analyses?

18 MR. HELLER: Objection. Vague.

19 A Yes, I have to provide my own assessment of
20 their evaluation.

21 BY MR. WARSHAWSKY:

22 Q And do you have to reach your own assessment

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1 of whether the OTC switch application should or
2 should not be approved?

3 A In this case Dr. Beitz was the lead for
4 that. So I provided her my assessment of the data
5 and my comments to her review. And she spoke for the
6 Office of Drug Evaluation 3 in her review.

7 Q Okay. Let's move on to another item that
8 you testified about earlier. You spoke about making
9 a, quote, overall benefit versus risk, end quote,

10 analysis of the application. Do you recall that?

11 A Uh-huh. Yes.

12 Q And in the course of your testimony about
13 that factor, you used two words that I'd like to ask
14 you about. You used the word "weighing" and you used
15 the word "ratio".

16 A Say it again.

17 Q Weighing, as in weighing the evidence, and
18 you used the word "ratio", as in a ratio of the
19 benefits to the risks. Now, to my mind those two
20 terms are mathematical or quantifiable type terms. A
21 ratio, for example, suggests a numerical comparison
22 of some sort. And weighing suggests some sort of

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1 amounts that are being weighed.

2 Whether or not that's the correct
3 impression, I guess my question is, when you
4 performed this benefit versus risk analysis, did you
5 assign any kind of numerical values or weights to the
6 different items on each side of that ratio? Or
7 alternatively, and I know this is compound, but just
8 to sort of jump ahead, alternatively, is it more of a
9 subjective judgmental process?

10 A Well, in weighing benefits, the numbers to
11 look at relate to numbers of unwanted pregnancies,
12 numbers of teenage pregnancy related deaths, numbers
13 of -- I'm using the word teen -- I'm focusing on
14 teenage because of --

15 Q Sure.

16 A -- the restrictions would prevent teenage
17 over-the-counter access to Plan B. You look at
18 numbers of abortions in that age group. So you can
19 look at numbers of hospitalizations for teenage-
20 related pregnancy morbidity.

21 So there are numbers for that -- for those
22 problems that this drug is meant to address. And

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1 then you look at risks. And so as I understand the
2 risks, I don't see that there's a toxicologic risk.
3 I am not aware of a cardiovascular risk. The risks
4 that Dr. Galson mentions as a potential harm of
5 taking it inappropriately to me is not a harm because
6 it's not that you take it wrong and you've overdosed,
7 or you've taken it wrong and there's a drug side
8 effect.

9 Then Dr. Galson's other concern relates to
10 whether this method may be substituted for regular
11 contraception or barrier contraception. And there

12 are data, numbers to address that concern for risks.
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4 Q Now, when you say our job is to the integral
5 of that, an integral is a mathematical term.

6 A Right.

7 Q Are you saying that you perform a
8 mathematical analysis on those various items that
9 were on those slides, or is it a judgmental analysis
10 where you look at the various items, and based on
11 your own experience and judgment, you reach a
12 conclusion as to which side of the ledger outweighs
13 the other side?

14 A Say that again.

15 MR. WARSHAWSKY: Could you read back the
16 question, please?

17 (Record read.)

18 A I guess I'm kind of at a loss to explain
19 that the discussion relates to prevention of serious
20 and life-threatening events versus the risks relating
21 to side effects of the drug, and which are mostly
22 nausea and vomiting. And so do I --

0165

1 BY MR. WARSHAWSKY:

2 Q Let me just clarify one thing. I'm not
3 asking about the merits of your judgment. That's not
4 what I'm trying to get at. I'm trying to understand
5 the process of your judgment. And so when you say
6 you look at the various items that were on the slide
7 or on the sheet of paper and you perform an integral
8 of them, my question is when you say that, do you
9 mean you're actually performing some sort of
10 mathematical or quantifiable analysis, or is it a
11 judgmental analysis, where it all just goes into your
12 brain and it results in a conclusion?

13 MR. HELLER: Objection. Argumentative.

14 A It's an evaluative process where we are
15 looking at data and we are making a conclusion about
16 that data.

17 BY MR. WARSHAWSKY:

18 Q Okay. I want to ask you just one more
19 question about this section. You mentioned before
20 that one of the risks identified by Dr. Galson was
21 whether or not the drug would be taken
22 inappropriately. And first of all, let me just

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1 clarify that by that you meant whether or not it
2 would be taken according to its prescribed regimen?

3 A I can find Dr. Galson's memo and --

4 Q Well, I'm asking you what your understanding
5 was when you said that. When you said that one of
6 the risks or the concerns was whether or not the drug
7 would be taken inappropriately, my question to you is
8 simply, by that did you mean whether or not the drug
9 would be taken according to its prescribed regimen?

10 A I believe Dr. Galson's concern was when
11 compared to older adolescents, over 17 years of age
12 and adults, early adolescents, ages 12 to 16, were
13 less likely to specifically comprehend Plan B
14 labeling instructions.

15 Q So is that referring to the prescribed
16 instructions for how you take the drug?

17 A Yes.

18 Q Okay. Isn't it an independent requirement
19 for approving an OTC switch that there be sufficient
20 evidence that the intended population of users is
21 able to take the drug according to its prescribed
22 regimen without the intervention of a learned

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1 intermediary?

2 A Yes.

3 Q And that's true regardless of what that drug
4 is, is that right?

5 A Yes.

6 Q Okay. Let's see. Let me show you some
7 documents now, please. The first document -- while
8 you're taking a look at it, I will just describe it
9 for the record -- are the meeting minutes for a
10 meeting held on February 5, 2001. And this document
11 is Bates stamped Tummino 30005 through Tummino 30019.
12 The very last page of this document shows an
13 electronic signature by Susan Allen dated March 6th,
14 2001.

15 And why don't you take a moment to look at

16 that document, and then I'll ask you a few questions.

17 A (Witness reviewing document.)

18 MR. HELLER: Steve, while she's looking at
19 that, do you have a sense of where you are, sort of
20 middle, beginning, end?

21 MR. WARSHAWSKY: I think I'll have a better
22 sense --

0168

1 MR. HELLER: After this document?

2 MR. WARSHAWSKY: -- after we get a couple of
3 documents done because I want to see how long it
4 takes to get through these. And if it doesn't take
5 as long as I -- as long as it doesn't take --
6 hopefully, it won't take very long. And then I just
7 have some selected items from her opening testimony.
8 I want to see how long it takes --

9 MR. HELLER: I was just going to ask for a
10 break at some point, if you think you have an hour
11 more or something maybe. But whenever you want.

12 MR. WARSHAWSKY: I may have that much more.

13 MR. HELLER: Would it make sense for us to
14 break now while she's reviewing the document maybe
15 for five minutes?

16 MR. WARSHAWSKY: We can do that. Sure. And
17 you know what, maybe -- why don't I do this first.
18 Why don't I present all the documents, and then
19 during the break if the witness wants to continue
20 reviewing the various ones, that might speed the
21 process a little bit.

22 MR. HELLER: Yeah. And let me also ask the

0169

1 videographer how much we have left on the tape?

2 THE VIDEOGRAPHER: An hour and 15 minutes.

3 MR. HELLER: We're fine then.

4 MR. WARSHAWSKY: Would that be okay with
5 you?

6 THE WITNESS: That sounds good.

7 BY MR. WARSHAWSKY:

8 Q Let's just introduce the other few
9 documents. The next document I'd like to show you,
10 Dr. Houn, is another set of meeting minutes. This
11 one is for a meeting dated September 23rd, 2002. And
12 it bears Bates stamps Tummino 30252 through Tummino
13 30257. And the last page of this document has an
14 electronic signature by Daniel Shames, S-H-A-M-E-S,
15 dated October 22, '02.

16 A Okay.

17 Q The third document I'd like to show you is a

18 set of meeting minutes from a meeting dated December
19 2, 2003. This has Bates stamps of Tummino 30435
20 through Tummino 30439. And this particular document
21 on the last page has an electronic signature of John
22 Jenkins, dated December 23rd, 2003.

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1 And the last document I'd like to show you
2 is a Summary of the Advisory Committee Meeting for
3 Plan B. That meeting was held on December 16, 2003.
4 And this particular document has Bates stamps Tummino
5 30421 through Tummino 30425. And this document does
6 not have an electronic signature page. So let me
7 show you that document. And why don't we take a
8 break at this time for five, ten minutes.

9 MR. HELLER: Thank you.

10 THE VIDEOGRAPHER: We're going off the
11 record. The time 3:45 p.m.

12 (Recess.)

13 THE VIDEOGRAPHER: We are back on the
14 record. The time is 3:51 p.m.

15 BY MR. WARSHAWSKY:

16 Q Dr. Houn, I provided you with four different
17 documents. I'd like to start by looking at the
18 document of the meeting minutes dated February 5,
19 2001.

20 A Uh-huh.

21 Q Do you have those?

22 A Yes.

0171

1 Q Have you ever seen these meeting minutes
2 before?

3 A Yes.

4 Q Did you attend this meeting?

5 A Yes.

6 Q Sitting here today, do you have an
7 independent memory or recollection of this meeting?

8 A I have a vague recollection of this meeting.

9 Q Let me ask you. Since you've been at FDA,
10 and specifically during the time that you were
11 Director of ODE-3, was it the general practice within
12 CDER to prepare meeting minutes of meetings held like
13 the one we see here?

14 A Yes.

15 Q And was it your own general practice to
16 review the meeting minutes of meetings that you
17 attended?

18 A Yes.

19 Q Okay. And has it been your experience that

20 the meeting minutes prepared of meetings that you
21 attended accurately reflected the content of those
22 meetings?

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1 A The meeting minutes are more likely to
2 reflect my recollection of the content when they
3 involve Office and Division and sponsor attendees
4 only.

5 Q Maybe my last question wasn't clear, or
6 maybe it was, but I'm going to ask it again to make
7 sure I understood your answer. My question was, in
8 your experience when you reviewed the minutes of
9 meetings that you attended, were those minutes -- did
10 those minutes accurately reflect the content of those
11 meetings?

12 MR. HELLER: Objection. Asked and answered.

13 A As I said, those meetings that I attended
14 and other Office and Division personnel attended,
15 whether they're with sponsors or without, probably
16 have a more accurate reflection of what actually
17 happened than meetings which I attended and I
18 reviewed the minutes, but I was not the final
19 decision-maker on the outcome of the minutes.

20 BY MR. WARSHAWSKY:

21 Q Okay. Well, let me ask the question
22 directly with respect to the minutes of the

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1 February 5, 2001 meeting. Do you know whether these
2 minutes accurately reflect what occurred during this
3 meeting, or would you have to look at individual
4 items separately?

5 A I would have to do that. And my
6 recollection of this one, this particular meeting, is
7 more vague than other meetings.

8 Q Okay. Okay. Well, let me ask you some
9 questions about this meeting. Do you recall what the
10 purpose of this February 5, 2001 meeting was?

11 A Yes.

12 Q What was that?

13 A That the sponsor was interested in switching
14 from over-the-counter status for their product -- I
15 mean switching from prescription status of their
16 product to nonprescription status.

17 Q And you're referring to the Women's Capital
18 Corporation, the sponsor of Plan B?

19 A Yes.

20 Q And so they were interested in making this
21 switch; hence, why was this meeting held?

22 A This meeting was held to discuss their plans
0174

1 for providing us study data to support that
2 application switch.

3 Q Do you know who asked for this meeting?

4 A I believe it was sponsor initiated.

5 Q Let me ask you about some of the entries in
6 these notes. Could you please turn to the third page
7 of these notes, which is Tummino 30007?

8 A Yes.

9 Q And from this page onto, oh, the next five,
10 six, seven, eight pages, we see a series of numbered
11 questions followed by a series of comments that are
12 more or less extensive in bullet point form. Do you
13 see that?

14 A Yes.

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9 Q What is DRUDP?

10 A Division of Reproductive and Urologic Drug
11 Products.

12 Q Now, I see that for Question 6 and for
13 Question 7 it indicates -- and for Question 8 and for
14 Question 9 and for Question 11, it indicates that the
15 answers were provided by the DRUDP. Same question as
16 before. As a practical matter, who was providing
17 this information on behalf of the Reproductive and
18 Urological Drug Product Division?

19 A I believe it was Dr. Daniel Davis, Medical
20 Officer.

21 Q And that, just to clarify on the first page
22 of the meeting minutes, that would be Daniel Davis,

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1 M.D., Medical Officer of the Division of Reproductive
2 and Urologic Drug Products?

3 A Yes.

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15 Q Now, if you turn please to -- I don't know,
16 it looks like the eighth or ninth page, at the bottom
17 it's Tummino 30013. At the -- I'm sorry. Let me
18 just clarify something. There's another acronym on
19 page Tummino 30011. It says CDRH, "answer is
20 provided by CDRH". Does that refer to the Center for
21 Devices and Radiologic Health?

22 A Yes.

0180

1 Q And then on the page Tummino 30013, at the
2 top there's something referred to as DDMAC. Would --
3 let's see, would that be the Division of Drug
4 Marketing Advertising and Communications?

A Yes.

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10 Q Is there any other way, generally speaking,
11 to determine in terms of absolute numbers whether you
12 have a sufficient number of test subjects in any
13 particular group?

14 A I think it would depend on -- I think it
15 would depend on the actual question in mind, what
16 data you do have in existence, whether that data is
17 sufficient to give you confidence that if you're
18 missing data from a strata, that that can be
19 interpolated or extrapolated. It also depends on
20 what the specific question is.

21 And then you will see here there's always
22 opportunity for the sponsor to provide us with a

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1 rationale on why they're, for example, unable to
2 enroll or unable to study in a specific population.
3 So the issue of then does the sponsor have sufficient
4 numbers in a study can be revisited with the Agency.

5 Q To your knowledge, were Dr. Galson or
6 Dr. Woodcock involved in this February 5, 2001
7 meeting?

8 A I'm just trying to recall if Dr. Galson even
9 was at CDER at that time. I don't -- I can't recall.
10 He might have come around that time but --

11 Q And who was the Commissioner in
12 February 2001?

13 A I don't believe there was a Commissioner.

14 Q Do you know if there was anyone from the
15 Commissioner's Office who was involved in the
16 February 5, 2001 meeting?

17 A I don't -- I don't recall.

18 Q Okay. If you could please turn now to the
19 next document that I've given you, which is the
20 meeting minutes from the September 23, 2002 meeting.
21 Do you have that?

22 A Yes.

0184

1 Q Let me just first ask you, have you ever
2 seen this document before?

3 A Yes.

4 Q And did you attend this particular meeting?

5 A Yes.

6 Q Sitting here today, do you have an
7 independent recollection of what occurred at this
8 meeting?

9 A I believe I do.

10 Q Can you tell me generally what was the
11 purpose of this September 23, 2002 meeting?

12 A The sponsor was preparing to submit an
13 application for Plan B OTC switch, and we were
14 discussing some of their findings from their
15 development program.

16 Q Okay. So is it fair to characterize this as
17 another one of the discussions that the sponsor had
18 with CDER to discuss its planned application for an
19 Rx to OTC switch to Plan B?

20 A Right.

21 Q Is it fair to say that this meeting was
22 similar in nature to the February 5, 2001 meeting?
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1 MR. HELLER: Objection. Vague.

2 A No. This was a little different.

3 BY MR. WARSHAWSKY:

4 Q How was this one different?

5 A Well, I believe this one, they provided us
6 with some preliminary information, and the other
7 meeting they had no information.

8 Q Okay. So this one, there was -- well, you
9 just answered that. Do you remember whether
10 Dr. Woodcock, Dr. Galson or anyone from the
11 Commissioner's Office participated in this
12 September 23, 2002 meeting?

13 A No. But we did have to report this meeting
14 to them. This was after, I think, the June 5th
15 briefing we did for Dan Troy and Dr. Crawford in the
16 Office of Commissioner. And we had to generate a
17 memo after that meeting because there was concern
18 about the Department needing to know about this
19 application coming in and their concerns about the
20 mechanism of action of Plan B.

21 So we wrote a memo to Dr. Crawford and to
22 Dan Troy, who in the June 5th meeting or maybe
0186

1 subsequently after --

2 Q Can I --

3 A Yeah.

4 Q I'm going to have to cut you off. I'm not
5 asking about the June 5th meeting. We have documents
6 about those. And I'm just simply asking about the
7 folks that participated in the September 2002
8 meeting. And I believe your testimony was, no, but
9 we provided -- we gave them information about this
10 meeting?

11 A Yeah, they did not attend. And we did have
12 to report the occurrence of this meeting and the
13 substance of the meeting. I'm trying to figure --
14 trying to recall if this was actually Dr. Jenkins
15 taking the information further up, which probably,
16 since I have no direct recollection myself of doing
17 it, probably since he was a senior person there, he
18 did that.

19 Q Okay. That was going to be my next
20 question, whether you knew who reported information
21 about the meeting. And you believe it was Dr.
22 Jenkins?

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1 A In addition, Ms. Lee Lemley works for the
2 Office of the Center Director, and as a Executive
3 Operations Officer, her job is to report to the
4 Office of the Commissioner, CDER events that they
5 need to get involved in. So she my also have had a
6 role.

7 Q Do you know if Lee Lemley, in fact,
8 communicated the substance of this meeting to either
9 the Commissioner's Office or the Office of the Center
10 Director?

11 A I'm thinking that part of her
12 responsibilities is to provide that information. But
13 specifically for this meeting, I don't recall.

14 Q And but you -- do you -- let me just clarify
15 something. Do you specifically recall that Dr.
16 Jenkins did make some sort of report, or are you also
17 just assuming that he did, given his role?

18 A No, I believe that this was discussed, that
19 because we had this Commissioner's briefing for them,
20 we didn't walk out of the room saying, that's it,
21 there was not an understanding. And I said it's
22 because John was the senior one, that he would take

0188

1 this information back up to probably Steve who would
2 then convey it.

3 Q Do you know if Dr. Jenkins spoke to Dr.
4 Galson about this meeting?

5 A I'm sure this also got into our report,
6 which I remember printing. No, no, no. I'm not sure
7 this got into the report. Let's see, this is 2002.
8 I'm sure that this meeting -- this is called a --
9 this meeting in anticipation of their submission was
10 communicated to higher-ups. And if -- yes, I'm sure
11 that it happened.

12 Q My question is, do you know that it

13 happened?

14 A I know it happened because it was not a
15 surprise that they came in. So they -- they knew
16 that the -- that Women's Capital Corporation were
17 planning to submit the NDA.

18 Q Okay. Now, if we take a look at this
19 document, like the one we looked at before, it has a
20 series of numbered questions followed by answers with
21 one or more bullet points. Do you see that?

22 A Yes.

0189

1 Q Now, again, are these questions that were
2 posed to FDA by the sponsor?

3 A Yes.

4 Q And do the answers reflect the information
5 or advice or recommendations provided by CDER back to
6 the sponsor in response to these questions?

7 A Yes.

8 Q Do you know specifically who provided these
9 answers to the sponsor in response to their questions
10 during this September 23rd, 2002 meeting?

11 A I don't recall the person who conveyed this
12 information.

13 Q Do you have a recollection of the
14 back-and-forth question and answering going on
15 during this meeting?

16 A Some.

17 Q Okay. Do you -- do you have any reason
18 yourself to doubt the accuracy of the September 23rd,
19 2002 meeting minutes?

20 A No.

21 Q Do you have any reason to doubt the accuracy
22 of the September 5, 2001 meeting minutes, which we

0190

1 just looked at a few minutes ago?

2 A No.

3 Q Let's take a look at the third document I
4 provided you, which is Memorandum of Teleconference
5 Meeting. And it's dated October 9, 2003. Thank you.
6 Do you see that?

7 MR. HELLER: Do I have that document?

8 A October 9, I don't have that.

9 MR. HELLER: We don't have the October 9
10 document.

11 MR. WARSHAWSKY: What was the third one I
12 gave you?

13 MR. HELLER: You gave me one December 2,
14 2003 and December 16, 2003.

15 THE WITNESS: That's the same case with me.
16 MR. WARSHAWSKY: I'm sorry. That was the
17 wrong one. He pulled the wrong document.
18 MS. SCHIFTER: Do you want to skip ahead and
19 give me the number and I'll go find it?
20 MR. WARSHAWSKY: Sure. Can I have those
21 back because I'm not going to --
22 MR. HELLER: Either of these?

0191

1 MR. WARSHAWSKY: No, the one that --
2 MR. HELLER: This one?
3 MR. WARSHAWSKY: Yeah, this December 2nd,
4 I'm not interested in December 2nd.
5 MS. SCHIFTER: What numbers?
6 MR. WARSHAWSKY: I'm looking for Tummino
7 30386.
8 MS. SCHIFTER: To what?
9 MR. WARSHAWSKY: To 90.
10 MS. SCHIFTER: And you need two copies?
11 MR. WARSHAWSKY: I need two copies, yes. So
12 let me clarify for the record that the document
13 previously provided to the witness, which is the
14 Meeting Minutes dated December 2nd, 2003, was not the
15 intended document, and we'll be getting the correct
16 document in a moment.

17 BY MR. WARSHAWSKY:

18 Q In the meantime, why don't we skip to the
19 last document that I provided you, and I hope it's
20 the right one, the Internal Report of the Advisory
21 Committee Meeting from December 16, 2003. Do you
22 have that?

0192

1 A Right. Yes.
2 Q Okay. Good. Let me first ask you whether
3 you've seen this document before?
4 A Yes.
5 Q And did you attend the Advisory Committee
6 Meeting?
7 A Yes.
8 Q Have you in addition to attending
9 the meeting -- strike that. Did you attend the
10 entire meeting?
11 A Yes.
12 Q And in addition to attending the Advisory
13 Committee Meeting, have you ever had a chance or had
14 occasion to read the hearing transcript?
15 A Yes.
16 Q I'd like to ask you a few questions. Let's

17 see. Now, this particular document has a few pages
18 that describes who attended, it describes the agenda,
19 and then it gives in the last few pages the questions
20 posed to the Committee and a tabulation of their
21 votes. Is that a correct summary?

22 A Yes.

0193

1 Q Okay. I would like to direct your attention
2 to the last page of this document, which is Tummino
3 30425. And before I ask you a specific question
4 about this, let me ask you just a few general
5 questions about the Advisory Committee itself.

6 A Yes.

7 Q What is the purpose of an Advisory Committee
8 Meeting of this type or, for example, or for that
9 matter, the purpose of this particular Advisory
10 Committee Meeting?

11 A The purpose of each Advisory Committee is
12 laid out in Part 14 of the Regulations. Each one has
13 a specific function. The purpose of the -- of this
14 Advisory Committee was to review the application for
15 OTC -- well, yes, nonprescription marketing of
16 Plan B, and to discuss questions that related to
17 whether there was sufficient data to support that
18 switch application.

19 Q Do you know what documentation or other
20 materials were provided by CDER to the Advisory
21 Committee, either in advance or at the time of the
22 joint meeting, relating to Plan B?

0194

1 A Yes. The Center For Drug Evaluation
2 Research compiles a briefing document for the
3 Advisory Committee members. In addition, the sponsor
4 provides their briefing document.

5 Q Did you participate in preparing the
6 briefing document for CDER to provide to the Joint
7 Committee in this case?

8 A From a supervisory level, I ensured that the
9 document met its deadlines for processing to be
10 distributed to the Advisory Committee members.

11 Q Did you have any role in the actual content
12 or substance of that document?

13 A I would probably state that Dr. Beitz may
14 have had more of a role than I did.

15 Q Do you recall how long a document this was
16 in terms of the number of pages?

17 A No.

18 Q Can you give an estimate, more than ten,

19 less than 100, 250, whatever it may have been?

20 A I believe it was less than an inch thick.

21 Q And do you know what was contained in this
22 briefing document?

0195

1 A What was contained in the document were
2 individual reviewers' preliminary assessment of the
3 application data.

4 Q And you said also that the sponsor provided
5 a briefing document as well, is that correct?

6 A Yes.

7 Q Do you remember seeing that particular
8 document in this case?

9 A I don't remember that document.

10 Q Okay. So how soon in advance of the meeting
11 is this briefing document provided to Committee
12 members? And I'm referring now to the CDER document.

13 A The attempt is to get the document to them
14 several weeks before the meeting, like two or three
15 weeks before the meeting.

16 Q Do you remember how soon in advance of the
17 meeting in this particular case the briefing document
18 was provided?

19 A No, I don't know the exact time.

20 Q But the general practice was two to three
21 weeks?

22 A Yes.

0196

1 Q Now, you've referred to the Advisory
2 Committee votes on several occasions during your
3 testimony today, is that correct?

4 A A few times.

5 Q Are those votes binding in any way on the
6 FDA?

7 A No.

8 Q What sort of weight is to be accorded the
9 Advisory Committee votes?

10 MR. HELLER: Can I ask to clarify, do you
11 mean by the FDA?

12 BY MR. WARSHAWSKY:

13 Q Yes, by the FDA or by CDER.

14 A Well, the Advisory Committee process, in my
15 mind, is a very important process. And I believe the
16 intent of the Federal Advisory Committee Act and the
17 regulations that support it wish the government to
18 seriously involve and consider advice given to us by
19 non-governmental as well as other members appointed
20 to these committees.

21 Certainly, industry views these meetings
22 very seriously because they know that the decisions
0197

1 and recommendations by the Advisory Committee are
2 taken by the staff equally seriously.

3 Q Are you aware of any statutory or regulatory
4 or policy guidelines that prescribe or require a
5 certain amount of weight or emphasis to be accorded
6 the Advisory Committee votes by CDER?

7 A I think there's probably language in the
8 Federal Register Notice of 1979, when Part 14 was
9 promulgated, that states the importance of this
10 Advisory Committee process. You know, I do know the
11 statute also refers -- the FD&C refers to the
12 Secretary impaneling experts to seek scientific
13 expertise on clinical investigations.

14 So I believe that given that the intent of
15 Congress was for us to have Advisory Committees and
16 so enacted and so were put forth in regulations, that
17 the weight accorded to these should be commensurate
18 with the amount of regulation that covered them.

19 Q Okay. In your professional opinion, do you
20 believe that the members of the Advisory Committee
21 for Plan B were sufficiently informed to render a
22 valid scientific and regulatory judgment with respect
0198

1 to whether Plan B should be made over-the-counter?

2 A Yes.

3 Q I would like to direct your attention to the
4 bottom of this last page of the document, Question 6,
5 which was the conclusion question posed to the
6 Advisory Committee asking about whether they
7 recommended the drug to be switched.

8 But I really want to direct your attention
9 to the comments underneath it. And it says, "If yes,
10 any modifications to labeling or distribution," and
11 then in italics we have the comments written,
12 "Phase 4 monitoring for changes in contraceptive
13 practices, surveillance for STDs, drug interactions,
14 effects of long-term use, implementation of the CARE
15 program" -- and that's capital C, capital A, capital
16 R, capital E -- and then "adolescent use patterns and
17 comprehension". Do you see where I'm reading?

18 A Yes.

19 Q Do you recall members of the Advisory
20 Committee Meeting making various recommendations --
21 making rather -- strike that. Do you recall members
22 of the Advisory Committee making recommendations for

0199

1 Phase 4 monitoring for these various items or issues?

2 A Yes.

3 Q Can you describe what Phase 4 monitoring
4 means?

5 A Phase 4 describes a period of drug studies
6 after marketing. It's in the regulation.

7 Q Okay. So this is referring to studies that
8 would go on after a drug has been approved for
9 general marketing?

10 A For in this case over-the-counter -- or
11 nonprescription status, excuse me.

12 Q Okay. And how long does Phase 4 monitoring
13 last?

14 A It lasts continuously. Your commitment for
15 a Phase 4 study will have a finite deadline, such as,
16 for example, if there was a Phase 4 study for
17 studying first, one, change in contraceptive
18 practice, the sponsor would propose what that study
19 would look like, and they would propose an end date
20 as well as beginning date. But in terms of Phase 4,
21 Phase 4 is post-marketing, the FDA's monitoring for
22 adverse events goes on indefinitely.

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1 Q Now, in terms of the Phase 4 monitoring
2 recommended here by the different members of the
3 Advisory Committee, what sort of monitoring is this
4 referring to?

5 A A study, a surveillance study.
6 Epidemiologic surveillance studies are common.

7 Q And who would perform that study?

8 A Usually these are commitments we obtain from
9 the sponsor.

10 Q So as part of the approval process, you'd
11 require them to perform some kind of Phase 4
12 surveillance study?

13 A Yes.

14 Q Now, in this case why did the members -- and
15 obviously we're not referring to all the members, but
16 whichever members made these recommendations -- why
17 did these members make the recommendation that there
18 be Phase 4 monitoring for these various issues or
19 items?

20 MR. HELLER: Objection. Calls for
21 speculation.

22 A Well, their reasons for wanting the study

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1 are well articulated in the transcript, and there are

2 differing ones. And I can go back to the transcript
3 and review them for you.

4 BY MR. WARSHAWSKY:

5 Q No, that's okay.

6 A But they're there. I've seen them.

7 Q Let me ask you some general questions then.

8 Is it fair to say that one of the reasons why one or
9 more members of the Advisory Committee recommended
10 Phase 4 monitoring was their concern that there was
11 insufficient data in the present application to
12 sufficiently answer particular questions like the
13 ones raised here on this page?

14 A They felt that if you are -- if they -- it
15 depends on the member. You would have to go back to
16 the transcript. If they voted no, that this
17 shouldn't be approved, and there are members that did
18 that, their reasons overlap these, there are other
19 members who voted for approval saying that there was
20 sufficient data, but in addition it would be
21 desirable to have additional information.

22 Q I'd like to focus on that last group, the

0202

1 folks who voted for approval but said that in
2 addition it would be desirable to have additional
3 information.

4 A It's desirable because there is no
5 regulation that sponsors must conduct the study. And
6 these are --

7 Q I guess my question is, if the drug's
8 already been approved for over-the-counter sales,
9 based on the existing data, what's the purpose of
10 this post-market surveillance? Does it anticipate
11 that the drug might actually be withdrawn from
12 over-the-counter sales?

13 A No. The purpose of this is to obtain
14 information that may be helpful such as in labeling,
15 and because there might be some information gained
16 where a warning needs to be placed or a precaution.
17 And if you look at the over the -- other applications
18 approved over the -- for nonprescription marketing,
19 they will also include Phase 4 study commitments.

20 Q Is there any other significance to a Phase 4
21 study commitment other than potential labeling
22 changes?

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1 A There might be other information that the
2 sponsor and FDA could use for either improving
3 educational efforts or in this case the CARE program

4 to make it more effective for consumers.

5 Q Okay. I'd like now to turn to the document
6 I meant to show you earlier. And this document --
7 let me describe it for the record. It's a memorandum
8 of a teleconference meeting dated October -- rather
9 the meeting date is October 9, 2003. The document
10 has Bates stamps Tummino 30386 through Tummino 30390.
11 The last page of this document bears an electronic
12 signature of Charles Ganley dated November 7th, 2003.

13 Why don't you take a moment to look through
14 that document. And I have just a few questions about
15 it.

16 MR. WARSHAWSKY: How much time is left on
17 the tape?

18 THE VIDEOGRAPHER: 18 minutes.

19 MR. WARSHAWSKY: And this is our last tape?

20 THE VIDEOGRAPHER: Unless you want me to run
21 to my car. I have more in my car.

22 MR. WARSHAWSKY: We're going to need one

0204

1 more tape, because you're going to have a few
2 questions.

3 MR. HELLER: I might have a few questions.
4 But do you know --

5 MR. WARSHAWSKY: I'm going to have more than
6 18 minutes.

7 MR. HELLER: Do you know how much more than
8 18 minutes, roughly?

9 MR. WARSHAWSKY: I'm going to guess half an
10 hour.

11 MR. HELLER: Okay. Thanks. So shall we go
12 off the record now and he's going to go get the tape,
13 the other tape? Is that what we're doing right now?

14 THE WITNESS: That would be good.

15 MR. WARSHAWSKY: Okay. Sure, that would be
16 fine. Why don't we do it that way.

17 THE VIDEOGRAPHER: This marks the end of
18 videotape number three in the deposition of Dr.
19 Florence Houn. We're going off the record. The time
20 is 4:43 p.m.

21 (Recess.)

22 THE VIDEOGRAPHER: Here begins videotape

0205

1 number four in the deposition of Florence Houn.
2 We're back on the record. The time is 5:01 p.m.

3 BY MR. WARSHAWSKY:

4 Q Dr. Houn, I'd like to ask you just a few
5 quick questions about the Phase 4 monitoring before

6 we move on. You testified earlier that on some
7 occasions the FDA negotiates with a sponsor for them
8 to do a Phase 4 survey as part of the FDA's decision
9 to approve an OTC switch application. Is that
10 correct?

11 A Yes.

12 Q My first question is, when the FDA or CDER
13 approves an OTC switch application, does CDER always
14 expect or require the sponsor to conduct a Phase 4
15 survey?

16 A They're called Phase 4 post-marketing
17 studies, and it's very usual. There are thousands of
18 Phase 4 post-marketing studies and --

19 Q I'm just referring now to OTC switch
20 applications.

21 A Yes, and they are also required of OTC
22 switch. And I believe the OTC switch application I

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1 was involved in that was a major OTC product,
2 Prilosec OTC, I believe that included some Phase 4
3 commitments as well. I'm sorry. I'm not speaking up
4 loudly.

5 Q When you -- you said just a moment ago that
6 it was required, so I just wanted to clarify. Is a
7 Phase 4 study always required as part of an OTC
8 switch approval?

9 A The OTC folks would probably best answer
10 that, but it is not unusual to have these commitments
11 prior to approval.

12 Q Okay. Okay. All right. Let's move on to
13 the next document, please, or the last document.
14 Right. This is the Memorandum of Teleconference
15 Meeting. The meeting date was October 9, 2003. And
16 this document is Tummino 30386 through Tummino 30390.
17 Do you have that document in front of you?

18 A Yes, I do.

19 Q Do you recognize this document?

20 A Yes.

21 Q You've seen it before?

22 A Yes.

0207
1 Q Did you attend the meeting that's
2 memorialized in this document?

3 A Yes.

4 Q Sitting here today, do you have an
5 independent recollection of what took place during
6 this teleconference meeting?

7 A Yes.

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14 Q Well, let's move on because I know we all
15 want to move on. And I won't be asking you about any
16 of these documents anymore.

17 I just want to follow up for on a few items
18 from your earlier testimony this morning. You
19 testified on a number of occasions about the
20 January 15, 2004 meeting at which Dr. Galson
21 presented his views about the insufficient data for
22 the younger age group?

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1 A Yes.

2 Q And Mr. Heller asked you at one point what,
3 if anything, you found striking about that
4 presentation by Dr. Galson. And your testimony was
5 at this particular moment -- you've testified about
6 this meeting on several occasions -- but part of your
7 testimony was that you found it unusual -- actually,
8 your actual words were, quote, very unusual, because
9 you said the offices had not finished the evaluation
10 process and were still getting data regarding
11 adolescent use of emergency contraception. Do you
12 remember that testimony?

13 A Yes.

14 Q Okay. And I wanted to ask you a couple of
15 questions about this, because isn't it true at the
16 time of the January 15, 2004 meeting, that the PDUFA
17 target date for issuing a decision on Plan B was in
18 early February of that year?

19 A Yes.

20 Q So the decision target date for Plan B as of
21 the time of the January 15, 2004 meeting was only
22 roughly three or four weeks away, is that right?

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1 A Right.

2 Q And at that time isn't it true that there
3 were several reviewers who had drafted their reviews
4 of the Plan B application?

5 A Everybody, I think, was in process.

6 Q And there were some folks who had completed
7 theirs?

8 A I don't know for Office of Drug Evaluation
9 5. I know for -- I know more about Office of Drug
10 Evaluation 3.

11 Q Now, you also testified previously in
12 response to my question that the material provided to
13 the Advisory Committee was sufficient for them to
14 reach an informed decision as to whether to recommend
15 that Plan B be approved for over-the-counter status.
16 So I guess in -- and you remember giving that
17 testimony, right?

18 A Yes.

19 Q So I guess my question here is, aren't you
20 overstating the significance of when Dr. Galson made
21 this presentation, because at this point in time
22 there already had been a lot of data generated, there

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1 already had been some reviews completed and several
2 in process, and there was in fact more material
3 available at that point in time than had been
4 presented to the Advisory Committee, right?

5 A We didn't understand how Dr. Galson could
6 come to his decision. So it wasn't a presentation,
7 it was his decision, when we were still in the middle
8 of conversations with primary investigators like Dr.
9 Gold to give us additional information, and Dr. Raine
10 as well.

11 And in fact in that meeting we had the
12 primary reviewers and Dr. Griebel tell him the
13 additional data they gathered because of concerns
14 about age were known at that point to the review
15 group, that these -- that those concerns may be such

16 that would preclude upper management from wanting
17 this application approved.

18 Q Well, let me ask this a little differently.
19 Are you aware of any statutory or regulatory
20 guidelines that required Dr. Galson to abstain from
21 reaching his own decision on Plan B until his
22 subordinate staff members had completed their reviews
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1 of the application?

2 MR. HELLER: Objection. There's been no
3 testimony that it was his own decision.

4 MR. WARSHAWSKY: Well, she just said that he
5 made a decision.

6 MR. HELLER: Sorry.

7 A He presented that decision to us. I thought
8 that in Part 10 requiring for the -- requirements for
9 the Administrative Record saying that major agency
10 decisions had to be written is in the regulation.

11 BY MR. WARSHAWSKY:

12 Q I'm not referring to a final official
13 decision. You said that he had essentially made up
14 his mind. So let's use that terminology.

15 A Yes.

16 Q So my question is, are you aware of any
17 statutory or regulatory requirement that prohibited
18 Dr. Galson, or for that matter Dr. Woodcock or Dr.
19 McClellan or anyone else, from making up his or her
20 mind about the Plan B application before the
21 subordinate staffers had completed their own reviews
22 of the application?

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1 A As I understood, their concerns related to
2 lack of information. So I think the concern we had
3 was at that time we knew we were gathering more
4 information; and if they were concerned about a lack
5 of information, that could be addressed. So to make
6 a decision that there was lack of information and
7 then be informed that we're gathering more
8 information and -- and whether this exercise was
9 fruitless is probably contrary to how matters had
10 been handled previously in terms of a regulatory
11 decision about application.

12 And I'm trying to recall -- you asked me if
13 there was any statutory requirement or regulatory
14 guideline. Well, I certainly know now there are
15 current guidelines relating to the requirements of
16 good review management practices that tell us what
17 has to be completed before the next level makes a

18 decision. I just cannot tell you back in January
19 15th of 2004 were those guidelines which are now
20 published in draft and in, you know, what stage of
21 acceptance they were.

22 Q Okay. I think you sort of answered my

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1 question. Let me ask a slightly different question.
2 Are you aware of any statutory or regulatory
3 requirements that prohibited Dr. Galson or Dr.
4 Woodcock or Dr. McClellan or anyone else from making
5 up their minds about the Plan B application before
6 the subordinate staffers had completed their searches
7 for additional data?

8 A By default, drugs have a nonprescription
9 status. The exemption is in Section 503-B-1. And
10 because of that, in this case to say that there's a
11 lack of data on a potentiality for harmful effect,
12 again, I would state that the construct of how this
13 law was created was that -- that it provides for
14 attaining data for this concern to be addressed.

15 Q And I don't want to get into any kind of
16 legal discussion or debate here because I think the
17 law is whatever the law is. So if I understand your
18 testimony, your position is that -- well, strike
19 that. I don't need to try to summarize it.

20 Okay, so, but let me ask you this, two
21 questions and then we'll move on. The first question
22 is, you already testified that the members of the

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1 Advisory Committee Meeting had a sufficient body of
2 data from which to draw a conclusion about the OTC
3 status of Plan B. So doesn't it logically follow if
4 the body of evidence available to Dr. Galson was even
5 larger than the body of evidence presented to the
6 Advisory Committee Meeting, that he also had a
7 sufficient body of data from which he could make up
8 his own mind? What's the difference here between Dr.
9 Galson and the Advisory Committee Meeting, the
10 Advisory Committee?

11 MR. HELLER: Do you want her to answer that
12 second question about the differences between Dr.
13 Galson and the Advisory Committee?

14 BY MR. WARSHAWSKY:

15 Q It was a compound question, but let's focus
16 on the first part of my question.

17 A What's the first part?

18 Q The first part of my question is, you've
19 testified that the members of the Advisory Committee

20 were sufficiently informed to -- and this is the
21 testimony, and we can read it back -- were
22 sufficiently informed to render a valid scientific

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1 and regulatory judgment about whether Plan B should
2 be over-the-counter.

3 And my question is, if they had sufficient
4 information to reach a judgment, on what grounds are
5 you now saying that a month later Dr. Galson does not
6 have sufficient information from which he can reach
7 his own judgment?

8 A He stated that he did not have sufficient
9 information. This was his statement that there was a
10 lack of data to support use in 14 to 16, therefore we
11 need to restrict the sales to under -- to over 18.
12 He did not feel there was sufficient information to
13 address his concerns. And his concerns were conveyed
14 as representing Dr. McClellan's concerns. The staff
15 then went on -- the staff gathered additional
16 information.

17 Q Okay. And let's come to that in a moment.
18 But I want to focus on the first part of your answer.
19 First of all, I think you mischaracterized what Dr.
20 Galson said. I don't believe he said he had a lack
21 of information from which to reach a conclusion. I
22 believe what he said was, there is a lack of

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1 information in the record from which he could
2 conclude that over-the-counter status of Plan B would
3 be appropriate for a certain age group.

4 So he was commenting on the lack of evidence
5 for a certain age group in the record, not his
6 inability to draw a conclusion from the existing
7 evidence.

8 MR. HELLER: Objection.

9 BY MR. WARSHAWSKY:

10 Q Is that a fair characterization here?

11 MR. HELLER: Let me just state my objection.
12 My objection is you're characterizing -- I don't know
13 if you're characterizing Mr. Galson's testimony or
14 his written portions of the record, but I think it's
15 an inaccurate characterization.

16 A As I recall it, he stated that this was
17 his -- that this was his concern. It was sincere,
18 that there wasn't enough information to support
19 use -- there wasn't enough information in the
20 14-to-16-year-old strata.

21 And because of that concern, during that

22 meeting we said there are additional data, and he was
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1 not aware that we were gathering that data. And so
2 those efforts continued to gather the information to
3 address senior management's concerns about is there
4 enough data to support use in that age group.

5 Now, some people felt there was already
6 existing sufficient data, but senior management who
7 said that they were making this decision did not. So
8 in order to show them here are additional data, the
9 review team contacted these primary investigators to
10 obtain that for the Administrative Record.

11 BY MR. WARSHAWSKY:

12 Q Just to clarify, is it your testimony that
13 Dr. Galson could not have reached a valid
14 scientific professional -- excuse me, a valid
15 scientific and regulatory judgment about the Plan B
16 OTC switch application until this additional evidence
17 that you just referred to was gathered by the staff
18 and presented to him?

19 A He identified his concern, the
20 administration's concern for the lack of data. And
21 we stated that there were additional data to address
22 his concern. So could he then state, well, I still

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1 made my decision and I don't need to look at your
2 data? He could do that, but it is not right.

3 Q It's not right or it's not scientific --
4 it's not a valid professional decision?

5 A I -- I guess I would have to look at his
6 position description to see if it falls outside what
7 his responsibilities were. But I don't -- I am not
8 sure that such an action would be supported by his
9 responsibilities in his position description.

10 Q Just to clarify, are you suggesting that as
11 CDER Director, Dr. Galson did not have the statutory
12 or regulatory or other lawful authority to make a
13 decision on the Plan B switch application?

14 A No, I'm not stating that.

15 Q Okay. That's all I wanted to clarify. I
16 don't want to keep beating a dead horse. Are you
17 going to add anything else to -- or do you want to
18 add anything else to my questions? I mean, you see
19 the point I'm just trying to get at.

20 A No, actually, I don't. I just don't get it.
21 So perhaps that's why --

22 Q Okay. Let me clarify. Let's do this one

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1 more time because I think it's important. You
2 testified earlier that the members of the Advisory
3 Committee had sufficient information before them to
4 render a valid scientific and regulatory judgment
5 about whether Plan B should be made OTC, correct?

6 A Yes.

7 Q So they could render a valid judgment
8 despite the fact that they didn't have access to any
9 of this additional information that the staff
10 gathered in January and February of '04, correct?

11 A Right. And some members voted no, this
12 should not be approved because there is lack of
13 information. Perhaps they would have voted, oh, in
14 favor of the application should this additional data
15 come forward.

16 Q So are you suggesting that the --

17 A So they identified a deficiency. They --
18 you said there were, I forgot, four votes or so that
19 did not support it going over-the-counter.

20 Q Right.

21 A And in the transcript they explain why. And
22 some of it's -- it relates to a lack of data in a

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1 young group.

2 Q Right.

3 A And if this view of, no, it should not be
4 over-the-counter because there is lack of data is
5 shared by Dr. Galson and Dr. McClellan and others, it
6 could be addressed by the presence of data.

7 Q Okay. But that's not my question.

8 A Oh, I guess --

9 Q My question isn't whether their concerns
10 could somehow be addressed with additional or further
11 information. Okay?

12 A Okay.

13 Q That's not my question. I understand that's
14 your position. My question is different. My
15 question is, at a specific point in time, given the
16 body of evidence presented, can someone reach a valid
17 judgment about that evidence? And you said that at
18 the specific point in time of December 16, 2003, the
19 members of the Advisory Committee had sufficient
20 information to render a valid scientific and
21 regulatory judgment. That's what your testimony was.

22 Your testimony wasn't, well, it's contingent

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1 on what information might be gathered two months
2 later, right?

3 A Uh-huh.

4 Q You said that their judgment at that time
5 was valid.

6 A Uh-huh.

7 Q Okay. Now, you said something a moment ago
8 that I want to clarify. You're not suggesting, are
9 you, that the members of the Advisory Committee
10 Meeting who voted yes, that only their judgment was
11 valid, but that the ones who said no were invalid?
12 Are you making that distinction?

13 A I'm stating that if you look at the
14 transcript and the reasons why people voted no, that
15 I recall some of the reasons relate to wanting more
16 data.

17 Q So is it your position that if you have a
18 little bit of data and you decide to vote yes, that's
19 okay; but if you have a little bit of data and you
20 decide to vote no because you think there should be
21 more data, that's not okay, you have to wait for
22 there to be more data?

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1 MR. HELLER: Objection. Argumentative,
2 badgering, and mischaracterizes her testimony.

3 BY MR. WARSHAWSKY:

4 Q I'll withdraw the question. Why don't we
5 move on. I just have a few other topics I want to
6 address. You mentioned that a week -- in your
7 earlier testimony you said that approximately a week
8 or so before the January 15, 2004 meeting, you were
9 advised that there were or would be problems with the
10 Plan B application by Dr. Mark Goldberger, is that
11 correct?

12 A (Witness nods.)

13 Q And is it correct that Dr. Goldberger is
14 your husband?

15 A Yes.

16 Q Just a couple more questions, and I really
17 do appreciate your patience. You testified a couple
18 of times earlier today about a telephone conversation
19 that you had with Dr. Woodcock perhaps later the day
20 of that January 15 meeting or the next day. Do you
21 remember that earlier testimony?

22 A Yes.

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1 Q Did Dr. Woodcock during that telephone
2 conversation tell you -- strike that. And you
3 testified that she conveyed an opinion to you about
4 why the Plan B application would be not approved on

5 this cycle, but that there was some plan or path for
6 a later approval?

7 MR. HELLER: Objection. I don't think she
8 testified that it was an opinion.

9 A I stated that she stated to me that this
10 application had to be not approved to appease the
11 administration's constituents, and that later, only
12 after the non-approval, could there -- could this be
13 approved.

14 BY MR. WARSHAWSKY:

15 Q Okay. Did she tell you who, if anyone, told
16 her this?

17 A No.

18 Q Did she tell you, and just to clarify, did
19 she tell you that this was a position or information
20 that she obtained from Dr. McClellan?

21 A No.

22 Q Did she -- okay. Have you -- no. Just give

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1 me one moment. I think I'm just about done.

2 MR. WARSHAWSKY: I have no further questions
3 at this time. Thank you very much, Dr. Houn.

4 THE WITNESS: Thank you.

5 MR. HELLER: Dr. Houn, I have a couple of
6 questions, and I hope we'll be done for the day.

7 THE WITNESS: Okay. Great.

8 FURTHER EXAMINATION BY COUNSEL FOR PLAINTIFFS

9 BY MR. HELLER:

10 Q Do you have Dr. Griebel's memo still there
11 in front of you somewhere?

12 A Yes.

13 Q If you wouldn't mind pulling it out and
14 turning to Page 12?

15 A Of the --

16 Q Of her --

17 A April 1st?

18 Q -- April 1st memo, April 1st, 2004. And
19 there were some questions about the table?

20 A Yes.

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18 Q Thank you. At the beginning of his
19 questioning, Mr. Warshawsky reassured you that
20 nothing you said here today would be the basis of
21 retaliation or repercussions for you. Do you have
22 any -- do you still have any concerns about that?

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1 A Yes.

2 Q Can you tell me what those concerns are?
3 Well, let me say a different question. Would you
4 prefer not to tell me what those concerns are?

5 A Not at this point.

6 Q You would prefer not to do it at this point?

7 A (Witness nods.)

8 MR. HELLER: Okay. Thank you. I have no
9 other questions for you at this time. Thank you.

10 MR. WARSHAWSKY: Thank you very much, Dr.
11 Houn.

12 MR. HELLER: Did you talk about signing and
13 review with her? We can do that -- we can go off the
14 record.

15 THE VIDEOGRAPHER: Here marks the end of
16 videotape number four in the deposition of Dr.
17 Florence Houn. Going off the record. The time is
18 5:41 p.m.

19 (Signature having not been waived, the
20 deposition of FLORENCE HOUN, M.D., was concluded at
21 5:41 p.m.)

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1 ACKNOWLEDGMENT OF DEPONENT

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

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CERTIFICATE OF SHORTHAND REPORTER - NOTARY PUBLIC

I, Nancy K. Barker, Certified Shorthand Reporter, the officer before whom the foregoing proceedings were taken, do hereby certify that the foregoing transcript is a true and correct record of the proceedings; that said proceedings were taken by me stenographically and thereafter reduced to typewriting under my supervision; and that I am neither counsel for, related to, nor employed by any of the parties to this case and have no interest, financial or otherwise, in its outcome.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my notarial seal this 24th day of July, 2006.

My commission expires:
September 30, 2007

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NOTARY PUBLIC IN AND FOR THE
STATE OF MARYLAND

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E R R A T A S H E E T

IN RE: TUMMINO, et al. Vs. VON ESCHENBACH

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2 IN RE: TUMMINO, et al. Vs. VON ESCHENBACH

3 RETURN BY:

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