1 UNITED STATES DISTRICT COURT

2 EASTERN DISTRICT OF NEW YORK

3 - - - - - - - - - - - - - - - X

4 ANNIE TUMMINO, et al., :

5 Plaintiffs, :

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

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

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

9 the Food & Drug :

10 Administration, :

11 Defendant. :

12 - - - - - - - - - - - - - - - X

13 Videotaped Deposition Of Steven Galson, M.D.,

14 M.P.H. Volume 2

15 Rockville, Maryland

16 Thursday, April 27, 2006

17 1:19 p.m.

18

19 Job No.: 1-77268

20 Pages 214-296

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

22

1 Videotaped deposition of Steven Galson, M.D.,
2 M.P.H., held at the offices of:
3
4 FOOD & DRUG ADMINISTRATION
5 5600 Fishers Lane
6 Rockville, Maryland 20857
7 (301) 827-1152
8
9 Pursuant to agreement, before Cynthia R.
10 Simmons Ott, Registered Merit Reporter, Certified
11 Realtime Reporter, and Notary Public of the State of
12 Maryland.
13
14
15
16
17
18
19
20
21
22

1 A P P E A R A N C E S

2 ON BEHALF OF THE PLAINTIFFS:

3 SIMON HELLER, ESQUIRE

4 BONNIE SCOTT JONES, ESQUIRE

5 NAN STRAUSS, ESQUIRE

6 VIVIEN LABATON, ESQUIRE

7 THE CENTER FOR REPRODUCTIVE RIGHTS

8 120 Wall Street

9 New York, New York 10005

10 (917) 637-3600

11

12 ON BEHALF OF THE INDIVIDUAL PLAINTIFFS:

13 ANDREA COSTELLO, ESQUIRE

14 SOUTHERN LEGAL COUNSEL, INC.

15 1229 NW 12th Avenue

16 Gainesville, Florida 32601

17 (352) 271-8890

18

19

20

21

22

1 A P P E A R A N C E S C O N T I N U E D

2 ON BEHALF OF THE DEFENDANT:

3 F. FRANKLIN AMANAT, ESQUIRE

4 STEVEN WARSHAWSKY, ESQUIRE

5 UNITED STATES ATTORNEY

6 EASTERN DISTRICT OF NEW YORK

7 One Pierrepont Plaza, 14th Floor

8 Brooklyn, New York 11201

9 (718) 254-6024

10 and

11 KAREN SCHIFTER, ESQUIRE

12 ERIC BLUMBERG, ESQUIRE

13 OFFICE OF THE CHIEF COUNSEL

14 FOOD AND DRUG ADMINISTRATION

15 5600 Fishers Lane, GCF-1

16 Rockville, Maryland 20857

17 (301) 827-1152

18

19

20

21

22

1 A P P E A R A N C E S C O N T I N U E D

2 ON BEHALF OF DURAMED RESEARCH, INC., AND BARR

3 PHARMACEUTICALS, INC.:

4 ANA C. REYES, ESQUIRE

5 WILLIAMS & CONNOLLY LLP

6 725 12th Street, Northwest

7 Washington, D.C. 20005

8 (202) 434-5276

9

10

11

12

13

14

15

16

17

18

19

20

21

22

1 C O N T E N T S

2 EXAMINATION OF STEVEN GALSON, M.D., M.P.H. PAGE

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

1 P R O C E E D I N G S
2 - - - - - - - - - - -
3 THE VIDEOGRAPHER: Here begins tape number
4 1, volume 2 in the deposition of Steven Galson, MD,
5 MPH, in the matter of Annie Tummino, et al. versus
6 Andrew C. von Eschenbach, as Acting Commissioner of
7 the Food and Drug Administration. Today's date is
8 April 27th, 2006. The time is 1:19 p.m. I would
9 like to remind the witness he is still sworn in from
10 yesterday.
11 MS. REYES: Before we begin, I'd like to
12 make a clarification from yesterday. We discussed a
13 document at Tummino 270 to 272, which in the morning
14 session we discussed as not being confidential, but
15 in the afternoon session, we marked as confidential.
16 And we are marking that document as confidential.
17 MR. AMANAT: And before we begin, may I
18 just ask the court reporter for the current time
19 index in terms of how much time has elapsed towards
20 the seven hour allocation so far.
21 EXAMINATION BY COUNSEL FOR PLAINTIFFS (RESUMED)
22 BY MR. HELLER:

1 Q Good afternoon, Dr. Galson. Did you tell
2 anyone at any time around December of 2004 or January
3 of 2005 that action on Plan B might be delayed for a
4 short period because the confirmation hearings of
5 Secretary Leavitt were underway in January of 2005?
6 A I might have -- that what would be
7 delayed?
8 Q Action on Plan B.
9 A 2005.
10 Q Just to remind you of the time frame,
11 we're talking about the period around when the action
12 package coming up through Dr. Jenkins had come to
13 you, and I think sometime thereafter, your delegated
14 authority was withdrawn by Dr. Crawford. But that
15 before that happened, and you might have thought that
16 there would be approval, that you might have told
17 somebody this is going to be held up for a little
18 while because of the confirmation hearings, is that
19 possible?
20 A I don't remember specifically saying that,
21 but it's possible. That wasn't an event in the
22 approval process of the approval consideration of

1 Plan B that sticks in my head. But frequently, for
2 example, if I have a meeting with the Acting
3 Commissioner, the Commissioner, it may be delayed if
4 there are things going on in the Department. For
5 example, they're having meetings because of a
6 confirmation or something else.
7 So events having to do with people in
8 charge at the Department sometimes do delay decisions
9 or discussions that have to take place. So it's not
10 out of the realm of possibility that I might have
11 said something like that if I was waiting to meet
12 with Dr. Crawford, and he had to delay a meeting
13 because he had to meet with somebody in the
14 Department about the confirmation. So I don't
15 remember that, but it's possible that I said that.
16 Q Do you know whether the confirmation
17 hearings of Secretary Leavitt resulted in any delay,
18 even of a matter of days, on the basis that this is a
19 high profile drug and the Department did not want
20 action on it to occur in the midst of the
21 confirmation hearings, do you know?
22 A I had certainly -- that wouldn't make

1 sense because the action wasn't until August, so it
2 was so delayed from the confirmation, I certainly
3 don't remember anything like that. Anything that
4 specific, you know.
5 Q When did CDER first start to consider the
6 possibility of a dual status or split label approval
7 for Plan B?
8 A Again, I definitely don't remember the
9 exact time. But, you know, this concept came up back
10 of course before the 2004 action. But I don't
11 remember where, you know, between the advisory
12 committee and the May date it first came up, I just
13 don't remember the first time it came up.
14 Q Do you know what the source was for the
15 idea of possible dual status for Plan B?
16 A I think the idea evolved with the
17 evolution of the concern about the lack of adequate
18 data in the younger age group. And as you know, that
19 started even before the advisory committee was
20 brought up by the staff, you know, in the fall time
21 frame. So it was -- that's what it was related to,
22 but again, sequentially, I don't --

1 Q I'm not talking about sequencing, I'm
2 asking whether you know who, what person sort of
3 first proposed --
4 A No.
5 Q Maybe we should have dual status for this
6 drug?
7 A I don't remember that.
8 Q Did there come a point where CDER became
9 concerned about possible legal obstacles to dual
10 status for Plan B?
11 A We were concerned from the very first time
12 there was a discussion about this dual status about
13 the legal and regulatory feasibility of doing this,
14 because it was something new. And whenever we do
15 something new, there's always a question about
16 whether it is consistent with the statutes, with
17 precedent, with judicial findings and other matters.
18 So it was the very first idea -- the time the idea
19 came up, there was a question about, could we do this
20 under the regulations.
21 Q And that would have been, then, sometime
22 probably early in 2004?

1 A I don't remember an exact date, but it
2 would have been at the same time as the idea first
3 arose.
4 Q When that happens, when CDER is sort of
5 concerned about legal issues surrounding an action,
6 do you typically seek legal guidance from lawyers in
7 the Department of HHS, or what would you typically do
8 under those circumstances?
9 A There's several different layers of steps,
10 depending on the severity and complexity. I have
11 some attorneys who their work in CDER is as
12 regulatory counsel, so they're not providing legal
13 advice, but they're experts in the regs. And if it's
14 something, you know, straightforward that doesn't
15 appear to be an actual formal legal issue, but has to
16 do with interpretation of the regs.
17 Q Okay.
18 A Then I get advice from that -- the staff
19 in CDER, who are lawyers. But if it actually is a
20 legal issue that's going to need that sort of formal
21 input, we would consult with the attorneys that are
22 housed in FDA here in this building, who are actually

1 part of the Department office. And I don't know
2 exactly what you meant by HHS, because the people
3 here actually report through to HHS, even though
4 they're assigned to FDA.
5 Q Is there a person named Axelrad, is she
6 someone -- within CDER, one of the regulatory people?
7 A She is the Associate Center Director for
8 Regulatory Policy, and she runs the Office of
9 Regulatory Policy in CDER.
10 Q Did she give you guidance or advice about
11 possible legal obstacles to dual status approval?
12 MR. AMANAT: I'm going to object to that
13 question, and instruct the witness not to answer the
14 question on the grounds of attorney-client privilege.
15 MR. HELLER: I don't want to know the
16 content of the advice, just whether she gave advice.
17 Is that --
18 MR. AMANAT: Could you read back the
19 question, please.
20 THE REPORTER: "Question: Did she give
21 you guidance or advice about possible legal obstacles
22 to dual status approval?"

1 MR. AMANAT: I withdraw my instruction.
2 The witness may answer the question.
3 THE WITNESS: She doesn't give me legal
4 advice. That's not her job. If I need legal advice,
5 I go to the Office of Chief Counsel.
6 BY MR. HELLER:
7 Q Is she a lawyer?
8 A She has a law degree, she's a lawyer,
9 right.
10 Q Would you turn in the notebook to tab
11 D-270.
12 A D, again?
13 Q 270 to -- these are documents marked
14 Tummino 270 to 272. Before I ask you about this
15 document, am I correct that she did not give you
16 legal advice, then, about possible legal obstacles to
17 dual status approval for Plan B because she never
18 gives you legal advice?
19 A I really need to have you be more precise
20 about the meaning of the term legal advice, because
21 this is of course an issue in the agency. That's not
22 her job, but she does have background as a lawyer and

1 she talks to me about interpretation of regulations.
2 But she is not giving me formal legal advice. I know
3 that sounds ambiguous, but it is a little bit
4 ambiguous sometimes. There's a gray area and it all
5 depends exactly what your definition of legal advice
6 is.
7 Q Would you look at this document and tell
8 me if you've seen it before or read it?
9 A We discussed it yesterday.
10 Q Okay, we did discuss it yesterday. Do you
11 view this -- in your definition of legal advice is
12 this legal advice?
13 A Let me just review it again. Let me just
14 note it's not addressed to me, first of all, I'm just
15 copied on it, so it wouldn't be advice to me. This
16 is one of the things that I rely on our attorneys to
17 define legal advice. So I don't know whether it --
18 this constitutes legal advice or not, because I'm not
19 an expert at how you define that.
20 MR. AMANAT: Counsel, just before you go
21 on, the witness has answered the question. But I
22 just wanted to state for the record that it is

1 defendant's formal position, as we will communicate
2 to you in the letter that I discussed yesterday, that
3 the defendant, the agency, does not consider this to
4 be formal legal advice.
5 BY MR. HELLER:
6 Q Did there come a time when you requested
7 legal advice about possible legal obstacles to dual
8 status approval, then, from the lawyers from HHS who
9 are housed in this building?
10 MR. AMANAT: That I'm going to object to
11 and instruct the witness not to answer the question
12 on the grounds of attorney-client privilege. Your
13 question -- the portion of your question after the
14 word about goes to the content of the communication,
15 not simply the existence of the communication by
16 virtue of the fact that you ask about communications
17 with a specific subject matter. By the very nature
18 of your question, you're asking about the content of
19 the communications, and I'm not going to allow the
20 witness to answer that question.
21 BY MR. HELLER:
22 Q I'll withdraw that question and try to

1 rephrase it.
2 Did you request legal guidance or advice
3 from the HHS lawyers that are housed here in this
4 building regarding Plan B.
5 MR. AMANAT: You can answer that question.
6 THE WITNESS: Is that okay? Yes.
7 BY MR. HELLER:
8 Q And did there come a time when you
9 received a response to your request?
10 A Is that okay to answer?
11 MR. AMANAT: You can answer that question.
12 THE WITNESS: Yes.
13 BY MR. HELLER:
14 Q Can you tell me approximately when you
15 received a response?
16 A There isn't any written response that I'm
17 aware of. I had meetings.
18 Q So the response was not in writing, it was
19 oral. Am I understanding you correctly? It was
20 conveyed to you orally, rather than in a written
21 document?
22 MR. AMANAT: Do you need to confer off the

1 record to discuss this?
2 THE WITNESS: Yes.
3 MR. AMANAT: Could we have a moment to
4 confer as to whether privilege may apply to his
5 answer?
6 MR. HELLER: About whether it's oral or
7 written, okay.
8 THE VIDEOGRAPHER: We are going off the
9 record. The time is 1:32 p.m.
10 (Recess.)
11 THE VIDEOGRAPHER: We are back on the
12 record. The time is 1:37 p.m.
13 MR. AMANAT: Would you please read back
14 the last question?
15 THE REPORTER: "Question: So the response
16 was not in writing, it was oral. Am I understanding
17 you correctly? It was conveyed to you orally, rather
18 than in a written document?"
19 MR. AMANAT: I'm going to object to the
20 question and instruct the witness not to answer the
21 question on the grounds that his answer would require
22 disclosure of material protected by the

1 attorney-client privilege.
2 MR. HELLER: Just for the record, could
3 you -- can you say what material it would require
4 disclosure of. I don't mean the content of it, but
5 in what way would that require disclosure of
6 material?
7 MR. AMANAT: The discussion of the form in
8 which he may have received legal advice from the
9 Office of Chief Counsel is itself privileged.
10 MR. HELLER: Okay.
11 BY MR. HELLER:
12 Q Let's see, can you turn to tab 3151 in the
13 binder. And this is pages marked Tummino 31214
14 through 31226. And this is your August 26th, 2005
15 memo. We spoke about it yesterday a little bit.
16 A Let me just spend a minute and refresh my
17 memory about it. Okay.
18 Q If you'd turn to the page marked 31216,
19 there's a paragraph starting with the word first, do
20 you see that paragraph?
21 A Yes.
22 Q And I think this paragraph is summarizing

1 information about the label comprehension study
2 submitted by the sponsor for Plan B, do I understand
3 that correctly?
4 A Let me just read the whole paragraph.
5 Q Sure.
6 A I can't be positive that some of that
7 wasn't from the actual use study, but I believe it
8 comes from the label comprehension study.
9 Q In your tenure at CDER, when considering
10 OTC switch applications, have you typically received
11 label comprehension studies from the sponsors?
12 A Yes.
13 Q And in those label comprehension studies,
14 is it unusual for younger -- well, first of all, not
15 all of them necessarily included adolescents at all,
16 is that right?
17 A I don't know, without, you know, going
18 back to those.
19 Q When they do include adolescents and
20 younger adolescents, is it usual for the younger
21 adolescents to comprehend the labels less well than
22 older adolescents and adults?

1 A Again, I don't -- I would have to refresh
2 my memory by going back to those applications. As
3 far as I can recall, there's only been one other
4 switch that occurred since I was at the agency, the
5 antihistamine that we discussed yesterday.
6 Q Wouldn't you expect, just as a matter of
7 common sense, for younger people to not comprehend a
8 label as well as older people with more education?
9 A Not really. The whole idea of the label
10 is that it's written at a reading level that is going
11 to be well below anyone who would need to take the
12 drug, so that there's no question who takes it is
13 able to understand it, so no.
14 Q So you would expect that, for example, a
15 12-year-old would comprehend the label as well as an
16 adult?
17 A They better, yes, I would hope so.
18 Q If you turn two pages forward, the page
19 marked 31218. The fourth paragraph starting with the
20 word further, "further, younger adolescents may
21 believe that Plan B could be substituted for other
22 forms of birth control," et cetera, do you see that

1 sentence?

2 A Yes.

3 (The following testimony was designated

4 "PROTECTED TESTIMONY".)

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22

1
2
3
4
5 (Conclusion of "PROTECTED TESTIMONY.")
6 BY MR. HELLER:
7 Q By the way, all the professional staff was
8 satisfied with the answer on this question, other
9 than you, is that right?
10 A I don't think so.
11 Q Who wasn't?
12 A I think Dr. Chen, I think that's her name,
13 that was one reviewer that --
14 Q You tell me, I don't know her name.
15 A I'd have to refresh my memory. There was
16 one review that didn't believe that the application
17 should be approved that's in the record.
18 Q But she believed that in August of 2005?
19 A I'd have to go back through her review
20 again, and I'd have to go back through each of the
21 individual reviews on that specific question to know
22 for sure what the answers -- there's so many

1 scientific issues that came up in each of the
2 people's reviews.
3 Q If you'd -- in the next paragraph, if you
4 would just read that paragraph to yourself, and
5 then --
6 A The one that begins "in addition."
7 Q Yes.
8 A Okay.
9 Q So my question about -- related to this
10 paragraph is, how does the increased risk of an
11 unwanted pregnancy from improper or -- from not
12 taking the Plan B properly compare to the risk of
13 unwanted pregnancy from not taking Plan B at all?
14 A Can you repeat that?
15 Q Yeah. So you have the risk, I think
16 you're talking here that there's a greater risk of
17 having an unwanted pregnancy if a young adolescent
18 does not follow the protocol for Plan B, basically
19 what she's supposed to do, she's supposed to take one
20 dose and then a second dose. And if she doesn't do
21 that, there's a greater risk of unwanted pregnancy,
22 is that right?

1 A Uh-huh. Yes. That has to do with the
2 effectiveness of the product.
3 Q Right.
4 A It wasn't a comparison.
5 Q No, no, no. But my question is, is she --
6 does that increase her risk of unwanted pregnancy
7 beyond the risk if she didn't take any Plan B at all
8 in the first place?
9 A We didn't assess that.
10 Q You don't know the answer?
11 A I don't know the answer.
12 Q Really?
13 A No, we didn't assess that. This has to do
14 with whether the product is effective in using -- if
15 someone can read the instructions, understand the
16 instructions, and use the product properly, so that
17 it works.
18 Q Right.
19 A If the evidence shows that they can't do
20 that, then we have a question about whether the
21 product is effective, is going to be effective. Is
22 it more effective than doing nothing? That wasn't

1 one of the things we looked at.
2 Q And you don't know?
3 A I don't know. We didn't look at the data,
4 so I can't -- it's a database question.
5 Q In fact, it might actually increase the
6 risk of an unwanted pregnancy to take just one dose
7 and not the second dose, because you don't know?
8 A Is that a question?
9 Q Yes.
10 A What's the question?
11 Q In fact, because there's no data, it may
12 well be the case, may it not, that just taking the
13 first dose of Plan B without the second one actually
14 increases the risk of unwanted pregnancy?
15 A Why would it do that? Of course, it
16 wouldn't.
17 Q You don't know.
18 A I said I don't know what the comparative
19 risk is. Of course, taking Plan B doesn't increase
20 your risk of pregnancy.
21 Q How do you know that? There's no data, is
22 there?

1 A Because I went to medical school.
2 Q But there's no data on that, because you
3 didn't have data about just taking it once?
4 A You don't need data for everything.
5 Things that are intuitively obvious, you don't need
6 data.
7 Q Now, isn't it correct that adolescents can
8 take risks with all sorts of over the counter drugs
9 if they don't use them properly.
10 A Of course.
11 Q Now, when you -- by the way, have you
12 examined any studies that specifically reference the
13 cognitive ability of adolescents with respect to
14 family planning matters?
15 MR. AMANAT: What are you referring to
16 when you say family planning matters, how far --
17 MR. HELLER: Family planning, whatever he
18 understands family planning to be.
19 THE WITNESS: Well, I think this actual
20 use study was that. It was a study of ability to
21 understand and use properly a family planning method.
22 So both the actual use study and the label

1 comprehension study were just that. You mean in the
2 literature?
3 Q Yeah, in published literature, is what I
4 meant.
5 A I have reviewed a huge amount of data and
6 number of papers and reviews, and nothing pops out.
7 If you want to ask about a specific one if I remember
8 it, I can try to recall. But nothing, of course,
9 pops out in my memory.
10 But I, of course, wouldn't need that. The
11 concept on which I based, partially based this
12 decision is the idea that the cognitive skills of
13 younger adolescents are different from the cognitive
14 skills of older adolescents. The risk taking, the
15 ability to balance benefit and risk. And that
16 applies to drug use, including all other drug use.
17 There isn't a special portion of the brain that has
18 to do with just family planning drugs.
19 Q As far as you're aware?
20 A No, I know that from medical school, too.
21 Q But do you know if there's published
22 literature indicating that, for example, adolescent

1 decision making about family planning is different
2 from adolescent decision making in other areas of
3 decision making?
4 A There may well be studies about that.
5 And, again, that wouldn't -- it's not relevant, I
6 think. Unless there was some studies showing that
7 there's huge increase in cognitive skill when it
8 comes to family planning. And if there was a study
9 like that, I would know about it because the
10 reviewers and you all would have highlighted it
11 already. So I don't think there's anything out there
12 like that.
13 Q If you could turn to page 31220, that's
14 two pages forward in your memo, the paragraph
15 beginning with the word third at the bottom of the
16 page. Could you read that paragraph, and then I want
17 to ask you a question about it.
18 A Sure.
19 Q Thank you.
20 A Uh-huh.
21 Q I just have a question. What do you mean
22 sort of in the middle of that paragraph by the term

1 "unprotected sexual intercourse," I guess roughly in
2 the middle of that paragraph.
3 A I mean the risks of unprotected sexual
4 intercourse related to transmission of sexually
5 transmitted diseases and HIV.
6 Q And is it -- and do you view unwanted
7 pregnancy as a risk of using Plan B? I'm trying to
8 understand --
9 A Their unwanted pregnancy is next in that
10 sentence.
11 Q The sentence says, "other noncontraceptive
12 OTC products, such as antacids, are indicated for
13 uses that are normally associated with risks much
14 less serious than unprotected sexual intercourse,
15 unwanted pregnancy and the risk of stroke"?
16 A Okay. So you didn't understand the
17 sentence. You want me to explain it better.
18 Q Is unwanted pregnancy a risk of Plan B?
19 A No, no, no, no, no, no.
20 Q So what does that mean?
21 A The concept here is that antacids, that's
22 the example, right, antacids are taken for, you know,

1 excess stomach acid, which has certain risks. But
2 Plan B is taken as a contraceptive. And both
3 unprotected sexual intercourse and unwanted pregnancy
4 are associated with health risks to the woman. What
5 I was trying to say is that those are more serious
6 than health risks associated with the condition and
7 the use for which antacids are indicated.
8 Q But unwanted pregnancy is a health risk
9 that Plan B is actually designed to prevent?
10 A Right, and that's the point we're trying
11 to make. The health condition for which Plan B is
12 indicated, both if you use it properly or improperly,
13 is a different type of health condition. The point
14 here is that contraceptives have to be considered,
15 particularly hormonal contraceptives, and that's part
16 of the discussion, differently from other OTC
17 products. They're not all the same.
18 Q And what about the last risk mentioned
19 there, the risk of stroke, is there a risk of stroke
20 from using Plan B?
21 A There's a risk of stroke from using
22 hormonal oral contraceptive products. The concept

1 here is that if the instructions aren't followed and
2 the product is used for regular birth control, that
3 is, it would be used a lot more frequently than is
4 indicated and that is conceived in the studies, it
5 would result in a higher exposure to these hormones
6 that are known to be associated with a whole litany
7 of risks, including stroke.
8 Q And is the risk of stroke specifically one
9 of the risks for Plan B?
10 A If it's used properly, that hasn't been
11 studied. But if it's used improperly, yes, because
12 it's a hormonal contraceptive. If it's used too
13 much, yes.
14 Q Is it not the case that a progesterone
15 drug like Plan B has no risk of stroke established in
16 the literature?
17 A I don't believe that's the case but, you
18 know, I think we wouldn't have put that in there if
19 that was the case.
20 Q Right. Because you worked on this memo
21 for months to make it as strong as you could?
22 A Right.

1 Q Is it your understanding that progesterone
2 only hormonal contraceptive drugs are associated with
3 the risk of stroke?
4 A Based on this sentence, yes. I mean, as
5 you know, the health effects of oral contraceptive
6 products is constantly evolving. There are studies,
7 you know, I've reviewed studies this year having to
8 do with some of these products. And so, you know,
9 the knowledge is changing, it's in dispute. Some
10 people believe one thing or another, there's
11 controversy in the literature. But we wouldn't have
12 put that in if our experts didn't think that was an
13 accurate statement.
14 Q Is it your understanding that, for
15 example, stroke is listed on the label for
16 progesterone only contraceptives as a risk?
17 A I don't know.
18 Q Is it your understanding that blood clots
19 are listed as a risk for progesterone only hormonal
20 contraceptive products?
21 A I don't know.
22 Q You also mentioned blood clots further on

1 in this paragraph as a serious health risk of Plan B,
2 is that right?
3 A Where is that?
4 Q Further on in the paragraph, I guess
5 second line from the bottom.
6 A Please, you know, that sentence doesn't
7 say that risk of stroke is a serious risk related to
8 Plan B. That's not what that sentence says.
9 Q Okay, what does it mean?
10 A It's trying to make a comparison that I
11 just described to you, that oral contraceptive
12 products and the condition for which they're used are
13 different from other OTC products. It's not trying
14 to talk about the science of the relation between use
15 of contraceptive products and specific adverse
16 events. That's not the goal of the sentence or of
17 this paragraph.
18 It's trying to make the comparison between
19 products that there's an intrinsic difference between
20 an antacid and an oral contraceptive product, which
21 is really incontrovertible. No one would say that an
22 OTC -- an antacid has the same risk as a

1 contraceptive product as a systemically absorbed
2 hormonal contraceptive product. That's the point,
3 not the specific risk.
4 Q I want to switch gears a little bit now.
5 A Sure.
6 Q To August 26th of 2005. This is a
7 different aspect of that date, so to speak.
8 On that date, the FDA announced publicly
9 it was going to initiate a process of proposed rule
10 making, is that your understanding?
11 A Right.
12 Q Excuse me, related to Plan B?
13 A It was -- we issued an advance notice of
14 proposed rule making.
15 Q Okay.
16 A Which may or may not result in a rule
17 making.
18 Q Do you know who made the decision to make
19 that announcement?
20 A Made the decision to do?
21 Q To do this advanced notice of proposed
22 rule making?

1 A Dr. Crawford.
2 Q Do you know if anyone from outside the FDA
3 provided input on that decision?
4 A I don't know. I'm not aware of any.
5 Q Did you give input on that decision?
6 A My assessment, as documented in this memo,
7 was limited to the scientific issues and the public
8 health issues related to proving --
9 Q I understand that. I'm just asking, did
10 you give input on --
11 A On the legal aspects?
12 Q I don't know if they're legal aspects or
13 not.
14 A Yeah.
15 Q But did you give input on the decision to
16 do an advanced notice of proposed rule making?
17 A I was -- as you know, Dr. Crawford told me
18 that he was going to make that decision, so I wasn't
19 invited to comment on it, you know --
20 Q Did you offer comment anyway?
21 A I really -- I don't remember whether -- I
22 know I didn't to him. He knew what my recommendation

1 was. I don't know whether I may have mentioned
2 something offhand to someone, I don't remember.
3 Q Did he ask you to sign the August 26th,
4 2005 letter to the manufacturer of Plan B that he
5 wound up signing?
6 A Can you point me to that?
7 Q I think I can find the document here
8 somewhere. You know that he sent -- someone sent a
9 letter.
10 A This is the action letter.
11 Q Yeah.
12 A To Barr, explaining -- I still would like
13 to see it, if you're going to ask me a specific
14 question about it.
15 Q It's 1041 in the binder, it's sort of at
16 the beginning part.
17 A Okay. So what's the question?
18 Q Did he ask you to sign this letter? Did
19 Dr. Crawford ask you to sign this letter?
20 A Well, the way this works is these letters
21 are put together by the center, because we have the
22 expertise, the format and the computer system and all

1 that. And my recollection about this is actually I
2 asked him to sign it. Because we normally sign
3 regulatory action letters.
4 Q Why did you ask him to sign it?
5 A Because it was his decision to do the
6 ANPR.
7 Q With which you strongly disagreed?
8 A Is that a question?
9 Q Yes. Did you strongly --
10 A What's the question?
11 Q Did you strongly disagree with his
12 condition to issue that action letter?
13 A Didn't you just ask me about that, and I
14 said that, you know, my role was to sign the
15 assessment of the scientific data. And the fact that
16 I thought that the application was --
17 Q I'm not asking about your role. I'm
18 asking you whether you strongly disagreed with what
19 -- the action he was taking in the letter?
20 A I wouldn't characterize it like that.
21 Q How would you characterize it?
22 A I felt that the application was strong

1 enough scientifically to be approved. I was aware
2 that there were legal and regulatory issues that the
3 Office of Chief Counsel and Dr. Crawford were
4 concerned about. So in that -- you know, I deferred
5 to them on it.
6 Q You don't have a choice about whether to
7 defer to them. I mean, the Commissioner decides.
8 A Right. Yeah. I made an assessment,
9 there's no point to me banging my fist on the table.
10 They have my written, and I knew it was going to
11 become public, assessment of the fact that the
12 application was strong enough from a public health
13 perspective. It's not my role in the agency to make
14 those sort of judgments. They knew I would have
15 preferred to approve the application, there's no
16 question about that.
17 Q If you'd go back to 3151 for a moment, I
18 have I think a quick question about it. This is
19 again your August 26th, 2005 memo. If you'd turn to
20 the last page, which is marked Tummino 31226.
21 There's an electronic signature and there's a name,
22 David -- how do you say this person's --

1 A Hilfinger.
2 Q Hilfinger. And there's a statement, "my
3 assistance in the finalization of this memo does not
4 indicate my agreement with its content or
5 recommendations"?
6 A That's just --
7 Q Have you ever had on another occasion
8 someone electronically sign something that you were
9 working on, where they put in this sort of statement?
10 A I think there was another one in this
11 binder, I can't remember when it was --
12 Q Other than with Plan B, have you ever had
13 someone do that?
14 A I haven't, but I rarely sign these kind
15 of -- I don't do very many electronic signatures,
16 because of the delegation in the center.
17 Q Do you know who Pat Ronin is?
18 A Uh-huh. Yes.
19 Q Who is that?
20 A He's one of the employees of the Office of
21 the Commissioner, he's currently the chief of staff.
22 And he's had -- he was the head of our legislative

1 operation before that.
2 Q Have you had communications with him about
3 Plan B?
4 A When?
5 Q At any time?
6 A Sure.
7 Q Can you tell me when?
8 A I've been working with him for four years
9 or so, so you have to try to -- I talk to him every
10 couple of days or every day sometimes.
11 Q So just to get a sense of, like have you
12 had five conversations with him about Plan B, or more
13 like a hundred, or somewhere in between?
14 A I really don't know. I would probably
15 guess somewhere -- you mean, in the whole, since
16 2004?
17 Q Yeah.
18 A Probably somewhere in between, I would
19 say. We have daily meetings of the coordination
20 meetings. And Plan B may come up, you know
21 frequently, so I wouldn't want to guess a count.
22 Q From the testimony of Dr. Woodcock, we

1 understand that there has been some sort of contract
2 between someone at the FDA and a private company
3 to --
4 A Right.
5 Q Organize comments that have been made in
6 response to the ANPR, the advanced notice of proposed
7 rule making. Do you know anything about that
8 contract?
9 A Yes.
10 Q Do you know who within FDA made the
11 contract with this company?
12 A It was done through the Office of Policy,
13 which is part of the Office of the Commissioner.
14 Q Have you seen the contract?
15 A No.
16 Q Do you know what the status of the
17 contract is, has it been completed or not?
18 A The latest that I've heard, and this goes
19 back to probably a week, a week and a half ago, a
20 week ago, was that they were very close to completing
21 the work of categorizing the comments that came in.
22 And they were preparing a summary, and that would be

1 ready for me and others to look at pretty soon.
2 Q Do you anticipate being involved in the
3 process around this ANPR, once this contract is
4 completed, and you get some summary from them?
5 A Yes.
6 Q Have you had involvement in either sort of
7 monitoring the contract or determining its specifics
8 in some way?
9 A No.
10 Q In previous instances where comments were
11 solicited by the FDA related to some product that had
12 been under consideration within CDER, has CDER ever
13 itself organized the comments or done what this
14 company is doing, but done it internally within the
15 FDA?
16 A Yes. There are a variety of different
17 offices and different methods that the agency has
18 used to handle comments that come in in response to
19 rule making.
20 Q Do you know why, in this instance, it was
21 not done within CDER, but instead contracted out?
22 A Yes, I think it was done this way because

1 we were short staffed, and we thought that the most
2 efficient way to get it done in a reasonable length
3 of time was to have someone else do it and pay for
4 it, because we didn't have the person power to get it
5 done quickly.
6 Q Were you interviewed by the General
7 Accounting Office in connection with their
8 examination or investigation around Plan B?
9 A Yes.
10 Q Do you know if Dr. Crawford was
11 interviewed by the GAO?
12 A I don't recall. I think it lists in the
13 report who they interviewed, but I just can't
14 remember if he was or wasn't.
15 Q Have you read the GAO report as it finally
16 was issued?
17 A Yes, yes.
18 Q And you don't recall whether Dr. Crawford
19 was interviewed?
20 A No, I don't.
21 Q Do you recall if Dr. McClellan was
22 interviewed?

1 A I think they were not able to interview
2 Dr. McClellan, I do remember that part.
3 Q So if it's the case -- I mean, if it's the
4 case that Dr. Crawford wasn't interviewed, you don't
5 know why he would not have been interviewed?
6 A My recollection is that they wanted to
7 interview him because I suggested during my interview
8 with them that they should talk -- many of the
9 questions they asked me had to do with things that I
10 knew Dr. McClellan or Dr. Crawford could help them
11 with. So I recall that I did suggest that they do
12 that, so I know they tried. I just can't remember
13 whether if they succeeded with him. I remember they
14 didn't succeed with Dr. McClellan, but I just can't
15 remember. I read a lot.
16 Q Do you remember some of the things that
17 you thought -- some sort of categories of information
18 that you thought they might be able to get from
19 Dr. McClellan or Dr. Crawford? What were you
20 thinking they could get from those two individuals
21 when you spoke to them, what sorts of information?
22 A They asked me, similarly to what you've

1 asked me, about what their role in the decision
2 making process was, and you know, what they were
3 thinking, or why they did things. And when they
4 asked me questions like that, that had to do with
5 their motivation or people they had spoken to, things
6 like that, I told them that I didn't have -- I didn't
7 know. And I suggested that they should meet with
8 them and ask them.
9 Q When they were conducting your interview,
10 and I just don't know how this process works, did
11 they record the interview, is there just someone
12 taking notes?
13 A They just take notes.
14 Q Do you remember the name of the person who
15 interviewed you?
16 A One of them is Martin, was Martin
17 Gerhardt.
18 Q I think I've seen his name in some of the
19 e-mails.
20 A The names are in the report. We can
21 get --
22 Q Do you remember other, just off the top of

1 your head?
2 A No, I don't. I know Marty, because he has
3 participated in a number of different GAO
4 investigations. And I see another person's face, but
5 I just can't remember her name.
6 Q Are you familiar with a letter sent by
7 Secretary Leavitt to Senator Enzi, United States
8 Senator Enzi, indicating that he believed FDA would
9 take action on Plan B by September 1st, 2005?
10 A I'm sorry, the beginning of the question
11 was, do I --
12 Q Are you familiar with that letter?
13 A Yes, yes, I don't think I ever actually
14 saw the letter, but I heard about it.
15 Q Well, the letter, if I can -- of course, I
16 won't be able to find it -- is at D81 in the binder.
17 And if you wouldn't mind taking a look at it, and
18 reading it over, it's fairly short. But take your
19 time.
20 A Yes.
21 Q You haven't seen this before?
22 A I don't remember for sure whether I've

1 seen it. I don't, I don't think I've seen it.
2 Q The question I have about it really
3 relates to the sentence starting, "however, I have
4 spoken to the FDA, and based on the feedback I have
5 received, the FDA will act on this application by
6 September 1st, 2005".
7 Do you have any idea who Secretary Leavitt
8 spoke to at the FDA?
9 A No.
10 Q Did anyone sort of come to you, I guess
11 this letter is -- at least it's stamped July 13th,
12 2005. Did someone come to you in June or July or any
13 time in 2005, and say, the Secretary of HHS wants to
14 know when there's going to be action, and they asked
15 you?
16 A No.
17 Q Do you know if this letter was
18 provided -- I'll withdraw that question.
19 Do you know why Dr. Crawford resigned
20 shortly after he was confirmed by the United States
21 Senate permanently as Commissioner of the FDA?
22 A All I know is what I read in the

1 newspapers.
2 Q He never told you anything about it?
3 A No.
4 Q Do you know if it had -- okay. Do you
5 know if it had anything to do with mifepristone?
6 A I don't.
7 Q Did you hear anything about Dr. Crawford
8 in connection with mifepristone?
9 A You mean having to do with his
10 resignation?
11 Q Or around the time of his resignation?
12 A Only what I read in the news. I think
13 there was some reference in one of the interviews
14 that he did or family members did after. But nothing
15 internally.
16 Q Do you know a person named first initials
17 M.A., last name Gold?
18 A M.A. Gold.
19 Q Does that name mean anything to you off
20 the top of your head?
21 A No.
22 Q Do you know anything about a

1 teleconference between the FDA and M.A. Gold around
2 January 22nd, 2004?
3 A Doesn't ring a bell.
4 Q I think you've said a few times during the
5 course of your testimony that the manufacturer has
6 the burden to disprove risks, to show that there are
7 no significant risks when they're seeking OTC status
8 for a prescription drug. Am I understanding you
9 correctly?
10 A Their burden is to demonstrate safety.
11 Q Okay.
12 A Yeah.
13 Q When they are trying to demonstrate
14 safety, does the manufacturer have to demonstrate the
15 danger -- I mean, the opposite of safety, I'll say --
16 that dangers don't exist when those dangers are
17 purely speculative?
18 A Are you asking about a standard drug
19 approval or an OTC switch?
20 Q An OTC switch.
21 A What I just said before about
22 demonstrating safety is really shorthand for what's

1 actually required in our regs and our guidances. And
2 has to do with demonstrating that a patient can use
3 the drug safely without the intervention of, you
4 know, what we call a learned intermediary, a
5 physician.
6 Q Right.
7 A And no, they don't have to make -- they
8 don't have to demonstrate that something that's
9 purely speculative is, has been met. But it depends
10 what you mean by purely, because that's what you said
11 purely speculative.
12 Q I'll give you an example that I thought of
13 last night, I mean, Plan B is designed to be used
14 sort of in a sense in a very emergency setting,
15 something needs to be done quickly. So if someone,
16 this is going to sound kind of crazy, but if someone
17 said, well, it's an emergency drug, if we make it
18 available over the counter for people, we're going to
19 have all these people driving fast to the drugstore
20 to get it where they can buy it without ever going to
21 a doctor, so maybe we should see if it's going to
22 cause more car accidents. That might be the kind of

1 thing you'd say that the manufacturer does not need
2 to address in its application, or might you say, now
3 that I've mentioned it, they should have addressed
4 that? Should they have addressed -- should they have
5 provided data on that question?
6 A No, they shouldn't have.
7 Q Because why not?
8 A It doesn't make any sense.
9 Q Okay. Do you know Susan Wood?
10 A Yes.
11 Q And you're aware that she resigned her
12 position at the FDA?
13 A Yes.
14 Q Do you know why she resigned?
15 A Her resignation statement is public, so I
16 know the same thing -- I don't know anything beyond
17 what she said, that she was unhappy about the
18 decision making process, that she wasn't involved,
19 and she was unhappy with the decision itself.
20 Q About Plan B?
21 A Right, right.
22 Q Have you spoken with her since she

1 resigned?

2 A Yes.

3 (The following testimony was designated

4 "PROTECTED TESTIMONY".)

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16 (Conclusion of "PROTECTED TESTIMONY.")
17 BY MR. HELLER:
18 Q What sort of numbers would you like to
19 have seen that would have been satisfactory to you?
20 A In the hundreds, similar to what they had
21 for the, you know, 18, 26-year-old.
22 Q So you would have liked to see hundreds in

1 which age group?
2 A I'd have liked to see more between 14 and
3 16, and then some even younger than 14. There's good
4 documentation that a sizable number of women in the
5 country younger than 14 are sexually active. And I
6 really was disturbed that there was no data at all in
7 that age group was one of my major problems.
8 Q During the period after your authority to
9 take action on Plan B was withdrawn by the
10 Commissioner, so sometime after January of 2005
11 through the, let's say the resignation of
12 Dr. Crawford, I'm not sure exactly when that
13 happened, were you unhappy with the process that had
14 occurred with respect to Plan B?
15 A What was the beginning of the start date
16 of the question?
17 Q During the period from when your authority
18 to take action was withdrawn, or the delegation was
19 withdrawn by the Commissioner, through when he
20 resigned, that particular individual resigned, were
21 you unhappy with the process that had evolved with
22 respect to Plan B?

1 A I think that's fair to say, yeah.
2 Q And -- I have no further questions.
3 MR. AMANAT: Can we just take a break for
4 a few minutes while I evaluate if I have any
5 questions on redirect?
6 THE VIDEOGRAPHER: We're going off the
7 record. The time is 2:25 p.m.
8 (Recess.)
9 THE VIDEOGRAPHER: We are back on the
10 record. The time is 2:33 p.m.
11 EXAMINATION BY COUNSEL FOR DEFENDANT
12 BY MR. AMANAT:
13 Q Admiral Galson, Dr. Galson, let me ask you
14 first, in your current position as director of the
15 Center for Drug Evaluation and Research, is that a
16 politically appointed position?
17 A No.
18 Q Are you a political appointee or a career
19 government employee?
20 A I'm a career government employee.
21 Q Your title as rear admiral in the Public
22 Health Service, does political affiliation factor

1 into your having risen to that title in any way?
2 A No.
3 Q Does your political affiliation or
4 political connections, did it factor into your
5 appointment as director of CDER?
6 A No.
7 Q Have you held positions in the past of in
8 other administrations other than the current one?
9 A Yes.
10 Q Which previous administrations have you
11 held positions in?
12 A I reported to political appointees for
13 the -- really almost the full period of the Clinton
14 administration, both terms.
15 Q Are you a Republican?
16 A No.
17 Q Do you have a party affiliation?
18 A I'm a registered Democrat.
19 Q Did political factors, political
20 considerations factor in any way in your decision to
21 issue the May 2004 nonapprovable letter?
22 A No.

1 Q Did ideological considerations factor in
2 any way in your decision to issue the May 2004
3 nonapprovable letter?
4 A No.
5 Q Did political considerations factor in any
6 way into your arriving at the conclusions that you
7 arrived in your August 26th, 2005 memorandum?
8 A No.
9 Q Did ideological considerations factor in
10 any way in your arriving at the conclusions set forth
11 in that memorandum?
12 A No.
13 Q So are you a member of the vast right wing
14 conspiracy?
15 A I don't think so.
16 Q Let me ask you, did you obtain your
17 current position as a result of any connection to
18 Secretary Thompson?
19 A No, I was hired by Dr. Woodcock before
20 there were any political appointees at the FDA. And
21 then I was promoted, you know, by the political
22 appointees, but not through any kind of connection.

1 Q In your day-to-day work as director of
2 CDER, do political considerations arise in the course
3 of making decisions on drug applications?
4 A No.
5 Q Now, you testified earlier that you had a
6 concern about the studies that had been submitted
7 with the Barr supplemental new drug application; is
8 that correct?
9 A Right.
10 Q And I believe you testified that your
11 concern, by and large, derived from insufficient
12 number of adolescents and younger adolescents that
13 were included in this study?
14 A That's correct.
15 Q Did -- is there anything in your
16 background, your training, your professional
17 expertise which you felt qualified you to assess
18 whether the data in the studies with regard to
19 juveniles was adequate?
20 A Yes, I think so.
21 Q And what is it in your background, your
22 experience, your qualifications which contributed to

1 that conclusion?
2 A Sure. When I moved from the Department of
3 Energy to the Environmental Protection Agency, you'll
4 have my CV there, my first job was scientific
5 director of the Office of Children's Health
6 Protection. And that office was put together by
7 Administrator Browner to try to assess the
8 effectiveness and the protectiveness of environmental
9 regulations, specifically for children.
10 So I spent several years there and then
11 several years at a different job at EPA in pesticide
12 safety, spending a huge proportion of my time on the
13 specific issue of the adequacy of scientific data and
14 information for protecting children from
15 environmental toxins. And it was many of the same
16 issues that had to do with differences in behavior
17 between children and adults that were relevant to
18 what we looked at at EPA -- at FDA with this
19 application.
20 So the concept that children, for
21 regulatory purposes, and even adolescents, younger
22 adolescents and older adolescents, can't be treated

1 like adults is something that I've been working on
2 for many, many years. And this is an extension of
3 this. As well I worked closely in understanding the
4 new legislation that Congress passed, the BPCA and
5 the PREA, the Pediatric Research Equity Act. The
6 concept around both of those pieces of legislation is
7 that you can't treat children for drug regulatory
8 purposes like adults. And then in some
9 circumstances, special data was necessary and needed.
10 And so all of this, really the Plan B
11 decision and assessment was really a logical
12 outgrowth from my previous career experiences that I
13 described.
14 Q Can you give an example from your previous
15 career experiences, for example at EPA, or one of the
16 other previous career experiences you had, where
17 your -- where in the course of evaluating a
18 regulatory policy, you had occasion to give special
19 consideration to the impact that regulatory policy
20 would have on children?
21 A A non-FDA example?
22 Q Yes, correct.

1 A And you're not asking for one that's
2 particularly relevant?
3 Q Correct.
4 A Just another example of one.
5 Q Right.
6 A Well, the regulations surrounding exposure
7 to lead in children. Lead exposure is a big issue
8 for children and children's health, having to do with
9 lead in the ground and lead in paint. And there are
10 a number of issues surrounding how do you calculate
11 how children are exposed to lead that has to do with
12 their behavior, and the fact that small children
13 behave differently than even adolescents and adults.
14 And the operative issue there is that
15 small children are always putting their hands in
16 their mouth. And so where they crawl around on the
17 ground, they get dust on their fingers either outside
18 or inside, and then they put their hands in their
19 mouth and they can be exposed to lead at a much
20 higher rate than an adult, even an adult in a dusty
21 environment or even an adolescent. So that was an
22 example, of course, not directly relevant to Plan B,

1 where the behavioral issue played into a regulatory
2 decision having to do with exposure to lead.
3 Q So when you moved from the Environmental
4 Protection Agency to the Food and Drug
5 Administration, did you bring with you this kind of
6 sensitization to children's -- to the effect that
7 regulatory policy may have on children?
8 A Absolutely brought that with me.
9 Q Okay. Did you find -- I mean, what did
10 you find in terms of the extent to which those types
11 of concerns or considerations were already part of
12 the FDA culture, or have historically been a part of
13 the FDA culture?
14 A They haven't historically been
15 specifically part of the FDA culture. We've always
16 done pediatric evaluations as part of labeling, how
17 do you label a drug for children. But the idea that
18 this is a separate discipline, that you have to do
19 separate assessments, that the labeling for adults
20 may not necessarily apply to children and not in a
21 predictable way.
22 In some cases, the labeling may be

1 adequate, in some cases, the dose or the interval of
2 dosing may be too high. In other cases, it would be
3 too low. The idea that you might need special
4 information for children in order to adequately use
5 the products in certain age groups has become more
6 and more of a realization at FDA, even in the years
7 that I've been here.
8 Dr. Woodcock, for the first time, created
9 a specialized pediatric group in the center. And you
10 know, one of -- if I could do Plan B over again, one
11 of the things that I would really have assured is
12 that we had consultation with that group of pediatric
13 experts very, very early in the assessment of the
14 application. And unfortunately, that didn't happen.
15 Q To the best of your knowledge, did any of
16 the subordinate officials, subordinate to you in the
17 scientific review process for FDA, have any of, any
18 kind of experience similar to what you had in dealing
19 with these issues involving children and juveniles?
20 A There are definitely people subordinate to
21 me at FDA, but not in the Plan B group, the group
22 that dealt with the application. The specific

1 pediatric group that was under Dr. Murphy at that
2 time, there wasn't a connection between them and the
3 Plan B review, they didn't consult with each other.
4 Q To the best of your knowledge, did any of
5 the members of either of the advisory committees that
6 was providing advice to CDER with regard to Plan B
7 have any background in this area? By this area, I'm
8 referring to the area of --
9 A Pediatric.
10 Q Pediatrics and pediatric behavior in
11 particular?
12 A Again, I want to be careful without, you
13 know, having the CVs of the group in front of me. I
14 may have neglected to notice something, but there was
15 certainly -- we didn't specifically ask for that
16 expertise on the advisory committee. We didn't seek
17 someone out as that expert. In retrospect, I would
18 have done that.
19 Q And when you say we didn't specifically
20 ask for that, were you involved in the process of
21 identifying who the members of the advisory
22 committees would be for purposes of Plan B?

1 A No.
2 Q Who was involved in that process, that
3 decision making process?
4 A The way this works in the agency is that
5 the initial recommendations for members in an
6 advisory committee come from our review group. So
7 the people who are best, really, at knowing the
8 expertise out there in academia in their particular
9 area. So they nominate names, put together a review
10 package that comes up. And then, since these
11 committees are all officially Department committees,
12 they have to go through an approval process. And not
13 all the nominations that we made were accepted. And
14 there were some other names that were brought from
15 outside of that group who ended up on the committee,
16 as we all know.
17 (The following testimony was designated
18 "PROTECTED TESTIMONY".)
19
20
21
22

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22

1
2
3
4
5 (Conclusion of "PROTECTED TESTIMONY.")
6 BY MR. AMANAT:
7 Q Did you -- was there, just to follow up on
8 my earlier question, was there any extent to which a
9 kind of moral or judgmental or ideological concern
10 about adolescent sexual behavior factor into your
11 assessment of those risks?
12 MR. HELLER: Objection, compound.
13 MR. AMANAT: Let me rephrase the question.
14 BY MR. AMANAT:
15 Q To what extent, if any, did any kind of
16 moral objection to adolescent sexual behavior factor
17 into your assessment of that risk?
18 A It wasn't relevant. I don't have the
19 luxury of letting my personal views interfere with my
20 professional scientific judgments.
21 Q Are you familiar with the FDA's regulation
22 codified at 21 CFR section 310.200?

1 MR. HELLER: Objection, beyond the scope
2 of direct.
3 MR. AMANAT:
4 Q Answer the question, please.
5 A I'm not familiar with that cite, you have
6 to describe to me what that is.
7 Q Are you familiar as to whether there is a
8 regulation by FDA which describes the standards which
9 allow the Commissioner to declare a drug -- to allow
10 a drug to be marketed over the counter?
11 A Absolutely.
12 Q Let me read you the portion of the
13 regulation, "any drug limited to prescription use
14 shall be exempted from prescription dispensing
15 requirements when the Commissioner finds such
16 requirements are not necessary for the protection of
17 the public health by reason of the drug's toxicity or
18 other potentiality for harmful effect." Are you
19 familiar with that regulation?
20 A Yes.
21 Q As director of CDER, is it part of your
22 responsibility to interpret and apply that

1 regulation?
2 A Absolutely.
3 Q When -- one phrase that's mentioned in
4 there is "protection of the public health." Explain
5 to me how your decision to issue the nonapprovable
6 letter in May '04 was directed to protect the public
7 health?
8 A This is a source of major disagreement of
9 the public on the part of what we do with an OTC
10 switch. The idea here is that the default position
11 of a drug is prescription. And to move off that
12 default, the applicant has to demonstrate that the
13 drug can be used safely in the over the counter
14 setting.
15 If they don't do that, if they don't
16 provide definitive data to demonstrate that that
17 could be done safely, used safely in the over the
18 counter setting, you go back to the default of the
19 prescription.
20 So lacking that data demonstrating that
21 they've met the threshold that we've laid out more
22 specifically on when a drug can move to OTC, we're

1 protecting the public by leaving it as a prescription
2 status, in the prescription status.
3 Q And the phrase in the regulation which
4 refers to "other potentiality for harmful effect," as
5 a general matter, what does that phrase mean to you
6 in the course of applying that regulation as a drug
7 regulator as director of CDER?
8 MR. HELLER: Objection, outside the scope
9 of direct.
10 MR. AMANAT: Objection noted, please
11 answer.
12 THE WITNESS: What that means there really
13 is whether the drug is going to cause other harms
14 that were not anticipated by the way that it's going
15 to be used, or whether it will effectively treat the
16 condition for which it's intended.
17 MR. AMANAT:
18 Q Did you believe that such a potentiality
19 for harmful effect exists in the case of Plan B?
20 A Yes.
21 Q And what was that potentiality for harmful
22 effect?

1 A Well, if it's not used according to the
2 instructions, and if it's not -- if it's used as a
3 substitute for barrier contraception, then it could
4 result in an increased use, increased risk to women
5 of becoming infected with sexually transmitted
6 diseases including HIV, which can be fatal.
7 Q The claimants have made a number of
8 amendments in their complaint. And I would like to
9 ask you about a few of those allegations and ask if
10 you agree with them.
11 MR. HELLER: If I may, Frank, I think I
12 know what you're going to ask. And I'd just like to
13 state my continuing objection that these are outside
14 the scope of direct examination.
15 MR. AMANAT: Objection noted. I don't
16 believe they are, but I'm going to ask the question.
17 BY MR. AMANAT:
18 Q Okay. Dr. Galson, paragraph 83 of the
19 plaintiff's complaint, and I will show it to you,
20 states, "the FDA applied a different and higher
21 standard to Plan B's OTC switch than it has applied
22 to OTC switches of other drugs."

1 To the best of your knowledge, is that a
2 truthful statement?
3 A Absolutely not.
4 Q Can you explain why, please?
5 A Because every drug is assessed based on
6 the risks and benefits of that drug. We never, no
7 two evaluations are exactly the same, no two data
8 requests are the same. Even a different -- two
9 contraceptives may be switched with different data
10 because every drug is different in the way it's used
11 and what it's used for, and how it may potentially be
12 used.
13 Q Paragraph 84 of the complaint states, and
14 I quote, "there is no medical and scientific basis
15 for the FDA's application of a different and higher
16 standard to Plan B's OTC switch." To the best of
17 your knowledge, is that a truthful statement?
18 A Well, there wasn't a higher standard, so
19 no.
20 Q Do you believe there was a medical or
21 scientific basis for the FDA's application of the
22 standard that it did apply to the OTC switch?

1 A Yes, yes. As we've discussed, yeah.
2 Q Paragraph 85 of the complaint alleges that
3 "the FDA's failure to approve Plan B for OTC use is
4 based in part on outmoded stereotypes of women and
5 girls." Is that a truthful statement?
6 A That's preposterous, I don't even know
7 what they're talking about.
8 MR. AMANAT: I have no further questions
9 of the witness. Thank you, Admiral Galson.
10 EXAMINATION BY COUNSEL FOR PLAINTIFFS (RESUMED)
11 BY MR. HELLER:
12 Q Dr. Galson, if Plan B is used when
13 indicated and according to the instructions, it can
14 prevent unwanted pregnancy, is that right?
15 A Yes.
16 Q And you don't have serious doubts about
17 the evidence for that?
18 A As I've documented in my reviews, yes.
19 Q And consequently, it can also prevent
20 abortions?
21 A Yes, in theory, numerous investigators,
22 researchers have tried to prove that. And there

1 isn't really good data one way or the other. There
2 have been a couple studies that haven't been able to
3 show that. But it should, it should. But I don't
4 know why it's been difficult to prove.
5 Q And if properly used in appropriate
6 situations, having Plan B available over the counter
7 would be likely, would it not, to prevent more
8 unwanted pregnancies than if it were available only
9 by prescription, is that right? Easier access would
10 improve, make access easier, and would prevent more
11 pregnancies, is that right?
12 A Yes.
13 Q Okay. The disagreement that you had in
14 May of 2004 with some of your subordinate
15 professional staff who believed it should be
16 approved --
17 A Right.
18 Q And I think in some sense that
19 disagreement continued after that when again the
20 professional staff thought it should be approved for
21 women of all ages, and you continued to believe it
22 should not. Was that a disagreement which, in your

1 view, was one about which sort of -- could reasonable
2 people disagree about that?
3 A Yes.
4 Q So looking back on this entire process, if
5 you had known that your nonapprovable letter in May
6 2004 would lead down a path where now the FDA has
7 launched into some possible rule making process that
8 could take -- has no particular time limit on it, and
9 that during the course of even just the last two
10 years since your nonapprovable letter, many women
11 might have avoided unwanted pregnancy by the easier
12 access afforded by OTC status, would you have still
13 made that same decision in retrospect, or might you
14 have thought, well, if that's going to happen, I'll
15 go with the professional staff and approve this?
16 A I'm sorry, I don't understand the
17 question. Can you come back at me?
18 Q Yeah, I'm saying in retrospect, with what
19 is it called, 20/20 hindsight, might you have decided
20 to sort of agree with the professional staff, despite
21 your misgivings, and approve Plan B for the over the
22 counter use if you had known that the process as it

1 unfolded would lead to this rather long period in
2 which it was available only by prescription and
3 consequently women would have less access to it?
4 A You know, when I think about that
5 question, what I think about is if all the resources
6 that have gone into this lawsuit had been spent on
7 collecting more data, we would have maybe been able
8 to approve the product. That's what I think about.
9 So absolutely not. I don't have any second thoughts
10 or doubts about the decisions I made.
11 Q Okay. And then I thought I had one other
12 question. Maybe my piece of paper is so tiny that
13 I'm trying to get it from. If you'll give me a
14 moment.
15 MR. AMANAT: Take your time.
16 MR. HELLER: I have no additional
17 questions.
18 MR. AMANAT: Nor do I. Thank you,
19 Dr. Galson for your time.
20 THE VIDEOGRAPHER: This marks the end of
21 the deposition of Dr. Galson. The total number of
22 tapes used today was one. We are going off the

1 record. The time is 2:59 p.m.
2 (Signature having been not waived, the
3 deposition of STEVEN GALSON, M.D., MPH, was concluded
4 at 1:40 p.m.)
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22

1 ACKNOWLEDGMENT OF DEPONENT.

2 I, STEVEN GALSON, M.D., M.P.H., do hereby
3 acknowledge that I read and examined the foregoing
4 testimony, and the same is a true, correct, and
5 complete transcription of the testimony given by me
6 and any corrections appear on the attached Errata
7 sheet signed by me.
8
9 _____ _____
10 (DATE) (SIGNATURE)
11
12
13
14
15
16
17
18
19
20
21
22

1 CERTIFICATE OF SHORTHAND REPORTER - NOTARY PUBLIC
2 I, Cynthia R. Simmons Ott, Registered
3 Merit Reporter, Certified Realtime Reporter,
4 the officer before whom the foregoing hearing was
5 taken, do hereby certify that the foregoing
6 transcript is a true and correct record of the
7 testimony given; that said testimony was taken by me
8 stenographically and thereafter reduced to
9 typewriting under my supervision; and that I am
10 neither counsel for or related to, nor employed by
11 any of the parties to this case and have no interest,
12 financial or otherwise, in its outcome.
13 IN WITNESS WHEREOF, I have hereunto
14 set my hand and affixed my notarial seal this
15 2nd day of May 2006.
16 My commission expires:
17 August 1, 2006
18 _____
19 NOTARY PUBLIC IN AND FOR
20 THE STATE OF MARYLAND
21
22

1 E R R A T A S H E E T

2 IN RE:

3 RETURN BY:

4 PAGE LINE CORRECTION AND REASON

5 _____ _____ _____

6 _____ _____ _____

7 _____ _____ _____

8 _____ _____ _____

9 _____ _____ _____

10 _____ _____ _____

11 _____ _____ _____

12 _____ _____ _____

13 _____ _____ _____

14 _____ _____ _____

15 _____ _____ _____

16 _____ _____ _____

17 _____ _____ _____

18 _____ _____ _____

19 _____ _____ _____

20 _____ _____ _____

21 _____ _____

22 (DATE) (SIGNATURE)

1 E R R A T A S H E E T

2 IN RE:

3 RETURN BY:

4 PAGE LINE CORRECTION AND REASON

5 _____ _____ _____

6 _____ _____ _____

7 _____ _____ _____

8 _____ _____ _____

9 _____ _____ _____

10 _____ _____ _____

11 _____ _____ _____

12 _____ _____ _____

13 _____ _____ _____

14 _____ _____ _____

15 _____ _____ _____

16 _____ _____ _____

17 _____ _____ _____

18 _____ _____ _____

19 _____ _____ _____

20 _____ _____ _____

21 _____ _____

22 (DATE) (SIGNATURE)