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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 DONNA GRIEBEL, M.D.
14 Rockville, Maryland
15 Wednesday, July 19, 2006
16 9:46 a.m.

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19
20 Job No.: 1-82113
21 Pages 1 - 184
22 Reported by: Nancy K. Barker, CSR

0002

1 Videotaped Deposition of DONNA GRIEBEL,
2 M.D., held at the offices of:

3
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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1 A P P E A R A N C E S
2 ON BEHALF OF THE PLAINTIFFS:
3 NAN STRAUSS, ESQUIRE
4 SIMON HELLER, ESQUIRE
5 Center for Reproductive Rights
6 120 Wall Street
7 14th Floor
8 New York, New York 10005
9 917-637-3600

10

11

12 ON BEHALF OF THE DEFENDANT AND WITNESS:
13 STEVEN M. WARSHAWSKY, ESQUIRE
14 F. FRANKLIN AMANAT, ESQUIRE
15 U.S. Department of Justice
16 United States Attorney's Office
17 Eastern District of New York
18 147 Pierrepont Street
19 Brooklyn, New York 11201
20 718-254-6060

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0004

1 A P P E A R A N C E S
2 (CONTINUED)
3 ON BEHALF OF THE DEFENDANT:
4 KAREN E. SCHIFTER, ESQUIRE
5 Associate Chief Counsel
6 U.S. Dept. of Health & Human Services
7 Food and Drug Administration
8 Office of the Chief Counsel
9 5600 Fishers Lane, GCF-1
10 Rockville, Maryland 20857
11 301-827-1152

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13

14

ALSO PRESENT:

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William Schurmann, Intern, Dept. of Justice
Santiago Murillo, Videographer

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C O N T E N T S

EXAMINATION OF DONNA GRIEBEL, M.D.	PAGE
By Ms. Strauss	8
By Mr. Warshawsky	86
By Ms. Strauss	178

E X H I B I T S

(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. Donna Griebel in the matter of Annie Tummino, et al., versus Andrew C. von Eschenbach, as Acting Commissioner of the Food and Drug Administration, in the United States District Court, Eastern District of New York, Case Number 05-CV-366.

Today's date is July 19th, 2006. The time on the video monitor is 9:46 a.m. The video operator today is Santiago Murillo. This video deposition is taking place at the Food and Drug

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13 Administration located at 5600 Fishers Lane in
14 Rockville, Maryland.

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

17 MS. STRAUSS: Nan Strauss from the Center
18 for Reproductive Rights for plaintiffs.

19 MR. HELLER: Simon Heller from the Center
20 for Reproductive Rights for the plaintiffs.

21 MR. AMANAT: Frank Amanat from the U.S.
22 Attorney's Office in the Eastern District of

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1 New York, for the witness and for the defendant.

2 Also entering the appearance for Steven W.
3 -- Steven M. Warshawsky, also from the U.S.
4 Attorney's Office in Brooklyn. He'll be representing
5 the witness and the defendant as well. He's
6 momentarily outside the room, but will be returning
7 shortly.

8 MS. SCHIFTER: Karen Schifter from FDA for
9 the defendant.

10 THE VIDEOGRAPHER: Mr. Schurmann? Just
11 state your name.

12 MR. SCHURMANN: William Schurmann.

13 MR. AMANAT: He doesn't need to enter his
14 appearance.

15 THE VIDEOGRAPHER: Okay. Thank you. The
16 court reporter today is Nancy Barker of LAD
17 Reporting. Would the reporter please swear in the
18 witness?

19 DONNA GRIEBEL, M.D.,
20 having been duly sworn, testified as follows:

21 THE VIDEOGRAPHER: Thank you. You may
22 begin.

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1 EXAMINATION BY COUNSEL FOR PLAINTIFFS

2 BY MS. STRAUSS:

3 Q Good morning, Dr. Griebel.

4 A Good morning.

5 Q I'm Nan Strauss. And is that the right way
6 to pronounce your name, Dr. Griebel?

7 A Uh-huh.

8 Q I'll be asking you some questions today,
9 and I'd like you to answer them as completely as you
10 can. Also, I'd like you to give a verbal answer so

11 that the court reporter can take down what you're
12 saying.

13 If the question doesn't make sense to you,
14 please let me know and I'll try to rephrase it so
15 it's clear. At times Mr. Amanat or Mr. Warshawsky
16 might object to a question that I ask, but unless
17 they specifically instruct you not to answer, you can
18 still go ahead and answer the question.

19 If you need to take a break at any point,
20 just let me know. We might finish up a question if
21 there's a question that's been asked and not
22 answered, but then we'd be happy to take a break when

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1 it's -- when you like.

2 (Mr. Warshawsky entered the room.)

3 BY MS. STRAUSS:

4 Q A couple of background questions for you.
5 Can you tell me how you prepared for your deposition
6 today?

7 A I had a meeting with the attorneys for the
8 defendant. And that was pretty much it. My -- I
9 think everyone's aware my husband was interviewed
10 yesterday or deposed yesterday, so I asked him how
11 that went.

12 Q Did you speak with anybody else about the
13 deposition today?

14 A There was a question that the defendants
15 asked me about the history in our division. And I
16 contacted the Deputy Director to ask them if there
17 was any public information that I could share that
18 would answer that question. And so that was the only
19 other contact.

20 Q Did you learn of any information?

21 A It really wasn't relevant to the specific.
22 It was just history of the FDA.

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1 Q Did you review any other documents in
2 preparation for today's deposition?

3 A No. The other depositions are on the Web.
4 I did not read them. I -- when we were told that
5 they were available, I opened a couple of the links
6 and scanned them but did not read them in depth.

7 Q Why don't you start by telling me about your
8 educational background.

9 A I did my undergraduate -- I did all of my
10 training at University of Kansas. And my
11 undergraduate was a degree in chemistry and
12 biochemistry at University of Kansas, medical school
13 University of Kansas, internal medicine residency at
14 University of Kansas, and medical oncology fellowship
15 at University of Kansas.

16 Q And what was the development of your
17 professional career after that point?

18 A After that I went into private practice for
19 a few years in Wichita, Kansas. I also had a joint
20 appointment, an academic appointment at the
21 University's campus in Wichita and saw patients at
22 the Veterans Administration Hospital. Then moved to

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1 the University of Texas Medical Branch at Galveston
2 at a -- I was assistant professor in the Hematology
3 and Oncology Division, in internal medicine there.

4 Subsequent to that, I came to this area and
5 joined the Division of Oncologic Drug Products in
6 CDER, was a medical reviewer there, then a team
7 leader there, and then became Deputy Director for the
8 Division of Reproductive and Urologic Drug Products.

9 And after that I have moved into my current
10 position, which is a Program Director in the Division
11 of Cancer Prevention, the Gastrointestinal and Other
12 Cancers Research Group.

13 Q Can you just tell me the years when you
14 joined the FDA, when you became the Deputy Division
15 Director and when you left the FDA?

16 A In -- well, I left the FDA, the most recent,
17 so I would say I left the FDA in September, late
18 September of last year, so 2005; came to the FDA in
19 1997, went to -- moved from Oncology to the Urologic
20 Drug Products Group, three years before I left. So I
21 would say that was, what, 2002.

22 Q Okay. Can you just describe your

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1 involvement in the FDA's handling of the Plan B SNDA
2 and the Citizens Petition up to the time of the
3 Agency's issuance of the non-approvable letter in May
4 of 2004?

5 A Could you repeat that question? I'm sorry.

6 Q Could you just give me an overview of your

7 involvement in the process of reviewing the Barr SNDA
8 for Plan B?

9 A Well, our division is -- the Reproductive
10 and Urologic Drug Products Division is a very busy
11 division, so the Director and the Deputy Director
12 split the four medical review teams. So I -- of the
13 two review teams that I supervised, one was the
14 review team that was reviewing that application. So
15 I supervised that review from the Reproductive review
16 group's standpoint.

17 Q And what did those responsibilities entail?

18 A Responsibilities entailed attending the
19 meetings, giving feedback on issues that came up in
20 the meeting, making sure that issues were being
21 attended to so action items were being attended to,
22 reviewing documents that were prepared, reviewing

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1 presentations that were prepared. I also, I think,
2 made at least one presentation.

3 Q Do you remember where that presentation was?

4 A It was to Mark McClellan here in the
5 Parklawn Building.

6 Q Was there anything unusual about that
7 over-the-counter switch process for Plan B?

8 MR. WARSHAWSKY: Objection. The term
9 "unusual" is vague and undefined.

10 BY MS. STRAUSS:

11 Q If you understand the question, you can go
12 ahead and answer it.

13 A So repeat the question.

14 Q Was there anything unusual about the
15 over-the-counter switch process for Plan B?

16 A And I guess I would have to ask what --
17 could you be more specific about what you're asking
18 me?

19 Q If there's anything that stood out in the
20 process that was unlike other processes or that was
21 surprising to you?

22 MR. WARSHAWSKY: Objection. Compound and --

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1 I'll leave it at that.

2 A So you're asking me if there's anything --
3 could I ask you to ask it again? I know you're
4 asking about the review process and what -- whether I

5 was surprised by anything during the review process?

6 BY MS. STRAUSS:

7 Q If there was anything atypical about the
8 over-the-counter switch process for Plan B?

9 MR. WARSHAWSKY: Same objection to use of
10 the term "atypical".

11 THE WITNESS: Atypical. So I can answer
12 this, correct?

13 MR. WARSHAWSKY: Uh-huh.

14 A Okay. So it did seem atypical to me that
15 the level of involvement from upper level management
16 during this, including the preparation for the
17 Advisory Committee Meeting, but also during the
18 initial review process in getting instructions in
19 what we needed to be doing and obtaining from the
20 company. So there seemed to be an unusual amount of
21 involvement from upper level management.

22 BY MS. STRAUSS:

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1 Q At what point do you recall upper level
2 management becoming involved?

3 MR. WARSHAWSKY: Objection. The term "upper
4 level management" has not been defined.

5 MS. STRAUSS: Well, I'm using the term that
6 the witness used. So she can --

7 BY MS. STRAUSS:

8 Q If you'd like, you can describe upper level
9 management.

10 A Let me clarify. Because I haven't had the
11 documents to go back through and look through to
12 refresh my memory, I remember that there were -- that
13 we were -- had a scripted teleconference with the --
14 the applicant to discuss restricting the distribution
15 to try to get it restricted to behind-the-counter.
16 And that was -- that script was read by Dr. Shames.

17 I don't know at what point that was because
18 I don't have the documents with the dates. And in
19 terms of -- so we were told to do that, so I'm trying
20 to define who upper level management is. Do I
21 remember who upper level management was.

22 I guess I would say that we were getting

0016

1 told directly from our office directors what they had
2 been told that they were from -- that we were told

3 that they had been told from people above them. And
4 so I can't be more specific than that because I don't
5 know what they were told, who told them what, that we
6 needed to have this meeting.

7 Q Okay.

8 MR. AMANAT: For the record, Shames is
9 S-H-A-M-E-S.

10 BY MS. STRAUSS:

11 Q Do you know who wrote the script that was
12 presented at that scripted meeting?

13 A I don't remember that. I don't remember.

14 Q Do you recall if upper level management was
15 involved before the Advisory Committee Meeting?

16 MR. WARSHAWSKY: I object to that question.
17 Lack of foundation. I think all she's said is she's
18 had some communications by office directors. It
19 really hasn't been established who this upper level
20 management you're referring to is. So the question
21 really is meaningless.

22 MS. STRAUSS: Well, the witness has said

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1 that at some point there was an unusual degree of
2 involvement of upper level management. So I'm just
3 asking her if she recalls if that began before the
4 Advisory Committee Meeting.

5 BY MS. STRAUSS:

6 Q You can answer the question.

7 MR. WARSHAWSKY: I'll renew my objection.
8 The term "upper level management" has yet to be
9 defined.

10 MR. HELLER: What kind of objection is that
11 when the witness uses a term and she's asking her
12 when that occurred? What -- do you not understand
13 what the word "upper" means, or "level" or
14 "management"? Which of those words don't you
15 understand?

16 MR. AMANAT: The witness is allowed to be
17 ambiguous. The lawyers asking the questions are not.

18 MR. HELLER: She's not being ambiguous.
19 She's asking with respect to an answer that the
20 witness gave, when something occurred. Are you
21 trying to instruct the witness how to answer the
22 question?

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1 MR. AMANAT: No.
2 MR. WARSHAWSKY: I'm identifying an
3 ambiguous term in the question. It's the form of the
4 question that I'm objecting to.
5 MR. HELLER: Which word don't you
6 understand?
7 MR. WARSHAWSKY: Upper level management.
8 MR. AMANAT: It's an objection to the form
9 of the question. She can answer the question but --
10 BY MS. STRAUSS:
11 Q You can go ahead and answer the question.
12 A So was the question -- can I ask you to
13 repeat the question?
14 Q Sure. Do you recall if what you described
15 as an unusual degree of involvement by upper level
16 management, do you recall that occurring -- if that
17 began prior to the Advisory Committee Meeting?
18 A Yes.
19 Q And what was that involvement?
20 A What I remember as seeming unusual to me
21 before the Advisory Committee Meeting was we had --
22 we had a meeting with the applicant that was attended

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1 by John Jenkins, who was the head of Office of New
2 Drugs. I had never had that happen before in
3 Advisory Committee Meeting.
4 And in addition, in preparation for the
5 Advisory Committee Meeting, I had involvement from
6 Dr. Galson and his Acting Deputy at the time, Dr.
7 Goldberg, and going over the members that would be
8 asked to participate -- the scientific professionals,
9 SGEs, that would be asked to participate in the
10 Advisory Committee on the panel.
11 And Dr. Galson was involved in reviewing the
12 questions that would be asked of the Committee. I
13 had never had that happen before. Dr. Galson was
14 involved in discussions with the Committee chair,
15 discussing the meeting. I had never had the head of
16 CDER be involved in discussions with the Advisory
17 Committee chair about the Advisory Committee that was
18 coming up. And there were discussions of the
19 Advisory Committee questions that he was involved in
20 in that meeting, which was not something that I was
21 accustomed to.
22 Q Do you remember what happened during the

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1 meeting that you said happened with John Jenkins?

2 A I have only vague recollection of that
3 meeting.

4 Q Can you describe it at all?

5 A The company -- the applicant attended and
6 I believe presented what their plans were for
7 presenting at the Advisory Committee Meeting in the
8 -- asking for feedback on what their plans were for
9 presenting. And that's -- that's all I can remember,
10 just the general concept.

11 Q Did they receive any feedback?

12 A I'm sure they did. I don't remember
13 specifics.

14 Q And why was John Jenkins there?

15 A I remember that he thought it was very
16 important to have that meeting. So you would have to
17 ask him why he was there. I don't know.

18 Q You were also just describing the
19 involvement of Dr. Galson prior to the Advisory
20 Committee Meeting, and that he was unusually involved
21 in the process going over who the members of the
22 Advisory Committee would be, going over the

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1 questions. Do you recall his input during that
2 process?

3 A I remember what I was told was his input,
4 but I was not in terms of the -- are you specifically
5 asking me about the -- let me ask you to repeat the
6 question.

7 Q I would like you to just describe in more
8 detail what you know about Dr. Galson's involvement
9 during that time. And I was going back to the
10 unusual level of involvement that you had mentioned a
11 moment ago, mentioning that he had input, he had
12 reviewed who the members of the Advisory Committee
13 were going to be, and he had reviewed the questions.
14 And I was asking if you recall what the substance of
15 his contribution was in those discussions?

16 A Okay. So you brought up two points, that
17 was the members that would participate and the
18 questions. In terms of the members that would
19 participate, I was not in direct discussions with
20 him, so everything was -- people using his name and
21 saying you need to do this because of this. So I

22 can't -- I don't have direct -- I don't know the --

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1 that's as best I can do.

2 Q That's okay if you don't -- if you're
3 repeating something that you heard from someone else.
4 You can still tell me what you heard.

5 A So there were additional members that we
6 were nominating to bring in expertise on
7 contraception because our committee was very strong
8 on maternal/fetal medicine and infertility, but in
9 terms of contraception it was -- there were not a lot
10 of people that that was their main focus. So we were
11 trying to bring in in addition to experts in
12 adolescent medicine.

13 So what I was told that there were -- that I
14 had to write just detailed justifications for each
15 one. And then I was told subsequent to that that
16 some of them would not -- would not be supported
17 based on -- and again this is through other people --
18 based on whether they would be disruptive.

19 In terms of the --

20 Q I'm going to just stop you there and ask you
21 a few more questions about that, if that's all right.
22 Do you recall who you heard this information from?

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1 A I don't. I -- I believe that it came from
2 Dr. Houn, and that she heard it from Dr. Goldberg.
3 But I don't -- that's my -- those are the only two
4 other people that would have been involved.

5 Q Okay. Thank you. Who were the experts on
6 contraception that were proposed?

7 THE WITNESS: Is that something I'm allowed
8 to answer?

9 MS. SCHIFTER: I'm not sure if that -- is
10 that something that we would normally not disclose?

11 THE WITNESS: Well, it's an internal process
12 that -- it doesn't matter, I don't remember their
13 names anyway, so -- I -- I don't remember the names.

14 MS. SCHIFTER: If you recall it later, I'll
15 go check with someone. So why don't you let me know
16 before you testify.

17 MR. HELLER: Can I just ask, what would be
18 the nature of the inability to answer the question?

19 MS. SCHIFTER: Well, if there is something

20 that we promise people that we won't disclose our
21 identity until they're nominated or something like
22 that, I would have to go check with the process,

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1 whether we promise people some sort of privacy if
2 they're considered but not --

3 MR. HELLER: If that does turn out to be the
4 case, we would certainly agree to seal that portion
5 of the transcript. We don't want to expose anyone to
6 anything.

7 BY MS. STRAUSS:

8 Q Do you still have the documents where you
9 wrote up the justification supporting those people?

10 A I don't. I don't work here anymore. I know
11 that when we have been asked before, when I was still
12 here, for e-mails, that it was attached to e-mails
13 that I submitted.

14 MR. HELLER: Do you all know if that
15 document has been produced to us or withheld?

16 MS. SCHIFTER: I don't recall seeing it.

17 MR. AMANAT: I've never seen it.

18 BY MS. STRAUSS:

19 Q And when you say that it was attached to
20 e-mails that were submitted, to whom were they
21 submitted?

22 A We were asked to submit, to give all of our

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1 e-mails what seems like multiple occasions, but I
2 don't remember. I'm assuming that it was with -- and
3 this is an assumption I'm not supposed to make, but
4 the only requests that I can remember was when the
5 GAO did their investigation, I think they requested
6 all the e-mails.

7 Q And did you hear that Dr. Galson wanted any
8 specific people on the Advisory Committee?

9 A No.

10 Q You said that some of those recommended were
11 not supported based on an assumption that they would
12 be disruptive at the meeting, is that right?

13 A Yes. Uh-huh.

14 Q And you understand that that came from Dr.
15 Galson?

16 A Again, I heard that third-hand when I was
17 told that they couldn't participate.

18 Q Do you know anything more about why they
19 were -- it was thought that they would be disruptive?
20 A No.
21 Q And these were people that you had
22 recommended for the Advisory Committee?

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1 A Yes.
2 Q How did you go about selecting them for
3 membership?
4 MR. WARSHAWSKY: I'm going to make a
5 continuing objection to this line of questioning. I
6 don't think it's either relevant to the issues in
7 this case or reasonably calculated to lead to
8 discovery of admissible or relevant evidence for that
9 matter. The Advisory Committee Meeting assembled and
10 voted, and that vote was taken into consideration by
11 the various folks in this case. And so I'm going to
12 make a continuing objection to this line of
13 questioning. I also think that it's a waste of time.
14 MR. HELLER: You may think the whole case is
15 a waste of time.
16 MR. WARSHAWSKY: Perhaps but --
17 MR. HELLER: It's not a valid objection.
18 MR. WARSHAWSKY: But this particular
19 question I think is a waste of time.
20 MR. HELLER: Can I say something for the
21 record. If someone was constructing the Advisory
22 Committee to achieve impermissible results, that

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1 certainly is relevant to this case.
2 MR. WARSHAWSKY: Not in the absence of any
3 evidence of impermissible results.
4 MR. HELLER: But that's what she's asking
5 about.
6 MR. WARSHAWSKY: No, she's not. She's
7 asking about what perhaps went on prior to the
8 convention of the Advisory Committee Meeting. But
9 there's no indication and never has been any
10 indication that the vote that was achieved at the
11 Advisory Committee Meeting was improper in any way.
12 You certainly haven't proposed that there was
13 something about the Advisory Committee Meeting that
14 was improper.
15 MR. HELLER: No, no, no. It doesn't matter

16 if the vote was improper. If the Committee's
17 composition was impermissibly influenced for
18 impermissible reasons, that's relevant to the case
19 because it's part of a pattern of improper behavior
20 by the Agency.

21 MS. STRAUSS: Or if there was an attempt to
22 do so that failed.

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1 MR. WARSHAWSKY: We disagree.

2 MR. AMANAT: I share Mr. Warshawsky's
3 objection, but the witness can answer that.

4 MR. HELLER: But your objection basically is
5 irrelevant.

6 MR. AMANAT: The witness can answer the
7 irrelevant question if --

8 MR. HELLER: It's not an irrelevant
9 question.

10 A So it's multi -- multi-pronged, asking
11 colleagues who are the known experts in the field,
12 doing quick literature search to see who's written
13 recent papers or reviews, and looking on the Web at
14 the societies, professional societies, and looking
15 who the leaders are and who are members.

16 BY MS. STRAUSS:

17 Q Thank you. Do you remember even a single
18 name of a person that Dr. Galson believed would be
19 disruptive?

20 A No.

21 Q How were you told that certain people would
22 be disruptive?

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1 A I -- it would have had to have been -- I
2 don't believe that's documented in an e-mail. I
3 believe it was a telephone conversation that I
4 received. And so that's why I believe that it was
5 Dr. Houn who told me.

6 MR. AMANAT: For the record, Houn is
7 H-O-U-N.

8 BY MS. STRAUSS:

9 Q And why does the fact that it was a
10 telephone conversation make you believe that it was
11 Dr. Houn who told you?

12 A Because I don't ever remember talking to Dr.
13 Goldberg on the phone.

14 Q Okay. Thank you. Do you believe that a
15 higher standard was applied to the Plan B
16 over-the-counter switch than to other
17 over-the-counter switches?

18 MR. WARSHAWSKY: Objection to the use of the
19 term "higher standard".

20 MR. HELLER: Because you don't understand
21 what the word "higher" means, or because you don't
22 understand what the term "standard" means, or what

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1 any of the other words in that question? Which word?

2 MR. AMANAT: Because the objection is --

3 MR. HELLER: Because it strikes me,
4 Mr. Warshawsky, that you are objecting to questions
5 in an effort to steer the witness not to answer.

6 MR. WARSHAWSKY: No. I'm objecting to
7 questions that use terms that are vague and
8 undefined. Hence the form of the question is
9 improper.

10 MR. AMANAT: And also the question contains
11 an assumption in it.

12 MR. HELLER: That standards can be higher or
13 lower.

14 MR. AMANAT: The question contains an
15 assumption which is an invalid assumption.

16 MR. HELLER: What's the assumption?

17 MR. AMANAT: The assumption that there is
18 such a thing as a standard by which -- by which all
19 drug applications or OTC switch applications are to
20 be adjudicated so that there is such a thing as
21 higher or lower standards as opposed to each drug
22 being a sui generis consideration.

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1 MR. HELLER: I would love to have you
2 stipulate that the Agency's consideration of drug
3 applications is standardless.

4 MR. AMANAT: That's not what I said, Mr.
5 Heller.

6 MR. HELLER: There's no standard?

7 MR. AMANAT: I said that each drug is
8 sui generis, and so that you can't -- you can't
9 compare what approach is used for one drug or
10 extrapolate from the approach that's used for one
11 drug the approach that should be used for a different

12 drug. It's been the Agency's position since the
13 beginning of this litigation. It's not news to you.
14 Your question contains an assumption which
15 we consider to be an invalid assumption. The witness
16 can answer the question if she can. But it's a valid
17 objection to the form of the question.
18 MR. HELLER: It's also a speaking objection
19 in which you're trying to tell the witness that you
20 don't think this -- this assumption is correct,
21 therefore she shouldn't.
22 MR. AMANAT: Mr. Heller --

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1 MR. WARSHAWSKY: Hold on. Hold on. I want
2 to make something very clear about this, Mr. Heller.
3 These are not speaking objections until you turn them
4 into a colloquy with opposing counsel, asking us to
5 explain the nature of the objection. The basic
6 objection is stated succinctly and to the point and
7 is appropriate. If you don't like to have a
8 continuing colloquy about the basis for the
9 objection, don't have one. That's what turns it into
10 a, quote, unquote, speaking objection.
11 MR. HELLER: Well, you may be right in part.
12 MR. WARSHAWSKY: Of course I'm right on that
13 point.
14 MR. HELLER: I don't know about of course.
15 MR. WARSHAWSKY: You challenge every single
16 objection.
17 MR. HELLER: Well, I think they're all
18 invalid.
19 MR. WARSHAWSKY: Fair enough.
20 MR. AMANAT: Fair enough but --
21 MR. WARSHAWSKY: That's your opinion, but
22 the form of the objection is appropriate.

0033
1 MR. AMANAT: And under Rule 30, we have not
2 only the right but an obligation to state objection
3 to the form of the question on the record during the
4 deposition. We're not instructing the witness not to
5 answer the question. The witness can answer the
6 question if she finds the form acceptable. But we
7 have not only the right, but also in order to
8 preserve the objection, the obligation to make it on
9 the record, and that's what we're doing. If the

10 witness wants to answer the question, she can answer
11 the question, but it's objectionable.

12 MR. HELLER: Probably now she doesn't
13 remember what the question was.

14 MS. STRAUSS: Yeah, I can rephrase it.

15 BY MS. STRAUSS:

16 Q I can ask you again if you'd like or you can
17 just go ahead and answer if you recall what the
18 question was.

19 A I recall what the question was. And even
20 without the objections, I was going to say I don't
21 know what higher standard is as a regulatory
22 terminology, which is what our brains think of. If

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1 you had asked me that, not even in this room, I would
2 not know how to answer that.

3 My review makes it clear that I believe
4 that -- that the applicant had established that the
5 drug was safe and effective for over-the-counter use
6 and approval. So therefore I felt that it met the
7 standard for approval.

8 Q Did people other than you think that the
9 application met the standard of approval?

10 A I think the record reflects that a number of
11 people felt that it met the standard of approval.

12 Q Who disagreed that it met the standard of
13 approval?

14 A There was a primary reviewer in OTC, Dr.
15 Chen, who did not agree that -- with approving it,
16 and Dr. Galson.

17 Q And do you know if Dr. McClellan thought the
18 application met the standard of approval?

19 MR. AMANAT: I didn't hear the end of your
20 question. I'm sorry.

21 BY MS. STRAUSS:

22 Q Do you know if Dr. McClellan thought that

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1 the application met the standard of approval?

2 A Well, we had a meeting with Dr. McClellan
3 and I believe that's the meeting where I presented.
4 And after the presentation, he had a number of
5 comments of which it was not clear what his -- it was
6 not clear what he believed about the -- whether it
7 met the standard of approval based on his comments.

8 Multiple people who left that room had
9 different opinions on what he said. Subsequently,
10 Dr. Woodcock met with us, with Dr. Galson, and we
11 were told that he did not believe that it met the
12 standard of approval.

13 Q Why did Dr. McClellan not believe that the
14 application met the standard of approval?

15 A I don't remember that being -- I don't
16 remember what she said specifically.

17 Q Do you know if that was the meeting that
18 happened the day after the meeting with Dr.
19 McClellan? I believe there was a meeting on February
20 18th with Dr. McClellan, and then there was a
21 subsequent meeting on February 19th with Dr.
22 Woodcock. And I can go ahead and show you some of

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1 those minute notes that might refresh your
2 recollection if that would be helpful.

3 A It might be helpful.

4 Q Okay. (Handing document to witness).

5 A So this is the February 18th meeting with
6 Dr. McClellan. And your question was about the
7 subsequent meeting?

8 Q Can I have that back?

9 A Uh-huh. (Handing document to counsel.)
10 (Discussion off the record.)

11 MS. STRAUSS: Forgive me for a moment while
12 I address the documents.

13 THE WITNESS: So the first one is meeting
14 minutes from the meeting attended by Dr. McClellan.

15 BY MS. STRAUSS:

16 Q Right.

17 A And you asked me about Dr. -- the one led by
18 Dr. Woodcock. And now I have a review memo that is
19 from --

20 Q You have two documents. The first one is
21 marked Tummino 30719, and those are the minute
22 meetings from February 18th.

0037

1 MR. WARSHAWSKY: 2004.

2 BY MS. STRAUSS:

3 Q 2004. Thank you. -- which was a meeting
4 with Dr. McClellan to discuss the Plan B application.
5 And then the next document that I've given you that

6 starts on Tummino 30745 and ends on Tummino 30783 is
7 a Division Director memo. It's not your memo, but it
8 does mention the February 19th meeting in the last
9 paragraph of the first page, which is 30745. There
10 are no meeting minutes that I'm aware of for that
11 meeting, and that's why I've given you this document.

12 A So that meeting is the one that I was
13 referring to, the February 19th meeting.

14 Q Since we have these documents out, why don't
15 you just take a look at the document that starts on
16 30719 and ends on page 30744, the meeting with Dr.
17 McClellan.

18 MR. WARSHAWSKY: Feel free to look at the
19 documents as thoroughly as you feel a need to be
20 comfortable asking questions -- answering questions.

21 BY MS. STRAUSS:

22 Q And if at any point I ask you a question and

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1 you need a moment to refer to it, feel free to take
2 that. Do you recall what the purpose of this meeting
3 was?

4 A Well, we had been told that -- we had been
5 told that we did not have -- that the application
6 could not be approved, and that our conclusions that
7 we knew that we had were not going to be supported.
8 And we were told that we would have an opportunity to
9 present why we believe that we had evidence the
10 product was safe and effective for over-the-counter
11 use to Dr. McClellan.

12 Q Okay. I think what I'm going to do is go
13 back in time so that we're not starting in the
14 middle, go back to some earlier documents and take
15 you through them. And then you can hang onto those
16 for when we get to them. (Handing documents to
17 witness.) This is a letter to the Women's Capital
18 Corporation. The page number is Tummino 30311
19 through 30313. And you'll see that your electronic
20 signature is appended on the last page, and it's a
21 letter signed by you, is that right?

22 A Uh-huh.

0039

1 Q It's a letter that is about introducing
2 Plan B in a responsible manner. And toward the
3 bottom of the first page -- do you need another

4 minute to look at it?

5 A No. Go ahead.

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1 Q And who did not want it to be out sitting on
2 the shelf?

3 A Again, we were told from our office director
4 that that was coming from folks above them.

5 Q And do you know -- even if you don't know
6 for certain, do you have a sense or even a guess
7 about who that was coming from?

8 MR. WARSHAWSKY: Objection. It calls for
9 speculation.

10 THE WITNESS: So do I still answer?

11 MR. AMANAT: You can answer.

12 A At the time it was not my impression that
13 this would be something that John Jenkins would have
14 on his radar screen as something that he would
15 initiate. So my impression was that it had to be
16 coming from above him. And because we have reference
17 to public sensitivities and concerns, that sounds
18 like something that isn't -- that doesn't sound like
19 science, when I sit here and look at it. So it just
20 sounds like it's -- I agree with you, it sounds now
21 when I sit and look at it, it sounds -- I don't know
22 who it came from.

0041

1 BY MS. STRAUSS:

2 Q And forgive me if I've asked this and you've
3 already answered it. But what do you think those
4 public sensitivities are?

5 MR. WARSHAWSKY: I'm going to object to that
6 question.

7 A Again, this was a script, and I would have
8 to -- I would be interpreting it now.

9 BY MS. STRAUSS:

10 Q Did you share those concerns?

11 MR. WARSHAWSKY: Objection.

12 A Did I share concerns at this time about this
13 paragraph? I don't think so.

14 BY MS. STRAUSS:

15 Q That's it for that document. So if you just
16 want to send it back, I'll hold these for you.

17 MR. WARSHAWSKY: Do you want these too?

18 MS. STRAUSS: You can hold onto them.

19 BY MS. STRAUSS:

20 Q So I'm handing you a document that's marked
21 as the bottom Tummino 30393 and it ends on page
22 30420. This is an Executive Summary of an Office of

0042

1 the Commissioner Meeting on December 10th, 2003.
2 They're the minutes of a meeting about the planning
3 for the Advisory Committee Meeting at which Doctors
4 McClellan and Dr. Galson were present.

5 MR. WARSHAWSKY: I'm sorry. Are you asking
6 a question or are you characterizing the document?

7 MS. STRAUSS: I'm characterizing the
8 document. And the witness appears to be reading it,
9 so I'm giving her a moment to look it over.

10 THE WITNESS: Okay.

11 BY MS. STRAUSS:

12 Q Do you recall any comments made by Dr.
13 McClellan or Dr. Galson at this meeting?

14 A (Witness reviewing document.) Well, this is
15 the first time I remember that this meeting happened.
16 I had forgotten about this meeting. And I don't
17 remember. I remember the prep, but I don't remember
18 the comments made at the meeting.

19 Q That's fine. Thanks. I've just handed you
20 a document marked 30666 through 30670. These are
21 meeting minutes of a meeting that took place on
22 January 15th of 2004. And the minutes indicate that

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1 the purpose was to inform the two ODE's about the
2 Commissioner's position on acceptability of the
3 application. Why don't you take a minute to review
4 it.

5 A (Witness reviewing document.) Okay.

6 Q On the second page, 30667, the meeting
7 objective indicates that the objective was to inform
8 the offices of the Office of the Commissioner's
9 position on the acceptability of the application.
10 What was the Commissioner's position as conveyed in
11 that meeting?

12 A Well, this is another meeting I don't
13 remember. You asked me a previous question about the
14 meeting with the Commissioner and what the
15 Commissioner said and the reason why that meeting
16 happened. Here's the reason that's -- that's I think
17 documented.

18 So my recollection of having the meeting
19 with the Commissioner was that we understood that the
20 product couldn't be approved, and that he didn't
21 support the approval, and that we were to give our
22 reasons that we were being given the opportunity to

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1 show him why we thought it could be. But the action
2 items here or the -- above the action items, Dr.
3 Galson reported the OC has requested a willingness to
4 meet with the review team to further discuss the data
5 and these concerns. I don't remember the details of
6 this meeting. All I can --

7 Q Okay. I'm going to give you another
8 document. And just tell me if you don't recall it,
9 and that's fine. We can keep moving through them.

10 MR. AMANAT: Recall the document or recall
11 the event memorialized in the document?

12 MS. STRAUSS: If there's something that the
13 witness doesn't recall that I'm asking her about, she
14 can just let me know.

15 MR. AMANAT: I'm asking what you meant by
16 "recall it". That was a fair question.

17 BY MS. STRAUSS:

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3 Q Were teleconferences usually scripted?

4 A These are the only two teleconferences that
5 I can remember having a script for. It's very common
6 to have your bullet points that you want to make sure
7 you cover everything in a meeting. But to have your
8 exact words written out and read, those are the only
9 two meetings that I can remember during the time
10 that --

11 Q And were you on very many teleconferences?

12 A Well, during -- having been at the FDA for
13 seven to eight years, there have been a lot of
14 teleconferences. I think, just to qualify that, if
15 there was ever something that I wanted to be sure
16 that I said it exactly right, I can't say that
17 somewhere along the line if there was a very
18 important message that I didn't write it out for
19 myself to be sure that I got it right.

20 Q But am I correct in understanding that these
21 two scripted teleconferences that we've discussed
22 today, this one and the one that we discussed

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1 previously, are the only two teleconferences that you
2 recall being entirely or predominantly scripted?

3 A Yes.

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15 Q What do the negotiations look like when you
16 have an exchange -- a label negotiation, as you just
17 described that?

18 A It varies with divisions. They can be

19 actual face-to-face meetings with the label
20 projected. They can be exchanging labels that are
21 with track changes. They can be teleconferences
22 where you discuss labels.

0049

1 Q And about how many exchanges or meetings
2 might you have or over -- yeah. I'll leave the
3 question at that.

4 A It's usually multiple.

5 Q And over how long of a period of time might
6 that take place?

7 A Well, ideally, it would take place over a
8 long time, because that would reflect that the
9 division has completed their review and everyone's
10 done and on schedule and you have time to do -- the
11 goal is to have adequate time to do label
12 negotiations in a methodical and thoughtful way.

13 Many times a review gets completed later in
14 the game, and then it becomes more of a -- in the
15 last days negotiation, or you may have your label
16 negotiated except for a small piece of it and you're
17 just still going back and forth at the last minute
18 over one point.

19 Q During those negotiations does the Agency
20 typically give the sponsor guidance on what it would
21 like to see?

22 A Yes.

0050

1 Q Do you know why this teleconference was so
2 carefully scripted?

3 A Well, I thought I answered that. I thought
4 because this was not the usual, because this -- and
5 we wanted to be careful to not miscommunicate or give
6 false information, it got written down to paper.

7 Q And do you know why the usual back and forth
8 was not going to occur?

9 A The usual back and forth was not going to
10 occur because it was -- the review decision was
11 disparate. We had come to our review decisions and
12 it was going up to upper level.

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MR. WARSHAWSKY: It's 1/23/04.

THE WITNESS: Okay. Could I see the minutes
from that?

BY MS. STRAUSS:

Q Sure. I'm really just asking if you
remember?

A If I remember?

Q Yeah.

A Well, I remember in terms of -- it's because
there were age issues brought up, the adolescent
issues. And I was just looking to see -- I guess I
need you to ask the question again because I must
have misunderstood your question.

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4 Q Do you know if you did a search for
5 literature beyond that provided by the sponsor?

6 A We definitely did.

7 MR. WARSHAWSKY: Do you want these also now?

8 MS. STRAUSS: Sure.

9 MR. WARSHAWSKY: I mean if you're done with
10 them. Otherwise I'll hold onto them.

11 BY MS. STRAUSS:

12 Q I want to turn now to the review that you
13 wrote. In a minute I'll be handing you a document
14 marked 30829 through 30880. You wrote a very
15 thorough review, so feel free to take time to look
16 over the many pages.

17 A There's no way. So I'll look at -- I'll
18 look at specific sections as --

19 Q Okay. I'll give you time to look at it as
20 we go. Does this appear to be the review that you
21 wrote as Deputy Division Director?

22 A Yes, it does.

0056

1 Q And around April 1st of 2004?

2 A Yes.

3 Q Were these your opinions when you wrote this
4 review?

5 A They -- I would suppose that they would be
6 because I don't know why I would have written this
7 down.

8 Q And are these still your opinions today?

9 MR. WARSHAWSKY: I'm going to object to that
10 question only on the grounds that the witness has

11 indicated that she hasn't reviewed the whole
12 document. And it's conceivable that there's some
13 line in there that she might not in fact subscribe to
14 today.

15 MS. STRAUSS: All right.

16 BY MS. STRAUSS:

17 Q Are you aware of any change in your
18 opinions -- strike that. Let me ask that a different
19 way. Do you believe that your opinions on the
20 acceptability of the Plan B SNDA have changed since
21 the time that you wrote this review?

22 MR. WARSHAWSKY: I'll object sort of on the

0057

1 same grounds. I think if you sort of want to ask her
2 the ultimate conclusion question, I think that's
3 probably something that she can answer. But I think
4 if you're talking about the various conclusions and
5 so forth, again, that might be in that document, I
6 think it's a little overbroad.

7 BY MS. STRAUSS:

8 Q Well, why don't you go ahead and answer it,
9 because I think I've asked are you aware of anything,
10 understanding that there may be some minute subpoint
11 that you are not recalling now? Is there anything
12 that you're aware of that you have changed your
13 opinion on?

14 A Well, I guess my answer -- I don't guess.
15 My conclusion now is the same conclusion I had then,
16 that the risk/benefit ratio supports it approval
17 without restricted access.

18 Q And do you know of anything that you've
19 become aware of after this review, after writing this
20 review, that would have contradicted your conclusion?

21 A No.

22 Q Okay. On the first page in the second

0058

1 paragraph toward the bottom, there's a sentence, "The
2 divisions presented adolescent data in an effort to
3 address these concerns in a meeting with the
4 Commissioner on February 18th, 2004."

5 A Uh-huh.

6 Q That's the meeting of which you were looking
7 at the meeting minutes a little while ago. "These
8 data, however, were considered inadequate to

9 establish that there would be no potential for
10 negative impact from nonprescription access to
11 emergency contraception in the adolescent
12 population."

13 My question is, what was the proposed
14 negative impact?

15 MR. WARSHAWSKY: Proposed?

16 BY MS. STRAUSS:

17 Q What was the stated -- what was the negative
18 impact that you were referring to?

19 A The major -- my recollection, the major
20 concerns were that -- were behavioral.

21 Q What sort of behavioral impact?

22 A That it would have an impact on promiscuity.

0059

1 Q Were there any other negative impacts that
2 you recall?

3 A Yes. Other listed impacts, I believe, are
4 listed in reviews. The major one was behavior; how
5 do you know that adolescents could read the
6 directions adequately to take -- follow the
7 instructions. That was the major thing.

8 Q Okay. Were you concerned about those
9 negative impacts yourself after reviewing the data?

10 A No.

11 Q If you look down to the next paragraph, the
12 very last sentence says, "The divisions and offices
13 have concluded that the risk/benefit ratio for this
14 product supports its approval for nonprescription
15 marketing without an age restriction."

16 When you say the risk/benefit ratio, what
17 were the risks on the risk side of that ratio?

18 A I think that's just a phrase we use a lot
19 because you always consider the risks, and you always
20 look for the risks associated with the product, and
21 you always look for the evidence of the -- whether
22 benefit has been established and weigh the two and

0060

1 come to your conclusions, so.

2 Q But what are the risks associated with
3 Plan B?

4 A Well, I'm assuming that my review talked
5 about the safety. Yes, it's got extensive safety.
6 So it would be what I wrote in terms of the -- in the

7 safety review.

8 Q Okay. Could you please turn to page 30830?
9 I have one sort of initial question on the page.
10 Where it says "reviewer comment"-- I'm sorry, the
11 next, 30830.

12 A Uh-huh.

13 Q There are several paragraphs throughout the
14 document where it says reviewer comment that are
15 broken out from the rest of the text and italicized.
16 Are those your comments?

17 A Right. That's a commonly used style in
18 reviews.

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5 Q Okay. Thank you. Could you turn to page
6 30833, the section marked 1.2.1, young age group
7 performance. And I have some questions here
8 involving just this one paragraph. And just for your
9 reference, there are different study objectives
10 referred to in this paragraph. And if you want to
11 look back at what those were, they are set forth in
12 Section 1.1, which is two pages back.

13 So if you could take a minute to read "young
14 age group performance", 1.2.1, I'll ask you a couple
15 of questions clarifying the statistical significance
16 of some things.

17 A (Witness reading document). Okay.
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MR. WARSHAWSKY: Nan, can we take a short break at this time?

MS. STRAUSS: Sure.

MR. HELLER: Can we just wait one minute, a couple of minutes? I just want to look at this and see if we want to finish this up.

(Discussion off the record.)

MR. HELLER: Just a couple more questions

0067

1 and then we'll break.

2 BY MS. STRAUSS:

3 Q Could you turn please to 30834? I believe
4 it's the next page. If you look down under Section
5 2.0, it's the second paragraph. And could you just
6 read to yourself the first couple of sentences, the
7 first three sentences?

8 A (Witness reading document.) Okay.

9 Q So the first sentence says, "The Advisory
10 Committee has voted overwhelmingly in response to FDA
11 Question Number 2 that the results of this Actual Use
12 Study were generalizable to the overall population of
13 potential non-Rx users of Plan B," in parentheses,
14 "yes equals 27 and no equals one," end parentheses,
15 period.

16 My first question is, can you explain in lay
17 person's terms what it means to be generalizable to
18 the overall population of potential non-Rx users?

19 A I guess my first question would be to
20 establish that these aren't my words and that those
21 were actually the words in an Advisory Committee
22 question. And I don't know if we have the list of

0068

1 questions or if -- did I reproduce them in this
2 review?

3 Q You may have.

4 MR. WARSHAWSKY: I think you did.

5 BY MS. STRAUSS:

6 Q On page 30867 you did reproduce the
7 questions.

8 A Okay. So that kind of question would be
9 whether you can determine -- whether you can conclude
10 or come to conclusions about how the product will be
11 used once available to the nonprescription population
12 based on the Actual Use Studies. So how the -- are
13 the data generalizable, so are the -- the study
14 conduct and the results, can you come to conclusions
15 about the population at large that could walk up to
16 the product over-the-counter and buy the product.

17 Q Is that another way of saying that you can
18 extrapolate from the Actual Use Study to determine
19 the effects on the relevance to the overall
20 population?

21 A I think that's another way of saying what I
22 said.

0069

1 Q Okay. Going back to 30834, the sentence
2 after you describe Question 2 that was before the
3 Advisory Committee, you wrote "FDA and CDER upper
4 level management have expressed that they do not
5 concur with this conclusion." Can you explain why
6 they did not concur with this conclusion?

7 A Unfortunately, it's not there in that
8 sentence, and I don't have -- I haven't really read
9 my review. Based on my memory of the meetings that
10 we've discussed earlier, it had to do with the
11 adolescent population.

12 Q And what about the adolescent population was
13 a problem for them?

14 A I think I already said that, was that the
15 issues that were raised, I think I gave you two or
16 three issues. One was behavioral, and then taking
17 the -- taking the pills as prescribed -- as written
18 on the label.

19 Q So it would be the same issues that you
20 mentioned when we were talking this document at the
21 beginning?

22 A (Witness nods.)

0070

1 MS. STRAUSS: Okay. Why don't we take a
2 break now. And when we come back, you can hang on to
3 that document because I do have a few more questions
4 about it.

5 THE VIDEOGRAPHER: Going off the record.
6 The time is 11:29 a.m.

7 (Recess.)

8 THE VIDEOGRAPHER: We are back on the
9 record. The time is 11:46 a.m.

10 BY MS. STRAUSS:

11 Q Can I ask you please to turn now to page
12 30849 of the same document that you've been looking
13 at?

14 MR. WARSHAWSKY: 49?

15 MS. STRAUSS: 49.

16 BY MS. STRAUSS:

17 Q And I want to just ask you a clarifying
18 question about the second sentence of the second
19 paragraph. So why don't you take a second to look at
20 that.

21 A (Witness reading document.) Okay.

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Q Thank you. Then if you turn to page 30877,
there's a place at the top where some information has

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1 been taken out. Do you know what was taken out?

2 MR. WARSHAWSKY: Objection.

3 MR. AMANAT: Objection.

4 MR. WARSHAWSKY: Assumes facts not in
5 evidence.

6 A I don't know what was taken out.

7 BY MS. STRAUSS:

8 Q Does it appear to you that something was
9 redacted from this document?

10 A Well, what you usually see when something is
11 redacted is big black lines. And I don't see big
12 black lines, so.

13 Q Do you see a big blank space on the top
14 of --

15 A I see a big blank space.

16 MR. HELLER: Maybe we should just ask.
17 Karen, do you know if this document was redacted?

18 MS. SCHIFTER: I don't remember specifically
19 this document, but it looks to me like it was. But
20 didn't we give to them the annotated index which
21 indicated what was --

22 MR. HELLER: It may be on there.

0073

1 MS. SCHIFTER: If it was, if I redacted it,
2 it's on the index.

3 MR. HELLER: It should be on the index.

4 MS. SCHIFTER: And it will tell you the
5 privilege.

6 MR. WARSHAWSKY: The normal practice isn't
7 to indicate on the document redacted?

8 MS. SCHIFTER: Well, you know, there's
9 normal Agency practice, and then there's what my
10 paralegal and I do. And that might not be --

11 MR. WARSHAWSKY: What you have time to get
12 done and everything else.

13 MS. SCHIFTER: We're not -- this isn't the
14 normal course of business. This is just for this
15 lawsuit.

16 BY MS. STRAUSS:

17 Q Can you tell me who this document was

18 addressed to when you wrote it?
19 A Is it addressed to somebody.
20 Q Who did it go to?
21 A It got entered into the division or into
22 CDER's file system on applications. It's an

0074

1 electronic file system. So it got entered into the
2 system as my review of the application.
3 Q Did you send this document to lawyers at the
4 Agency?
5 A No.
6 MR. AMANAT: And just for the record, the
7 annotated index of the Administrative Record reflects
8 that this document has redacted attorney-client
9 communications.
10 MR. HELLER: And she just testified that it
11 wasn't communicated to lawyers by her.
12 MR. AMANAT: Well, regardless, there's --
13 MR. HELLER: I understand. Just so we --
14 MR. WARSHAWSKY: Let me clarify. She
15 testified that this particular document wasn't given
16 to a lawyer.
17 MS. SCHIFTER: But it could still reflect a
18 communication from a lawyer.
19 MR. HELLER: So it might be reflecting a
20 communication --
21 MR. AMANAT: From a lawyer.
22 MR. HELLER: -- from a lawyer.

0075

1 MR. AMANAT: In the document which appears
2 to have been once redacted according to the log that
3 we gave you.
4 MR. HELLER: Okay.
5 BY MS. STRAUSS:
6 Q Do you think that that document included
7 summaries of communications from lawyers?
8 A Let me read this. (Witness reading
9 document.) So what was your question again?
10 MS. STRAUSS: Can you read back my question,
11 please?
12 (Record read.)
13 A So this blacked-out --
14 BY MS. STRAUSS:
15 Q Whited-out portion.

16 A I -- I don't know what -- I don't know what
17 those communications would be. So since I don't know
18 that, I'm assuming it must not be. But I don't know
19 what summaries of communications with lawyers means.
20 What --

21 Q Did you have conversations with lawyers at
22 the FDA around -- before you wrote this memo that you

0076

1 believe would have been reflected in your memo?

2 A When I wrote the memo in April, we had
3 had -- and this follows the sentence "on a restricted
4 distribution plan".

5 MR. WARSHAWSKY: I'm going to have to advise
6 you not to disclose the content of any communications
7 that you had with counsel or that was communications
8 conveyed to you, conveying counsel's legal advice
9 about these issues.

10 THE WITNESS: Okay. So could I talk to you
11 off line then?

12 MR. WARSHAWSKY: I think that would be a
13 good idea, just so we can see what she's going to
14 say.

15 MS. STRAUSS: That's fine. So we're going
16 off the record.

17 THE VIDEOGRAPHER: We're going off the
18 record. The time is 11:55 a.m.

19 (Recess.)

20 THE VIDEOGRAPHER: We are back on the
21 record. The time is 12:01 p.m.

22 MR. WARSHAWSKY: At this time we're going to

0077

1 object to this line of questioning and instruct the
2 witness not to answer questions aimed at determining
3 the content of the redacted portion of the review.
4 We acknowledge that there was a redaction done, and
5 that the asserted grounds for the redaction was -- is
6 attorney-client privilege.

7 And if you feel the need to probe that
8 further, of course we can go to the magistrate judge,
9 and if he wants to see that passage in camera, we can
10 address it in that manner. But at this point we are
11 asserting the attorney-client privilege with respect
12 to this portion of the review.

13 MS. STRAUSS: Well, what I would just like

14 to confirm with the witness is that there was some
15 time that she received advice from legal counsel that
16 was of a sort that she might have been relaying here
17 and not delve further into the substance of what that
18 was. Because the matter of whether or not --

19 MR. WARSHAWSKY: We're representing that
20 there was in fact something in this document that she
21 wrote relating to advice from legal counsel.

22 MR. HELLER: I guess, Steve --

0078

1 MR. AMANAT: She may not have recognized
2 this.

3 MR. HELLER: I understand that. But I mean,
4 she may say yes or no to this question. I'm not
5 saying that would affect the assertion of your
6 privilege. But I guess what we want to know is, does
7 she recall knowing of any legal advice related to
8 Plan B that she might have memorialized in this
9 document. And whether she says yes or no, we're not
10 going to probe further beyond that.

11 MS. STRAUSS: But the existence of a
12 communication --

13 MR. HELLER: Or knowledge of some, it seems
14 to me we're entitled to find that out, whether she
15 believes that she had some knowledge about legal
16 communication, legal advice.

17 MR. WARSHAWSKY: We won't object to asking
18 the witness the question as you just phrased it.

19 MR. HELLER: So maybe she could just answer
20 my question. I mean Nan can say that.

21 MR. WARSHAWSKY: Sure. If the reporter can
22 read back the way you phrased your question.

0079

1 MR. HELLER: Do you want me to just say it
2 again? Dr. Griebel, I'll just -- if you don't mind,
3 Frank.

4 MR. AMANAT: No.

5 BY MR. HELLER:

6 Q Dr. Griebel, as of the date that you wrote
7 this memo, do you know whether you had some knowledge
8 of legal advice regarding Plan B that you might have
9 summarized in this document?

10 MR. WARSHAWSKY: I'm going to object to the
11 form of the question. But that's fine. Let's just

12 get an answer and move on.

13 A And based on the discussion that we just
14 had, yes, I wrote -- I wrote something here, so.

15 MR. HELLER: That's fine.

16 BY MS. STRAUSS:

17 Q I'm very quickly going to show you this next
18 document. It appears to me -- it's marked 30918
19 through 30920. And it appears to be a document
20 reflecting a request for guidance from Jane Axelrad
21 in the Office of Regulatory Policy, is that correct,
22 requested by you?

0080

1 A Let's see the dates. (Witness reviewing
2 document.)

3 Q It's dated July 27th of 2004 on one side,
4 and then on the other side it's dated July 22nd,
5 2004. But my question is, did you ever receive a
6 response to this request?

7 A Okay. Let me read what it was.

8 Q Sure.

9 A (Witness reading document.) I don't
10 remember receiving a written response. I can
11 remember meetings discussing this issue with -- with
12 Jane.

13 Q Did you feel that you received an oral
14 response?

15 A In terms of a conclusion? I don't remember
16 that. I just remember discussions.

17 Q Okay. If you can hand me the document.

18 MR. WARSHAWSKY: Do you want this back, the
19 review?

20 MS. STRAUSS: Yes, please.

21 BY MS. STRAUSS:

22 Q And we're done with your review as well.

0081

1 Here's another document marked at the bottom 31031
2 through 31084. This is a memorandum written by you.

3 And I think that we will take a short break
4 now. If you can take a look at the document, and
5 then when we come back, I'll just ask you a couple of
6 quick questions about it. We're going to take a
7 break for the videotape to be switched. Thank you.

8 THE VIDEOGRAPHER: This marks the end of
9 tape number one in the deposition of Dr. Donna

10 Griebel. We're going off the record. The time is
11 12:08 p.m.

12 (Recess.)

13 THE VIDEOGRAPHER: Back on the record. Here
14 marks the beginning of videotape number two in the
15 deposition of Dr. Donna Griebel. The time is 12:13
16 p.m.

17 BY MS. STRAUSS:

18 Q So we're looking at the document that starts
19 on page 31031, and this is a memorandum that you
20 wrote in January of 2005, is that correct?

21 A Correct.

22 Q The second paragraph begins, "No new safety

0082

1 and efficacy data had been presented in this NDA
2 submission or in the Division's updated review of the
3 medical literature and post-marketing safety reports
4 for levonorgestrel that alters my original
5 recommendation that the risk/benefit ratio of
6 nonprescription access to Plan B supports its switch
7 to nonprescription status without age restriction. I
8 continue to support Plan B switch to nonprescription
9 status without age restrictions."

10 I just wanted to ask you a question. In
11 this memo where you reconfirm your prior memo and
12 you've in fact attached it, I know that you indicate
13 in that first sentence that there was no conflicting
14 evidence that you reviewed. But did you review
15 additional data before -- between writing the first
16 memo and writing the second memo?

17 A I don't remember the content of this NDA
18 submission. In just reading the sentence, it appears
19 that what I did review was updated review of the
20 literature and post-marketing safety reports. So
21 that based on what is in the sentence, that looks
22 like what I can definitively say that I reviewed.

0083

1 Q Okay. Did you have any involvement in the
2 Plan B over-the-counter switch process after you
3 submitted this memo?

4 A What do you mean by involvement?

5 Q Did you participate in the process in any
6 way? Did you write any further memos, any -- it's a
7 broad question. I'm just asking what you recall.

8 A I don't recall -- this is after the
9 resubmission, so I'm just trying to get the timeline
10 again. So they resubmitted. The memo date is
11 January 2005. And when did they get a response to
12 the submission, official response from FDA?

13 Q Well, the next action that I'm aware of was
14 the announcement in August of -- August 26th of 2005
15 of the Advance Notice of Proposed Rulemaking
16 announced by Dr. Crawford. But I'm just asking if
17 you recall participating in the process in any way,
18 in discussions with people, meetings, reviews,
19 between those dates?

20 A I'm -- I'm sure there were discussions.
21 This brings to closure in terms of what the
22 recommendation is. But certainly I don't remember

0084

1 discussions with or meetings with people higher than
2 our office level. I just don't remember.

3 Q Okay. What was the nature of those
4 discussions that took place that you do recall?

5 A I don't remember specifics, and at this
6 point I don't remember if what I am remembering was
7 related to the first action or this action. So I
8 might say something wrong.

9 Q Do you believe that the Agency's failure to
10 approve the Plan B over-the-counter switch has had
11 any negative effects on the population that needs
12 Plan B?

13 MR. WARSHAWSKY: I'm going to object to the
14 characterization of the FDA's actions in the
15 question.

16 A I think I wrote in my review that I thought
17 it would be a positive impact on the public to
18 have -- a positive public health impact to have
19 easier access to the product. So to take that action
20 I thought would be a positive -- have a positive
21 effect.

22 BY MS. STRAUSS:

0085

1 Q And so by not taking that action you think
2 that it would have had a negative impact?

3 A I think that improving access would be a --
4 would improve public health.

5 MS. STRAUSS: Okay. Thank you. I don't

6 have any more questions for you at this time. It's
7 possible that after Mr. Warshawsky asks you his
8 questions, I might have some follow-up questions,
9 just to give you a warning.

10 MR. WARSHAWSKY: I think now might be a good
11 time to break for lunch. Is that okay?

12 MR. HELLER: I was going to say if it turned
13 out that you only had half an hour of questions and
14 wanted to do them now and just release the witness
15 after that. But if you think you have --

16 MR. WARSHAWSKY: I'll have more than that,
17 yes. So why don't we reconvene at say ten after one?

18 MR. HELLER: Quarter after one is fine, too.
19 It's entirely up to -- maybe we should ask the
20 witness how much time you'd like for lunch.

21 THE WITNESS: Fifty minutes would be fine,
22 so a quarter after is fine.

0086

1 MR. WARSHAWSKY: Say a quarter after?

2 THE WITNESS: Uh-huh.

3 THE VIDEOGRAPHER: Going off the record.

4 The time is 12:20.

5 (Luncheon recess.)

6 VIDEOGRAPHER: We are back on the record.

7 The time is 1:16 p.m.

8 EXAMINATION BY COUNSEL FOR DEFENDANT

9 BY MR. WARSHAWSKY:

10 Q Good afternoon, Dr. Griebel. I'm going to
11 be asking you some questions now about your
12 involvement in the Plan B application process, and
13 specifically about some of the statements and
14 conclusions included in your reviews of that
15 supplemental drug application.

16 First, let me hand you a document. This is
17 a copy of Dr. Griebel's review dated on the front
18 April 1, 2004, and bearing Bates stamps beginning at
19 Tummino 30829 through the page with the electronic
20 signature, which is Tummino 30880. And this should
21 be copy of the same document that we've looked at
22 earlier today. Here's one for you. Did I describe

0087

1 the document accurately?

2 A Yes, you did.

3 Q If you could please turn to the second page

4 of this document. And on this page we see a heading
5 near the top, 1.0 Summary of Label Comprehension
6 Study Review Findings. And then there's various
7 information included in here about the Label
8 Comprehension Study in this case. I'd like to direct
9 your attention to the reviewer comment closer to the
10 bottom of that page.

11 A Yes.

12 Q And you testified earlier that the reviewer
13 comments in italics represent your conclusions or
14 assessment of the particular material at issue in the
15 section, is that correct?

16 A I think I indicated that it's my comments.

17 Q Your comments?

18 A Uh-huh.
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20 Q And within the framework of CDER's review
21 process, were your conclusions and judgments as
22 expressed in this particular review memo binding on

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1 higher-level officials?

2 A No.

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4 Q Have you seen this particular document
5 before?

6 A I'm sure I have.

7 Q Did you review this particular document in
8 the process of completing your own review of the
9 Plan B applications?

10 A I don't remember. I know I've read this
11 document. Whether I read it immediately -- well, now
12 I'm looking at it and I remember these QQQ's, yeah.
13 So I suspect I read it right before my review as
14 well. But I know we read these before the -- read
15 these in detail before the Advisory Committee.

16 Q And do you know Karen Lechter?

17 A I know her. I met her for this -- for this
18 review and grew to know her during the course of the
19 review. So yeah.

20 Q Do you have any reason to believe that she
21 wasn't qualified to prepare the analysis presented in
22 this particular document?

0096

1 A No.

2 Q How about -- I'll ask you a couple of
3 questions about that. But how about the second
4 document I've shown you?

5 A Uh-huh.

6 Q This is the Medical Officer Addendum to Dr.
7 Lechter's review. Have you ever seen this document
8 before?

9 A Let me see if I recognize it. I don't
10 remember this.

11 Q Do you remember if you reviewed this
12 document as part of your process in preparing your
13 own review of the Plan B application?

14 A I don't remember.

15 Q Do you know who conducted or performed this
16 Medical Officer Addendum?

17 A No, I don't. There's no signature on here.
18 You abstracted it from a clinical review, so it must

19 be from -- I mean, it's got "clinical review" at the
20 top so it must be from a clinical reviewer.

21 Q Okay. And do you know who that would have
22 been?

0097

1 A Do we know what means that it came out of --
2 clinical reviewer, it had to have been a reviewer on
3 one of the two teams, I believe. What's the date on
4 it?

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Q Do you know what the age distribution of
Plan B users is?

15 A Off the top of my head, I don't. And I
16 can't recall if I ever knew that.
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Q And I understand that, and we'll get to the
Actual Use Study in a moment.

5 In looking at the numbers of participants
6 included in the Label Comprehension Study, is there
7 any objective way to determine in the context of this
8 study where the line between enough and not enough
9 participants would be drawn?

10 A I'm not aware of any. I don't know what the
11 objective -- there's not a regulatory document that
12 I'm aware of sitting in place that says that.

13 Q I'd like you to turn now please to the
14 second document that I've -- or the second report,
15 the Medical Officer's Addendum, and take a look at
16 that document. And in particular, please turn to
17 Page 12 of that document, which is Tummino 10180.
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Q Yes, the document we were just looking at.

A I'm sure that I was referring to looking at the data that was submitted in the application.

Q So you're referring to --

A I wouldn't be reproducing this review's data here. So I am talking about -- so I -- since I'm not sure I remember this document, and I know that I spent a good deal of time looking at the actual data submitted in this application, that this would have been written about what I looked at and reviewed in the application.

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Q Let's go back to your review now, please.
Let's turn to Page 3 of your review, please. And,
actually, just for document management purposes, I
can take these back to get them out of your way.

A Now is this --

MR. WARSHAWSKY: Thank you.

MR. HELLER: Steve, which ones are you
taking back?

MR. WARSHAWSKY: Well, you can hold on to
that.

THE WITNESS: There's another piece of the

22 clinical review.

0118

1 MR. WARSHAWSKY: I'm just getting them out
2 of her way, that's all. I'll get those back.

3 MS. STRAUSS: And for clarification, when
4 you say Page 3 of Dr. Griebel's review, you're
5 talking about Tummino 30831, is that correct?

6 MR. WARSHAWSKY: That's correct.

7 BY MR. WARSHAWSKY:

8 Q Now, at the top of this page or near the top
9 of this page, there's a reviewer comment. And let me
10 read --

11 A Can I ask you again what page we're on?

12 Q Oh, yes. This is the third page. I want to
13 -- actually, why don't you just read the reviewer
14 comment to yourself, and then I'll have a few
15 questions on that.

16 A (Witness reading document.) Okay.

17 Q In evaluating the meaning or significance of
18 a Label Comprehension Study for purposes of an OTC
19 switch application, are there any statutory or
20 regulatory or policy guidelines that prescribe how
21 much weight or emphasis should be given to that
22 study?

0119

1 A Not that I'm aware.

2 Q Are there, similarly for Actual Use Studies,
3 are there any statutory or regulatory or policy
4 guidelines that prescribe how much weight or emphasis
5 should be given to an Actual Use Study?

6 A Not that I'm aware. My statement here is
7 based on interaction with OTC, with them explaining
8 how these things are approached and the discussion at
9 the Advisory Committee Meeting.

10 Q Now, in terms of your point here about
11 greater than usual emphasis on the Label
12 Comprehension Study, was that your own opinion or was
13 that an opinion given to you by other people on the
14 OTC side?

15 A There's two components to that question.
16 Greater than usual gives the perspective of -- usual
17 means having a historic context to rely upon, which I
18 would have to rely upon OTC to give me that
19 perspective. The placing of greater than usual

20 emphasis implies that somebody -- that there was a
21 perception that there was -- there was indeed
22 emphasis being placed on this Label Comprehension

0120

1 Study. And that of course would come from my
2 interactions in the various meetings that we had.

3 Q Who in the OTC side offered the opinion that
4 greater than usual emphasis was being placed on the
5 Label Comprehension Study?

6 A In terms of usual emphasis in the context,
7 we had meetings that were attended by Dr. -- by Dr.
8 Rosebraugh, by the review team, Arlene -- not Arlene
9 -- I'm drawing a blank on names now -- the medical
10 team leader for this application, and the actual
11 Division Director of OTC, Charlie Ganley.

12 Q Now, when you say here that placing greater
13 than usual emphasis on the Label Comprehension Study
14 compared to the Actual Use Study, quote, is not
15 appropriate, end quote, what standard or rule or
16 guidelines are you applying in drawing -- or making
17 that observation?

18 A I think that's linked in that phrase with
19 "or usual review practice". It was not the usual
20 review practice, and so it seemed that if you were
21 placing all of your eggs in that basket and focusing
22 on the Label Comprehension Study, when that's not the

0121

1 usual review approach to switches, that is why I used
2 the word "appropriate".

3 Q Well, let me just clarify this. Are you
4 aware of any statutory or regulatory or policy
5 guidelines that prohibit placing more emphasis on a
6 Label Comprehension Study than on an Actual Use Study
7 in conducting an OTC analysis?

8 A Not regulatory guidelines.

9 Q Now, the rest of your reviewer comment
10 appears to be making the argument that the Label
11 Comprehension Study was flawed in some fundamental
12 way, and that the Actual Use Study was actually a
13 better study. Is that a fair characterization of the
14 remainder of that comment?

15 A I think that is not a fair -- a fair
16 description of that comment.

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8 Q And when you look at an Actual Use Study
9 that's presented as part of an OTC application, do
10 you analyze the degree to which the design and
11 execution of the study succeeded in simulating an
12 OTC-like setting?

13 A Yes.

14 Q And in conducting that evaluation of the
15 design and execution of the Actual Use Study itself,
16 what sorts of factors or standards or measures,
17 et cetera, do you apply to determine if in fact
18 sufficiently and adequately simulates the OTC
19 setting?

20 A Well, I think the -- I'd have to look at
21 what my review said.

22 Q Well, I'm asking more of a general question.

0125

1 In general.

2 A Well, you would look at the design and see
3 how it was set up and whether it did the best it
4 could to simulate the OTC setting.

5 Q Is there any objective measure that would
6 tell the regulator whether a particular Actual Use
7 Study adequately simulated an OTC setting?

8 A Is there any objective measure?

9 Q Yes.

10 A Can you give me an example of an objective
11 measure? I don't know how you would measure
12 something like that. I mean, if you set up the study
13 in a nursing home when it was for emergency

14 contraception, then that's clearly inadequate. I
15 don't know what objective measure you would be
16 looking for.

17 Q Well, you testified previously that you
18 conduct some sort of an evaluation of how
19 successfully the study simulates the OTC environment.
20 And I guess my question is, do you make that
21 evaluation sort of based on your own personal,
22 scientific, regulatory experience and judgment and

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1 knowledge and various factors that go into your own
2 ability to assess that, as opposed to for example
3 some sort of objective, say, a table of criteria that
4 a third person could independently verify and
5 replicate without having your particular experience
6 and knowledge base and so forth?

7 A I'm not aware of the existence of such a
8 table, if that's what you're asking.

9 Q Are there any -- just to bring this full
10 circle, are you aware of any statutory or regulatory
11 or policy guidelines that prescribe -- that are
12 either prescribed or recommended to CDER reviewers to
13 use in evaluating whether an Actual Use Study
14 adequately simulates on OTC-like setting?

15 A I don't remember that there is one. I don't
16 remember that there's a guidance. There may be a
17 guidance. I just don't remember. I would have
18 thought that would have been addressed as part of the
19 Advisory Committee presentations, but I don't -- I
20 don't recall it.

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Q Okay. I'd like to turn now to a different document. We need Document 6, tab 6. Yes. Thank you. Dr. Griebel, if you could please take a look at

0130

1 the next document that I've provided to you. Let me
2 describe it for the record. This is the Clinical
3 Review of the Plan B OTC Actual Use Study. And it is
4 Bates stamped Tummino 10191 through Tummino 10242.

5 A Yeah. And what am I looking at? I just
6 looked at the last page because that was the last
7 number you said. What number am I supposed to be
8 looking at?

9 Q Well, actually, for now I'm just going to
10 ask you a couple of general questions about the
11 document, and then we'll look at a specific page.

12 My first question is, have you ever seen
13 this particular review before?

14 A I don't remember. Whose review is this?
15 This is clinical review -- this looks like the same
16 thing that we had the excerpt from.

17 Q Right. Well, it doesn't say on this
18 document, but I will represent that this clinical
19 review and the earlier one we looked at were
20 conducted by Dr. Jin Chen. So does that refresh your
21 recollection as to whether you've actually seen this
22 document or not?

0131

1 A I have seen this document.

2 Q And did you review this document as part of
3 your process of completing your review of the Plan B
4 application?

5 A I reviewed portions of it. I don't remember
6 which portions, but I reviewed his review of the
7 literature and the Actual Use Study.

8 Q Do you know if this particular study was
9 provided to members of the Advisory Committee?
10 A This study. You mean this review?
11 Q Uh-huh.
12 A Was the review complete then? It wasn't
13 complete then. Dr. Chen, I believe, presented at the
14 Advisory Committee, but the review would not have
15 been completed, that I recall. Was it entered in DFS
16 at that point?
17 Q Offhand, I don't know the answer to that. I
18 believe it was completed, but I don't know.
19 MR. HELLER: It has a date on it. On the
20 front it says "report date updated January 30th,
21 2003."
22 MR. WARSHAWSKY: Oh, I see.

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1 MR. HELLER: But I don't know if that's the
2 last time. I don't know what that means.
3 MR. WARSHAWSKY: Yeah, it has report --
4 yeah.
5 MR. HELLER: It doesn't have a sort of date
6 for the document, does it?
7 MR. WARSHAWSKY: Yeah. And I'm not sure if
8 that report date is referring to the clinical review.
9 I think that's referring to a Barr submission or a
10 Women's Capital Corporation submission. In any
11 event --
12 MR. HELLER: But January 30th, 2003 is
13 before they even filed their SNDA. So I don't
14 know --
15 MR. WARSHAWSKY: Right. I think he's
16 referring to their internal documentation.
17 BY MR. WARSHAWSKY:
18 Q Well, let me ask you, also. So you're not
19 sure exactly. The earlier two studies we looked at
20 for Dr. Lechter and the other clinical review on the
21 OTC Label Comprehension Study, do you know if either
22 of those reviews were provided to members of the

0133

1 Advisory Committee?
2 A I don't remember that they were.
3 Q All righty. Well, I'd like to direct your
4 attention now to Page 14 of the clinical review that
5 I just gave you, which is also Tummino 10204.

6 Now, before we look at this particular
7 table, let me ask you the general question. In
8 designing and executing an Actual Use Study, is the
9 age -- are the ages of the participants of that study
10 relevant in the design of that study?

11 A I think it's the same answer that I gave you
12 before, that you want a representative population of
13 the ones that would be users, and you wouldn't want
14 to design it with -- a contraceptive trial with
15 postmenopausal women in it.

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1 Q You would agree, would you not, that having

2 some understanding of the age distribution of Plan B
3 users in the general population is a pertinent or
4 relevant piece of information for CDER's reviewers to
5 have?

6 A That's -- yes, I would agree that would be
7 important information.

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3 Q Let me ask the question more generally then,
4 given that you haven't had recent exposure to this
5 and I don't expect you to remember and to regurgitate
6 what's in your review. We can always ourselves look
7 at the review.

8 Generally speaking, when you're presented
9 with an Actual Use Study, with respect to population
10 you testified earlier that one goal, one design goal
11 of an Actual Use Study is to have a representative
12 population of the target population.

13 A Uh-huh.

14 Q Generally speaking, when you're looking at
15 that level of representation and you're making a
16 determination whether it's adequate or not, what
17 standards or measures or other criteria do you
18 apply in determining -- to determine that the
19 representation is adequate?

20 A Again, in terms of having a guidance, I'm
21 not aware that there's a guidance. And I don't
22 remember what I relied upon at that time to -- to go

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1 through this, other than looking at the objectives of
2 the study and looking at what the objectives are of
3 an Actual Use Study and using the -- using clinical
4 sense, so.

5 Q Is it fair to say that what you do in
6 performing the evaluation that we were just
7 discussing is in essence to exercise your own
8 personal scientific and regulatory judgment as
9 informed by your medical training, your work
10 experience, your own logical and thinking abilities
11 and so forth, and that all works together to reach
12 your conclusion as to whether there's adequate
13 representation or not?

14 A Well, again, I don't remember how I
15 approached this. This was -- if this was new to me,
16 which I think it may have been, I would have asked
17 them what -- asked others that have experience doing
18 it what are -- what's the approach, is there -- is
19 there something written somewhere on how you approach
20 these, is there a template, is there a previous

21 review that somebody has done that I could see how
22 they looked at something.

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1 But then there's a basic approach that you
2 take to evaluating studies and data and which just
3 starts at looking at what the objectives are, what
4 the primary end point is, and then evaluating how it
5 was designed around those to see if you think that
6 it's adequate, and then looking at the data as it was
7 obtained to see if it was done as it was supposed to
8 have been done.

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6 Q Well, let me ask you the question a little
7 differently or let me ask a slightly different
8 question. Would you expect if Plan B were made
9 over-the-counter without an age restriction that
10 there would be users for the product age 12 and 13?

11 A I suspect there will be.

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Q And -- okay. Now, if you would please turn to the next page. And this -- the next page shows a different breakdown --

MS. STRAUSS: Excuse me. What page are you on now?

MR. WARSHAWSKY: Page 15 or Tummino 10205.

MS. STRAUSS: Thank you.

0149

1 BY MR. WARSHAWSKY:

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Q Well, let's address this study in isolation to begin with. How would you go about deciding whether the absolute number of participants in this or another Actual Use Study was adequate?

And by that, again let me give an example to clarify what I'm driving at. Let's say for Plan B, we know the age distribution for the general population, and we're going to design an Actual Use Study that adequately represents that target population. But let's say the total number turns out

13 to be 14 people, you know, one in this age range and
14 two in this age range and five in this age range and
15 three in this age range and two in that age range.
16 You could have that kind of number of participants,
17 or you could have 5,000 participants hypothetically.
18 And they're distributed in a certain manner with a
19 hundred in this category and a thousand in this
20 category and so forth.

21 My question is, in looking at the study as
22 conducted in terms of the total number of

0151

1 participants, how do you as a -- in your former
2 capacity as a CDER regulator determine whether the
3 total number of participants is adequate such that
4 you can draw meaningful conclusions from the data
5 those participants give you?

6 A It would depend on what you were trying to
7 gets from the age groups. It's not very common to
8 spend a lot of time parsing out the age groups in
9 reproductive trials. So in terms of a -- it would --

10 Q Make it any age group. Make it zero to a
11 hundred if you want. I'm just asking -- however you
12 want to parse it out -- how do you know when you have
13 a sufficient and total number of participants so that
14 you can draw meaningful conclusions from their data?

15 A I guess again it comes back to what is the
16 meaningful conclusion that you think that you are
17 drawing and whether you have a need to make a
18 meaningful conclusion in a subset by age.

19 And, again, the subsetting by age that we
20 normally do in drug trials is looking at what happens
21 to the elderly in studies because they
22 physiologically are different in terms of their --

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1 how they deal with drugs, their bodies deal with
2 drugs.

3 And then you have pediatric trials that are
4 set up different because physiologically that's a
5 group that is individual, too, and you have laws that
6 have been set up to actually have trials set up to
7 study that subgroup in drugs so that they're not left
8 behind. So in taking that approach it's just what --
9 it's looking at what are you gaining from this and
10 what is it that you're looking for.

11 And I'd have to go back and re -- go through
12 the history of this application. I can't remember if
13 this was discussed at -- if it was posed as a
14 question in the Advisory Committee. I think that it
15 was, it was described adequately represented, and the
16 Advisory Committee said yes. The -- in the process
17 of the review, when did the adequacy of those numbers
18 become an issue? It may be that we didn't really
19 think that was a big issue until it got brought up.
20 And then we went, okay, if this was not -- if this
21 doesn't meet someone else's comfort level, then we
22 need to start looking for other additional data.

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1 But, again, this is all based on not having
2 all the documents and rereading history in the past.

3 Q Let me ask it a little differently. First
4 of all, to make it more direct, are you aware of any
5 statutory, regulatory, or policy guidelines that
6 prescribe or recommend a certain total number of or
7 certain absolute numbers of participants to be
8 included in Actual Use Studies?

9 A I'm not aware.

10 Q Are you aware of any objective standards or
11 measures by which to assess whether an Actual Use
12 Study includes an adequate number of participants?

13 A I think I told you before I don't know
14 whether there's a guidance on Actual Use Studies. I
15 can't remember.

16 Q Now, I'd like to take this more generally
17 because, again, I don't want to necessarily limit
18 your ability to answer the question based on factual
19 information that you may not be familiar with
20 anymore.

21 Generally, when you're looking at an Actual
22 Use Study, however you want to say it's defined --

0154

1 designed, I don't care. But an Actual Use Study
2 includes a certain number of participants to prove
3 something or to show something or reach some kind of
4 results that allow you to reach some conclusions.

5 My question is simply, how do you go about
6 evaluating whether in the first instance there's even
7 enough participants in the study?

8 A Again, in setting up the Actual Use Study,

9 you would be looking at, they'd propose a design,
10 they'd propose the primary end points, point or
11 points, the statistical analysis plan. And the
12 numbers would be powered based on what your
13 confidence interval is, since that was a single-arm
14 trial, what the confidence intervals would be. And
15 that would -- the stats would drive the numbers.

16 I don't know -- again, I don't know what --
17 I don't remember seeing the guidance that they had
18 given on designing their Actual Use Study and whether
19 they were told a certain proportion of this, a
20 certain proportion of that, this many numbers of
21 this, this, this and this.

22 Q Now, you used a couple of terms just now.

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1 You referred to the power of the study and you also
2 talked about, quote, confidence intervals, end quote.
3 Are those terms of art in the field of statistics?

4 A Uh-huh.

5 Q Do you mean to suggest by using those terms
6 that there is a statistical test that one could use
7 and which could be replicated by other individuals
8 that would tell you whether a particular study has a
9 sufficient number of participants?

10 A I'm not sure how this study was designed. I
11 wasn't part of the design, and I don't design --

12 Q I'm just asking generally.

13 A Generally, studies have a -- in general,
14 studies have a primary end point, and you know what
15 you want to show, and you have a hypothesis. And
16 based on the hypothesis and what you want to show,
17 you can power it to have confidence intervals around
18 whatever is the end point, the outcome is going to
19 be.

20 With an Actual Use Study, I don't remember
21 what their plan was, so I can't comment on that. I
22 don't remember.

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MR. WARSHAWSKY: Yes. Why don't we take a

3 break.

4 THE VIDEOGRAPHER: We're going off the
5 record. The time is 2:59 p.m.

6 (Recess.)

7 THE VIDEOGRAPHER: We are back on the
8 record. The time is 3:13 p.m.

9 BY MR. WARSHAWSKY:

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19 Q Sure. Generally speaking, how do you
20 determine whether the length of an Actual Use Study
21 is adequate?

22 A Again, I don't know what the guidance -- if

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1 there's a guidance on this. What makes sense if an
2 Actual Use Study is for something that's going to be
3 used within a few-day period, then four weeks seems
4 -- makes sense that it would be adequate. It seems
5 you could even make it a week. But I don't know if
6 there's a guidance that they have in terms of how
7 short the therapy is, how long you follow up. I
8 don't recall that.

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22 Q And generally now, not talking specifically

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1 with respect to the Actual Use Study in this case or
2 with respect to any guidelines or directives that may
3 have been given to Barr about the Actual Use Study;
4 just generally speaking, how would you go about
5 determining whether the length of an Actual Use Study
6 was adequate?

7 A Well, if I was dropped into the OTC Division
8 today and someone told me that a company had
9 submitted an Actual Use Study proposal that I needed
10 today come and give them feedback on, I would ask is
11 there -- do you have some standard that you go by, is
12 there a guidance on this.

13 And then I would sit down with the team and
14 discuss what's being studied and come to and have a
15 discussion about what we would like to know, what
16 would -- so in a team approach come to the
17 conclusions on what I thought would be adequate. So
18 that's how I would do it.

19 Q And would there be any kind of objective
20 measures or standards or other type of criteria or
21 indicia that you would apply in reaching that
22 conclusion?

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1 A Again, I would use whatever standards they
2 had written down, what the -- what the -- if it's
3 unwritten, what has been the approach of the Division
4 and take it on an individual basis from there about
5 what was being studied and what was -- what we needed
6 to know from an Actual Use Study.

7 Q If you could please turn now to the next
8 page, and that would be Page 11 of your review, which
9 is Tummino 30839. And at the top of this page
10 there's another reviewer comment. And this sort of
11 summarizes in a general form the various topics I
12 think that we've just covered.

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MR. WARSHAWSKY: We have to change the tape.
So why don't we take just a two-minute break to do
that.

THE VIDEOGRAPHER: This marks the end of
videotape number two in the deposition of Dr. Donna
Griebel. We're going off the record. The time is
3:21 p.m.

(Recess.)

THE VIDEOGRAPHER: Here marks the beginning
of tape number three in the deposition of Dr. Donna
Griebel. The time is 3:27 p.m. We're back on the
record.

22 BY MR. WARSHAWSKY:

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1 Q Dr. Griebel, would you please now turn to
2 Page 40 of your review, which is also page Tummino
3 30868. And at the bottom of this particular page you
4 discuss the Advisory Committee, and on the next page
5 or two you quote some statements made by various
6 members of the Advisory Committee. I'm not going to
7 ask you anything about what specifically you wrote
8 here. I'd like to talk to you a few minutes about
9 the Advisory Committee.

10 A Okay.

11 Q What was the purpose of holding an Advisory
12 Committee Meeting for the Plan B OTC switch
13 application?

14 A The purpose would be written in the Federal
15 Register and would be reflected in the questions that
16 were asked. And it would be to get the input from
17 the Committee, the advice from its Advisory
18 Committee, advice to the FDA on the approvability of
19 the switch with regard to the specific questions.

20 Q And in terms of this advice given by the
21 Advisory Committee, how much -- well, let me ask the
22 first question. Is the Advisory Committee's vote

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1 binding --

2 A No.

3 Q -- on the FDA?

4 A No.

5 Q How much weight is to be ascribed to the
6 vote of the Advisory Committee?

7 A There is nothing written about 50 percent
8 weight, 100 percent weight, 20 percent weight. You
9 have assembled a group of experts, and so you
10 should -- so the purpose is to weigh very carefully
11 what they say. And if you should decide that you
12 dismiss any particular part of what they say, because
13 they are experts, you need to have carefully thought
14 out why you disagree with what this panel of experts
15 has said.

16 Q I'd like to show you what I believe will be
17 the final document. The document that I've just
18 provided to you, if I can find it, is a Summary of
19 the Advisory Committee Meeting, and it is Bates

20 stamped Tummino 30421 through Tummino 30425. Let
21 me first ask you if you've ever seen this particular
22 document?

0168

1 A It was probably -- usually these are
2 circulated immediately after a meeting.

3 Q So it's your recollection that you did see
4 it or you probably saw it?

5 A I'm sure it was sent to me, but I -- I don't
6 remember.

7 Q And you participated in the Advisory -- or I
8 should say you attended the Advisory Committee
9 Meeting, is that correct?

10 A Correct.

11 Q Let me turn your attention to the last two
12 pages of this document. And this document or these
13 pages show the various questions presented to the
14 Advisory Committee and a summary of the Advisory
15 Committee vote, along with the summary of some of the
16 comments made by various members. Is that a correct
17 characterization of these last two pages?

18 A That's correct.

19 Q And is it fair to say that the Advisory
20 Committee voted quite strongly in favor of making
21 Plan B OTC for all age groups, is that correct?

22 A That's my recollection of it.

0169

1 Q Well, we see from the various votes, for
2 example, that the very last question, for example
3 Question 6, "Do you recommend Plan B be switched from
4 Rx to non-Rx status?" 23 out of 28 members voted
5 yes, is that correct?

6 A Yes. Correct.

7 Q And is it also correct that in your own
8 review at different points throughout your analysis
9 you pointed to the vote of the Advisory Committee
10 Meeting -- the vote of the Advisory Committee to
11 support your own conclusions about OTC acceptability
12 for Plan B, is that correct?

13 A That's how I remember it. I'd have to
14 look -- you pointed out -- what section was it?
15 Because I think that section did have Advisory
16 Committee. Enclosed is my review --

17 Q I think the section we were just looking at

18 did. That was page Tummino 30868. But I believe
19 there were some others as well.

20 A I know that issues that people raised as
21 concerns, I did try to address in the course of the
22 review.

0170

1 Q And is it fair that you and other reviewers
2 within CDER took the Advisory Committee's vote as
3 being supportive of your own analyses in favor of
4 making Plan B OTC?

5 A I think that it's fair to say that we took
6 their votes as supportive of the switch of Plan B
7 OTC. Do I -- your question implied that we already
8 made a decision at the time of the meeting, and we
9 didn't have a decision at the time of the meeting.

10 Q I didn't mean to imply that. And is it fair
11 to say that in your own analysis of whether Plan B
12 should be over-the-counter, you gave some weight to
13 the Advisory Committee's vote on that issue?

14 A I always take into consideration what the
15 experts have to say. If they over -- if they had
16 reservations, then those should be considered even if
17 it's a minority reservation to see what their concern
18 was and weigh that in.

19 Q And do you know what documentary or other
20 written materials were provided to the Advisory
21 Committee, either at the meeting or in advance?

22 A There's a standard package that's -- well,

0171

1 that's a good question. There was a standard
2 package. There's a background document from the FDA
3 that has to get prepared, and that is usually
4 prepared -- has to be prepared a month in advance of
5 the meeting, but this one came in way late because of
6 multiple revisions that were made at the request of
7 folks beyond the Division. The -- the applicant
8 submits the material as well that they get. And
9 that's what I'm aware of that they receive.

10 Q Other than this summary memo that you
11 referred to, was there any other documentary
12 materials provided to the Advisory Committee by CDER?

13 A By CDER. I am not aware of any. There's
14 the Backgrounder.

15 Q What went into the Backgrounder?

16 A I would have to have the Backgrounder.

17 Q Do you know if members of the Advisory
18 Committee were provided with either complete copies
19 or summaries of the various clinical reviews done of
20 the initial application?

21 A I'd have to look at what the background
22 document was.

0172

1 Q Now, is it your opinion that the members of
2 the Advisory Committee Meeting -- the Advisory
3 Committee, after receiving whatever documentation
4 they received, and after listening to the
5 presentations at the meeting were sufficiently
6 informed to render a scientific and/or regulatory
7 judgment about Plan B and whether it should be OTC?

8 A That would be the intent.

9 Q In other words, yes, you think that they
10 were sufficiently informed to render those judgments
11 and recommendations?

12 A That's -- you do your best to do that for
13 the meeting. So that's your goal.

14 Q And was that goal in your opinion achieved
15 in this case?

16 A I would say it was achieved in this case.

17 Q I'd like you to please turn now to Page 49
18 of your analysis, which is also Tummino 30877. And
19 this -- I want to direct your attention to Section
20 9.0, the Deputy Director's Recommended Regulatory
21 Action. And you're the Deputy Director referred to
22 here, is that right?

0173

1 A Correct.

2 Q And it looks like -- well, at the beginning
3 of this section you -- I tell you what, why don't you
4 just read that paragraph and then I'll ask you a
5 question.

6 A (Witness reading document.) Okay.

7 Q You summarized the various, some, probably
8 not all, but some of the various pieces of evidence
9 that you looked at. And then you wrote near the end
10 of this, "I conclude that the risk/benefit ratio of
11 the nonprescription access to Plan B supports
12 approval for switch to nonprescription status." Do
13 you see that?

14 A Uh-huh.
15 Q Now, when you use the phrase "risk/benefit
16 ratio", what do you mean?
17 A That's something we use all the time.
18 They're words that we -- when you do a review, you
19 weigh risk and benefit and you come to a conclusion.
20 So that's just -- that's part of the review, so
21 therefore it's the phraseology that's used.
22 Q Now, correct me if I'm wrong, did you just

0174

1 say you weigh the risks and the benefits and come to
2 a conclusion?
3 A That's what -- that's what CDER reviewers
4 do.
5 Q How do you know how much weight to give to
6 the items on the risk side of the analysis and to
7 items on the benefit side of the analysis?
8 A Well, sometimes it's very easy. If you have
9 a trial and one arm that you compare is killing
10 everybody and the other arm is not and you don't get
11 any benefit, then that's very clear. Otherwise, you
12 weigh whether it's worth to have some nausea and
13 vomiting in 40 percent of the population. So I've
14 had experience where a -- a product, a substantial
15 proportion of the patients couldn't tolerate it
16 because it made them nauseated and they wouldn't take
17 it, but those who could tolerate it benefitted from
18 it. So that product got approved.
19 So that's a risk/benefit analysis that you
20 do that -- so it's -- there's not, as we have seen in
21 the news, a so much percentage risk versus so much
22 percentage benefit. I think it's very difficult for

0175

1 a clinical scientist to create a formula that would
2 make everything easy. That would be very -- that
3 would be nice if there was something that you could
4 just dump it in and it would spit out the answer.
5 Q To clarify this particular point, is it fair
6 to say then that the risk/benefit analysis that
7 you're describing is not an objective or quantifiable
8 analysis?
9 A I don't think those are fair words.
10 Objective, yes, you look at the data. You have
11 objective percentages of bad outcomes, you have

12 objective percentages of benefits. And you look
13 at -- you examine both of those. So objective, I
14 don't think is a fair word. What was the second
15 word?

16 Q Quantifiable.

17 A Quantifiable again is a -- fair word -- is
18 there -- not a fair word. Is there a formula where
19 you put it in both and it spits out yes/no? No,
20 there's no formula for it, if that's what you're
21 looking for.

22 Q That's partly what I'm looking for. In

0176

1 conducting the risk/benefit analysis yourself, two
2 words -- well, we've just used the word "weight", and
3 weight implies an amount, how much a thing weighs, it
4 weighs a numerical amount, whatever those units are.
5 Assuming that's the use -- assuming that's what the
6 word means, in conducting the risk/benefit analysis
7 that you just described, did you ever in the Plan B
8 setting ever actually assign numerical values to the
9 different items on the risk side or the benefit side
10 before reaching your conclusion?

11 MS. STRAUSS: Objection. I think that the
12 question is very unclear. And I don't think that the
13 assumptions you're making are necessarily the
14 assumptions that the witness is making.

15 MR. WARSHAWSKY: Fair enough. Let me just
16 ask the question more directly.

17 BY MR. WARSHAWSKY:

18 Q In conducting your risk/benefit analysis in
19 this case, did you actually assign numerical values
20 to the different items on the risk side as well as
21 the different items on the benefit side?

22 A Well, certainly in the discussions you do.

0177

1 What is the benefit, what is the known efficacy of
2 the product, what is the known safety record of the
3 product, what is the known -- if you are avoiding an
4 unintended pregnancy, what bad outcomes can happen in
5 pregnancy. This is commonly done in contraceptive
6 reviews, what pregnancies have attendant risks of
7 pulmonary emboli, myocardial infarctions, strokes.
8 So pregnancy itself has its attendant risks. So
9 avoiding an unintended pregnancy is a benefit. And

10 so you evaluate -- we evaluated that efficacy.

11 So in terms of looking at risks, we looked
12 at the safety record of the product versus the
13 efficacy. And we examined the unknowns that were
14 raised by individuals that I'm sure were outlined in
15 my review point by point, and then came to the
16 conclusion.

17 But did we put that into a formula with,
18 this is an unknown, I will give it on a risk, because
19 it's an unknown, a zero or a hundred on a zero to
20 hundred scale? No, I never -- I never did that.

21 MR. WARSHAWSKY: I have no further
22 questions.

0178

1 MR. HELLER: Let us take a moment to confer.

2 We don't need to go off the record.

3 (Discussion off the record.)

4 FURTHER EXAMINATION BY COUNSEL FOR PLAINTIFFS

5 BY MS. STRAUSS:

6 Q I just have a couple of very, very quick
7 questions for you. You indicated in your testimony
8 earlier, I believe, that the Dial study from North
9 Carolina would provide data about the age
10 distribution of users of Plan B, is that right?

11 A Well, the issue of the age distribution
12 being whether I knew what the age distribution was, I
13 said that was a potential source that you could look
14 at to see if you could find that, that was what I
15 intended it to be. I don't know if that -- I'd have
16 to look at it again.

17 Q Okay. And do you know if the North Carolina
18 Dial study had a lowest age below which they would
19 not take calls?

20 A I don't know that. I think they had -- all
21 I remember is there was a single very young
22 individual that did call.

0179

1 Q And counsel for the government referred to
2 your personal, scientific and regulatory judgment
3 earlier when he was asking you questions. And in
4 answering those questions, you didn't mean that you
5 were using your personal judgment reflecting your
6 personal values, did you? I understood you to mean
7 that you were using your professional --

8 A Professional judgment.
9 Q -- judgment?
10 A Correct.
11 Q I don't know if the court reporter was able
12 to capture your answer. Could you just --
13 A I would not intend to say personal judgment
14 bringing in my own value system in making a
15 regulatory decision.
16 Q So it's more accurate to say that you were
17 exercising your professional judgment?
18 A Correct.
19 MS. STRAUSS: Thank you. Those were the
20 only questions that we had. Thank you very much for
21 your time today.
22 MR. WARSHAWSKY: Thank you very much,

0180
1 Doctor. Hold on. You're attached and we have to go
2 off the record.
3 THE VIDEOGRAPHER: Here marks the end of
4 videotape number three in the deposition of Dr. Donna
5 Griebel. Going off the record. The time is
6 3:49 p.m.
7 (Signature having not been waived, the
8 deposition of DONNA GRIEBEL, M.D. was concluded at
9 3:49 p.m.)
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0181
1 ACKNOWLEDGMENT OF DEPONENT
2 I, DONNA GRIEBEL, 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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(DATE) (SIGNATURE)

0182
1 CERTIFICATE OF SHORTHAND REPORTER - NOTARY PUBLIC
2 I, Nancy K. Barker, Certified Shorthand
3 Reporter, the officer before whom the foregoing
4 proceedings were taken, do hereby certify that the
5 foregoing transcript is a true and correct record of
6 the proceedings; that said proceedings were taken by
7 me stenographically and thereafter reduced to
8 typewriting under my supervision; and that I am
9 neither counsel for, related to, nor employed by any
10 of the parties to this case and have no interest,
11 financial or otherwise, in its outcome.
12 IN WITNESS WHEREOF, I have hereunto set my
13 hand and affixed my notarial seal this 24th day of
14 July, 2006.
15 My commission expires:
16 September 30, 2007

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20 _____
21 NOTARY PUBLIC IN AND FOR THE
22 STATE OF MARYLAND

0183
1 E R R A T A S H E E T
2 IN RE: TUMMINO, et al. Vs. VON ESCHENBACH
3 RETURN BY: _____

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