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1 IN THE UNITED STATES DISTRICT COURT  
2 EASTERN DISTRICT OF NEW YORK

3 - - - - - +  
4 ANNIE TUMMINO, et al,  
5 Plaintiffs,  
6 vs.  
7 ANDREW C. VON ESCHENBACH,  
8 as Acting Commissioner of the  
9 Food & Drug Administration,  
10 Defendant.  
11 - - - - - +

Civil Action No.  
05-CV-366  
(ERK/VVP)

12 Videotaped Deposition of  
13 CURTIS J. ROSEBRAUGH, M.D.  
14 Washington, D.C.  
15 Tuesday, July 18th, 2006  
16 10:00 a.m.

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19  
20 Job No. 1-82112  
21 Pages 1 - 217  
22 Reported by: Laurie Bangart-Smith

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1 Confidential Videotaped Deposition of  
2 CURTIS J. ROSEBRAUGH, M.D.

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5 Held at the offices of:  
6 FOOD AND DRUG ADMINISTRATION  
7 5600 Fishers Lane, Room 6-21  
8 Rockville, Maryland 20857  
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15

16 Taken pursuant to the Federal Rules of  
17 Civil Procedure, by notice, before Laurie  
18 Bangart-Smith, Registered Professional Reporter  
19 and Notary Public in and for the State of  
20 Maryland.  
21  
22

0003

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

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14 William Schurmann  
15  
16  
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P R O C E E D I N G S

THE VIDEOGRAPHER: Here begins videotape Number 1 in the deposition of Curtis Rosebraugh, M.D., in the matter of Annie Tummino, et al, versus Andrew Eschenbach as Acting Commissioner of the Food & Drug Administration, pending in the United States District Court, Eastern District of New York, Case Number 05-CV-366.

Today's date is July 18, 2006. The time on the video monitor is now 9:58 a.m. The video operator today is Scott Pickering with L.A.D. Reporting. This video deposition is taking place at the Food & Drug Administration building, 5600 Fishers Lane, Rockville, Maryland.

Would counsel please identify yourselves and state whom you represent.

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

MS. STRAUSS: Nan Strauss from the

20 Center for Reproductive Rights for plaintiffs.  
21 MR. WARSHAWSKY: Steven Warshawsky from  
22 the United States Attorneys Office for the  
0007 defendant.

2 MR. AMANAT: Frank Amanat from the U.S.  
3 Attorney's Office in Brooklyn for the defendant.

4 MS. SCHIFTER: Karen Schifter from FDA  
5 for the defendant.

6 THE VIDEOGRAPHER: Okay. The court  
7 reporter today is Laurie Bangart-Smith of L.A.D.  
8 Reporting. Would the reporter please swear in the  
9 witness.

10 CURTIS J. ROSEBRAUGH, M.D.,  
11 having been duly sworn, testified as follows:

12 EXAMINATION BY COUNSEL FOR PLAINTIFFS

13 BY MR. HELLER:

14 Q Good morning, Dr. Rosebraugh.

15 A Good morning.

16 Q Am I saying your name correctly?

17 A You're about as close as you can get.

18 Q Okay. Well, first of all, I want to  
19 apologize for getting a little bit of a late start  
20 this morning. My name is Simon Heller. I'm one  
21 of the lawyers for the plaintiffs in this case,  
22 and before I start asking you more substantive

0008  
1 questions, I want to just review for you the  
2 deposition process.

3 Do you have any questions that you'd  
4 like to ask about how the deposition works?

5 A No.

6 Q Okay. The basic process is I ask you a  
7 series of questions, and I'd like you to answer  
8 them as completely as you can. If you need to  
9 take a break at any point, let me know, and we'll  
10 try and take a break sort of shortly thereafter.  
11 I might finish up a line of questions that I have,  
12 but we'll break whenever you want.

13 There may be objections to some of my  
14 questions, in which case I'd like you not -- to  
15 wait in giving your answer until we, the lawyers,  
16 have discussed the objection.

17 Does that make sense to you?

18 A Yes.

19 Q Okay. I want to ask if you, to start  
20 with, how you went about preparing for today's  
21 deposition. Did you review any documents or have

22 any meetings in preparation for the deposition?

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1 A Didn't have any meetings. I thumbed  
2 through my review and some of the other reviews.

3 Q Have you met with lawyers from the  
4 Justice Department about this deposition?

5 A Yes.

6 Q Okay. Have you -- did you meet with  
7 anyone other than lawyers, the lawyers who are  
8 here today, about your deposition?

9 A Did I have a specific meeting about the  
10 deposition? No.

11 Q Did you have conversations with other  
12 people about the deposition?

13 A Yes.

14 Q Can you tell me who if you remember.

15 A It's mainly just acquaintances or people  
16 at work would ask about it.

17 Q Okay. Can you tell me a little bit  
18 about your educational background.

19 A How far back?

20 Q After college, let's say.

21 A I graduated from college with a pharmacy  
22 degree, worked a year in industry, then went back

0010

1 to medical school at the University of Kansas.

2 Did my internship and residency in internal  
3 medicine at the University of Kansas. Was on --  
4 do you want me to keep going, or --

5 Q Yeah, please.

6 A Okay. Was on the faculty there for  
7 about four years. Moved down to Texas. Was on  
8 the faculty at the University of Texas Medical  
9 Branch in Galveston for around four years. Moved  
10 to this area, where I returned to Georgetown and  
11 did a fellowship in clinical pharmacology. Also  
12 got a master's in public health and then started  
13 at the Agency.

14 Q What year did you start at FDA?

15 A 2000.

16 Q And just to, so I have this timing in my  
17 head, when did you finish medical school at the  
18 University of Kansas?

19 A Oh, my. Um, '86.

20 Q What positions have you held at FDA?

21 A I started out as a Reviewer in the  
22 Division of Pulmonary and Allergy Drug Products,

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1 which was its name at the time. Um, did a, um,  
2 um, did a -- I can't remember how long it was, but  
3 it was -- I think it was a three-month stint in  
4 the Ombudsman Office. Then I was Deputy Division  
5 Director in Over-the-Counter Drug Products. Then  
6 that subsequently became an office, so I became  
7 the Deputy Office Director and Acting Director in  
8 OTC Drug Products, and I currently am the Deputy  
9 Director for the Office of Drug Evaluation, too.

10 Q Just one thing you mentioned, the  
11 Ombudsman Office; what is that?

12 A The Ombudsman Office is an office that  
13 coordinates and tries to resolve complaints that  
14 outside people may have with the Agency.

15 Q Have, have you been involved or have you  
16 worked on Over-the-Counter Switch Applications  
17 during your time at FDA?

18 A You mean besides Plan B?

19 Q Besides Plan B.

20 A Yes.

21 Q Roughly how many have you worked on?

22 A I'm not sure.

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1 Q Would you say it's like in the  
2 neighborhood of ten or fifty or just a rough  
3 ballpark figure?

4 A It's really hard to tell, because  
5 there's, there's a lot of different switches  
6 happening and they're at different stages, and it  
7 would be hard for me to guess. As a guess I could  
8 tell you it was probably more than ten.

9 Q And then you were involved also in the  
10 OTC Switch Application for Plan B?

11 A Yes.

12 Q Most of my questions are going to be  
13 about that. Do you have any sort of general  
14 understanding about what this case -- the case  
15 we're here for today -- is about?

16 A A general layman's non-lawyer type  
17 understanding.

18 Q Can you tell me what that understanding  
19 is roughly.

20 A Uh, well, my understanding is that the  
21 lawsuit is in New York, and they are suing because  
22 they feel that the decision was delayed and they

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1 want a decision made. Is that anywhere close to  
2 the --

3 Q That's probably part of it. Are you  
4 aware that FDA recently denied a Citizen Petition  
5 seeking an over-the-counter switch for Plan B?

6 A Just -- I'm aware of it but not any of  
7 the details.

8 Q Have you seen the actual document letter  
9 denying it?

10 A Um, I don't recall whether I saw it or a  
11 news clip just saying that they had denied it.

12 Q Is that how you found out about it, like  
13 from a news clip, or did someone within FDA tell  
14 you about it?

15 A I don't recall.

16 Q Can you describe for me in general what  
17 your involvement in the Plan B OTC Switch process  
18 has been, sort of an overview of what your  
19 involvement has been.

20 A Well, the way that the Division -- at  
21 the time it was a Division -- was arranged is  
22 there is a Division Director and a Deputy, and we

0014

1 tended -- my boss and I tended to kind of split up  
2 Applications so that we could manage the work load  
3 that came through. And so my involvement would  
4 have been as the divisional sign-off, so it would  
5 have been in sort of coordinating the divisional  
6 review and just keeping track of where it was at  
7 in the review process. And finally I would have  
8 had to have made the divisional decision on how we  
9 felt about the Application.

10 Q Um, what was the divisional decision  
11 about Plan B?

12 A Well, the divisional decision was that  
13 it could be marketed OTC.

14 Q And in the ordinary course of the  
15 Agency's process, would you have just then -- you  
16 or your boss -- just made that decision and  
17 finalized it, issued a ruling on it, so to speak?

18 MR. WARSHAWSKY: Objection.

19 MR. HELLER: What's the objection?

20 MR. WARSHAWSKY: Objection to the term  
21 "ordinary course." Plan B --

22 MR. HELLER: Because you don't

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1 understand what it means?

2 MR. WARSHAWSKY: No, because you haven't  
3 established that Plan B --

4 MR. HELLER: You can tell me --

5 MR. WARSHAWSKY: -- is anything other  
6 than a single drug application, so yes --

7 MR. HELLER: It is nothing but a  
8 single --

9 MR. WARSHAWSKY: -- I think the term is  
10 vague and misleading.

11 BY MR. HELLER:

12 Q "Ordinary" means typical, what you  
13 typically do in the Agency. Do you typically, you  
14 or your boss, typically make a divisional decision  
15 and then that's the decision of the Agency on an  
16 OTC switch?

17 A It depends on what sort of switch it is.  
18 If it's a new molecular entity, which Plan B would  
19 have been, then that is not what happens. The  
20 decision is usually made at the Office level, so  
21 the Division would give a recommendation to the  
22 Office, and then the Office would make the final

0016

1 decision. I should add that they -- typically in  
2 a switch, it's a two-office sign-off, so whatever  
3 Office had housed the prescription product would  
4 also have to co-sign the letter.

5 Q Which Office would that be for Plan B?

6 A ODE 3.

7 Q Do you know if they recommended that the  
8 switch be approved?

9 A Yes, they did recommend that the switch  
10 be approved.

11 Q So typically your Division, the Division  
12 as you described it, I think, in which the  
13 prescription -- how did you say it? The  
14 prescription was --

15 A Uh, the prescription product was housed.

16 Q The prescription product was housed;  
17 those two Divisions would typically make a  
18 recommendation or reach a decision, and that would  
19 be the decision of the Agency?

20 A Let me go over it again. Typically what  
21 happens is the two Divisions will make their  
22 decision and make recommendations up at the Office

0017

1 level.

2 Q I'm sorry. Yeah.

3 A And then the Office level would co-sign  
4 a letter saying what the Action was.

5 Q And what's the "Office level"? What  
6 does that mean?

7 A Well, "Office" would be -- it's called  
8 ODE 3, so it's the Office of Drug Evaluation 3.

9 Q And the Office of Drug Evaluation 3  
10 would make the final approval or other Action that  
11 the Agency was going to take?

12 A They typically would sign the Action  
13 Letter.

14 Q What person would that have been at the  
15 time that Plan B was under consideration; do you  
16 know?

17 A At the time Plan B was under  
18 consideration, the Office Director was Florence  
19 Houn and the Deputy Director was Julie Beitz.  
20 It's my understanding that Julie was for the most  
21 part in charge of Plan B and was going to be the  
22 signatory for their Office.

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1 Q Do you know why she was not the  
2 signatory for that Office?

3 A The Action wasn't done at the Office  
4 level.

5 Q Do you know why the Action wasn't done  
6 at the Office level?

7 A Well, it was my understanding that  
8 higher up the chain they didn't agree with the  
9 Action.

10 Q Do you know where higher up the chain  
11 the disagreement came from?

12 A Well, ultimately Dr. Galson signed the  
13 Action Letter, and Dr. Jenkins reviewed the  
14 product, was also for approval, so it must have  
15 been at a level higher than Dr. Jenkins.

16 Q Do you know if it was at a level higher  
17 than Dr. Galson?

18 A No, I don't.

19 Q Do you know what the reasons were that  
20 higher-up folks at the Agency did not agree with  
21 the decision made within your Division?

22 MR. WARSHAWSKY: Objection.

0019

1 BY MR. HELLER:

2 Q Or the recommendation made within your  
3 Division. Excuse me.

4 A Ultimately I -- what was relayed to us  
5 was that they felt that there was not enough data  
6 regarding adolescent use to make sure that the  
7 drug could be used safely. There was some  
8 question about whether it was being used correctly

9 by adolescent use, too, but I think ultimately it  
10 was just that they felt there just wasn't enough  
11 data.

12 Q Do you agree with the assessment that  
13 there wasn't enough data?

14 A No.

15 Q Do you have an opinion about whether the  
16 belief that there was not enough data was a  
17 scientifically valid belief?

18 MR. WARSHAWSKY: Objection; vague.

19 MR. HELLER: What part is vague, or just  
20 the whole thing?

21 MR. WARSHAWSKY: I found the question to  
22 be unclear, yes.

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1 MR. HELLER: Okay.

2 BY MR. HELLER:

3 Q Do you understand my question?

4 A I think it's kind of vague.

5 Q I mean besides his comment, do you  
6 understand what I mean? Do you believe that -- or  
7 do you have an opinion -- excuse me -- do you have  
8 an opinion about whether the views about the  
9 insufficiency of adolescent data were  
10 scientifically valid views or scientifically valid  
11 objections?

12 A That's still kind of a vague question.  
13 I think what I would say is different people can  
14 look at scientific data and interpret it  
15 differently.

16 Q That's absolutely right. I mean let me  
17 try to put it in -- do some sort of analogy, and  
18 you can tell me if this makes sense. I'm going to  
19 make this up, so it's probably going to be fixed a  
20 few times during the course of it.

21 Looking at a set of data about, let's  
22 say adolescent data for Plan B, one could reach a

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1 number of different conclusions within the  
2 reasonable spectrum of scientific opinion. Could  
3 one, for example, conclude from the data that was  
4 before the Agency that, that, uh, adolescent use  
5 of Plan B leads to serious health damage to  
6 adolescents?

7 MR. WARSHAWSKY: Objection; vague.

8 BY MR. HELLER:

9 Q Is it vague? Could you conclude from  
10 the scientific data that the Agency had in front

11 of it that adolescent use of Plan B leads to great  
12 risk of heart attacks? Do you understand the  
13 question?

14 MR. WARSHAWSKY: I do, but I think the  
15 question is speculative without any foundation in  
16 the record at this point, so it's not even clear  
17 what you're asking.

18 BY MR. HELLER:

19 Q I -- do you understand my question?

20 A Not really.

21 Q What don't you understand about my  
22 question?

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1 MR. WARSHAWSKY: Well, one of the things  
2 I just said was there is no foundation in the  
3 record about some risk of heart attacks. Is that  
4 what you said? I just find the question to be  
5 completely out of left field.

6 MR. HELLER: Well, that's not a valid  
7 objection.

8 MR. WARSHAWSKY: Lack of foundation is a  
9 valid objection.

10 MR. HELLER: At a deposition?

11 MR. WARSHAWSKY: Sure. It's the form of  
12 the question.

13 MR. AMANAT: Object to the form of the  
14 question.

15 BY MR. HELLER:

16 Q What are the risks of using Plan B; do  
17 you know?

18 A There's risks. Do you mean serious  
19 risks, or --

20 Q Are there serious risks from using Plan  
21 B?

22 A Not that I'm aware of.

0023

1 Q Okay. So if someone were to conclude  
2 that the data for adolescents that was before the  
3 Agency regarding Plan B demonstrated serious risks  
4 from Plan B, would that be outside the  
5 reasonable -- the range of reasonable scientific  
6 opinion?

7 MR. WARSHAWSKY: Objection.

8 MR. HELLER: What's your objection now?

9 MR. WARSHAWSKY: I think the question is  
10 completely speculative and is asking a  
11 hypothetical that lacks foundation in the record.

12 MR. HELLER: I'm asking a hypothetical

13 question. Why can't I ask a hypothetical  
14 question?

15 MR. WARSHAWSKY: You haven't established  
16 any foundation for that particular question. I'm  
17 just objecting to the form of the question.

18 MR. HELLER: All right.

19 MR. WARSHAWSKY: Speculation, unfounded  
20 hypotheticals is form of the question.

21 MR. HELLER: Okay.

22

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1 BY MR. HELLER:

2 Q You can go ahead and answer.

3 A I think that -- let me try to turn your  
4 question another way. I think that when you are  
5 reviewing an Application, you can sometimes look  
6 at the Application and say I wonder if behaviors  
7 will be X, Y and Z. We do that in OTC all the  
8 time, and so a lot of times when people design  
9 Actual Use Studies, we'll say, look, in the Actual  
10 Use Study we want to see if this behavior occurs  
11 or not, and that might be something that you  
12 really have never had data on, that you have never  
13 seen that it occurs, but you're concerned about  
14 switching it that it might occur, and so you might  
15 want that tested. Is that kind of the gist of  
16 your question?

17 Q Well, not really, but it's an  
18 interesting comment anyway. The gist of my  
19 question is: Can you get -- well, let's -- I'll  
20 turn it around different. Can you give me an  
21 example of a conclusion that someone might reach  
22 about Plan B that would not be a reasonable

0025

1 conclusion based on the scientific data?

2 MR. WARSHAWSKY: I'm going to object to  
3 that question. I'm going to object to that  
4 question.

5 MR. HELLER: Why?

6 MR. WARSHAWSKY: Because --

7 MR. HELLER: Because you don't want him  
8 to answer it?

9 MR. WARSHAWSKY: No, because it's an  
10 absolutely stupid question. His answer could  
11 be --

12 MR. HELLER: I can ask stupid questions.

13 MR. WARSHAWSKY: -- sure, blue whales  
14 will grow if you put Plan B in the ground. It's

15 a meaningless question.

16 MR. HELLER: You want me -- it's not  
17 meaningless. I get to decide what questions to  
18 ask, and I can ask stupid ones. I'll ask another  
19 stupid one.

20 BY MR. HELLER:

21 Q Do you think the decision over the  
22 process about Plan B was directed from outside

0026

1 FDA?

2 A I would have no way of knowing that.

3 Q Do you have, do you have a personal  
4 opinion about it?

5 MR. WARSHAWSKY: Objection.

6 MR. HELLER: What's the objection now?

7 MR. WARSHAWSKY: The witness just told  
8 you that he lacked any personal knowledge with  
9 which to respond to that question. You're asking  
10 him to speculate without --

11 MR. HELLER: Yes.

12 MR. WARSHAWSKY: -- without being a  
13 qualified witness. He just said he has no  
14 personal knowledge on that issue.

15 MR. HELLER: A qualified witness?

16 MR. WARSHAWSKY: You have to have  
17 personal knowledge to be a qualified witness.

18 MR. HELLER: I'm asking for hearsay.

19 MR. WARSHAWSKY: You're asking him for  
20 an opinion, and he just said he has no knowledge,  
21 so I'm just establishing -- I'm preserving my  
22 objection that he lacks any qualification on this

0027

1 question. He just said he has no knowledge on it.

2 BY MR. HELLER:

3 Q Do you have a personal opinion, Doctor?

4 A Well, let me just kind of give you a  
5 little background. At the Agency we tend to be  
6 data-driven, so I always get a little  
7 uncomfortable when I'm asked questions that I  
8 don't have data on. Now, I think the thing that I  
9 can tell you is for the Plan B Application, we had  
10 a lot of involvement from upper management at a  
11 very early time course for this Application that  
12 is unusual for an Application. It certainly is  
13 not outside of the realm of people's  
14 responsibility, though, to be involved in high  
15 profile drug, but we had a lot of involvement. I  
16 don't know where that direction was coming from.

17 I just know that we had a lot of direction. Not  
18 direction. Let me correct that. We had a lot of  
19 involvement.

20 Q How early was that involvement?

21 A I'm a little fuzzy on the time frame  
22 with Plan B, because it's been a while, but I know

0028

1 that as early as August we were being directed  
2 to -- August is when the Application came in. I  
3 think it came in at like --

4 Q 2003.

5 A Right. As early as August we were being  
6 directed that we needed to talk to the sponsor  
7 about a distribution restriction plan, and that's,  
8 that's highly unusual.

9 Q Who directed you to talk to the sponsor  
10 about that?

11 A Dr. Jenkins.

12 Q Do you know if that was his own idea or  
13 if he, in turn, had been directed by someone else?

14 A I don't know.

15 Q Who in upper management became involved  
16 early on in the process as far as you know?

17 A Dr. Jenkins was involved; Dr. Kweder was  
18 involved some; Dr. Galson was involved;  
19 Dr. Woodcock.

20 Q Was Dr. McClellan involved?

21 A I made a presentation to him. I think  
22 it was before the Advisory Committee meeting, and

0029

1 I wouldn't have characterized that as unusual. I  
2 would have said that that's probably something  
3 that should have occurred, because it was a high  
4 profile meeting. I do know that in getting ready  
5 for the Advisory Committee meeting on some of the  
6 direction we were getting, Dr. Galson said I know,  
7 I know what direction Dr. McClellan wants to go,  
8 and this is it. So he had some involvement, but I  
9 didn't have personal contact with him.

10 Q What did Dr. Galson say that the  
11 direction of Dr. McClellan was?

12 A In regard to what?

13 Q In regard to Plan B. I think you said  
14 that Dr. Galson said that he knew what direction  
15 Dr. McClellan wanted to go in.

16 A It was mainly with the, um -- again in  
17 regard to August and talking to the sponsor about  
18 having some sort of restricted distribution plan.

19 At the Advisory Committee meeting, they -- at one  
20 point in time they wanted to discuss -- one of the  
21 questions -- they wanted to add a question about  
22 behind-the-counter, and we were concerned about

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1 asking a question like that when we didn't know if  
2 we had regulatory authority to enforce it, and  
3 Dr. Galson said I know this is where Dr. McClellan  
4 wants to go, so we need to go in this direction.

5 Q And that was before the Advisory  
6 Committee meeting?

7 A Correct.

8 Q Tell me what, if you can, what  
9 "behind-the-counter" means.

10 A Well, in this country we do not have  
11 behind-the-counter, but behind-the-counter would  
12 mean that the drug would be under the control of  
13 the pharmacist and that you would have to go  
14 through the pharmacist to obtain the drug.

15 Q Behind-the-counter sorts of arrangements  
16 exist in other countries?

17 A Correct.

18 Q And so --

19 A I should also add they, they can exist  
20 at a State level, but from a  
21 federal-agency-dictating level, we have never  
22 asserted that we have that authority.

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1 Q Are you aware of any scientific basis  
2 for exploring behind-the-counter status for Plan  
3 B?

4 MR. WARSHAWSKY: Objection; vague.

5 BY MR. HELLER:

6 Q Is there any scientific reason that you  
7 would want to go in the direction of  
8 behind-the-counter availability for Plan B?

9 A I personally did not see a reason for  
10 that. I think that there were concerns from upper  
11 management about whether there would be misuse or  
12 abuse of the product.

13 Q Were the concerns about misuse and abuse  
14 justified by the scientific data?

15 A Well, obviously I didn't think there  
16 were, because I said that it could be distributed  
17 as an OTC agent, so my opinion was is that there  
18 were not.

19 Q Do you still feel confident in that  
20 opinion?

21           A     Well, I would, I would have to -- it's  
22     been several years since I have worked on Plan B,  
0032

1     so I would have to have a reevaluation. I'd have  
2     to have an update on the safety data, and I'd  
3     probably want to see some of the stuff that I saw  
4     up to my last review. If nothing has changed,  
5     then I would feel confident that that is not a  
6     concern.

7           Q     In your time at the Agency have you ever  
8     experienced a situation where you were, as you  
9     indicated at the time -- I think at the time you  
10    made your recommendations you were confident, for  
11    example, that behind-the-counter, there was no  
12    scientific justification for that. Yet upper  
13    management was directing the Agency to go that  
14    way, this sort of -- what I'm getting at is: Have  
15    you ever had the experience of a divide about, a  
16    division about the scientific opinion that is  
17    similar to the one that you've described for Plan  
18    B?

19           A     Do you mean specifically about whether  
20    something should be behind-the-counter or --

21           Q     Yes.

22           A     No.

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1           Q     Have you ever experienced that kind of  
2    scientific division between, sort of between your  
3    own opinion, your own scientific opinion, and  
4    upper management's scientific opinion about safety  
5    of adolescent use of a particular drug?

6           A     Not that I recall.

7           Q     Did you -- by the way, did you attend  
8    the Advisory Committee meetings that took place  
9    about Plan B?

10           A     Yes.

11           Q     Uh, those -- as I understand it, there  
12    were two Advisory Committees that were meeting  
13    jointly; is that right?

14           A     Correct.

15           Q     And what -- who is on these Advisory  
16    Committees? What sorts of people are on them?

17           A     Well, typically the OTC Committee, which  
18    I was in charge of the OTC Committee, we tend to  
19    have a variety of people on there, because we get  
20    a variety of products. And usually the meetings  
21    that OTC have -- has are joint meetings, because  
22    we are usually switching in other products, so we

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1 have to meet wherever that product is housed, with  
2 their Advisory Committee meeting. So the people  
3 that are on the OTC Committee -- is that what  
4 you're asking me about?

5 Q Yeah.

6 A They tend to be, um, a wide variety of  
7 people. They can be pharmacists, pediatrician.  
8 We have a pediatrician on the committee for Plan  
9 B. We have a few clinical pharmacologists. Um,  
10 we can have poison control experts. Um, usually  
11 we try to keep a variety of disciplines on there.

12 Q Did Dr. Galson attend the Advisory  
13 Committee meetings; do you know?

14 A Yes.

15 Q Did Dr. McClellan attend?

16 A Not to my knowledge.

17 Q Did Dr. Woodcock attend?

18 A I don't remember that she did.

19 Q Okay. I'm going to show you some  
20 documents that I think are associated with you at  
21 least because you either wrote them or your name  
22 appears on them somewhere and ask you some

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1 questions about them.

2 A Okay.

3 Q Let me find the first one I want to ask  
4 you about.

5 MR. AMANAT: No handy-dandy binders this  
6 time?

7 MR. HELLER: Too bulky.

8 (Discussion was held off the record.)

9 BY MR. HELLER:

10 Q This is a document that's marked at the  
11 bottom Tummino 30443, and it ends, I believe, at  
12 Tummino 30456. Take a look at it, please, and let  
13 me know if you are familiar with it.

14 A Yes.

15 Q Okay. And this is a memo you, yourself,  
16 wrote in January 2004 or finalized in  
17 January 2004?

18 A Uh, well, I would say that that is the  
19 date on it, January 2004, right.

20 Q Okay. So I have some questions about  
21 what you wrote here, and I, and I want to sort  
22 of -- I'll try to -- I'll direct your attention to

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1 specific pages and paragraphs to make it easier, I

2 guess.?

3 MR. WARSHAWSKY: Can Dr. Rosebraugh have  
4 the opportunity to read the document before he  
5 answers questions about it?

6 BY MR. HELLER:

7 Q Would you like to read the whole  
8 document before you answer questions?

9 A Well, why don't you just tell me what  
10 you got a question about.

11 Q Okay. On the first page, the paragraph  
12 starting "Plan B was approved for prescription use  
13 on July 28th, 1999" --

14 A Uh-huh.

15 Q -- the third sentence or the second and  
16 third sentences say, "Prescription directions for  
17 use indicate that to obtain optimal efficacy, the  
18 first tablet should be taken as soon as possible,  
19 within 72 hours of intercourse, and the second  
20 tablet should be taken 12 hours later. It has  
21 been demonstrated that the sooner the first pill  
22 is taken, the greater the effectiveness the

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1 product is in preventing pregnancy."

2 Do you know if that -- is that true?

3 A To my knowledge, it's true, yes.

4 Q Do you know if upper management ever  
5 expressed any disagreement -- upper management in  
6 FDA, meaning Dr. Galson or above -- ever expressed  
7 any disagreement with what you stated there?

8 A Not that I know of.

9 Q Okay. If you turn to the next page --

10 A Can I just correct that statement a  
11 little bit?

12 Q Sure.

13 A Are you asking me did upper management  
14 ever disagree with that opinion, or are you asking  
15 me did upper management ever read my review and  
16 disagree with the review?

17 Q Well, maybe I better ask both. Do you  
18 know if upper management ever read your review?

19 A No, I do not know that.

20 Q But the second question, regardless of  
21 whether they read your review, did you ever have  
22 any reason to believe that upper management

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1 disagreed with these two opinions?

2 A Not that I know of.

3 Q On the second page of this document, the

4 third paragraph starts with the words, "The three  
5 key elements of the above."

6 A Uh-huh.

7 Q And you list three, numbered three  
8 elements, and the first you have in quotes, and I  
9 think this is a quote from the Code of Federal  
10 Regulations. You have this quote. "The drug's  
11 toxicity or other potentiality for harmful  
12 effects," then in parenthesis, "acceptable safety  
13 profile, low misuse and abuse potential,  
14 reasonable therapeutic index of safety."

15 So my question about this is: What you  
16 have in parenthesis, is that something you,  
17 yourself, developed, or does it come from someone  
18 else? That sort of -- I don't know. Is it a  
19 clarification of what's in quotes?

20 A Yeah, the thing that's in quotes is from  
21 the Code of Federal Regulations, and then the  
22 thing that is in parenthesis is sort of how the

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1 Division interprets it.

2 Q Okay.

3 A So when we approach a drug and we are  
4 saying the drug's toxicity or potential for  
5 harmful effects, at least when I was there, the  
6 way we would view that is just to say does it have  
7 an acceptable safety profile, what is its misuse  
8 and abuse potential, what is its therapeutic index  
9 of safety.

10 Q So those three things you just read are  
11 essentially what your Division, at the time you  
12 were there, would have looked at in OTC Switch  
13 Applications in general on this first element?

14 A Correct.

15 Q And the same with the other two  
16 elements: You have the sort of quote from the  
17 Code of Federal Regulations, followed by a  
18 parenthetical statement that reflects the  
19 Division's interpretation of how they would  
20 interpret that; is that basically correct?

21 A Correct.

22 Q Okay, but you don't know if they're

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1 still adhering to those interpretations now in  
2 that Division?

3 A No, I don't.

4 Q Who would know that? Who is the --

5 A Dr. Ganley.

6 MR. AMANAT: Dr. Who?

7 THE WITNESS: Ganley.

8 BY MR. HELLER:

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12 Q I understand. Thank you.

13 Then just below that, your first  
14 conclusion/recommendation is that the Application  
15 should be approved, and you believed that at the  
16 time; is that right?

17 A Correct.

18 Q Do you -- in retrospect, do you believe  
19 that it should have been approved at that time?

20 A Well, I'm going to answer that, but  
21 this, this memo was done in January, because as I  
22 recall, we had a February PDUFA date, and usually

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1 the Divisions try to get everything tied up and  
2 get it to the Office several weeks early, so at  
3 the time I wrote this for the February PDUFA date,  
4 I did believe it should be approved, yes.

5 Q Did anything ever change your opinion  
6 about that? Did you ever come to believe that it  
7 should not be approved?

8 A No.

9 Q Did anyone ever, within the Agency, ever  
10 present you with scientific data or reasons that  
11 it should not be approved?

12 A No.

13 Q I want to go down to Number 5 in the  
14 list under "Conclusions and Recommendation," and  
15 the last sentence -- or that paragraph makes  
16 reference to a Citizen Petition, and the last  
17 sentence says, "Should the Agency follow the OTC  
18 Division's recommendation of approval, the  
19 response to this Petition, at least in regards to  
20 addressing Plan B, will be that we agree and the  
21 issue will become moot." Does that -- am I  
22 understanding that correctly to mean that if the

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1 OTC Switch Application was approved, then the  
2 Citizen Petition, at least regarding Plan B, would  
3 become moot, because what the Citizen Petition was  
4 asking --

5 A They were requesting it to be approved  
6 OTC, so if we approved it OTC on the basis of the  
7 Application, we in essence would have been doing  
8 what the Citizen Petition was asking.

9 Q At the time you wrote this, if you  
10 remember, do you have any -- did you have any  
11 reason to believe that the Agency would not follow  
12 the OTC Division's recommendation of approval?

13 A At the time that I wrote this, I felt  
14 that the Agency probably would not approve the  
15 drug.

16 Q And why did you feel that way and why  
17 did you believe that?

18 A It seemed that upper management had  
19 concerns about the drug, and I felt that they  
20 would probably not follow our recommendation.

21 Q And in what you just said, when you're  
22 referring to "upper management," are you talking

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1 about Dr. Jenkins --

2 A Well --

3 Q -- or higher up than that?

4 A -- at the time that I wrote this review,  
5 I don't think Dr. Jenkins had declared where he  
6 stood on the Application, and so I wasn't real  
7 sure where he was at.

8 Q Who would you, who would you -- who are  
9 you thinking of when you say "upper management"?

10 A Well, certainly Dr. Galson's level, and  
11 again at Dr. Jenkins' level, I really wasn't sure  
12 where he was at with the Application. However,  
13 Dr. Jenkins had not seen any of the reviews.

14 Q Had Dr. Galson seen any of the reviews?

15 A I don't know. At the time that, um --  
16 at the time that, um, this was written and filed,  
17 I'm not real sure, um -- I'm not real sure how  
18 many -- yeah, I, I'm not sure. I don't know if he  
19 would have seen them or not.

20 Q Would it be -- wouldn't it be unusual  
21 for Dr. Galson to have seen the reviews before  
22 Dr. Jenkins saw them?

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1 A It would be, yes.

2 Q Why did you think Dr. Galson would not  
3 accept your recommendation?

4 A Well, he, he had voiced concern  
5 throughout the process, and so based on his  
6 concerns that he had voiced and that he -- I'm  
7 trying to get the time frame of this. I think  
8 that he had said that the Commissioner had some  
9 concerns also, so I think based on those things, I  
10 was not confident that they would take our  
11 recommendation.

12 Q I guess sort of my follow-up question  
13 then, what I'm trying to get at is, people can  
14 express concerns and you can still think, oh,  
15 well, we can address these concerns and it will  
16 work out all right, they'll take our  
17 recommendation, versus people can express concerns  
18 in a manner or of a type of concern such that you  
19 believe, you know, I'm going to make this  
20 recommendation, but it's not going to be, it's not  
21 going to be adopted. Could you say that  
22 Dr. Galson's concerns fell into one or the other

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1 of those categories, or is that -- can you say?

2 MR. WARSHAWSKY: Objection; vague.

3 THE WITNESS: So when you object, am I  
4 supposed to answer that?

5 MR. WARSHAWSKY: Oh, yes. Unless we  
6 tell you not to answer, you should answer if you  
7 can.

8 THE WITNESS: I felt that it fell into  
9 the category that they were not going to take my  
10 recommendation.

11 BY MR. HELLER:

12 Q Okay. So an example, just as an  
13 analogy, a concern might be, well, they need to do  
14 this one more study, and you might feel, okay,  
15 this is something we can go to the manufacturer  
16 with, say they should do this, and it will come  
17 back and things will go fine. This was more of a  
18 concern that you felt that, that your  
19 recommendation was going to be, in a sense,  
20 rejected, is that right, as opposed to a concern  
21 that might be addressed by further work?

22 A Well, that's part of the -- I'm trying

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1 to get the time. I'm having trouble remembering  
2 what the time flow was. Somewhere in January we  
3 met with Dr. Galson. I actually was on the phone,  
4 and he met with people in Park Lawn, and at that  
5 meeting he said this will be -- at least my  
6 recollection of what he said was this will be a  
7 Non-Approvable Action.

8 Q Okay.

9 A And there's different levels of Action.  
10 There's Non-approvable, there's Approvable and  
11 then there is Approved, and we asked several  
12 questions about why this wasn't an Approvable  
13 Action and really couldn't get an answer from  
14 Dr. Galson. And so then he said this would be a  
15 non-approval, and when we asked what it would take  
16 for the sponsor to go forward, we really couldn't  
17 get a sense of what it was that he wanted or what  
18 he needed or what sort of studies were needed. I  
19 just can't remember whether that -- how that  
20 happened around where this review went in.

21 Q I think the meeting that you're  
22 referring to occurred on January 15th, and I'm

0048

1 going to show you another document that may help  
2 you get that time frame, because I'm not trying to  
3 confuse you about dates.

4 A Well, I thought that I filed this -- the  
5 way that my somewhat faulty memory is working is I  
6 thought I filed this the same day, because I  
7 essentially had --

8 Q I think it is dated the 15th also.

9 A Right, and so based on that interaction,  
10 I felt that it was going to be very difficult to  
11 define what the sponsor needed to do to go  
12 forward. Does that answer your question?

13 Q Yes. Thank you.

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22 Q Okay. And you describe the study, the

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1 design of the studies in your memo, and then if  
2 you'd turn to Page 30450, you, you reach certain  
3 conclusions about the behavioral studies, I think,  
4 on that page, and just above the line that says  
5 "Relevant Advisory Committee questions and votes,"

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16 MR. WARSHAWSKY: Objection. I don't  
17 believe that sentence purports to summarize all  
18 those studies.

19 MR. HELLER: Okay.

20 BY MR. HELLER:

21 Q Is that sentence -- was it your opinion  
22 at the time you wrote it?

0051

1 A Well, yes.

2 Q Okay.

3 A I wouldn't have wrote it.

4 Q Now, these -- one of the things you said  
5 about, about these studies under Number 2 above  
6 there is that they did not simulate an OTC  
7 setting, but you still found them of value, I  
8 guess, in assessing the OTC Switch Application.  
9 Can you explain why that would be.

10 A Yeah. You know, in an Actual Use Study,  
11 in reality it is very hard to totally simulate an  
12 OTC environment, and anytime that you start  
13 interjecting things like consent forms or things  
14 like that, you introduce confounding and bias. So  
15 even in an Actual Use Study where you're trying  
16 your hardest to simulate an OTC environment, you  
17 really can't do it, so you just do the best you  
18 can. So in reality, a lot of Applications will  
19 come in with other studies that they say, well,  
20 this kind of has a feature like OTC, and it kind  
21 of evaluates either a different population or a  
22 different feature.

0052

1 Now, some of these had Advance  
2 provision, and so in Advance provision the women  
3 were just given the pills to take home to use as  
4 they needed to use them. Well, that, in a way,  
5 kind of simulates an OTC environment where you can  
6 buy something, take it home and just keep it there  
7 until you need it, so you get some sense of, after  
8 they get them, how long before they use them, how  
9 many times do they use them, what are the  
10 circumstances they use them under, so I think some  
11 of these studies can give those types of answers.

12 Q In terms of simulating an OTC setting,  
13 have you ever seen an OTC Switch Application in  
14 which the OTC setting was really simulated exactly  
15 as it would be if the drug were available over the  
16 counter?

17 MR. WARSHAWSKY: Objection.

18 THE WITNESS: I'd probably have to think  
19 about that a while, because I've seen a lot of  
20 studies come in, but just off the top of my head  
21 I've never seen one -- I think, from what you're  
22 describing, that it would be like people across

0053

1 the country can just walk into a pharmacy and get  
2 the drug.

3 BY MR. HELLER:

4 Q Because that's -- so in some sense the  
5 reason you can't simulate it is that the only way  
6 to simulate it is to actually put it over the  
7 counter and see what happens.

8 A Well, and you have to have some way to  
9 follow up on the patients, and you have to have  
10 study coordinators, so it would be very difficult  
11 to do that.

12 Q Could you -- have you had instances  
13 where that you know of where people, manufacturers  
14 or others, have submitted evidence from other  
15 countries in which a similar drug or the same drug  
16 is really available over the counter?

17 A Well, we typically ask manufacturers to  
18 come in, if it's over the counter in any other  
19 country, and to submit what they know about it.  
20 You have to be kind of careful. "Over the  
21 counter" in other countries can mean different  
22 things. It can actually mean pharmacy only and

0054

1 things like that, so you kind of have to be a  
2 little careful, when you're talking about other  
3 countries, what you're talking about.

4 Q In some countries "over the counter"  
5 really does mean "over the counter" in the same  
6 way as it does here; is that right?

7 A Well, most countries have a kind of a  
8 schema of how they actually hit what we mean over  
9 here, how they actually get to over the counter,  
10 so they tend to have kind of a behind-the-counter  
11 system where it will move from prescription to  
12 behind the counter for a number of years, and then  
13 it moves from behind the counter to true  
14 over-the-counter status.

15 Q And we don't have that system in the  
16 United States?

17 A No.

18 Q Going on a little further in your memo  
19 on the next page, 30451, you express your

20 disagreement with Dr. Jin Chen's conclusions in a  
21 number of, I guess five numbered paragraphs, and I  
22 have a couple of questions about this. In the

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1 first paragraph you have the statement, "Studies  
2 have demonstrated that when users have ready  
3 access, they seldom use emergency contraception  
4 more than three times per year." Do you remember  
5 any more detail about those studies?

6 A Not more than just the bottom line  
7 that -- and I'm also trying to remember whether  
8 they were domestic or foreign. There's a lot of  
9 data on Plan B from foreign countries. A lot of  
10 it comes from Britain. There's some stuff in  
11 Britain. It's over the counter in Britain. And  
12 there's a lot of stuff in France. Actually, in  
13 France they pay for it. The government pays for  
14 it.

15 Q So it's free to the public?

16 A Right, and so I can't, I can't remember  
17 what -- because after this review, I subsequently  
18 did a more thorough review, and I just can't  
19 remember where I got what data from, but, but the,  
20 the bottom line was that typically when people  
21 had, had free and ready access, they seldom used  
22 the drug more than three or four times a year.

0056

1 Q Incidentally, do you remember  
2 Dr. McClellan talking about a study by Tina Rain  
3 at some meeting that you had with Dr. McClellan?

4 A We had a meeting in --

5 Q I think it was in February of 2004.

6 A So when Dr. Galson in January said that  
7 there was not enough data, we said there actually  
8 is quite a bit of data, and it was from these  
9 studies, so -- and we had these studies in an  
10 Advisory Committee package, so he didn't seem to  
11 be aware that they were in there, but we said we  
12 have these studies and there's quite a bit of data  
13 in there, and he said, well, you need to get that  
14 together then and present it to Dr. McClellan.

15 So when we presented to Dr. McClellan,  
16 the only thing I can kind of remember -- and I  
17 think it was on the Tina Rain study that we were  
18 presenting to him, he said, I see, I see  
19 disturbing trends, and when we said, well, what,  
20 what are the disturbing trends? Perhaps we can  
21 address those. We really had problems getting him

22 to identify what the trend was he was concerned  
0057

1 about.

2 Q Do you know if this is the same Tina  
3 Rain who later published a short article  
4 explicitly advocating over-the-counter status for  
5 Plan B?

6 A Well, she's published a lot of stuff  
7 about Plan B, so I don't know what specific  
8 article you're talking about.

9 Q I remember just seeing in some documents  
10 that we got from the FDA, like a two-page article,  
11 three-page, sort of an opinion where she said  
12 that. Do you know if she does believe that it  
13 should be over the counter?

14 A The last I knew, I thought she did, yes.

15 Q Did you ever sort of get from anyone  
16 within the Agency, actually outside the Agency,  
17 any explanation of what the trends were that  
18 Dr. McClellan found to be troubling in the Tina  
19 Rain study?

20 A I don't, I don't recall that I ever got  
21 an explanation of what they were concerned about.

22 Q In the second Number 2 paragraph on this  
0058

1 page, you have the following -- well, why don't  
2 you just -- if you don't mind reading that  
3 paragraph to yourself and telling me if it's  
4 still, if this is still your opinion today.

5 A What I would have to say -- I really  
6 haven't had interaction with the reproductive  
7 folks to see if they've changed the way they're  
8 doing things, and I haven't been in OTC in a  
9 while, but clearly at the time that was my  
10 opinion, and I don't know that anything has  
11 changed since then.

12 Q I have a couple of questions about what  
13 you said in this paragraph.

14 A And here I thought it was so clear.

15 Q It is very clear. In the second  
16 sentence you say, "This would be placing a new  
17 regulatory burden on Plan B, an agent that would  
18 be associated with less 'sexual exposure' than  
19 regular contraceptives." Can you tell me what you  
20 mean by being associated with less sexual  
21 exposure.

22 A Well, I think what I was trying to say

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1 was that we have recognized in the OTC environment  
2 that contraception is an OTC indication, because  
3 we have contraceptives out there. And so if we  
4 are saying that contraceptives is an OTC  
5 indication, these are contraceptives for regular  
6 use, where people would use them regularly to  
7 prevent pregnancy.

8 And so you sort of intellectually say to  
9 yourself, well, if that's the case, they would  
10 have -- these regular contraceptives would have  
11 more sexual exposure, because people would be  
12 using them regularly instead of just when you have  
13 an emergency or have a contraceptive misadventure.  
14 And so it wasn't clear to me why I would ask Plan  
15 B to show that there wasn't risky or unsafe sexual  
16 behaviors when I already had a regular  
17 contraceptive over the counter that I didn't ask  
18 the same question of them; particularly, if you  
19 think about it, this was a drug that was going to  
20 be used less frequently, theoretically, because  
21 it's for misadventures when your regular  
22 contraceptive fails.

0060

1 Q Can you give me some examples of other  
2 regular contraceptives that are available over the  
3 counter.

4 A N9, condoms.

5 Q So, for example, someone can go in right  
6 now, a person any age, and go buy N9 at drug  
7 stores?

8 A Yes.

9 Q And the same with condoms?

10 A Correct.

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2 Q Have you ever seen any scientific data

3 that makes you doubt that that's correct?

4 A Well, I haven't, I haven't really kept  
5 up on the scientific data with Plan B after I was  
6 no longer involved with the Application.

7 Q What I mean is did you ever, during the  
8 rest of the course of your involvement, ever see  
9 scientific data that made you doubt these  
10 conclusions?

11 A No.

12 Q If you turn to Page 30455 of this memo,  
13 you are here describing some of -- you say,  
14 "Further thoughts regarding the benefit of Plan  
15 B," and you have a paragraph that expands on that.  
16 During your involvement in the Plan B process, did  
17 you hold the opinion that Plan B had the potential  
18 to decrease unwanted pregnancies significantly?

19 Let me rephrase my question, because  
20 that wasn't very good.

21 Did you hold the opinion that OTC status  
22 for Plan B had the potential to decrease unwanted

0062

1 pregnancies in the United States?

2 A Yes, I had the opinion that it had the  
3 potential to do that.

4 Q And did you have the opinion also that  
5 it would also have the potential to decrease the  
6 number of abortions in the United States?

7 A Yes.

8 Q And did you also hold the opinion that  
9 you express in the final paragraph there, that the  
10 potential benefit of these things for teen  
11 physical and mental health far outweigh the minor  
12 risks associated with Plan B use?

13 A Yes.

14 Q Do you have any idea how, given the  
15 benefits that -- just these benefits that you've  
16 just talked about, I mean the obvious benefit,  
17 that's what Plan B is intended for, I guess, is to  
18 avoid pregnancy, but avoiding unwanted pregnancy,  
19 avoiding abortions, given those potential benefits  
20 and the minor risks associated with using it, do  
21 you have any idea how or rather why the Agency  
22 didn't wind up approving it for OTC use?

0063

1 MR. WARSHAWSKY: I'm going to object to  
2 that question.

3 BY MR. HELLER:

4 Q What led to that, given this weighing of

5 benefits versus the risks?

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

8 THE WITNESS: Well, you'd have to ask  
9 the people that didn't approve it. My impression  
10 from what they had said at the time is that they  
11 were being cautious, that there might be  
12 unforeseen consequences that we hadn't  
13 anticipated.

14 BY MR. HELLER:

15 Q Is it fair to say that on the other hand  
16 the consequences, for example, of unwanted  
17 pregnancies and abortions as a result of that are  
18 foreseeable consequences of decreased access to  
19 Plan B?

20 MR. WARSHAWSKY: I'm going to object to  
21 that question.

22 MR. HELLER: On what basis?

0064

1 MR. WARSHAWSKY: Lacks foundation. It's  
2 argumentative. There's no evidence in the record  
3 that the failure to approve Plan B for OTC status  
4 results in more abortions, which I believe is how  
5 that question was just phrased.

6 MR. AMANAT: It was also a double  
7 negative.

8 MR. HELLER: I like double negatives.

9 MR. AMANAT: I know you do.

10 BY MR. HELLER:

11 Q I'll rephrase my question anyway,  
12 because maybe it was a little bit long. I'm  
13 sorry.

14 In this paragraph you're talking about  
15 the potential to decrease unwanted pregnancies and  
16 the potential to decrease the number of abortions  
17 if Plan B is available over the counter; is that  
18 right?

19 A Correct.

20 Q That's a potential that you believed was  
21 a real benefit of Plan B being over the counter,  
22 isn't it?

0065

1 A Yes.

2 Q I think we can put this document aside.

3 You were talking earlier about a meeting  
4 at which Dr. McClellan I think expressed something  
5 about trending, troubling trending in the Tina  
6 Rain Study. Do you remember anything else that

7 Dr. McClellan said at that meeting about his  
8 concerns about the Plan B Application?

9 A Well, I recall that Dr. Galson --  
10 actually, I'm not sure how it came up, but  
11 something about potential marketing based on age  
12 came up, and Dr. McClellan said that he thought  
13 that that would warrant yet another public  
14 discussion, and so even if they tried to do  
15 something based on age, he felt that it would have  
16 to be discussed publicly.

17 Q Do you recall him, at that meeting or  
18 ever, talking about any of the benefits of Plan B  
19 being over the counter?

20 A Well, "ever" is a long time, but I can  
21 only recall -- I think we only had two meetings  
22 with him that I recall of, and I don't recall him

0066

1 discussing it.

2 Q I think you've talked about a meeting at  
3 which before the meeting with Dr. McClellan, there  
4 was a prior meeting, a large meeting in which --  
5 well, do you recall a meeting that Dr. Galson ran,  
6 before the one with Dr. McClellan in January of  
7 2004, where he was conveying the Commissioner --  
8 the Office of the Commissioner's position on the  
9 Application?

10 A Let me just make sure I understand your  
11 question the way you asked it. You said a meeting  
12 before Dr. McClellan in January. The McClellan  
13 meeting was in February, as I recall, so you mean  
14 a meeting that Dr. Galson ran in January before  
15 the February meeting?

16 Q Yeah.

17 A Yes.

18 Q And did he -- did Dr. Galson at that  
19 meeting convey something about what the position  
20 was of the Office of the Commissioner on the Plan  
21 B Application? Do you remember him conveying that  
22 it was non-approvable?

0067

1 A Well, he said that the, the, um -- what  
2 I recall from the conversation is he said that the  
3 Action would be a not-approvable Action. I don't  
4 remember him specifically saying that it came from  
5 the Office of the Commissioner.

6 Q Do you know whether it came from the  
7 Office of the Commissioner?

8 A No.

9 Q It at least came from Dr. Galson, but  
10 maybe someone higher up?

11 MR. WARSHAWSKY: Objection.

12 THE WITNESS: Well, at least it came  
13 from Dr. Galson. I don't know about higher up.

14 BY MR. HELLER:

15 Q Do you know if at that time it came from  
16 someone at the level below Dr. Galson, like  
17 Dr. Jenkins?

18 A Again I think at the time Dr. Jenkins  
19 was still undecided in what he was going to do,  
20 and we did have a meeting -- I think that was the  
21 day after the Commissioner meeting, where -- so it  
22 would have been in February -- where we were

0068

1 trying to get a sense of what the process was,  
2 because we, we seemed to kind of be reporting to  
3 different people on different items, and it was  
4 getting kind of confusing. And so at this meeting  
5 the day after the Commissioner briefing, we said,  
6 "Who exactly are we reporting to?" And  
7 Dr. Jenkins said, "You will report to me, and your  
8 memos will come to me, and then I'll make my  
9 decision," and as I recall, at that time he said,  
10 "And if I can't or do not feel that it should be a  
11 Non-Approval Action, I'll send it to Steve,  
12 Dr. Galson."

13 Q Did he say what he would do if he felt  
14 that it should be approved?

15 A No. Well, let me, let me back up. I  
16 think that's what I just said. He said that if he  
17 could not sign an NA Action, which would be an  
18 approved Action, that if he could not sign an NA,  
19 he would send it to Steve. Is that what you just  
20 asked me?

21 Q I don't know. I'm not sure I'm  
22 understanding you. If you could not -- if Dr.

0069

1 Jenkins could not --

2 A Dr. Jenkins said, "If I cannot sign a  
3 Non-approval Action" -- in other words, if he felt  
4 that the drug needed to be approved --

5 Q Okay.

6 A -- and he felt that in his estimation he  
7 could not sign an NA because the data did not  
8 support that, then he would send it to Dr. Galson.

9 Q That seems rather odd. Would he have  
10 said the opposite as well, sir? "If I feel that I

11 cannot sign an Approval Letter for this, then I'll  
12 send it up to Dr. Galson."

13 A No. It would have stopped with him.

14 Q What I'm trying to get at is: Why would  
15 it only go up to Dr. Galson if he felt he could  
16 not sign the NA letter?

17 A Let me see if I understand your  
18 question. Why would it go to Dr. Galson if  
19 Dr. Jenkins could not --

20 Q Felt he could not sign the NA letter.

21 A Because upper management wanted an NA  
22 Action.

0070

1 Q Meaning Dr. Galson or someone --

2 A As far as I knew, that was -- Dr. Galson  
3 wanted an NA Action, so Dr. Jenkins was saying if  
4 I look at the data and I can't support an NA  
5 Action and can't sign that kind of letter, I'm  
6 going to send it to "you," meaning Dr. Galson.

7 Q And that's, in fact, what happened  
8 basically, right?

9 A Correct.

10 Q I have another document for you to look  
11 at, and this one is marked Tummino 30613 through  
12 30619, and on the last page is your name and the  
13 statement, "I concur with this review," so please  
14 take a moment to look it over and see if you have  
15 a basic memory of this, of this document.

16 A I have a basic memory without a lot of  
17 specifics.

18 Q Would you like to read it over? I have  
19 just a couple of questions about it.

20 A Well, why don't you ask the question,  
21 and if I don't know, then I'll --

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20 Q It sounds to me as if the concerns being  
21 addressed in the sentences I just read are  
22 essentially the same as the concerns you described

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1 upper management expressing. Am I correct, or is  
2 there a difference?

3 A They actually were broader. Dr. Chen --  
4 whereas upper management felt that it, there  
5 wasn't enough data in adolescents, Dr. Chen felt  
6 that there wasn't -- at least my understanding and  
7 what I recall from his review is that he felt that  
8 there was not enough data in general for, for all  
9 women. As I recall his review, I think he said  
10 especially adolescents, so he had a broader scope.

11 Q So is it fair to say then that if his  
12 concerns were speculative, the narrower set of  
13 concerns, a sort of subset of those concerns, are  
14 also speculative?

15 MR. WARSHAWSKY: I'm going to object to  
16 that question.

17 MR. HELLER: On what basis?

18 MR. WARSHAWSKY: The question -- the  
19 question itself is vague and frankly illogical,  
20 and if you're asking the plaintiff, yeah, it's  
21 illogical.

22

0073

1 BY MR. HELLER:

2 Q Let me put it in more specific terms.  
3 The set of concerns that is identified in this  
4 document as speculative included the concerns  
5 expressed by upper management but was broader.  
6 Isn't that what you just said?

7 MR. WARSHAWSKY: Objection. I think  
8 that mischaracterizes the witness's testimony.  
9 Why don't you specify the specific upper  
10 management concerns and just deal with those, deal  
11 with them in a concrete fashion?

12 MR. HELLER: I have no idea what the  
13 specific upper management concerns were.

14 MR. WARSHAWSKY: Precisely. There is a

15 lack of foundation for this question. Why don't  
16 we establish what those concerns are?

17 MR. HELLER: I don't think he's been  
18 able -- I think he testified already that he was  
19 unable to get clarification from upper management  
20 about what those concerns were. That's what he  
21 testified.

22 MR. WARSHAWSKY: Again I think you're

0074

1 misrepresenting his testimony.

2 BY MR. HELLER:

3 Q In any case, you can answer my question  
4 if you can remember it.

5 A What was the question?

6 Q I think you said that the concerns that  
7 this document responds to were broader than the  
8 concerns expressed by upper management, because  
9 they applied across the board to all women, not  
10 just adolescents.

11 A Correct. Yes.

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21 Q Okay. Do you think you could not apply  
22 the data from a broader population to a, to the

0075

1 subpopulation of younger women with respect to  
2 Plan B? Do you believe that?

3 A Do you mean with all the data that we  
4 had in hand?

5 Q Yes.

6 A Well, I think we had -- I think we had a  
7 rich body of data on adolescents.

8 Q With respect to other OTC Switch  
9 Applications that you've been involved with, have  
10 you ever had an equally rich body of data for  
11 adolescents?

12 A Well --

13 MR. WARSHAWSKY: Objection.

14 MR. HELLER: What's the objection?

15 MR. WARSHAWSKY: The objection is that  
16 you're comparing apples and oranges. That

17 particular problem --  
18 MR. HELLER: Well, that's --  
19 MR. WARSHAWSKY: Let me finish my  
20 objection. That particular --  
21 MR. HELLER: That objection -- it's not  
22 an objection to his answering the question. It's  
0076  
1 a legal argument.  
2 MR. WARSHAWSKY: Your question is  
3 misleading. The terms that you're using are  
4 ambiguous, and you're misleading the witness. I  
5 think the form of the question is misleading and  
6 vague in that by using a single term you're  
7 actually comparing two different things.  
8 MR. HELLER: They're not different.  
9 MR. WARSHAWSKY: Yeah, they are.  
10 MR. HELLER: Have you established that  
11 they're different? What's the difference?  
12 MR. WARSHAWSKY: Well, if you'd like me  
13 to testify, I'd be happy to.  
14 MR. HELLER: I'd love it if you'd tell  
15 me what the difference is, because I still don't  
16 know what it is.  
17 Could you read back --  
18 MR. WARSHAWSKY: I'll explain it to you.  
19 You like me to explain it to you?  
20 MR. HELLER: Sure.  
21 MR. WARSHAWSKY: The data that they get  
22 to support these Applications is tailored to  
0077  
1 address the issues raised by the Application, so  
2 just because the data might involve a 20-year-old  
3 or a 12-year-old doesn't mean the data is  
4 comparable between different Applications, because  
5 they're testing for different issues raised by the  
6 different drugs.  
7 MR. HELLER: Could you read back my  
8 question, please.  
9 (Whereupon, reporter reads requested  
10 material.)  
11 MR. WARSHAWSKY: Same objection.  
12 MR. AMANAT: It's a valid objection.  
13 The witness can answer.  
14 THE WITNESS: I'm thinking.  
15 No.  
16 BY MR. HELLER:  
17 Q Okay. Thank you.  
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Q Could you turn to 30617, which is two pages past that. There's a paragraph starting "it

is important," the big paragraph on that page.

A Uh-huh, yes.

Q So I'm just going to read the first three sentences. "It is important to remember that women who need emergency contraception for pregnancy prevention have already experienced risk, either unintentionally, because a condom broke, inadvertently, because they forgot to take their routine birth control pills, or because no contraception was used. In his review Dr. Chen expresses concern that if Plan B were sold OTC, that it would result in risky sexual behavior among women. This concern is not supported by the data."

Do you agree with what is expressed -- with what was expressed in these sentences as of the time it was written?

A Yes.

Q Did you ever see any data that supported Dr. Chen's concern?

20

21 A No.

22 Q Is there a way -- if there is no data

0080

1 that supports the concern and there was no data at  
2 the time this was written, how could a scientist  
3 conclude that, in fact, that concern was a valid  
4 one? How did Dr. Chen -- how could Dr. Chen reach  
5 that conclusion if it wasn't supported by the  
6 data?

7 A Well, I think first of all you'd have to  
8 ask Dr. Chen. On the other hand, let me just say  
9 that you can have a concern about something and  
10 say, look, I wonder if this is going to be an  
11 unintended consequence, and not have data for an  
12 unintended consequence, because it hasn't really  
13 been tested, so you don't know. And, you know, a  
14 sponsor can design a study to try to make sure  
15 that the unintended consequence doesn't happen so  
16 that you don't generate any data on it, so that  
17 can happen.

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0081

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2 Additionally, if you think about it,  
3 when Plan B came to us, it, for all intents and  
4 purposes, had easy access in five states, so it  
5 was sort of behind-the-counter in -- it actually  
6 wasn't behind the counter. There were  
7 prescriptions involved and that sort of thing, but  
8 women could walk into a pharmacy and just get it  
9 in five states, and it was over the counter in 30  
10 countries, and it was true OTC in at least two of  
11 them, and it had been that way for several years,  
12 and nothing had been reported. And it had been  
13 studied, and nothing had showed up, so that's a  
14 lot of data for an OTC switch.

15 A lot of the switches that we have, if  
16 you think about like Prilosec, you don't have that  
17 kind of involvement where somebody can just walk  
18 in and get it. So a lot of the switches, we don't  
19 have that much data involved, and we don't have  
20 that much history of people using it where they  
21 can get easy access to it.

22 Q So, for example, I'm going to say the

0082

1 name -- Prilosec -- am I saying that right?

2 A Correct.

3 Q That drug, for example, as far as you  
4 are aware, you didn't have behind-the-counter  
5 status for that drug in 30 countries and two of  
6 them were true over-the-counter as far as you  
7 know?

8 A Well, I don't remember. I don't  
9 remember the foreign data on Prilosec and whether  
10 it was --

11 Q So there might have been some?

12 A I just don't remember.

13 Q But you didn't have this like five  
14 states having it available in pharmacies  
15 essentially without a prescription?

16 A No.

17 Wait a minute. It was not available  
18 without a prescription. The way that these states  
19 had their thing set up, women could go in and get  
20 a prescription for -- get Plan B by asking for it,  
21 and then somehow a prescription was generated, but  
22 they did it without going through a health care

0083

1 provider.

2 Q So without, for example, a visit to the  
3 doctor's Office?

4 A Correct.

5 Q I think I'm done with this one. Thank  
6 you.

7 Okay. I'm going to show you another  
8 document, assuming I myself can find it. And  
9 these are what I believe are meeting minutes from  
10 a January 23rd, 2004, meeting that was chaired by  
11 Dr. Griebel about Plan B, in which you are listed  
12 as one of the people attending. And if you want  
13 to, please take some time to look it over, tell me  
14 if it reminds you of this meeting.

15 A I have some recollection of it.

16 Q Of the meeting?

17 A Yeah.

18 Q Okay. Is it sort of dim at this point  
19 maybe?

20 A It's fairly dim, yeah.

21 Q Okay. Let's put this aside. Thank you.

22 Thanks.

0084

1 I'm showing you a document that I think

2 is marked Tummino 30745 on the first page, all the  
3 way to 30783 at the last page, and if you look at  
4 the last page, the very last page, it has your  
5 name at the end as well as Dr. Bull's name. And  
6 this document on the first page is dated  
7 March 23rd, 2004. Do you know -- do you know --  
8 did you write this jointly with Dr. Bull, or do  
9 you know if one of you primarily wrote it?

10 A Well, I primarily wrote it. The other  
11 thing I should probably point out is that back in  
12 those days I was technically challenged, and  
13 fortunately I have resolved that in that now when  
14 I open these up, it automatically updates the  
15 date, and so the only thing the date on the front  
16 page assures you of is that somewhere around the  
17 23rd I was working on it, but that doesn't tell  
18 you I started it then or what process I was in,  
19 and the date that's accurate is the one that's in  
20 the back. That's the last time I would have  
21 looked at it and put it in.

22 Q Which is March 30th?

0085

1 A Right.

2 Q By the way, my understanding is that  
3 Dr. Bull is no longer at FDA.

4 A That's correct.

5 Q Do you know where she went to?

6 A She went to private industry.

7 Q So I have some questions about this  
8 document, and I'm going to try to speak faster and  
9 shorter.

10 The first sentence of the memo says,  
11 "Since my previous memo, January 9, 2004, upper  
12 management above the ODE level has expressed  
13 additional concerns regarding the possible  
14 over-the-counter status of Plan B." So was this  
15 memo in part a response to the concerns that had  
16 been expressed at the January meeting by  
17 Dr. Galson and then the February meeting with  
18 Dr. McClellan?

19 A Yes.

20 Q And here in the second paragraph, "On  
21 January 15th, 2004, Dr. Steven Galson, Acting  
22 Director of CDER, convened a meeting and conveyed

0086

1 that he felt there was insufficient evidence,  
2 based on the Actual Use and Label Comprehension  
3 Study, to demonstrate appropriate adolescent use

4 to support approving Plan B for OTC marketing. He  
5 stated that the Plan B Application would receive a  
6 Non-approval Action." Is that what happened at  
7 the January -- among other things, is that what  
8 happened at the January 15th meeting?

9 A That's my recollection of it.

10 Q The second or rather third full  
11 paragraph on that page refers to the  
12 February 18th, 2004, presentation to  
13 Dr. McClellan, and the third sentence states,  
14 "Dr. McClellan expressed concern about adolescent  
15 behavior, although he did not articulate the exact  
16 nature of his concern, what ages were included in  
17 his concern, what data was lacking or a path  
18 forward for the sponsor."

19 What did he articulate if he didn't  
20 articulate any of these things? Were the concerns  
21 he articulated very unclear to you, or were they  
22 very broad?

0087

1 A Well, he, you know -- I mean it was a  
2 one-hour meeting, and he got called out for part  
3 of that, and then we did a presentation, which is  
4 appended on the back. These were the slides that  
5 were presented to him. At least I believe that's  
6 what these are. And so after the presentation,  
7 then my recollection of what he did is he said "I  
8 see disturbing trends here." And as I recall,  
9 Dr. Houn said, "Can you elaborate on what the  
10 trend is. Perhaps we can try to explain that."  
11 And he said, "They're just disturbing," and that's  
12 what he said.

13 Q The next paragraph talks about a  
14 subsequent meeting on February 19th with  
15 Drs. Woodcock, Jenkins, Kweder and Galson, at  
16 which you wrote, "Dr. Woodcock expressed that she  
17 felt that the Commissioner and herself was  
18 concerned with adolescents and stated that she  
19 felt we did not really know what behaviors  
20 adolescents would exhibit. As an example, she  
21 stated that we could not anticipate or prevent  
22 extreme promiscuous behaviors, such as the

0088

1 medication taking on an 'Urban Legend' status that  
2 would lead adolescents to form sex-based cults  
3 centered around the use of Plan B. Dr. Galson  
4 indicated that he shared Dr. Woodcock's concerns."

5 Did Dr. Woodcock express the concerns

6 that you describe here?

7 A Yes.

8 Q Was her expression of those concerns --  
9 did that clarify for you what Dr. McClellan's  
10 concerns were at all?

11 A Well, this meeting the next day, in my  
12 recollection, is that Dr. Woodcock called the  
13 meeting, and she said, "I'm calling this meeting  
14 to explain to you what it was that the  
15 Commissioner said at the earlier meeting," and  
16 their concern was that we could not predict  
17 adolescent behavior.

18 Q And did she give as an example, you  
19 know, being unable to prevent extreme promiscuous  
20 behaviors, such as formation of sex-based cults?

21 A Well, she said we couldn't anticipate  
22 that that may not happen.

0089

1 Q And did Dr. Galson share that concern?

2 A I don't know if he shared that -- let me  
3 just back up. And maybe I wrote this poorly in  
4 here where it sounds like he shares that exact  
5 sentence, but he certainly shared the concern that  
6 we could not anticipate adolescent behaviors and  
7 that there may be behaviors that would be damaging  
8 to adolescents.

9 Q Could the same not be said of adults,  
10 that you couldn't anticipate adult behaviors?

11 A Well, let me put it to you this way:  
12 When you have a theory that something might happen  
13 and you're saying prove to me that it won't  
14 happen, you are asking someone to prove a  
15 negative; okay? So yes, you could have that  
16 theory that the exact same thing could happen in  
17 adults, exact same thing. I have college-age  
18 kids. It could happen in college-age kids, too.  
19 And, you know, you could say, well, I've got a lot  
20 of data on that, but if you're being asked to  
21 prove something that may never occur, how much  
22 data is enough?

0090

1 Q Did Dr. Galson or Dr. Woodcock at that  
2 meeting, as you recall, did they give you an  
3 indication of how much data, additional data they  
4 would need to allay their concerns?

5 A No, that actually -- we were trying to  
6 get a sense of what it is that they would need and  
7 how much data, and I never really did -- my time

8 working on this, I never really did have a clear  
9 picture of what that would be.

10 Q If you turn to Page 30747, I guess  
11 that's two pages, about two pages on, there's a  
12 bar graph about abortion ratio, but under the  
13 graph you have this statement: "Plan B is  
14 available as a full unrestricted OTC drug in two  
15 countries, Norway and Sweden, and it is  
16 instructive to examine abortion rates before and  
17 after approval of Plan B in these two countries,"  
18 and then you describe what happened in Sweden and  
19 Norway.

20 What did the information as of that  
21 time, the time that you wrote this memo, from  
22 Sweden and Norway, what did it -- what did it

0091  
1 indicate?

2 A In regard to what?

3 Q In regard to any possible effect of Plan  
4 B on abortion rates.

5 MR. WARSHAWSKY: Objection. Do you mean  
6 other than what he's stated in his report?

7 MR. HELLER: No, I'm asking him to sort  
8 of --

9 MR. WARSHAWSKY: You're just asking him  
10 to read what he said in his report?

11 MR. HELLER: -- to rephrase what his  
12 report said about Norway and Sweden.

13 THE WITNESS: I guess I'm not, I'm not  
14 sure what it is you're asking me.

15 BY MR. HELLER:

16 Q Well, okay. Is what you say here about  
17 Norway -- okay. You say that it's instructive to  
18 look at Norway and Sweden where Plan B was  
19 available unrestricted OTC, and then you look at  
20 Sweden and you say that "the Swedish government  
21 approved Plan B with subsequent full OTC approval  
22 in 2001. In the first six months of 2003, teenage

0092  
1 abortions were reduced by approximately five  
2 percent." What's the relevance of the decrease in  
3 teenage abortions in Sweden in the first six  
4 months of 2003?

5 A Well, I think one of the things that --  
6 you know, if you're wondering is there going to be  
7 an unanticipated consequence that you really  
8 didn't think about and would adolescents really  
9 engage in more promiscuous behavior that you

10 didn't anticipate, one of the things that might  
11 happen is abortion rates might go up instead of  
12 down. And so that's why I was trying to say,  
13 well, if you look at this, if you look at two of  
14 the countries that have OTC availability, at least  
15 abortion rates didn't go up; in fact, they  
16 actually went down some, so maybe Plan B was doing  
17 what it was designed to do.

18 Q Can you turn to the next page. Well,  
19 let me ask you a broader question, because I don't  
20 want to take up the whole day with this.

21 A I'm all for that.

22 Q Me, too.

0093

1 Okay. So do you know if there is  
2 anything in this memo that you disagree with  
3 today, that sort of you've seen something  
4 subsequent to this memo that makes you doubt the  
5 conclusions you stated here?

6 A No.

7 Q There is nothing?

8 A No.

9 Q Okay. Then without reviewing the  
10 conclusions in detail, I want to ask a couple more  
11 questions about this document. Well, first of  
12 all, did you view this as responding essentially  
13 to the concerns raised by upper management at FDA  
14 about the Plan B OTC switch? Is that the reason  
15 you wrote the memo?

16 MR. WARSHAWSKY: Objection; asked and  
17 answered.

18 MR. AMANAT: You can answer.

19 THE WITNESS: Oh. Yes.

20 BY MR. HELLER:

21 Q And did you feel that it adequately  
22 responded to all the concerns that they had

0094

1 raised, insofar as you understood those concerns?

2 A Well, I felt the data here, in my view,  
3 would have been adequate to respond to them.

4 Q If you turn to Page 30754, you have a  
5 section captioned "Raines Study." Do you know if  
6 this is a discussion of the Raines Study which  
7 Dr. McClellan found disturbing in some way or  
8 having disturbing trends in it, or is this a  
9 different Raines Study?

10 A I was trying to remember -- I couldn't  
11 remember whether she had one or two studies that

12 we looked at. I believe this was the study, yes,  
13 that he had concerns about.

14 Q And you wrote a fairly -- well, a  
15 summary with these two tables in it of that study.  
16 You concluded that, at the bottom of 30754, that  
17 "the behavioral data comparing the adolescents in  
18 the Advanced Provision Group compared to the  
19 Pharmacy Access Group revealed no differences in  
20 frequency of sex per month, number of sex  
21 partners, or failure to use a contraceptive  
22 method, as listed in Table 11."

0095

1 In Table 11 you're comparing advanced  
2 provision to pharmacy access; is that what the  
3 comparison is?

4 A Correct.

5 Q And there were no differences for  
6 those -- no statistical significant differences  
7 for those two groups?

8 A Correct.

9 Q And in Table 10 above that, you're  
10 comparing 15- to 17-year-olds to 18- to  
11 21-year-olds; is that right?

12 A Correct.

13 Q Was there -- were there statistical  
14 differences there between those two groups?

15 A I actually don't know that we ran  
16 statistical analysis. This was more of a, just a  
17 comparison to get some sense of where the numbers  
18 were.

19 Q So right above that table you have the  
20 sentence, "That study in the 15- to 17-year-old  
21 compared to the 18- to 20-year-old had no  
22 significant differences in emergency contraception

0096

1 use on study, emergency contraception use a second  
2 time, unprotected sex, or STDs as seen in Table  
3 10." Does that reflect a statistically  
4 significant result; do you know?

5 A Well, I probably would have said  
6 "statistically" in that thing if it was.

7 Q Did you find disturbing trends in the  
8 Raines Study, as you recall?

9 A Not that I recall. There was one  
10 study -- I can't remember if it was -- I think it  
11 was the Raines Study where there was decreased use  
12 of condoms, but there was a corresponding  
13 increased use of oral contraceptives, and so it

14 kind of depends on how you look at unprotected  
15 intercourse. Now, the way most people define  
16 "unprotected intercourse" is to say you are not  
17 using a contraceptive, and so if that's the way  
18 you look at it, then their unprotected intercourse  
19 really didn't change.

20 Now, if you're specifically concerned  
21 about condom use, the condom use went down, but I  
22 think that's kind of a dicey way of looking at

0097

1 things, because if someone is in a relationship  
2 where they really do not need to be using a  
3 condom, they're in a stable relationship, that  
4 sort of thing, it really shouldn't matter if  
5 they're not using condoms, if you're really  
6 concerned about what their overall contraceptive  
7 use is. Does that clear it up?

8 Q Yes.

9 If you would turn to the next -- or I  
10 guess the next page, 30755, I just want to ask you  
11 a couple of questions.

12 The paragraph right below Table 11,  
13 you're describing pregnancy rates, and about the  
14 third or fourth sentence down you say, "This  
15 demonstrates the great need for this product in  
16 high-risk youths and also demonstrates that  
17 adolescents are poor contraceptors. Without the  
18 availability of EC in this group, an even greater  
19 number of pregnancies would be expected."

20 Does that -- to say that an even greater  
21 number of pregnancy would be expected, does that  
22 mean that, that it appears that emergency

0098

1 contraception prevented some pregnancies in those  
2 adolescents?

3 A No.

4 Q What does that mean?

5 A It means that if they would not have  
6 had -- they're poor contraceptors, so if they  
7 would not have had availability of EC, you might  
8 expect to see even a greater number of  
9 pregnancies, because they're poor contraceptors.

10 Q They're not using contraception well,  
11 regular contraception well?

12 A Correct.

13 Q And then you say, "Sexually transmitted  
14 disease rates were similar, regardless of age,"  
15 and that the contraceptive behaviors of

16 adolescents were similar to older age groups. Is  
17 that all -- was all that true?

18 A Yes.

19 Q Okay. If you'd turn to Page 30757, two  
20 more pages.?

21 MR. WARSHAWSKY: What page?  
22

0099

1 BY MR. HELLER:

2 Q 30757, under "Conclusions," the second  
3 paragraph under that heading, at the very end you  
4 have the sentence, "If this is not enough data  
5 upon which to base a decision, it is unclear what  
6 would constitute enough data or even if that is an  
7 obtainable goal."

8 Can you explain what that means? Is  
9 that just saying that, that there is an  
10 unsurmountable obstacle to satisfying the need for  
11 additional data?

12 MR. WARSHAWSKY: Objection;  
13 argumentative. You're testifying now. Just ask  
14 him what it means.

15 MR. AMANAT: Let him read the document.

16 BY MR. HELLER:

17 Q You can answer my question.

18 A Um, well, I mean it sort of means what  
19 it says, that we had, we had what I felt was a lot  
20 of data, and the data seemed to all not cause any  
21 concerns that were being voiced to upper  
22 management, and it was unclear to me, if this was

0100

1 not enough, how much that they did need to feel  
2 reassured, and since I wasn't sure how much they  
3 needed, I wasn't sure if it really was an  
4 obtainable goal.

5 Q Have you ever experienced that situation  
6 before, where there were concerns expressed by  
7 anyone in the Agency, scientific concerns, where  
8 you felt you didn't know if you could obtain the  
9 data required to allay those concerns?

10 A Oh, yeah.

11 Q Can you give me an example.

12 A Well, it's proprietary.

13 Q Well, you don't need to say the name of  
14 any drugs. Just describe in general terms.

15 A There are a lot of drugs that come for  
16 OTC switching, and, you know, they are drugs that  
17 we traditionally have had health care advisors

18 use, and they want to explore the option of having  
19 a new indication that's OTC that's never been out  
20 there before. And to try to keep this general,  
21 some of the drugs even require blood monitoring to  
22 see if they are being effective.

0101

1 So the sponsor will come in and say we  
2 want to see about moving this to OTC, and you  
3 start saying, well, I'm not clear that people will  
4 actually monitor their drug -- their blood level  
5 like they're supposed to, because it makes them go  
6 to the physician, but yet they can get the drug  
7 whether they're at the physician or not. So  
8 you're going to have to generate data that I feel  
9 comfortable with, that they're getting their blood  
10 monitored on a regular basis even though they can  
11 get the drug without having to do that. So I'm  
12 not sure how much data they'd have to generate.  
13 There are cases where people come in and you go I  
14 just don't know that you can satisfy my concern  
15 here.

16 Q Because such data sort of can't be  
17 gathered?

18 A Well, it might take a huge trial or it  
19 might be hard to design a trial to show that it's  
20 going to happen. I mean it certainly happens.

21 Q As I understood your last answer, that  
22 seems to be a little bit different, because here

0102

1 it seems like the reason you couldn't obtain the  
2 data you need is because you don't even know --  
3 you don't know how much data would suffice,  
4 yourself. I mean in the situation you described,  
5 I think you know what kind of data you'd want, but  
6 here it seems to me you're saying you don't even  
7 know what data you'd need to gather that would  
8 satisfy the concerns; is that right?

9 MR. WARSHAWSKY: I'm going to object.

10 THE WITNESS: Well, again I think that  
11 the first question, if I understood your first  
12 question correctly, was is there ever a time a  
13 sponsor comes where you tell them I just don't  
14 know that you can collect enough data to make us  
15 happy, and yes, there are times like that. This  
16 situation again got back more to trying to prove a  
17 negative, and so we had a lot of data out there  
18 that said that there really didn't seem to be the  
19 concerns that they were expressing, and if that

20 wasn't enough data, I didn't know how much data  
21 they needed or how they wanted it obtained.

22 MR. HELLER: Thank you. I think we're  
0103

1 going to need a break to make sure the tapes are  
2 changed, or a longer break.

3 MR. WARSHAWSKY: Why don't we take a  
4 ten-minute break.

5 THE VIDEOGRAPHER: This marks the end of  
6 Tape Number 1 in the deposition of Curtis  
7 Rosebraugh, M.D. We are going off the record.  
8 The time is 11:56 a.m.

9 (Whereupon, a short recess was taken.)

10 THE VIDEOGRAPHER: We're back on the  
11 record. Here marks the beginning of Tape Number 2  
12 in the deposition of Curtis Rosebraugh, M.D. The  
13 time now is 12:12 p.m. You may continue.

14 MR. HELLER: Thank you.

15 BY MR. HELLER:

16 Q Dr. Rosebraugh, we were looking at I  
17 think Page 30757, that page of the document you  
18 have in front of you. At the bottom of that page  
19 you, you have a paragraph starting as follows: "A  
20 decision by the Agency to withhold OTC marketing  
21 of Plan B for reasons of theoretical abuse by a  
22 very small segment of the population, despite the

0104

1 great benefit that could be derived from easier  
2 access, could have ramifications for how we  
3 regulate other OTC drugs."

4 Was that your opinion at the time you  
5 wrote it?

6 A Yes.

7 Q Is it still your opinion?

8 A Yes.

9 Q Was it -- is it your view that the  
10 Agency has withheld OTC marketing of Plan B for  
11 reasons of theoretical abuse by a very small  
12 segment of the population?

13 A Well, I think that that was a partial  
14 reason. I think that what has been stated by  
15 upper management is that they still don't feel  
16 there is sufficient data for adolescents, and then  
17 part of the reasoning for wanting more data is to  
18 make sure that there won't be abuse or misuse of  
19 the product.

20 Q But is it your --

21 A I mean you'd have to ask them, but my

22 understanding from what I've gleaned is that is  
0105

1 what the reasoning was.

2 Q And do you also believe that there would  
3 be great benefits derived from easier access to  
4 Plan B?

5 A Yes.

6 Q And then you go on to say, "To ensure  
7 consistency of regulation and natural progression  
8 of this line of regulatory reasoning would require  
9 that the Agency remove OTC marketing status for  
10 many drugs with known abuses, including  
11 Dextromethorphan, and because of reports of  
12 adolescent abuse; laxatives because of abuse by  
13 people suffering from bulimia; analgesics because  
14 of abuse with subsequent health ramifications; or  
15 Acetaminophen because of its use in suicides."  
16 Aren't you just comparing apples and oranges  
17 there?

18 A Well, I think you have to look at these  
19 from a regulatory perspective, and so if part of  
20 your reasoning for not allowing something on --  
21 there's actually two points to be considered. If  
22 part of your reasoning for not allowing something

0106

1 onto the market is because there is a theoretical  
2 concern that it may be abused, you are never  
3 allowing it on the market to see if it is going to  
4 be abused. That's the first concern, so you're  
5 kind of in a Catch 22 with that sort of reasoning.

6 The second is that we do have drugs out  
7 there that we know are being abused, so if your  
8 reasoning for not allowing this out on the market  
9 is because it may be abused or misused by a  
10 segment of the population, well, we have drugs out  
11 there that we know are abused or misused. And so  
12 if you're holding this off the market, what is  
13 your regulatory reason for not removing these?

14 Q Do you know if the Agency has used its  
15 reason for withholding OTC status for Plan B as a  
16 precedent for other OTC switches in any way?

17 A I'm not sure what you're asking me.

18 Q I'll withdraw the question.

19 If, um, if you would turn to Page 30759,  
20 the last page of the text of this document, the  
21 first sentence says, "There is compelling data  
22 evidencing that Plan B fulfills regulatory

0107

1 requirements for OTC marketing."

2 Is there a difference between saying  
3 that there is sufficient data to meet the  
4 regulatory requirements and compelling data? Did  
5 you choose the word "compelling" because you felt  
6 it was especially strong in this case?

7 A Well, I, I don't know that I would have  
8 wordsmithed it that much.

9 Q Okay. Before we took the break, we were  
10 talking about instances where you could or could  
11 not obtain data to satisfy concerns, and I think  
12 you were talking about how, in the case of Plan B,  
13 the issue was data that would prove a negative; is  
14 that right? I don't want to mischaracterize what  
15 you said before we took the break.

16 A Well, it's how much, how much data do  
17 you need to obtain before you feel comfortable  
18 that this is not going to happen.

19 Q In the past, have there been OTC  
20 switches where you've been asked to -- or you've  
21 decided that there was insufficient data to prove  
22 that something would not happen, as you were with

0108

1 Plan B?

2 MR. WARSHAWSKY: I'm going to object to  
3 that question. It's unclear.

4 THE WITNESS: Um, that's kind of a  
5 tricky question. Nothing comes to mind, if I'm  
6 understanding the question correctly.

7 BY MR. HELLER:

8 Q Okay. I think we are done with this  
9 document, but sort of along the lines of this,  
10 what I want to show you is a document I guess I  
11 saw yesterday for the first time, and this is, I  
12 believe, a copy of an e-mail that you were cc'd on  
13 from Andrea Leonard-Siegle to Jin Chen, and take a  
14 moment, if you want, to look this over.

15 Do you have any memory of this e-mail?

16 A No.

17 Q Do you have any idea why the Prilosec  
18 Actual Use Study would be relevant to Plan B or  
19 someone might consider it relevant to Plan B?

20 A No.

21 Q Do you know what -- in the subject line  
22 it says there in parenthesis, "For reference of

0109

1 Plan B AC." Does "AC" mean Advisory Committee, do  
2 you think?

3 A Probably.

4 Q So would this -- is it possible -- I  
5 mean when I look at this, what I think is someone  
6 wanted this for comparison to Plan B in some way.

7 A Well, it could be -- you know, when we,  
8 when we get ready for ACs, we always try to  
9 anticipate questions that will come up, and  
10 usually half of the committee is not from the OTC  
11 realm, so they may or may not have seen Actual Use  
12 and Label Comp studies, and so I think to kind of  
13 go along with your supposition, it wouldn't be out  
14 of the realm of anticipating that somebody may  
15 say, well, how does this kind of compliance  
16 compare to other drugs that you've seen in the  
17 past.

18 Q And just for the record, this is marked  
19 Tummino 4522 at the bottom, is that right, what  
20 I've handed you?

21 A Yeah.

22 Q Okay. Thank you. That's all I have to

0110

1 ask about that.

2 So another e-mail I got a copy of  
3 yesterday I want to show you, and this one appears  
4 to be from Jane Axelrad to you, and it seems to  
5 have below there a note to Jane from you. If you  
6 wouldn't mind reading this over and telling me if  
7 you remember anything about this, this e-mail.

8 A Yeah, well, like I said, when this  
9 Application first came in, upper management wanted  
10 the sponsor to have some sort of restricted  
11 distribution program, and so they discussed  
12 wanting to have behind-the-counter as something  
13 that maybe we would be bringing up at the Advisory  
14 Committee meeting, and, you know, my position was,  
15 at least at that point in time, the Agency had  
16 always felt or had always expressed that we did  
17 not have regulatory authority to require  
18 behind-the-counter, and so my concern was: Why  
19 would we discuss this if this is not something  
20 that we can do? Why would we lead the sponsor in  
21 that direction?

22 And so Jane Axelrad's group, she had

0111

1 farmed out the question to this person that's  
2 listed at the top to discuss whether we could do  
3 behind-the-counter or not, and so we were waiting  
4 on that memo so that we would know whether this

5 was something we could discuss at the Advisory  
6 Committee meeting or not.

7 Q Do you know, did you ever -- did you  
8 ever see a memo back from Ms. Axelrad's Office  
9 about the -- that related to the questions you had  
10 asked?

11 A Yes.

12 Q And what did she conclude?

13 A Well, I'm not a lawyer, and it had lots  
14 of lawyer stuff in it.

15 Q Well, sir, what was the bottom line?

16 A Well, the bottom line was that, from my  
17 non-lawyer brain, was yeah, maybe, maybe not.

18 Q So this is Tummino 3232 at the bottom.  
19 Would you turn over to the opposite page, the  
20 other side, which is marked Tummino 3233, and this  
21 seems to be an e-mail from Daniel Davis to you and  
22 Donna Griebel, and it's talking about "two large

0112

1 ongoing USA behavioral studies." Do you remember  
2 anything about -- do you recall this interchange  
3 or this, receiving this e-mail?

4 A I, I don't recall the specific e-mail,  
5 but I'm sure we were exploring behavioral studies,  
6 so . . .

7 Q Do you know if you ever -- I mean this  
8 e-mail says, "We will not have the results of  
9 these large studies until 2005 or later." Do you  
10 know -- did you ever see the results of these two  
11 studies, as far as you know?

12 A Not that I know of.

13 Q Okay, thank you.

14 All right. Do you recall when in May --  
15 that in May 2004 Dr. Galson issued a  
16 Non-Approvable Letter for the OTC Plan B switch?

17 A Do I recall --

18 Q That he did that in May of 2004.

19 A I recall that he did. I can't remember,  
20 but I guess it is May, yeah.

21 Q Did he ever have discussions with you  
22 about his intended Action on the OTC Switch

0113

1 Application?

2 A Do you mean me personally, or did he  
3 discuss it with a group or --

4 Q I mean you personally, sort of where you  
5 were having a conversation with him.

6 A Oh, no.

7 Q Did Dr. Jenkins ever have conversations  
8 with you about the Plan B OTC switch process?

9 A Yes.

10 Q Was that frequent conversations, because  
11 you work in the same -- you work in his office, or  
12 is it two or three particular conversations that  
13 you remember? In other words, can you recall  
14 specific conversations you had with Dr. Jenkins,  
15 or are there so many that you can't recall  
16 specific ones?

17 MR. WARSHAWSKY: I'm going to object to  
18 the form of that question.

19 MR. HELLER: All right. That's a good  
20 objection. Thank you.

21 BY MR. HELLER:

22 Q Do you recall any of the specific

0114

1 conversations you had with Dr. Jenkins?

2 A Well, I mean I recall some of them. I  
3 don't know that -- you know, we had group meetings  
4 with Dr. Jenkins where we would have  
5 conversations. I can't remember if there was ever  
6 just a one-on-one where he and I discussed things.  
7 I mean there may have been. We had quite a few  
8 conversations on it.

9 Q Do you -- I'll withdraw that question or  
10 the start of that question.

11 I'm going to show you another document  
12 which is, which is marked Tummino 31026 through  
13 31030, and ask you if it looks familiar to you, to  
14 start with.

15 A Looks like something I wrote.

16 Q Okay. Well, I have some questions about  
17 this, and this, this memo was written after the  
18 Non-Approvable Letter in 2004 and after the  
19 manufacturer submitted an Application for dual  
20 status marketing. Is that basically right?

21 A Um, I'd have to -- let me --

22 Q Sure. Please.

0115

1 A In regard to your question, I believe  
2 that is correct.

3 Q And your summary conclusion on the third  
4 page of this document is that even though or  
5 despite the manufacturer having filed an  
6 Application that included an age restriction, that  
7 it's not appropriate but should be approved over  
8 the counter for -- without an age restriction,

9 basically; is that right?

10 A Correct.

11 Q Have you ever had that situation arise  
12 before where a manufacturer was asking for  
13 approval with some restriction and you recommended  
14 approval without the restriction that the  
15 manufacturer was requesting, that you can think  
16 of?

17 A Yes.

18 Q On Page 31027, which is the second page  
19 of the document, like the sixth line from the  
20 bottom, you have the sentence --

21 A Let me back up on your last question.

22 Q Sure.

0116

1 A I have in the past, when a  
2 manufacturer -- I'm thinking of a particular  
3 episode where a manufacturer came in and had a  
4 restriction in their labeling, and I didn't  
5 recommend that they take it out. I said, "I don't  
6 see the need for this. You need to justify why  
7 you have it in there." And they took it out.

8 Q Okay. I was going to Page 2, the  
9 sentence starting, "finally," sort of towards the  
10 bottom of the page, the paragraph starting  
11 "finally." "Finally, it is unclear what  
12 additional data could be provided on adolescent  
13 use that would be sufficient to lift the age  
14 restriction in the future."

15 Is this similar to your statement you  
16 made in your earlier memo that you didn't -- if  
17 you could just explain what you mean there.

18 A It's the same as the earlier memo. It  
19 was just never -- it had never been explained to  
20 me what the manufacturer, the sponsor needed to  
21 do.

22 Q Do you know whether, in the review of

0117

1 the manufacturer's Application for dual marketing,  
2 whether someone within the Office of New Drugs was  
3 asked to draft Approval Letters at some point for  
4 that dual status Application?

5 A I'm not aware of that.

6 Q Do you know whether Dr. Galson was  
7 planning in January of 2005 to approve the dual  
8 status Application?

9 A Well, I mean I don't remember the date,  
10 but there is -- he's made statements that he was

11 planning on approving.

12 Q Do you know roughly when he made  
13 those --

14 A No.

15 Q I mean was it early in 2005 or later?

16 A I really don't know.

17 Q And he made those statements orally in  
18 meetings or --

19 A Well, no, I think I read those  
20 statements someplace.

21 Q Okay. By the way, for today's  
22 deposition did you read the depositions of any

0118

1 other people that were taken in this case?

2 A Yes.

3 Q Do you remember which ones you read?

4 A I read Woodcock's, Galson's and the  
5 former Commissioner.

6 Q McClellan or Crawford?

7 A Crawford.

8 Q Was there anything in there that  
9 surprised you that you read? Were there any  
10 surprises in those documents for you that you  
11 recall?

12 A Well, nothing immediately comes to mind.  
13 I mean I didn't . . .

14 Q Okay. Next document -- I think we're  
15 done with that one -- I want to ask about is --  
16 it's really short --

17 A All right.

18 Q -- and it is marked Tummino 31181 to  
19 31182. It's a two-sided page, which is an  
20 Addendum I believe written by you to your -- the  
21 memo we were just looking at before, and I have a  
22 couple of questions about this. Please take a

0119

1 moment to read it over. It's fairly short, but  
2 let me know when you're ready.

3 A Okay.

4 Q There seems to be a sentence missing in  
5 the middle of this page, sort of a white space.

6 A Well, it has an odd format.

7 Q Do you know if something was taken out  
8 of this document?

9 A I don't -- I couldn't tell you. I don't  
10 recall this off the top of my mind.

11 Q Okay. And then the other question I  
12 have about this is at the end you sort of

13 reiterate "I do not agree with an age restriction  
14 but have given advice on labeling, as this is the  
15 course of action that Central Management has  
16 indicated it is taking." It seems to me that you  
17 are quite persistent in your view that the OTC  
18 Switch Application should be approved without an  
19 Application, and I'm wondering whether anyone  
20 above you ever commented to you in any way sort of  
21 that -- sort of enough is enough, you know where  
22 this is going. There's no reason to continue to

0120

1 reiterate your view that it should be approved  
2 without age restriction. Did anyone ever say  
3 anything like that to you?

4 A No, and I think that putting this in a  
5 memo, in a way, is just to say, look, we're  
6 helping with the labeling, but that should not be  
7 construed that we agree that it should be dual  
8 packaged. We're just trying to help with the  
9 labeling.

10 Q I understand. Okay. Thank you.

11 At what point did you stop being  
12 involved in the Plan B OTC switch process,  
13 roughly, if you can say? This last document I  
14 just showed you was dated February 7th of 2005.  
15 Did you have involvement after that in the  
16 process?

17 A I really don't remember much  
18 involvement.

19 Q Do you remember in August of 2005 when  
20 Dr. Crawford issued a letter announcing proposed  
21 rule-making or Advanced Notice of Proposed  
22 Rule-Making rather than approval or non-approval

0121

1 of the Plan B OTC switch?

2 A I remember he did that.

3 Q Were you surprised by that at all?

4 A Um, yeah.

5 Q Why did it surprise you?

6 A Well, I wasn't clear -- I mean it  
7 wasn't, I wasn't involved in it in any way as more  
8 than just an interested spectator, but it wasn't  
9 clear why he had initiated the rule-making. I  
10 didn't know what he hoped to achieve from it.

11 Q Looking back on the period during which  
12 you were involved in the Plan B OTC switch  
13 process, was there anything unusual about that  
14 process taken as a whole?

15           A     Well, the -- you know, it's -- I think  
16 it's unusual that upper management was as involved  
17 as early as they were involved. There did seem to  
18 be -- prior to even having reviews, you know, done  
19 or anything like that, there did seem to be a lot  
20 of direction to the sponsor saying that we want  
21 restricted distribution, as evidenced by calling  
22 them in August and saying, you know, you need to

0122

1     have some sort of management plan, and, you know,  
2 we really hadn't had the data -- at least I can't  
3 recall that we had the data at that point to see  
4 if there was a reason for that or not.

5           And then going into the Advisory  
6 Committee meeting, there was a lot going into that  
7 process where we were trying to design the  
8 Advisory Committee, and they wanted to have a  
9 question regarding behind-the-counter when it  
10 wasn't clear that we had that authority. That's  
11 kind of unusual. In fact, in most Advisory  
12 Committees we would say we do not have this  
13 authority. It either stands on its merit or not.  
14 Don't even weigh that into your consideration that  
15 there may be a fall-back position.

16           Now, in the end we ended up not having  
17 that at the AC, and the main reason we didn't have  
18 it is because the Chair of the Committee said if  
19 you guys can't tell me that you have the authority  
20 to do this, we shouldn't be asking it. So those  
21 were all kind of unusual things, and then in  
22 January when we -- at least my recollection of

0123

1     being told what the Action was, that was really  
2 before any of the reviews were done, and it's kind  
3 of unusual to say this is the Action before you  
4 have reviews to review.

5           Q     On that point, have you ever seen an  
6 Action -- have you ever had the experience of an  
7 Action sort of being announced before the reviews  
8 were done?

9           A     No.

10          Q     So please continue if there's more  
11 beyond that point. You were up to, I think,  
12 January of 2004.

13          A     Um, I guess that's probably about it.

14          Q     Do you know why the process was unusual?  
15 Do you know what caused it to be unusual?

16          A     No.

17 Q Have you heard anybody say anything  
18 about that, anyone at -- or anyone at all saying  
19 here's why I think the process was unusual?

20 A Well, I think people have opinions, but,  
21 you know, I personally don't. I have never heard,  
22 you know, someone that has been involved in upper

0124

1 level management discussions tell me why they  
2 thought things went the way they went.

3 Q Tell me some of the opinions you've  
4 heard, I guess, from people who are not in upper  
5 level management.?

6 MR. WARSHAWSKY: Objection.

7 THE WITNESS: So you want like gossip?

8 BY MR. HELLER:

9 Q Yes.

10 A Am I supposed to tell gossip?

11 MR. WARSHAWSKY: As long as you make it  
12 clear that it's gossip.

13 THE WITNESS: Well, and I think it needs  
14 to be clear that this is not anything that I  
15 necessarily endorse.

16 BY MR. HELLER:

17 Q Oh, I understand that. I'm just asking  
18 you to repeat what you've heard, so to speak.

19 A And you need to know that this is very  
20 speculative. That's just what people have said;  
21 well, you know, I feel that this probably has  
22 something to do with having a very conservative

0125

1 administration in place at the moment and that  
2 they're going to be conservative in their views of  
3 doing things. I mean that's sort of --

4 Q The gist of it?

5 A Yeah.

6 Q And this is gossip that was -- that you  
7 heard within FDA or outside FDA or both?

8 A It was within.

9 Q Within FDA. Within a certain department  
10 of the, or unit of the FDA or across the board?

11 A I think it was mainly just people  
12 involved with this Application.

13 Q So that people involved with this  
14 Application, some of them, expressed the view that  
15 you described?

16 A Yes.

17 Q Roughly how many people expressed that  
18 view?

19 A I, I, I don't know.

20 Q Was it a fairly common thing, the number  
21 of people expressed, or is it sort of one  
22 person --

0126

1 A It was fairly common.

2 Q Fairly common. Um, around the time of  
3 August Action by Dr. Crawford, the Advanced Notice  
4 of Proposed Rule-Making, did anyone within the  
5 Agency tell you anything about the reaction to  
6 that, to that announcement, like, "oh, this is  
7 great" or "this is terrible," anything like that?  
8 Did anyone --

9 MR. AMANAT: Which announcement?

10 MR. HELLER: That announcement of  
11 Proposed Rule-Making in August of 2005.

12 MR. WARSHAWSKY: I'm going to object to  
13 that question. You're asking him for -- to  
14 recount people's reactions?

15 MR. HELLER: Yes.

16 MR. WARSHAWSKY: Okay.

17 THE WITNESS: Well, I mean, you know,  
18 people discussed it, and I think people that had  
19 been involved in rule-making felt that it would  
20 probably take a while to get a result. It takes a  
21 while to get rule-making done, and I think a lot  
22 of people were surprised that there was a

0127

1 rule-making associated with it.

2 BY MR. HELLER:

3 Q That there was a rule-making associated  
4 with it?

5 A Yes.

6 Q In your professional scientific opinion,  
7 should the Plan B OTC switch have been approved in  
8 May of 2004?

9 A Well, I think I've stated that several  
10 times and have written it, yes.

11 Q And should it have been approved in  
12 January 2005 when you completed your second  
13 review?

14 A Yes.

15 Q Should it have been approved in August  
16 of 2005 without age restriction?

17 A Well, I've sort of lost track of where I  
18 kind of didn't have as much involvement, but, you  
19 know, every time there's a delay in something  
20 being approved, I think it warrants re-reviewing

21 safety data and that sort of stuff, so I'm kind of  
22 lost as to where I was at in that process, but the  
0128

1 most recent one I think that, you know, that you  
2 do need to re-review the safety data and that sort  
3 of thing, but if it hasn't changed and no new  
4 concern has appeared, yes.

5 MR. HELLER: Can we go off the record  
6 for a couple of minutes. I'm almost done.

7 THE VIDEOGRAPHER: We are off the  
8 record. It's 12:48 p.m.

9 (Whereupon, a short recess was taken.)

10 THE VIDEOGRAPHER: Back on the record.  
11 The time is now 12:50 p.m.

12 MR. HELLER: Dr. Rosebraugh, thank you.  
13 I have no further questions at this time.

14 MR. WARSHAWSKY: Then at this time we'll  
15 be taking a break for lunch, and then do you want  
16 to shoot for say 45 minutes?

17 MR. HELLER: It's up to you.

18 MR. WARSHAWSKY: Is that going to be  
19 enough time?

20 MR. HELLER: Shall we say 1:45?

21 MR. WARSHAWSKY: Why don't we say 1:45,  
22 and we'll resume and then we will have some

0129  
1 questions for you.

2 MR. HELLER: Thank you.

3 THE VIDEOGRAPHER: Going off the record.  
4 The time is now 12:51 p.m.

5 (Whereupon, the lunch recess was taken.)

6 THE VIDEOGRAPHER: Back on the record,  
7 the time is now 1:49 p.m.

8 CROSS-EXAMINATION

9 BY MR. WARSHAWSKY:

10 Q Good afternoon, Dr. Rosebraugh. I'll be  
11 asking you some questions now, covering much of  
12 the same material that we've discussed this  
13 morning, but hopefully with a slightly different  
14 angle. I'll try not to repeat things that have  
15 already been asked and answered. Let me ask you  
16 or let me just confirm for the record that you  
17 participated in the Advisory Committee meeting  
18 that took place in December of 2003 for Plan B?

19 A Yes.

20 Q And am I correct that you gave an  
21 introductory, uh, gave an introduction to that  
22 meeting?

0130

1 A Yes.

2 Q If you'd please take a look now at the  
3 first document that I'm showing you. Let me  
4 describe it for the record while you're looking at  
5 it. This is a four-page document. It's an  
6 excerpt from the transcript of the Advisory  
7 Committee meeting hearing dated December 16, 2003.  
8 It's a public FDA document with the web address at  
9 the bottom, and it's also been Bates stamped in  
10 this case as Tummino 10544 through Tummino 10547.  
11 And I believe this excerpt is the introduction  
12 given by Dr. Rosebraugh at that Advisory Committee  
13 meeting.

14 Have you had -- have you ever seen this  
15 document before?

16 A I think I have, yeah.

17 Q Let me -- I'd like to go through with  
18 you your introductory comments, and for purposes  
19 of context, why don't we just -- I will just start  
20 to read them out loud, and at various points in  
21 time we'll stop, and then I'll ask you some  
22 questions. Is that okay?

0131

1 All right. Let's begin. The transcript  
2 begins in the middle of Page Tummino 10544.  
3 Dr. Rosebraugh, quote: "Good morning. On behalf  
4 of the divisions of Over-the-counter Drug Products  
5 and Reproductive and Urologic Drug Products, I'd  
6 like to welcome the members of each respective  
7 Advisory Committee to today's meeting regarding  
8 the non-prescription status of Plan B. By way of  
9 introduction, I would like to briefly go over the  
10 regulatory history of Plan B, go over the  
11 regulatory requirements for non-prescription  
12 marketing of drug products, and outline today's  
13 agenda.

14 Plan B was approved for prescription use  
15 on July 28, 1999, for the indication as an  
16 emergency contraception to be used to prevent  
17 pregnancy following unprotected intercourse or a  
18 known or suspected contraceptive failure.  
19 Prescription directions for use indicate that to  
20 obtain optimal efficacy, the first dose" -- it  
21 says "does" in the transcript, but I believe that  
22 should read "dose" -- "needs to be taken as soon

0132

1 as possible within 72 hours of intercourse, and

2 the second dose needs to be taken 12 hours later.

3 "Women's Capital corporation, the  
4 applicant for the original prescription NDA,  
5 submitted an Application for Plan B switch from  
6 prescription to non-prescription status in April  
7 of 2003. As the efficacy of Plan B, when used as  
8 per directed, has already been established and the  
9 sponsor is not seeking a new indication of dosage  
10 regimen, this will not be a topic at today's  
11 meeting. However, the efficacy based on a use in  
12 a non-prescription setting is of interest to us."

13 So let me see if I understand the  
14 distinction that you raise here in the last two  
15 sentences that I just read. As I understand those  
16 two sentences, they state or they mean that the  
17 issue of the drug's safety and efficacy, when used  
18 as directed, was already established when the drug  
19 was approved for Rx status, and so the issue in  
20 the OTC Switch Application stage is whether and to  
21 what extent the intended population of Plan B  
22 users will be able to use the drug properly

0133

1 without the assistance of a learned intermediary.

2 MR. HELLER: Objection. The document  
3 says nothing of the kind, and it speaks for  
4 itself.

5 BY MR. WARSHAWSKY:

6 Q And my question is: Did I interpret --  
7 did I interpret those two sentences of your  
8 document -- of this document correctly?

9 A Well, you had a long interpretation, so  
10 let me tell you what I meant here. Again the  
11 efficacy had been shown in trials that allowed it  
12 to be approved for prescription status, and so I  
13 think that what the next sentence says is in  
14 essence how would it be used in actual use.

15 Q And is it fair to say that that question  
16 is primarily a question of behavior as opposed to  
17 pharmacology?

18 A I think that's fair.

19 Q You went on to state, quote, "The  
20 purpose of today's Advisory Committee meeting is  
21 to determine whether Plan B meets regulatory  
22 requirements for non-prescription marketing."

0134

1 May I ask you just a few questions about  
2 that statement. Was the Advisory Committee and  
3 the members which -- who composed the Advisory

4 Committee qualified to make a determination  
5 whether Plan B meets regulatory requirements for  
6 non-prescription marketing?

7 A Well, they're qualified to listen to the  
8 data, and I think I go further to outline what the  
9 regulatory requirements are. They are qualified  
10 to see if they think it meets that.

11 Q And based on the -- well, you said  
12 they're qualified to listen to the data, so you're  
13 referring to the data presented to them at the  
14 Advisory Committee meeting?

15 A I mean it's really not unusual. Most of  
16 the AC meetings that we have, the question is  
17 always should this be marketed OTC or not, and so  
18 we have joint meetings, and we always ask them  
19 should this be marketed OTC. That's always the  
20 bottom line. And so they have to have the  
21 qualifications to be able to make recommendations  
22 to us.

0135

1 Q And from your perspective as a  
2 regulatory official within CDER, do you think that  
3 the Advisory Committee meeting recommendation is  
4 one which is sufficiently informed and thoughtful  
5 to warrant giving any weight to in the  
6 decision-making process?

7 A I, I think Advisory Committee  
8 meetings -- we have them for a purpose, and that  
9 is to get experts and to get their opinion, and,  
10 you know, in my own personal experience they have  
11 been very valuable.

12 Q So an expert sitting on the Advisory  
13 Committee meeting, for example, in this case for  
14 Plan B, provided -- strike that. What sort of  
15 documentary materials are provided to Advisory  
16 Committee members by CDER?

17 A Usually a background package.

18 Q And what goes into the background  
19 package?

20 A Usually it will have -- it might have  
21 some literature in it. It may have, um -- it kind  
22 of varies between Division to Division, but it

0136

1 usually has at least some form of a review or  
2 parts of a review. It may not have the total  
3 review. There might be information about foreign  
4 marketing. There might be information from the  
5 OSE folks.

6 Q The which folks?

7 A They used to be called ODS. They're OSE  
8 now, so they're the Office of Surveillance and  
9 Epidemiology, I believe, so it's the safety folks.

10 Q And do you know in particular what  
11 materials were provided to the members of the  
12 Advisory Committee meeting for Plan B?

13 A They had some form of the reviews from  
14 both the repro folks and the over-the-counter  
15 folks. They had a synopsis of the literature that  
16 was out there. I think it was particularly the  
17 five domestic studies, so they had kind of a  
18 synopsis review of that. I can't remember if we  
19 actually had the studies in the package or not. I  
20 know at least one of them or maybe two weren't  
21 published yet, so they may have not been in there.  
22 At least I can't remember.

0137

1 We would have had an agenda and probably  
2 some preliminary questions. Usually the questions  
3 go in there to help guide the committee members as  
4 they read through the package to have some sense  
5 of what they're looking for. We probably had some  
6 updates of safety from ODS at the time, although I  
7 can't remember if we had that for sure or not, but  
8 we probably did. I can't remember what else is in  
9 there.

10 Q So let me just clarify. So the primary  
11 reviews from the reproductive and OTC folks, are  
12 you referring to, for example, the Label  
13 Comprehension Study Review performed by Karen  
14 Lechter and some of those other -- and Dr. Chen's  
15 primary review of the Actual Use Study, those,  
16 those initial CDER documents?

17 A Yeah, they're usually initial. We very  
18 seldom -- at least my experience is we usually  
19 don't put the actual review, because in essence  
20 most of the time you're asking the committee a  
21 question. At least the way I like to approach  
22 these is to not say that, if it is something of

0138

1 that nature, there's other instances that are  
2 different, but it's not to say this is our  
3 position at the moment. I would rather just say  
4 this is the data, these are the questions we and  
5 you are faced with, what is your position on it.

6 Q And in your scientific and regulatory  
7 opinion, do you consider this was a sufficient

8 amount of information for the members of the  
9 Advisory Committee meeting to reach conclusions as  
10 to whether Plan B should or should not be approved  
11 for over-the-counter status?

12 A I think the thing you have to realize is  
13 that, first of all, what they are doing is -- it's  
14 a non-binding recommendation, and so based on the  
15 fact it's non-binding and based on the fact that a  
16 lot of the folks that sit on the committee have  
17 experience with this and understand the issues  
18 quite well, I think it's enough for them to give  
19 us advice on how they view it.

20 Q And how does CDER use that advice?

21 A Well, it weighs into the  
22 decision-making.

0139

1 Q And how much weight is given to the  
2 Advisory Committee meeting vote?

3 A I don't really know how to answer that.  
4 I mean we don't, we don't have a checklist where  
5 we give certain percentages to each thing. It's  
6 just, you know, you have to look over the overall  
7 amount of data that you have, and then you try to  
8 weigh in what people have brought up at committee  
9 meeting and any concerns they may have voiced.

10 Q So there's no statutory or regulatory or  
11 policy guidelines that prescribe how much weight  
12 to give to an Advisory Committee meeting vote?

13 A Not that I'm aware of.

14 Q Is it fair to say that different  
15 regulators within CDER would give the Advisory  
16 Committee meeting votes different weights in their  
17 own individual analysis of the issue?

18 A I've never actually asked people  
19 particularly how they do that, but my -- I would  
20 guess that it is fair to say that everybody may  
21 weigh it a little differently.

22 Q And the fact that different regulators

0140

1 may weigh the Advisory Committee meeting vote  
2 differently is not in itself unreasonable, is it?

3 MR. HELLER: Objection; vague. My  
4 objection is to the word "unreasonable" as being  
5 vague, but if he knows.

6 BY MR. WARSHAWSKY:

7 Q Do you think -- well, let me rephrase  
8 it. The fact that different regulators within  
9 CDER may give different weight to a Advisory

10 Committee meeting vote, does that in your -- does  
11 that violate or contravene any statutory or  
12 regulatory or policy guidelines or requirements  
13 with respect to making OTC switch decisions?

14 MR. HELLER: I'll just object, state my  
15 objection that it's asking him to make a  
16 conclusion of law, but he can make it if he wants  
17 to.

18 THE WITNESS: I couldn't hear what you  
19 said.

20 MR. HELLER: Asking for a conclusion of  
21 law.

22 THE WITNESS: Oh.

0141

1 MR. HELLER: A legal conclusion.

2 THE WITNESS: Well, again, just I think  
3 I've said this several times; I'm not a lawyer, so  
4 just based on --

5 BY MR. WARSHAWSKY:

6 Q Well, let me clarify. I'm actually not  
7 asking for a legal opinion. I'm asking for your  
8 scientific and regulatory opinions.

9 A From what I know of the regs, there is  
10 no reg that says this is used in a certain  
11 fashion. On the other hand, having said that, if  
12 you are going to go counter to what an Advisory  
13 Committee panel has voted and it's a fairly  
14 lopsided vote, I think that -- and I have had  
15 experience with this, where reviewers have wanted  
16 to go counter to an Advisory Committee vote. I  
17 have told them you need to articulate in your  
18 document why you are going counter to what's been  
19 recommended so that I have some sense of how  
20 you're thinking about this.

21 Q Do the Advisory Committee meeting  
22 members provide any kind of written analysis or

0142

1 explanation for their votes?

2 A Not typically. Now, I'm hedging on that  
3 a little bit, because there are some Advisory  
4 Committees where they will assign one person -- if  
5 there is literature, they will assign one person,  
6 and I think in particular cardio-renal does this a  
7 lot, where they will assign one person to review  
8 the literature and give a summary of it, and they  
9 may even have either an oral or written  
10 presentation saying this is what I thought of the  
11 literature that is presented.

12 Q But there is no requirement or  
13 expectation that Advisory Committee meeting  
14 members justify their particular votes in writing?

15 A Not in writing. There is actually not a  
16 requirement that they do it orally, but what I  
17 typically say to them is, you know, I -- I get  
18 quite a bit out of their comments, not just an up  
19 or down vote, so I really am very curious on how  
20 they voted the way that they did. It helps me to  
21 see how they were thinking about it. Particularly  
22 a lot of times somebody may say -- as in the case

0143

1 of Plan B, they may say yes, I think this can be  
2 approved, I have these concerns. So it helps me  
3 to see how they are weighing the concerns versus  
4 the benefit to get the final yes or no, but I want  
5 to know what their concerns are to see if it's  
6 something we need to address.

7 Q Let's move on in this document. You go  
8 on to explain those various regulatory  
9 requirements for non-prescription marketing as  
10 follows: "Regarding non-prescription requirements  
11 or requirements for non-prescription marketing,  
12 the Durham-Humphrey Amendment to the Federal Food,  
13 Drug and Cosmetic Act, which was enacted in 1951,  
14 formally differentiates between prescription and  
15 non-prescription drugs. This is articulated in  
16 the Code of Federal Regulations 21 CFR, Section  
17 310-200(b), and states, 'Any drug limited to  
18 prescription use under Section 503(b)(1)(c) of the  
19 Act shall be exempt from prescription-dispensing  
20 requirements when the Commissioner finds such  
21 requirements are not necessary for the protection  
22 of public health by reason of the drug's toxicity

0144

1 or other potentialities for harmful effects, the  
2 method of its use, or the collateral measures  
3 necessary to its use, and he finds that the drug  
4 is safe and effective for use in self-medication  
5 as directed in the proposed labeling.'"

6 Let me ask you just a few questions  
7 about this. Just to confirm what I think the  
8 regulation states, the ultimate authority within  
9 FDA for making OTC Switch Application decisions  
10 resides with the Commissioner; is that correct?

11 A Well, my -- I would agree with you in  
12 reading this, although if you talk with people, it  
13 sounds like the delegated authority comes down

14 from the HHS Secretary, so I'm not sure exactly  
15 where it resides, but the reg definitely says it's  
16 the Commissioner.

17 Q Right. The statute provides that the  
18 authority is in the HHS Secretary that's delegated  
19 to the Commissioner and the regs, and then that  
20 gets further delegated in the ordinary course to  
21 lower level officials; is that right?

22 A That's my understanding.

0145

1 Q And is it fair then to characterize --  
2 and in this case we'll focus on CDER or the CDER  
3 line within FDA. Is it fair to characterize the  
4 line of authority within FDA and CDER as  
5 hierarchal in nature?

6 A Yes.

7 Q And by that is it also fair to say that  
8 higher ranking officials within that lawful chain  
9 of command have the authority to overrule  
10 subordinate officials?

11 A Yes.

12 Q I'd like to ask you a few questions  
13 about the specific phrases or the specific  
14 factors, I should say, that are included in the  
15 regulation, but let me first ask you if it would  
16 be easier, in terms of doing that explanation, for  
17 me to move on and to read the next major paragraph  
18 where you elaborate a little bit on some of the  
19 more specific factors about misuse and abuse and  
20 reasonable therapeutic index of safety and so  
21 forth. Would it be best to do that all in the  
22 context of that second paragraph?

0146

1 A Well, I'm sort of at your mercy, but if  
2 that's how you want to approach it, that's fine.

3 Q Well, why don't we start with the first  
4 paragraph in the regulation then and just address  
5 a few of these things and see where it goes. The  
6 regulation refers to the drug's toxicity. What  
7 does that particular factor or consideration refer  
8 to?

9 A Well, it would be the toxic effects of  
10 the drug and sort of if they're monitor-able, if  
11 people can recognize them and know that the drug  
12 causes -- that they need to stop the drug or seek  
13 some sort of help or professional opinion.

14 Q From a layman's perspective, that  
15 would -- this would be referring to sort of the

16 biochemical interaction with the drug with the  
17 human body and how it affects you  
18 pharmacologically?

19 MR. HELLER: Objection. I don't think  
20 that's a layman's characterization.

21 Other than that, if you can answer,  
22 that's fine.

0147

1 THE WITNESS: Well, I guess it might be  
2 best to just use an example. So like if someone  
3 took a drug and developed a rash, can they  
4 recognize that the drug caused the rash, first of  
5 all? If a drug does cause the rash, how often  
6 does it cause it and how toxic is it? Is that  
7 something that should be under the care of the  
8 health provider, or can people take it on their  
9 own? Does that help?

10 BY MR. WARSHAWSKY:

11 Q Yes. Now, how is that distinguished  
12 from other potentialities for harmful effects?

13 A Well, in my mind, other potentialities  
14 for harmful effect -- and I think what I have said  
15 in the past and may have had on the slide and  
16 maybe is in this second paragraph, is that you  
17 have to -- and I'm hedging a little bit on this,  
18 because I've got conflicting data back from Chief  
19 Counsel's Office, but we usually do have some sort  
20 of consideration about misuse and abuse potential  
21 of the drug.

22 Q Okay. So that refers to the misuse and

0148

1 abuse factor that you describe in the next passage  
2 or so?

3 A Right. So I mean, you know, you may use  
4 the drug appropriately and have a bad side effect  
5 and have a toxicity of the drug with appropriate  
6 use, but, on the other hand, you may have misuse  
7 or abuse and have a toxic effect, because they're  
8 not following the label directions, so you need to  
9 kind of think about is there a lot of potential  
10 for that to happen and how does that weave into  
11 the benefit of the drug.

12 Q How about the method of its use; what is  
13 that taking into consideration?

14 A It usually means how is it used. As an  
15 example, if it's in IV form, it's probably not  
16 real great for OTC use.

17 Q And how would that be distinguished from

18 collateral measures necessary to its use?

19 A It's kind of the same thing.

20 Q Now, with respect to -- well, and how  
21 would those four factors be differentiated from  
22 the last sentence of the regulation, that the drug

0149

1 is safe and effective for use in self-medication,  
2 as directed in the proposed labeling?

3 A I'm not sure I know what you're asking  
4 me.

5 Q In looking at the regulation, it lists  
6 several factors which we've just discussed, and it  
7 concludes with the last sentence, "And he finds  
8 that the drug is safe and effective for use in  
9 self-medication as directed in the proposed  
10 labeling," and my question is: Is that last  
11 sentence an additional factor, or is that a  
12 conclusion that sums up the other factors?

13 A I don't know. I think that kind of is  
14 an overall summary.

15 Q Now, within the context of the OTC  
16 Switch Application for Plan B, of the four factors  
17 listed in this regulation -- and I'm referring  
18 specifically to the drug's toxicity as the first  
19 factor, other potentialities for harmful effects  
20 as the second factor, method of its use is the  
21 third factor, and the collateral measures  
22 necessary to its use as the fourth factor. Of

0150

1 those four factors listed in the regulation, which  
2 of them -- for which of those factors were there  
3 concerns or considerations raised in the context  
4 of the Plan B OTC Switch Application?

5 A Do you mean -- I mean when we approach  
6 an Application, we think about all those factors  
7 with the Application, so do you mean which of  
8 those factors led to its not being approved?

9 Q Um --

10 A I'm not sure what you're asking me, so  
11 like with toxicities, of course, we would look at  
12 Plan B and say, okay, what are the toxicities of  
13 Plan B, what do we need to think about here.

14 Q Okay. I see. Yes, which of these  
15 factors were the considerations that, that played  
16 into Dr. Galson's decisions in this case?

17 MR. HELLER: Objection; calls for  
18 speculation.

19 THE WITNESS: Yeah, I mean it, it -- I

20 think that's something you'd kind of have to ask  
21 him, but if you are concerned about potentials for  
22 misuse and abuse, then it would be harmful

0151

1 effects. If, on the other hand, you're saying I  
2 don't have, you know, enough data in adolescents  
3 to know that they'll take the dosages at the right  
4 time or whatever thing, then it's more can they  
5 self-medicate with it and understand the label.

6 BY MR. WARSHAWSKY:

7 Q I see. And so in that context,  
8 self-medication as directed in the proposed  
9 labeling, that would be a separate factor that's  
10 considered in the OTC Switch Application analysis?

11 A Well, they have to understand how to  
12 take the medication.

13 Q Okay.

14 A They have to be able to self-diagnose.

15 Q Let's move on in this document, please.  
16 So continuing at the bottom of Page Tummino 10545,  
17 quote, "So the bottom line is this regulation  
18 provides that a drug be sold non-prescription if  
19 it is safe and if adequate directions for use can  
20 be written that are discernible to a layperson.  
21 When approaching a possible" -- continuing. "When  
22 approaching a possible prescription to

0152

1 non-prescription switch candidate, there are  
2 several questions that the Agency takes into  
3 consideration to assess whether the product is  
4 indeed a suitable switch candidate. Regarding the  
5 questions that we take into consideration, we  
6 wonder if the product has an acceptable safety  
7 margin, as demonstrated from prior prescription  
8 marketing experience; whether it has low misuse  
9 and abuse potential; a reasonable therapeutic  
10 index of safety; whether the condition that it is  
11 being used for can be adequately self-recognized  
12 and self-treated with minimal health care provider  
13 intervention; whether the benefits outweigh the  
14 risks; and whether (sic) the product used under  
15 non-prescription conditions" -- excuse me -- "and  
16 when the product is used under non-prescription  
17 conditions, is it safe and effective."

18 And I believe you testified previously,  
19 in response to Mr. Heller's question, that these  
20 factors reflect CDER's interpretation and  
21 application, if you will, of the regulatory

22 language which we just were discussing; is that  
0153

1 correct?

2 A Well, they did when I was in OTCs.

3 Q And they did at the time that you made  
4 this presentation to the Advisory Committee?

5 A Correct.

6 Q Were there any other factors that played  
7 a role in OTC Switch Application decisions?

8 A I'm not sure. Can you give me an  
9 example of what you're looking for?

10 Q Another one that might look like this.  
11 I don't know. I'm just asking. Is this a  
12 complete list that sort of gives the universe of  
13 factors that you would be analyzing an Application  
14 under?

15 A Well, this is kind of the standard list  
16 that we always give at ACs.

17 Q Now, are there any statutory or  
18 regulatory or policy guidelines that further  
19 explain or elaborate on these various factors that  
20 you've described here?

21 A Not that I'm aware of.

22 Q Are there any empirical or statistical  
0154

1 formulas or tables or benchmarks of any type that  
2 indicate how these various factors should be  
3 applied in practice?

4 A No.

5 Q Let me ask you some questions, please,  
6 about some of these factors. The first one listed  
7 is an acceptable safety margin. What is "safety  
8 margin" referring to here?

9 A Well, it can be a couple of things, and  
10 actually people kind of look at "acceptable safety  
11 margin" and "therapeutic index of safety" in  
12 different ways, and they kind of confuse the terms  
13 also, so -- and so that's why I'm doing them  
14 together, because they can be confusing.

15 Q Okay.

16 A And so in my mind, "therapeutic index of  
17 safety" means if you are taking a dose and you  
18 know what the dose is, how many extra doses could  
19 you take and not get into trouble. That's index  
20 of safety. "Acceptable safety margin" is more of  
21 a -- at least in my mind, is more of an efficacy  
22 safety ratio, so you want to know how safe is this  
0155

1 drug, how many adverse events have you seen with  
2 it, are the adverse events serious adverse events,  
3 are they predictable adverse events.

4 Q Okay. Um, it sounds to me -- and please  
5 explain if I'm misunderstanding this -- that  
6 safety margin is being used in a, in a broader, in  
7 a broader way. You're looking -- it sounds to me  
8 like you're looking at the use of the product  
9 across a broad population and looking to see, for  
10 example, how many adverse events per how many  
11 people are taking the drug have been reported,  
12 whereas it sounds to me like therapeutic index of  
13 safety sounds to me to be sort of like almost a  
14 laboratory test of how many -- if you keep  
15 increasing the doses, at what point for that given  
16 subject will you start to have an adverse  
17 pharmacological problem.

18 Is that sort of the distinction that  
19 you're referring to, or am I just completely  
20 misunderstanding this?

21 A Well, you're kind of maybe about halfway  
22 there. Safety margin is not necessarily just how

0156

1 many adverse events do you have culled in, and  
2 it's kind of hard to look at safety margin in  
3 isolation. You also have to look at the efficacy  
4 of the drug, and so it's not -- it's what's the  
5 safety -- perhaps a better word might be "profile"  
6 of this drug versus its efficacy profile.

7 Q Okay. And how does that distinguish  
8 from the therapeutic index of safety?

9 A Therapeutic index of safety, I think  
10 you're a little closer on target in that it is  
11 just how many multiples of the dose would someone  
12 take before they got into trouble.

13 Q Now, looking at the first factor, the  
14 safety margin factor, you state here that the  
15 product has to have a quote, unquote, "acceptable"  
16 safety margin, and my question to you is: What  
17 does "acceptable" mean?

18 A "Acceptable" is in the eye of the  
19 beholder.

20 Q Are there any statutory or regulatory or  
21 policy guidelines that define or further explain  
22 what "acceptable" means in this context?

0157

1 A Yeah, not that I'm aware of, and you  
2 still have to kind of consider in -- in reality,

3 these words are words that we have tried to apply  
4 to the reg to give people making, um, making  
5 evaluations for like AC members to try to put  
6 common words they may understand on it besides  
7 trying to read a reg which may have been written  
8 by someone in the legal profession, so that  
9 someone not in the legal profession would have  
10 trouble understanding what the words meant, so  
11 it's more a way to say, to use language that they  
12 understand so that they can try to give us  
13 reasonable assessments.

14 Q So if in this context whether something  
15 has an acceptable safety margin is in the eye of  
16 the beholder, as you stated, how do you decide,  
17 for example, if a particular drug has, in your  
18 estimation, an acceptable safety margin?

19 A Well, again it's the overall package of  
20 the drug, so you really have to look at what the  
21 efficacy of the drug is, what the safety of the  
22 drug is, what its indication is, what is it going

0158

1 to be used for, and, you know, how easy is it to  
2 use; do people understand it; what is their level  
3 of understanding; what happens if they don't use  
4 it correctly; what's going to happen to them, and  
5 you have to kind of "gamish" that all together.

6 Q And is it fair to say --

7 A Is that a legal term, "gamish"?

8 Q Sure. Is it a scientific term?

9 A It is now.

10 Q Well, there we go. And just to make  
11 sure I understand that term, is it fair to say  
12 that what you're talking about here is the  
13 exercise of scientific or regulatory judgment as  
14 opposed -- well, let's leave it at that. It  
15 sounds to me like you're talking about the  
16 exercise of judgment. Is that a fair  
17 characterization?

18 A Well, I think -- actually I think your  
19 previous characterization, I liked it better. I  
20 think it is a -- it is a blending of regulatory  
21 and scientific judgment and the meshing of those  
22 two, because we, we are guided by the regulations.

0159

1 That kind of gives us the authority, so you really  
2 have to mesh that in the context of the scientific  
3 data that you've been provided.

4 Q How about -- let's see. The second

5 factor listed here, where you refer to misuse --  
6 well, strike that. In the context of the OTC  
7 Switch Application for Plan B -- strike that as  
8 well. Let's -- yeah, let's go to the next factor  
9 where you write "misuse and abuse potential," and  
10 what does that factor mean? What does it entail?

11 A "Misuse" and "abuse" are two different  
12 things, so "misuse," at least in my mind, would be  
13 when you use the drug for its indication, but you  
14 don't use it as labeled. "Abuse" is when you use  
15 the drug and you don't use it for its indication  
16 and you don't use it as labeled.

17 Q Now, do those understandings of the  
18 terms "misuse" and "abuse" come from any external  
19 source, is it something shared within CDER, or is  
20 it your own idiosyncratic interpretation?

21 A I don't know about idiosyncratic, but --

22 Q Personally.

0160

1 A Can I object to that word?

2 Q You certainly may.

3 A It -- it's an internal use of the word,  
4 the words. I'm not sure how universal it is.  
5 However, I do think that in Senate testimony --  
6 I'm not a hundred percent certain of this, but I  
7 think that in Senate testimonies considering  
8 narcotic agents, they have been sort of defined  
9 that way.

10 Q And in this particular case -- well,  
11 strike that. Now, you also modify that factor  
12 with the adjective "low." You're looking for  
13 whether the product has a low misuse and abuse  
14 potential. To just cut to the chase, is the  
15 meaning of the word "low" here similar to the  
16 meaning of the word "acceptable" in that it is in  
17 the eye of the beholder, and it's an exercise of  
18 scientific and regulatory judgment in the manner  
19 that you just described with respect to the  
20 acceptable safety margin factor?

21 A Yeah, I guess that I would put it in  
22 kind of the same category, in that, you know, when

0161

1 we use adverbs like that, I'm not sure anybody  
2 really puts a number to the adverb, so . . .

3 Q Now, one of the other questions I had  
4 about this factor is the word "potential." When  
5 you say here whether something has a low misuse  
6 and abuse potential, what do you mean to be

7 described or what does CDER mean to be describing  
8 by the word "potential"?

9 A Well, what I would be describing it as  
10 is that it has the potential to be misused or  
11 abused.

12 Q And --

13 A So as an example, if you -- if you look  
14 in the monograph, codeine is actually a monograph  
15 OTC drug, but it's a narcotic, so it has potential  
16 for abuse and misuse, and so in that context we  
17 know there's a potential, because it's a narcotic  
18 agent.

19 Q And with respect to a new drug for which  
20 an OTC Switch Application is being proposed, do  
21 you evaluate its potential for misuse and abuse by  
22 essentially exercising your scientific or

0162

1 regulatory judgment in thinking about the possible  
2 ways that the drug may be abused or misused, and  
3 then -- well, leave it at that, in terms of  
4 thinking about the possible ways that it may be  
5 misused and abused.

6 A Well, typically what happens is that a  
7 sponsor will come in and say, you know, we would  
8 like to propose switching this to OTC status, and  
9 so, you know, the Review Divisions will get down  
10 and will get together and sit down and think  
11 about, well, if this were to go OTC, what are the  
12 potential things that could be a problem. And at  
13 that point in time we would say, well, this could  
14 happen or that, and you would try to identify  
15 those things that might concern you, like misuse  
16 and abuse. And then, you know, as the sponsor is  
17 going along in their developmental program, we  
18 would probably raise that with them, and if it was  
19 enough of a concern to us, we would say, you know,  
20 we need to have this evaluated so we have some  
21 reassurance in some fashion that this is not going  
22 to occur. Now, this doesn't always necessarily

0163

1 mean they need to do some new testing. Sometimes  
2 there is available data out there that they can  
3 submit to us and say, well, we've got this data,  
4 does that fulfill the requirement of what you've  
5 placed on us.

6 Q So as I understand your answer, when a  
7 sponsor comes to the FDA and says we would like or  
8 we're thinking about making a drug

9 over-the-counter, one of the things that the  
10 pertinent FDA officials do is in essence  
11 brainstorm the possible problems that might result  
12 in an OTC setting, and if those problems strike  
13 the officials as sufficiently, uh, sufficiently  
14 serious, I guess, to ask the sponsor to address  
15 those in some way in its Application.

16 A You know, I don't know if I'd say  
17 "serious." I would say if they seem sufficiently  
18 reasonable that it might occur, because, you know,  
19 I mean if you think about it, the Agency, for the  
20 most part, we, we get paid to worry, and some  
21 people are very good at worrying, and so they can  
22 really think of a lot of different things that can

0164

1 happen, and I think that you just need to have  
2 kind of a meeting to discuss, okay, is this  
3 reasonable, a reasonable concern or is that a  
4 reasonable concern, and so that usually -- and  
5 just the way that you were asking the question  
6 sort of made it sound like the sponsor comes in  
7 and they have this program, and then we tell them,  
8 well, this is our concern, but it doesn't really  
9 happen that way. What happens is they come in  
10 with the initial inquiry to switch, and then we  
11 sort of work together with them to try to sort out  
12 the factors as the program goes along. Is that --  
13 does that help clear it up, or --

14 Q Yes. Thank you. And do you agree that  
15 as part of this process it's important for the  
16 regulators within FDA, within CDER, to engage in  
17 an open and free-wheeling, unrestricted discussion  
18 about these potential concerns?

19 A You mean with each other or --

20 Q Yes, with each other.

21 A Well, I would say that that's the  
22 standard, that that's what happens.

0165

1 Q And -- okay. The next factor listed  
2 here -- I'll skip over the therapeutic index of  
3 safety, since we've already discussed that -- is  
4 whether the condition that it is being used for  
5 can be adequately self-recognized and self-treated  
6 with minimal health care provider intervention. I  
7 think I understand that factor, but let me just  
8 ask you again just to be clear on the record:  
9 What do you or CDER mean in this context by the  
10 word "adequately"?

11 A Well, again it's another one of those  
12 adverbs that's in there, but I think that, you  
13 know, just from an OTC standpoint, people have to  
14 be able to self-recognize and self-treat the  
15 condition. So to try to give you a different  
16 example for you to think about in the context of  
17 this, let's say that the sponsor wants to come in  
18 and have a bladder drug approved or a prostate  
19 drug approved, and they are having some symptoms  
20 that might be prostate. Well, can they actually  
21 tell that's what's doing it and it's not something  
22 else causing the problem; and if they can't, how

0166

1 many people can't; and if they don't pick it up in  
2 time, how serious a problem is it if the diagnosis  
3 is delayed a while. So it's all kind of part of  
4 the big package.

5 Q And I apologize, but just to complete  
6 the circle, how do you -- how do you decide  
7 whether the evidence that's presented on this  
8 particular factor shows that the OTC users can  
9 adequately perform this self-treatment function?

10 A Well, there's no set reg, if that's what  
11 you're asking me, or no certain percentage that  
12 they have to reach, so again it's part of it. You  
13 have to weigh it into the rest of the package.

14 Q And when you say that the FDA -- that  
15 the folks at FDA are paid to worry, is it fair to  
16 say that different folks within the FDA worry more  
17 than other folks within the FDA?

18 A Well, I was saying that somewhat to be  
19 humorous, but I think that people do have  
20 different thresholds of what they worry about and  
21 what it takes to satisfy their concerns.

22 Q Now, overall in considering an OTC

0167

1 Switch Application, am I correct that the burden  
2 of proof is on the sponsor to present sufficient  
3 evidence to meet these various factors that CDER  
4 takes into account?

5 A Um --

6 MR. HELLER: Before he answers I'm just  
7 going to object that that calls for a legal  
8 conclusion.

9 THE WITNESS: Well, I'm sort of -- I'm  
10 trying to think about -- can I hear your question  
11 again.

12 BY MR. WARSHAWSKY:

13 Q Sure. Let me rephrase it. Who bears  
14 the burden of proof that a drug is suitable for  
15 OTC status; the sponsor or the FDA?

16 MR. HELLER: Same objection.

17 THE WITNESS: Let me answer it in kind  
18 of a different way. At the end of the day, in the  
19 package there has to be adequate proof to allay  
20 concerns, and the reason why I'm kind of hedging  
21 on this a little bit is that a Reviewer may have a  
22 concern that they have, and they may say to

0168

1 themselves, "I wonder if this has ever been  
2 evaluated before," and they may actually go out on  
3 their own and check the literature and see, well,  
4 it has been evaluated and this is what was found,  
5 and they'll pull that into their review and not  
6 actually go to the sponsor and say you need to  
7 prove this.

8 And so it's not -- at the end of the  
9 day, the package has to contain enough to allay  
10 the concerns of the people involved. You don't  
11 always go to the sponsor. Sometimes you pull the  
12 data out yourself if you can find it in the  
13 literature.

14 BY MR. WARSHAWSKY:

15 Q And what "package" are you referring to?

16 A The Action Package.

17 Q And what goes into an Action Package  
18 typically?

19 A Practically everything that has to do  
20 with -- so all the reviews, all the legal stuff.  
21 I mean it's . . .

22 Q So to summarize, an Action Package is

0169

1 essentially the entire file as it's presented to  
2 the what; the relevant decision-maker on the OTC  
3 Switch determination?

4 A Yeah, it's the regulatory history of the  
5 drug. I think that's . . .

6 Q And when you say that the package has to  
7 have adequate proof to allay these concerns, what  
8 do you mean by "adequate" in that context?

9 A We've already been over this. You know,  
10 I don't know how many different ways I can say  
11 what "adequate" does or doesn't mean.

12 Q I'm just, just trying to be clear. So  
13 we're going back to the issue of the eye of the  
14 beholder and the "gamishing" of the evidence, so

15 to speak?

16 A Correct.

17 Q Now, when a drug has already been  
18 approved for Rx status, does that, under the  
19 regulatory framework, raise any presumptions of  
20 OTC suitability?

21 A Um, no, not that I'm aware of.

22 Q I'd like to ask you about the next line

0170

1 in your introductory statement. You write -- so  
2 just to clarify, as lawyers like to do --

3 A I was just sort of humorously thinking,  
4 if we're going to do every one of those pages in  
5 the detail you've spent on this, we're going to be  
6 here a while, aren't we?

7 Q Actually just a couple more pages in  
8 this document. This is just a couple more pages  
9 in this document.

10 MR. HELLER: We're limited. I think  
11 each side is probably limited to seven hours.

12 MR. AMANAT: We'll be fine.

13 BY MR. WARSHAWSKY:

14 Q Now, if the Action Package, as we were  
15 just discussing, does not contain adequate proof  
16 to allay the concerns about the OTC switch, am I  
17 correct that that means the particular drug cannot  
18 be approved for OTC status?

19 A Well, I would say that it has to --  
20 since you're asking a lot about the definition, I  
21 think it has to have adequate proof for whoever  
22 the signatory is. If it does not have adequate

0171

1 proof for whoever the signatory is, then it will  
2 not get an Approve Action.

3 Q The next line in your introduction  
4 states, quote, "If the answer to the above  
5 questions are yes, then the proposed product may  
6 meet regulatory requirements for non-prescription  
7 safety and effectiveness and is a candidate for  
8 consideration of non-prescription marketing. My  
9 question about this statement is: What do you  
10 mean that the product may meet the requirements  
11 and is a candidate for consideration even when  
12 these various factors have been answered yes?

13 A Yeah, in my mind, just to, just to kind  
14 of clear this up for you, this is an introduction  
15 to an Advisory Committee meeting. This is not a  
16 legal document that I would wordsmith to death.

17 Q Okay.

18 A Okay? And so since I'm trying to give  
19 the panel some guidance on what makes something an  
20 OTC drug or not, I don't want to say to them if it  
21 meets all of this stuff, you have to say it's okay  
22 for OTC marketing. What I'm trying to say is this

0172

1 is sort of the regulatory requirements that we  
2 have, go through and look at that, and if it kind  
3 of meets that, well, then you need to think about  
4 maybe it can be an OTC drug.

5 Q I see. Okay. Now, let's continue on  
6 with this statement. Quote, "In order to address  
7 the questions that face Switch candidates, the  
8 Plan B Switch NDA Application components included  
9 summaries from previously existing data and newly  
10 conducted studies. To address the safety profile  
11 and misuse and abuse potential of the product, the  
12 sponsor has submitted safety data from the  
13 original NDA and a review of post-marketing  
14 safety, both foreign and domestic, and a review of  
15 the published literature.

16 "To evaluate consumers' ability to  
17 self-recognize the condition they are treating and  
18 whether self-treating with the product is safe,  
19 the sponsor has conducted Label Comprehension and  
20 Actual Use Studies. We'll be hearing greater  
21 detail about these things during this morning's  
22 presentations. This type of data and the studies

0173

1 that the sponsor has performed are consistent with  
2 other submissions that have been evaluated in the  
3 past where the switch did not involve a change in  
4 dosage or indication."

5 And my question is with this last  
6 sentence: When you say that the type of data that  
7 the sponsor has performed, the type of data and  
8 the studies that the sponsor have performed are  
9 consistent with other submissions, what do you  
10 mean by this?

11 A Usually when we have an Advisory  
12 Committee, there are two committees involved, so  
13 one of them is an OTC Committee that's very used  
14 to seeing what's involved in a package. The other  
15 committee usually isn't, and depending on the  
16 length of time that someone's been on that  
17 committee, they may or may not know what a typical  
18 package looks like.

19           Usually on the prescription side, when  
20 they are called into committee, they are called  
21 because there are efficacy or safety questions,  
22 and they're used to seeing an efficacy or safety

0174

1 study. And so when they are getting something  
2 like this that has Actual Use or Label Comp  
3 studies where they have variable experience with  
4 it and with what goes into an OTC switch package,  
5 this sentence is to say basically this is what a  
6 typical package looks like, they've got most of  
7 the studies that go into a Switch Application, and  
8 so you shouldn't be questioning whether there are  
9 more or less studies that should be in it, because  
10 they've got the usual studies.

11       Q     I see. Okay. Then you go on to give an  
12 outline of what will happen at the Advisory  
13 Committee meeting. Let me just ask you a few  
14 questions about that.

15           You say that the meeting will begin with  
16 a presentation by the sponsor, followed by a  
17 question-and-answer session. Do you recall  
18 roughly how long the sponsor's presentation and  
19 question-and-answer session lasted?

20       A     No, I sure don't. It should be in the  
21 agenda, but -- although the agendas, sometimes  
22 they don't follow those strictly, so . . .

0175

1       Q     Advisory Committee meetings take place  
2 all in just a one-day period?

3       A     Kind of depends on the product. This  
4 one was a one-day, though.

5       Q     And then it says, "Following a break, we  
6 will have presentations by the FDA and then a  
7 question-and-answer session with the FDA." Do you  
8 recall how long the FDA's presentation and  
9 question-and-answer component lasted?

10       A     No, I sure don't.

11       Q     You then state, "We will then have an  
12 open public hearing," then lunch and so forth.

13       A     You missed the adjective, the "deserve,"  
14 "much deserved."

15       Q     "Much deserved lunch," yes. Do you have  
16 any recollection of how long the public hearing  
17 component of the Advisory Committee meeting  
18 lasted?

19       A     They're -- the public hearings are  
20 usually limited, and I just can't -- it's either

21 like an hour, hour and a half, and so they usually  
22 see how many people sign up to talk, and then they  
0176

1 divvy the time up per person. And in Plan B there  
2 were lots and lots of people that wanted to talk,  
3 so by the time they divvied it up, they didn't get  
4 a lot of time. It's usually like an hour, hour  
5 and a half, if I recall correctly.

6 Q Now, what's the regulatory relevance of  
7 having members of the public give little  
8 presentations, if you will, to the Advisory  
9 Committee meeting -- to the Advisory Committee?

10 A You mean is it in the regs that there is  
11 supposed to be an open public --

12 Q That's what I'm asking. Is there any  
13 regulatory relevance to this particular component  
14 of the meeting?

15 A Well, they -- we always have an open  
16 public session where people can express a view,  
17 and I'm not sure if that's in the regs or where  
18 that's at.

19 Q Are the views expressed by the public in  
20 that component of the meeting given any weight or  
21 consideration by FDA in making its final  
22 determinations?

0177  
1 A Usually listen to them. I don't know  
2 how much weight it's given.

3 Q And then at the end of your, uh, near  
4 the end of your presentation you said, "During the  
5 presentations, the Joint Committee members should  
6 consider the information and use the  
7 question-and-answer session to prepare to answer  
8 the questions posed to the committee regarding the  
9 possible prescription to non-prescription switch  
10 of Plan B," and I guess a couple of questions  
11 about this. And I apologize if I'm repeating  
12 myself, but I don't quite remember if I asked this  
13 specific question. Did -- strike that. Did  
14 the -- strike that. Just to confirm for the  
15 record, the members of the Advisory Committee did  
16 not have before them any of the CDER scientific  
17 reviews that were drafted by the various staff  
18 members in January and so forth after this  
19 meeting; is that right?

20 A They had the preliminary -- they had an  
21 edited version of the preliminary reviews.

22 Q Okay, and the material that they had --

0178

1 A I'm not -- let me just add a little bit  
2 to clarify that. It wouldn't have been all of the  
3 reviews, so it would have been the primary  
4 reviewers mainly, so as I recall it, there would  
5 have been -- Jin Chen's would have been in there,  
6 Dan Davis', Karen Lechter's, at least an edited  
7 version of them. I can't think of whether there  
8 was -- there was probably -- the Drug Safety folks  
9 had probably an edited version.

10 Q Now, in terms of the folks who gave the  
11 presentations on behalf of the FDA, why was  
12 Dr. Chen chosen to present at the Advisory  
13 Committee meeting?

14 A Well, there's really a different  
15 philosophy within Divisions of who's going to  
16 present at the AC. My own philosophy has always  
17 been that I try to, try to promote people's  
18 careers, because it goes into your advancement if  
19 you have presented at an AC. That's part of how  
20 you can jump up and get a higher grade. And so  
21 since he was doing the primary review, I felt that  
22 he should at least have an opportunity to present,

0179

1 because it could be good for his career, and it  
2 was -- I felt he hadn't, you know, had an  
3 opportunity to present at high-profile meetings,  
4 and I thought it would be a good experience for  
5 him.

6 Q And between the documentary material  
7 provided to the Advisory Committee members and the  
8 presentations made at the Advisory Committee  
9 meeting, do you feel that the members had  
10 sufficient information to make an informed  
11 recommendation with respect to the OTC switch for  
12 Plan B?

13 A I think they had sufficient information  
14 to make a non-binding recommendation to us, yes.

15 THE WITNESS: Would it be okay if we  
16 took a little break?

17 MR. WARSHAWSKY: Oh, absolutely.

18 THE VIDEOGRAPHER: This ends Tape Number  
19 2 of the deposition. We shall go off the record  
20 as of 2:52 p.m. to change videotapes.

21 (Whereupon, a short recess was taken.)

22 THE VIDEOGRAPHER: Here marks the begin

0180

1 beginning Tape Number 3 in the deposition of

2 Curtis Rosebraugh, M.D. The time is now 3:06 p.m.  
3 BY MR. WARSHAWSKY:

4 Q Dr. Rosebraugh, I'd like you to take a  
5 look now at a document which contains excerpts  
6 from the deposition of Dr. Woodcock, and I believe  
7 you testified earlier that you have read  
8 Dr. Woodcock's deposition in this case.

9 A Yes.

10 Q This particular set of pages from the  
11 deposition relates to the meeting held in February  
12 or on February 19, 2004, which you referred to in  
13 your review in January -- excuse me -- in March of  
14 2004, in which Dr. Woodcock made the comments  
15 about potential effects on teenage sexuality, and  
16 I'd like to read for you some selected portions  
17 from Dr. Woodcock's deposition about that meeting  
18 and ask you for your comments. I'd like to --

19 A So do you want me to read along or --  
20 where are you?

21 Q Yes, please. Let's start on the third  
22 page of this packet, which at the very top has 152

0181  
1 in the left-hand corner.

2 A Uh-huh.

3 Q And we'll begin Line 11. "Do you recall  
4 whether there was a meeting the following day on  
5 February 19th of '04? Answer: Yes. Question:  
6 Involving Plan B? Yes. And were you part of that  
7 meeting? I believe so. Question: Now, describe  
8 to the best of your recollection, Dr. Woodcock,  
9 what you recall about the meeting which took place  
10 on February 19th of 2004. Answer: We were  
11 discussing the issues that had been raised at this  
12 meeting the prior day, about whether or not there  
13 was need for further data in adolescents, and we  
14 were having some discussion about the degree to  
15 which one could extrapolate from the adult data  
16 and how much was actually known about the behavior  
17 of young teenagers with respect to this medication  
18 based on the data that had been submitted by the  
19 sponsor or based on the ability to extrapolate  
20 from what we know in older teenagers or adults."

21 My first question to you is whether  
22 Dr. Woodcock's general description of that meeting

0182  
1 on February 19th, 2004, is accurate in your -- to  
2 your recollection.

3 A My, my recollection was is that there

4 really was not a discussion between us and  
5 Dr. Woodcock. Dr. Woodcock said that in her view,  
6 and I think she said in the Commissioner's view,  
7 that there really wasn't enough data in  
8 adolescents and that the data that was in older  
9 adults couldn't be extrapolated, but I would not  
10 characterize it as a discussion seeking our view  
11 on it.

12 Q Okay. Now, with respect specifically to  
13 the comment that's attributed to Dr. Woodcock with  
14 respect to promiscuous behavior and the sex-based  
15 cult idea, was it your impression at that meeting  
16 that Dr. Woodcock was making that statement as an  
17 assertion of fact as opposed to thinking about the  
18 potential misuse or abuse of the drug in the  
19 manner in which we discussed several minutes ago?

20 A You mean making the assertion that there  
21 are sex-based cults?

22 Q Yes, either that there are such

0183

1 sex-based cults surrounding Plan B or that it was,  
2 I guess, a fact, if you will, that this was going  
3 to happen if the drug was made over-the-counter.

4 A The way I interpreted that response was  
5 that -- and it was a little hard to interpret that  
6 response, because it seemed to kind of come out of  
7 the context of what we were talking about, but the  
8 way I interpreted that is there is one or two ways  
9 you could look at it and try to interpret it.

10 If you are talking about having some  
11 sort of cult or some sort of abuse of the drug,  
12 then you would have to ascribe a characteristic to  
13 the drug that was abusable. And at the time when  
14 we were doing this, there actually -- in the lay  
15 press there were a lot of opinions floating  
16 around, and there were people that were saying  
17 things like, well, what if a predator slips it in  
18 a girl's drink in a bar. Well, in my mind that  
19 attributes that it has an aphrodisiac effect or  
20 some sort of CNS effect, which it clearly does not  
21 have.

22 And so it could be viewed from that

0184

1 context, or it could be -- which I don't think is  
2 what she was saying -- it could be viewed from the  
3 context of that is the level of data that she and  
4 the Commissioner wanted to have to be assured that  
5 there would not be abuse of the drug. In some

6 ways that's misuse, but misuse or abuse of the  
7 drug to the level that they needed to know that an  
8 occurrence like that would not happen, and I  
9 ascribe it more towards that side of it.

10 Q So your impression was that Dr. Woodcock  
11 specifically was proposing the issue of sex-based  
12 cults surrounding Plan B as something which needed  
13 to specifically be addressed in the evidence?

14 A I don't -- I actually don't know what  
15 she was ascribing, but if it was that she needed  
16 that level of evidence, that's, that's a very high  
17 standard to have to get through, and, you know,  
18 none of us really asked clarifying questions,  
19 because again this was really not a conversation.  
20 This was them telling us, you know, what their  
21 position and the Commissioner's position was.

22 Q Now, when you said a few moments ago

0185

1 that this statement seemed, quote, "out of  
2 context," why was it not -- why was it not in the  
3 context of considering adolescent behavior and  
4 whether adult data could be attributed to  
5 adolescent data? Isn't that what Dr. Woodcock was  
6 getting at?

7 A Well, again, I'm not exactly sure what  
8 Dr. Woodcock was getting at, but if, if there was  
9 going to be misuse and abuse of a compound, first  
10 of all, this drug has been fairly readily  
11 available, so in a sense you would -- you know,  
12 it's not unreasonable to think that there would  
13 have been reports of this happening already.  
14 Additionally, there are misuse and abuse of drugs  
15 from 18 and above, and so you can in some sense  
16 say, well, if you see it occurring at that level,  
17 you're going to see it at a younger age group  
18 also, and we didn't have reports there.

19 And then finally again it has  
20 remained -- and during this interval you have to  
21 understand it was never clear to us what level of  
22 evidence they needed and what kind of evidence

0186

1 they wanted, and so when a statement like that  
2 comes out, that makes it sound like that there is  
3 a fairly high level of evidence they're requiring  
4 to feel assured that it's not going to be misused  
5 and abused.

6 Q Let me ask you a few follow-ups on that  
7 First of all, with respect to Dr. Woodcock's

8 statement in particular, which you cited in your  
9 March 2004 review, if, as you testified a few  
10 moments ago, you were, quote, "not sure of what  
11 she was getting at" by that statement, why was  
12 that statement relevant in your discussion of  
13 whether Plan B should be approved for OTC status?

14 A Well, first of all, I didn't make the  
15 statement.

16 Q Right, but you discussed it in your --

17 A And so I cited, I cited the statement as  
18 an example of -- at least an interpretation of  
19 what level of evidence they may be requiring, and  
20 that was a very high level, and it would be very  
21 difficult to achieve.

22 Q Now, with respect to the level of

0187

1 evidence that they were requiring, isn't it  
2 correct that the discussion that Dr. Galson had  
3 with the staff in January of 2004 and the  
4 additional comments made by Dr. McClellan and/or  
5 Dr. Galson at the staff meeting in February 2004  
6 were directed towards the lack of data? In other  
7 words, Dr. Galson didn't say, "I don't have proof

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16 First of all, at the time we had five  
17 states that had easy access to Plan B. Plan B had  
18 been on the market many years, and we had five  
19 studies that had studied and had a large number of  
20 adolescent subjects in those studies. We had two  
21 Divisions that felt that there was adequate  
22 evidence that the drug could be marketed. In

0188

1 addition, not at that time, but later on,  
2 Pediatrics said that it fulfilled the pre-criteria  
3 for women that had undergone menarche, so  
4 essentially it was three divisions, although it  
5 wasn't at that time. And we also had an Advisory  
6 Committee meeting where everybody felt that the  
7 data was applicable to the full range of people  
8 that would be exposed. That's a lot of data. And  
9 so if that's not enough, what is enough to make a

10 decision on?

11 Q Well, let me ask you that question:  
12 Given the data, the universe of data that you just  
13 described, is it your opinion, either now or at  
14 the time of these events, that that entire  
15 universe of data was required in order to support  
16 an OTC switch?

17 A Well, it's hard to go back and say was  
18 it required or not. We had it at that time, and I  
19 think the data, as I have pointed out in my  
20 reviews, was adequate.

21 Q Is there any way for you to quantify  
22 what you mean by "adequate" or give some kind

0189  
1 of --

2 A I don't know what you're asking me.

3 Q I guess I'm trying to ask you: In your  
4 scientific and regulatory decision-making process,  
5 how did you reach the conclusion that the  
6 "universe of data," as you described it, was  
7 adequate in your mind to support the OTC switch?

8 A Well, I think that's fairly well  
9 outlined in my reviews.

10 Q If you would -- if you could turn to the  
11 fifth page of this document, which up at the top  
12 has the number 0154.

13 A Uh-huh.

14 Q And just to make this go a little more  
15 quickly, if you could read to yourself, beginning  
16 with Line 8 and continuing to the third -- to the  
17 three pages of 156, finishing with Line 15, so  
18 it's about half of a page, one page and then half  
19 of a page.

20 A Can I see your pen.

21 Q Sure.

22 A So you want me to read from what to

0190  
1 what?

2 Q From 154, Line 8 --

3 A Uh-huh.

4 Q -- to 156, Line 15. Thanks.

5 Now, taking a look at this lengthier  
6 passage in which Dr. Woodcock provides a little  
7 more detailed description of this February 19,  
8 2004, meeting, can you tell me what, if anything,  
9 of this description you disagreed with or you  
10 disagree with?

11 A Well, again if you look at this, the

12 things that she's citing, OxyContin and  
13 Dextromethorphan, all have CNS effects, so you can  
14 say to yourself that they do have abuse potential  
15 because of their CNS effects, whereas Plan B  
16 doesn't have CNS effects, so it is a little  
17 confusing if she's directly comparing that these  
18 are drugs of abuse and therefore we don't know  
19 whether Plan B will or not; that's comparing  
20 something that has a CNS effect to something that  
21 doesn't have a CNS effect. So it's a little  
22 difficult to know if she -- and additionally,

0191

1 Dextromethorphan's CNS effects are LSD type  
2 effects, so they cause disassociation, so if she's  
3 comparing it to that, I'm not sure what the  
4 analogy is she's getting at.

5 Q Well, let me ask you this: The, the  
6 comparisons to OxyContin, Dextromethorphan and so  
7 forth, were these comparisons that came up  
8 specifically in the February 19, 2004, meeting?

9 A I don't recall.

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14 And then in the Dial Study, that was a  
15 study where women could call and get a  
16 prescription called in, when they interacted with  
17 the pharmacist, again they just had a sheet that  
18 they went through, so there really was very little  
19 contact with health care practitioners in the  
20 studies.

21 Additionally, as I've already outlined  
22 before, some of those studies gave advance

0193

1 provisions, and I went through, you know, a lot of  
2 detail in my review to show that if you had had  
3 previous versus no experience with Plan B, the  
4 intervention of a health care practitioner really  
5 didn't make a difference in how you were using it.  
6 And so then to kind of bridge that and say, well,  
7 if you have advance provision that could be  
8 sitting in your house for several weeks or months  
9 before you use it without talking directly to a  
10 health practitioner, those folks had the same sort  
11 of usage, so there were a lot of bridges out there  
12 that sort of bridged things.

13 Q And how -- okay. And how about the last  
14 paragraph of the passages which we just were  
15 looking at? Dr. Woodcock stated, "I was  
16 reflecting the fact that we had no data on what it  
17 would become, that there could be a risk, and we  
18 were poorly prepared to extrapolate the health  
19 consequences. Everything we know about young  
20 teenagers is that their risk-taking behavior and  
21 their cognitive processes are different than the  
22 older adolescent age group or adults."

0194

1 Do you agree or disagree with that  
2 statement?

3 A Well, actually I'm reading -- let me  
4 read the question before that.

5 Well, again it's a little hard to think  
6 about this statement in regard to what I had  
7 already said, that we had lots of data that we had  
8 analyzed in detail, and their use of Plan B in  
9 adolescents did not seem to be any different  
10 between older age groups, and I thought that the  
11 data was valid.

12 Q Now, let me ask you: In, in one of your  
13 reviews -- I forget whether it was the January '04  
14 review or the March '04 review -- you made the  
15 statement which you testified to earlier, that,

16 quote, "adolescents are poor contraceptors." Do  
17 you remember making that statement?

18 A Yes.

19 Q What did you mean by that?

20 A If you, if you look through the studies,  
21 particularly if you look at oral contraceptives,  
22 they have -- in different studies they have -- I'm

0195

1 scared to use adjectives, because you'll want me  
2 to define them all.

3 Q Probably, but that's okay. Go right  
4 ahead.

5 A They have a poor continuation use of  
6 oral contraceptives, so they don't take oral  
7 contraceptives as long or as accurately as older  
8 age groups. They also -- if you look through the  
9 data right now, you see that they tend to not use  
10 condoms with the first intercourse, and they don't  
11 use condoms with every intercourse, so they're  
12 poor contraceptors, and that is right now, without  
13 Plan B being over the counter, so they are poor  
14 contraceptors.

15 Q And to what do you attribute the  
16 difference between adolescents and older age  
17 groups and adults in terms of their ability to  
18 effectively use contraception?

19 A I'm not sure if that's been studied.

20 Q Do you have any hypothesis?

21 A Not off the top of my head.

22 Q Does it have anything to do with the

0196

1 mental or psychological or social development of  
2 adolescents as opposed to older age groups or  
3 adults?

4 A I'm not sure.

5 Q I just have probably one more question,  
6 then I'll take a quick break, but in your -- or  
7 rather earlier you were testifying in response to  
8 various questions from Mr. Heller, and I believe  
9 in both your written reviews and in testimony  
10 today you made the point that it wasn't clear to  
11 you and the other folks who, I guess, favored OTC  
12 status for Plan B, what more the sponsor needed to  
13 do to allay the concerns, I guess, first raised by  
14 Dr. Galson in the January '04 meeting. Is that,  
15 is that a fair characterization, that it wasn't  
16 clear what more needed to be done?

17 A Well, yes, it wasn't clear what more

18 needed to be done or what sort of study that they  
19 wanted to see, and particularly in light of the  
20 fact where, when it was brought up that perhaps  
21 there could be something done based on age,  
22 different ages, and Dr. McClellan said, oh, that

0197

1 would probably -- at least my recollection is that  
2 he said that would probably require yet another  
3 public hearing. And so even if this labeling came  
4 in, in my mind it was unclear that that -- where  
5 they did it based on age, it was unclear if that  
6 would be satisfactory to at least the Commissioner  
7 that was the Commissioner at the time.

8 Q Well, let me ask you this question: Why  
9 couldn't the sponsor have planned and conducted an  
10 Actual Use Study that was simply larger than the  
11 one that it, in fact, completed, and included more  
12 adolescents and had a longer period of follow-up  
13 and basically did all the things which FDA  
14 recommended at the very beginning of this process?

15 A Typically when you meet with the sponsor  
16 and they want some sense of what it is that they  
17 need to do, you have to be able to give them some  
18 guidance, and so in internal discussions you  
19 usually are very straightforward in saying, look,  
20 I would have to see this kind of study, I want to  
21 see this many people, I want to see this many in  
22 this age category, and I want -- that's what I

0198

1 want. Well, we could never get that kind of data  
2 or that kind of discussion to say this is what  
3 Dr. Galson wants to see, he wants to see a study  
4 this big, so, you know, you have to be able to  
5 advise the sponsor on what it is they need to do  
6 and give them guidance, and we never got that kind  
7 of guidance.

8 Q To your knowledge --

9 A I would just add it's kind of hard when  
10 you've already made the decision that you  
11 personally think that it can be marketed, it's  
12 kind of hard, if you can't get guidance from them,  
13 to know what to tell the sponsor, because you're  
14 not the one making the decision anymore, it's  
15 Dr. Galson making the decision, so it has to  
16 satisfy his needs.

17 MR. WARSHAWSKY: Can we just take a  
18 short break, and I think I'm ready to wrap up.

19 THE VIDEOGRAPHER: Going off the record,

20 the time is now 3:33 p.m.  
21 (Whereupon, a short recess was taken.)  
22 THE VIDEOGRAPHER: Back on the record,

0199

1 the time is now 3:40 p.m.

2 MR. WARSHAWSKY: Dr. Rosebraugh, thank  
3 you very much for your time and help. At this  
4 point we do not have any further questions.

5 MR. HELLER: Dr. Rosebraugh, I have a  
6 few more questions. I apologize, but it really  
7 will be fast.

8 THE WITNESS: Can he do that?

9 MR. WARSHAWSKY: Unfortunately, yeah.

10 REDIRECT EXAMINATION

11 BY MR. HELLER:

12 Q You were asked to read some --

13 A Can you ask questions after he asks  
14 questions, or are we done?

15 MR. WARSHAWSKY: Technically I can, but  
16 I'll use my best judgment.

17 MR. AMANAT: Actually I get a turn, too,  
18 and then Karen gets a turn.

19 MR. HELLER: That's not true.

20 BY MR. HELLER:

21 Q You were asked to read some portions of  
22 Dr. Woodcock's deposition transcript in this case,

0200

1 and in one of them she was talking about how there  
2 had been -- or she knew of abuse of  
3 Dextromethorphan and OxyContin.

4 A Yes.

5 Q Dextromethorphan is available over the  
6 counter; is that right?

7 A Correct.

8 Q It has not -- its over-the-counter  
9 status has not been revoked by FDA?

10 A No.

11 Q And OxyContin is a prescription drug?

12 A Yes.

13 Q It hasn't been withdrawn from the market  
14 because of abuse by teenagers or others?

15 A No, it has not been removed from the  
16 market.

17 Q So in those cases where you have actual  
18 evidence of abuse and misuse, drugs stay on the  
19 market, including one over-the-counter drug; is  
20 that correct for those two drugs? One is  
21 over-the-counter, one is prescription; both are

22 still on the market; teenagers can still walk in  
0201

1 and buy Dextromethorphan at drug stores?

2 A They are both over-the-counter, and yes,  
3 people -- or I'm sorry. They are not both  
4 over-the-counter, but Dextromethorphan is still  
5 over-the-counter, and people can walk in and buy  
6 it. Now, let me add that Pseudoephedrine, which  
7 was over-the-counter, has been, by most states,  
8 and I think there was a rule-making that made it  
9 physician-accessible only, and so there is a  
10 potential that if something is abused, highly  
11 abused, that there can be limiting marketing it.

12 Q In the case of OxyContin, I think that  
13 Dr. Woodcock said in her deposition that  
14 originally when it was approved as a prescription  
15 drug for pain, I think she talked specifically  
16 about severe pain from cancer, and that people  
17 didn't think, necessarily, that it was going to be  
18 abused, or they didn't consider that. Does that,  
19 does that seem right to you? Do you remember  
20 her --

21 A I wasn't involved in that.

22 Q Oh, no, no, no, but I mean that she said  
0202

1 that, that she said that in her transcript.

2 A Well, she said that in her transcript.  
3 I don't remember if she said it when we met.

4 Q I just want to take that as an example,  
5 though. Do you know if, when pain medications  
6 have been approved -- let's take OxyContin as an  
7 example. Do you know if the Agencies, for  
8 example, would ask for a study saying this; maybe  
9 we want to know whether people will smoke more  
10 tobacco if OxyContin is approved, because if they  
11 know that it's available for cancer pain, they'll  
12 take more risks with cancer by smoking more? Do  
13 you know if that's the sort of issue that FDA  
14 would want a study on, sort of saying we want to  
15 find out, if this is approved for prescription  
16 use, are people going to smoke more because  
17 they'll know that if they get cancer and then have  
18 pain, they'll be able to treat the pain with  
19 OxyContin? Do you know if something like that  
20 will be considered by the FDA, whether they would  
21 want a study like that?

22 A That, that, um, seems a little past what  
0203

1 I think someone would reasonably --

2 Q And the reason I'm asking about that --  
3 I realize it sounds -- it sounds unreasonable to  
4 me, too. It seems to me that when you were  
5 talking about examining the risks or the  
6 possibility of abuse or misuse, you were talking  
7 about whether people are going to use it in a  
8 higher, a higher dose, or not use it as directed  
9 or not use it for the purpose for which it's  
10 supposed to be used; is that right?

11 A Correct.

12 Q But you don't look at, typically,  
13 whether people are going to, before they ever use  
14 it, change their behavior because they know they  
15 could use it later; that is, you know, maybe  
16 people -- maybe married couples will stop, stop  
17 using contraception because they know that this is  
18 available, so they don't need to anymore. Did you  
19 look for -- maybe people will start having sex  
20 earlier because they know this is available, et  
21 cetera, et cetera.?

22 MR. WARSHAWSKY: Just object to the form  
0204

1 of that question.

2 MR. HELLER: That's a good objection.  
3 Let me withdraw and ask my question a different  
4 way.

5 BY MR. HELLER:

6 Q Would you typically look at how it  
7 influenced -- how approval of a drug for OTC use  
8 will influence people to change their behavior  
9 before they ever use the drug, or are you  
10 typically looking at how they will -- whether they  
11 will use the drug appropriately itself?

12 A I'm just trying to roll that through my  
13 brain. That's kind of -- it's a complicated  
14 question, or I'm tired and it's really not that  
15 complicated. We, we certainly try to see what the  
16 behavior is with the use of the drug. In the case  
17 of Plan B, we actually did try to see if  
18 availability of Plan B affected contraceptive use.  
19 We don't typically do that, but we don't typically  
20 have an emergency contraceptive coming through.  
21 So you have to decide -- you have to see what the  
22 drug is that comes through, and a lot of times

0205

1 there is not a typical -- each drug presents its  
2 own challenges and its own things that we have to

3 evaluate, but in Plan B we did look to see if  
4 there were changes in contraceptive behavior  
5 because of availability of Plan B in the studies.

6 Q So did you, did you look also at whether  
7 it would change people's sexual behavior in  
8 general in a broader sense? Not their  
9 contraceptive behavior, but would they, for  
10 example, have more unprotected sex because they  
11 knew that Plan B was available?

12 A Can you define "unprotected" for me?

13 Q Okay, that's a good point. Would they  
14 have more -- engage in more sexual intercourse  
15 without contraception because they knew Plan B was  
16 available? Is that what you were just testifying  
17 about with the contraceptive behavior?

18 A Well, that is something that we looked  
19 at, and it was -- in the behavioral studies they  
20 looked at that also, so that was something that  
21 was part of the review.

22 Q So it's sort of looking at whether

0206

1 people are going to take more risks because they  
2 know that this alternative treatment is available?

3 A Yes.

4 Q And then for other over-the-counter  
5 drugs -- like, for example, in one of your memos  
6 you mentioned Acetaminophen, which is available  
7 over the counter. Do you know whether, in  
8 approving that, which is for pain, the Agency  
9 would have looked at whether people would engage  
10 in more pain-causing behaviors, you know, driving  
11 more recklessly, riding their bikes with one hand  
12 off the handle, et cetera, et cetera, because they  
13 knew that if they hurt themselves and had some  
14 pain, they would be able to take Acetaminophen and  
15 get treatment for it; do you know if that sort of  
16 thing would have been examined by the Agency?

17 A Acetaminophen is an old drug. I think  
18 that it's probably not something we would have  
19 examined.

20 Q So it sounds as if to me -- tell me if  
21 this is right -- in the case of Plan B you sort of  
22 went an extra step by examining how it might

0207

1 change people's behavior; just the availability of  
2 it would change people's behavior as opposed to  
3 the actual use of it harming people or helping  
4 people.

5           A     I don't know if I'd characterize it as  
6 an extra step, but I think it's one of the things  
7 we looked at.

8           Q     Okay. At one point you talked about  
9 there being conflicting data from OCC, I think,  
10 about the question of what is misuse or abuse of  
11 drugs. Do you remember answering, saying that  
12 there was conflicting information or data from  
13 OCC?

14           MR. WARSHAWSKY: Hold on one second.  
15           (Discussion was held off the record.)

16 BY MR. HELLER:

17           Q     The question is sort of -- am I  
18 remembering correctly that you said conflicting  
19 data from OCC about something, and what was the  
20 "something" you said before, if you recall what it  
21 was that you had the conflicting information  
22 about?

0208

1           MR. WARSHAWSKY: You can't divulge any  
2 conversations in which you were seeking legal  
3 advice, so if you want to go over the nature of  
4 whatever communication you received from legal  
5 counsel in this context, maybe we should discuss  
6 it first.

7           THE WITNESS: Well, why don't we discuss  
8 it and I can tell you what it's about.

9           MR. WARSHAWSKY: Okay.

10           THE WITNESS: Do you guys want to leave,  
11 or do you want us to?

12           MR. HELLER: Well, I mean all I was  
13 really asking him -- and I don't know if this  
14 requires a discussion -- is essentially could he  
15 restate what he already testified about,  
16 conflicting data about something and what was the  
17 thing. Can you just say that? Do you want to  
18 talk to him about that anyway?

19           Actually, let me do something different,  
20 which is, can you search for the word  
21 "conflicting" and see if I can just see what he  
22 said. That might help speed this up.

0209

1           THE WITNESS: It's a little hard for me  
2 to know, because it's not that I specifically  
3 sought legal advice.

4           MS. SCHIFTER: You might have obtained  
5 legal advice, which is the same thing.

6           MR. AMANAT: I know what Simon is

7 referring to, but why don't you read back the --  
8 (Whereupon, reporter reads requested  
9 material.)

10 BY MR. HELLER:

11 Q So my question is: Was the information  
12 you were getting from OCC about misuse and abuse  
13 or was it about potential harmful effects?

14 MR. WARSHAWSKY: I'm going to have to  
15 just object for one moment here, and I need to  
16 consult with Karen.

17 MR. HELLER: Okay.

18 MS. WARSHAWSKY: Could you read back the  
19 last question.

20 (Whereupon, reporter reads requested  
21 material.)

22 MR. WARSHAWSKY: I'm going to have to

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1 direct the witness not to answer this question,  
2 because you're seeking information about the  
3 substance of the communication from the Office of  
4 General Counsel.

5 MR. HELLER: I certainly understand your  
6 objection, but I think the privilege, if there was  
7 one, was waived when he answered the question you  
8 asked him or I asked him. I don't know who asked  
9 him that question. One of us asked him, and there  
10 was no objection before, but -- so for the moment  
11 I would just reserve the possibility that we might  
12 want to, to obtain further information on that  
13 subject, but I wouldn't want to do anything  
14 further with that right now.

15 BY MR. HELLER:

16 Q Just a couple more short questions. At  
17 Dr. Woodcock's deposition she was asked the  
18 following about you. She said, "Curt" -- the  
19 particular documents signed by you and Jonca Bull,  
20 she was asked on Page 158 of her deposition, "And  
21 who are they?" You and Jonca Bull. And she  
22 answered, "Curt was a medical officer, maybe the

0211

1 Deputy Director within the OTC Division, and Jonca  
2 was his supervisor, head of the -- the Office  
3 Director that oversaw that Division." Question:  
4 "So is it fair to say that Dr. Rosebraugh is about  
5 five levels below you in the chain of command at  
6 FDA?" Answer: "When I was head of CDER?"  
7 Question: "Yeah." Answer: "Or now?" Question:  
8 "When you were head of CDER." Answer: "All

9 right. Let me count on my fingers. One, two,  
10 three, four levels." Question: "Four levels  
11 below?" Answer: "Depending how you count."

12 So I think Dr. Woodcock was testifying  
13 that you were four levels below her in the chain  
14 of command at FDA, and my question is: Does your  
15 placement in the chain of command at FDA, is that  
16 any indication of the quality of your scientific  
17 work, do you think?

18 A Well, perhaps we should ask the lawyers  
19 if they always agree with the Attorney General and  
20 that's an indication --

21 Q I don't think they're going to answer  
22 that question, but does the rank system, is that

0212

1 an indication within the FDA of sort of the  
2 quality of scientific work?

3 MR. WARSHAWSKY: Object to the form of  
4 the question. "Quality" is --

5 BY MR. HELLER:

6 Q Or the competence of the scientist in  
7 question?

8 A I think you'd have to ask Dr. Woodcock  
9 her opinion. My opinion is no.

10 Q I was just asking for your opinion.

11 A Oh.

12 MR. HELLER: Let me just see if I have  
13 anything else here on my piece of paper.

14 Nothing else. Thank you,  
15 Dr. Rosebraugh, for your time.

16 MR. WARSHAWSKY: No further questions.

17 THE VIDEOGRAPHER: Here marks the end of  
18 Videotape Number 3 in the deposition of Curtis  
19 Rosebraugh, M.D. Going off the record, the time  
20 is now 3:57 p.m. Thank you.

21 THE WITNESS: Thank you.

22

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1 (Signature having not been waived, the  
2 confidential videotaped deposition of CURTIS J.  
3 ROSEBRAUGH, M.D., was concluded at 3:57 p.m.)  
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3 ACKNOWLEDGEMENT OF WITNESS  
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5 I, Curtis J. Rosebraugh, M.D., do hereby  
6 acknowledge that I have read and examined the  
7 foregoing testimony, and the same is a true,  
8 correct and complete transcription of the  
9 testimony given by me, and any corrections appear  
10 on the attached Errata sheet signed by me.  
11

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1 ERRATA SHEET

2 IN RE: TUMMINO V. VON ESCHENBACH

3 RETURN BY:

4 PAGE LINE CORRECTION AND REASON

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E R R A T A S H E E T

1 IN RE: TUMMINO V. VON ESCHENBACH

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3 CERTIFICATE OF SHORTHAND REPORTER -- NOTARY PUBLIC

4 I, Laurie Bangart-Smith, Registered  
5 Professional Reporter, the officer before whom the  
6 foregoing deposition was taken, do hereby certify  
7 that the foregoing transcript is a true and  
8 correct record of the testimony given; that said  
9 testimony was taken by me stenographically and  
thereafter reduced to typewriting under my  
supervision; and that I am neither counsel for,  
related to, nor employed by any of the parties to  
this case and have no interest, financial or  
otherwise, in its outcome.

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IN WITNESS WHEREOF, I have hereunto set  
my hand and affixed my notarial seal this \_\_\_\_\_  
day of \_\_\_\_\_, 2006.

My commission expires: February 3rd, 2010

\_\_\_\_\_  
LAURIE BANGART-SMITH  
NOTARY PUBLIC IN AND FOR  
THE STATE OF MARYLAND