

mcclellan

0001

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

4	ANNIE TUMMINO, et al.,)	
5	Plaintiffs,)	
6)	Civil Action No.
7	v.)	05-CV0366(ERK/VVP)
8	ANDREW C. vonESCHENBACH, as Acting)	
9	Commissioner of the Food and Drug)	
10	Administration,)	
11	Defendant.)	

VIDEOTAPED DEPOSITION OF
MARK MCCLELLAN, M.D., Ph.D., MPA
Washington, D.C.
Tuesday, June 13, 2006
9:41 a.m.

Job No. 1-80011
Pages 1 - 323
Reported by: Carl W. Girard, Notary Public

0002

Videotaped deposition of MARK MCCLELLAN, M.D.,
Ph.D., MPA, held at the:

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
200 Independence Avenue, S.W.
Washington, D.C. 20201

Pursuant to subpoena and notice before Carl W.
Girard, Notary Public within the District of
Columbia.

0003

A P P E A R A N C E S

ON BEHALF OF PLAINTIFFS:
SIMON HELLER, Esquire
and SANFORD M. COHEN, Esquire
CENTER FOR REPRODUCTIVE RIGHTS
120 Wall Street
New York, New York 10005
(917) 637-3616

ON BEHALF OF DEFENDANT AND WITNESS:
F. FRANKLIN AMANAT, Ass't U.S. Attorney
U.S. DEPARTMENT OF JUSTICE
One Pierrepont Plaza

mcclellan

15 Brooklyn, New York 11201
16 (718) 254-6024
17 and
18 STEVEN M. WARSHAWSKY, Ass't U.S. Attorney
19 147 Pierrepont Street
20 Brooklyn, New York 11201
21 (718) 254-6060
22 and

0004

1 A P P E A R A N C E S (continued)
2 KAREN E. SCHIFTER
3 ASSOCIATE CHIEF COUNSEL
4 FOOD AND DRUG ADMINISTRATION
5 5600 Fishers Lane GCF-1
6 Rockville, Maryland 20857
7 (301) 827-1152
8
9 ON BEHALF OF BARR PHARMACEUTICALS, INC. and
10 DURAMED RESEARCH, INC.:
11 ANA C. REYES, Esquire
12 WILLIAMS & CONNOLLY, LLP
13 725 12th Street, N.W.
14 Washington, D.C. 20005
15 (202) 434-5276
16
17
18
19
20
21
22

0005

1 A P P E A R A N C E S (continued)
2 ALSO PRESENT:
3 ON BEHALF OF PLAINTIFFS:
4 NAN STRAUSS, Esquire
5 CENTER FOR REPRODUCTIVE RIGHTS
6 VIVIEN LABATON
7 BLACKMUN FELLOW
8 CENTER FOR REPRODUCTIVE RIGHTS
9
10 SHELBI D. DAY, Esquire
11 SOUTHERN LEGAL COUNSEL, INC.
12 1229 NW 12th Avenue
13 Gainesville, Florida 32601-4113
14 (352) 271-8890
15
16 and
17
18 BETH JORDAN, Plaintiff
19
20
21
22

0006

1		INDEX OF WITNESS			
2	WITNESS		D	X	RD
3	MARK MCCLELLAN		22	253	316
4					
5		* * * *			

6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22

INDEX OF EXHIBITS

NO.	DESCRIPTION	IDENT
1	Group of documents	32
2	News Articles dated 4/21/03	301

* * * *

0007

P R O C E E D I N G S

1 MR. HELLER: So, I guess maybe we should
2 begin by stating our appearances for the record,
3 Simon Heller for the Plaintiffs.
4 MR. COHEN: Sanford Cohen.
5 MS. STRAUSS: Nan Strauss, attorney For
6 the plaintiffs.
7 MS. LABATON: Vivien Labaton for the
8 plaintiffs.
9 MS. DAY: Shelbi Day for the plaintiffs.
10 MS. JORDAN: Beth Jordan for the
11 plaintiffs.
12 MR. AMANAT: Frank Amanat here for the
13 defendant and also counsel for the witness today.
14 MR. WARSHAWSKY: Steven Warshawsky for the
15 defendant.
16 MS. REYES: Ana Reyes, Williams &
17 Connolly, LLP for Duramed Research, Inc. and Barr
18 Pharmaceuticals, Inc.
19 MR. AMANAT: We also have two law student
20 interns from our office here with us today: And
21 Karen Schifter from the Food and Drug Administration

0008

1 is not in the present room at present but also will
2 be here at counsel table momentarily.
3 MR. HELLER: Of course, we have the
4 deponent here.
5 MR. AMANAT: And the witness is here as
6 well.
7 MR. HELLER: Before we begin the
8 deposition, a couple of things arose before we
9 started that I wanted to put on the record.
10 Mr. Amanat, I think you indicated that the
11 depositions of Drs. Bull and Jenkins scheduled for
12 June 21st would be held at the Wilbur Cohen Building
13 at 330 independence Avenue S.W.?
14 MR. AMANAT: That's correct. That's the
15 adjacent building right next door.
16 MR. HELLER: In room 5336?
17 MR. AMANAT: That's correct.
18 MR. HELLER: You also then handed me six
19 notices of deposition for certain individual
20 plaintiffs as well as 30(b)(6) deposition notices for

mccllellan

21 two organizational plaintiffs at which point I said
22 something to the effect that we would have liked you

□
0009

1 to have conferred with us prior to announcing dates
2 for those depositions.

3 I think you indicated that you would be
4 amenable to changing the dates that you noticed if
5 these dates were not convenient for either counsel or
6 the deponents; is that right?

7 MR. AMANAT: That is correct, Simon, and I
8 can also say we have consulted with you in
9 propounding our discovery requests the exact same
10 extent that you've consulted with us in propounding
11 yours.

12 MR. HELLER: Actually, that's not correct,
13 because with respect to depositions we scheduled, for
14 example, Dr. McClellan's deposition has been in the
15 works since February of this year. We accepted your
16 representation that he was available at the earliest
17 June 13th, which is today. We scheduled his
18 deposition for the date and time and place that you
19 told us was most convenient for him.

20 We did the same with Dr. Crawford,
21 although you no longer represent him. We did the
22 same with Drs. Galson and Woodcock; that is, we

□
0010

1 scheduled them in advance with you as a matter both
2 of respecting The Court's order directing is to
3 schedule those in a manner that was convenient for
4 those witnesses but also as a matter of courtesy.
5 You have not extended that same courtesy.

6 I've already indicated to you during the
7 week of July 6th I will be on vacation, which is one
8 of the dates you've scheduled or you've noticed
9 depositions for.

10 I also indicated to you that I will check
11 with my clients about their availability. I have no
12 idea when they'll be available. They are busy
13 people, and you indicated, I think, that some of the
14 individual plaintiffs were college students who
15 probably have a lot of time on their hands; is that
16 right.

17 MR. AMANAT: Well, at least two of them
18 seem to be.

19 MR. HELLER: I would appreciate in the
20 future if you intend to demean, insult or
21 characterize my clients, you just do so on the
22 record.

□
0011

1 MR. AMANAT: Mr. Heller, that was not
2 intended to be an insult. It was meant to be a
3 statement that you said they were busy, and, as I
4 understand, at least a couple of them are college
5 students who may well be on summer break this summer,
6 so...

7 MR. HELLER: Where do you have that
8 understanding from, that they're college students on
9 break?

10 MR. AMANAT: Whatever. Do you have an
11 objection -- if you have an objection to our noticing

mcclellan

12 this depositions, it is certainly your prerogative to
13 notify the magistrate judge. That's your
14 prerogative. These individuals are parties. They
15 are signatories to the Complaint, which has been
16 filed in this case. They are plaintiffs.

17 We have not in noticing the depositions,
18 we have not taken any steps which are either contrary
19 to the normal practice in noticing depositions nor
20 have we taken any steps which have been contrary to
21 any order of The Court.

22 If we have offended you in noticing these

□
0012

1 depositions, without having conferred with you in
2 advance about the date, then I apologize. But, as
3 I've indicated repeatedly, we are willing to be
4 flexible on the dates and to accommodate your
5 schedule and the witnesses' schedule, and, if you
6 have an objection, it's your prerogative to file an
7 objection.

8 But, you know, I certainly don't
9 understand why you feel the need to have this lengthy
10 colloquy on the record about these deposition
11 notices.

12 MR. HELLER: Because I think it indicates
13 a lack of courtesy, and you made statements about my
14 clients about which you have no basis, as far as I
15 know, unless you've talked to them.

16 MR. AMANAT: I have not talked to your
17 clients, Mr. Heller. You know that only too well.

18 MR. HELLER: I don't think I've made any
19 disparaging comments about your clients, have I?

20 MR. AMANAT: I suppose that's an open
21 question, Mr. Heller, but (laughter) I think...

22 MR. HELLER: If I have, please tell me.

□
0013

1 MR. AMANAT: I think that's a matter -- at
2 that time open to significant debate, but regardless
3 of what comments you and your colleagues may have
4 made about my clients or government officials during
5 the course of this litigation, it certainly was not
6 my intention to disparage your clients.

7 I'm simply observing that they are
8 plaintiffs that as plaintiffs who have brought suit
9 in the Eastern District of New York, by virtue of the
10 fact they are parties to the case, they have an
11 obligation to make themselves available for a
12 deposition in the case, and the convenience of a
13 party-plaintiff is typically not a factor which is
14 taken into account in determining whether and when
15 they are to be deposed.

16 By the mere fact that they are plaintiffs
17 and that they have chosen to attach their names to a
18 Complaint filed in the Federal District Court civil
19 action, they, by that very act, have agreed to make
20 themselves available for deposition at times which
21 are convenient to the attorneys in the case.

22 If they wish to voluntarily dismiss

□
0014

1 themselves as plaintiff, that's certainly their
2 prerogative but as long as they're plaintiffs, as

mcclellan

3 long as they're plaintiffs, regardless of how busy
4 they are, they need to make themselves available.

5 MR. WARSHAWSKY: Mr. Heller, may I just
6 make one request? In terms of arranging for
7 convenient dates for these depositions, there are six
8 depositions we currently like to take. There are
9 limits to how long discovery is going to extend in
10 this case. I think that the prime consideration is
11 the convenience and availability of the witnesses
12 themselves.

13 I would note there are five attorneys on
14 your side of the table today that at every
15 deposition -- some of the depositions there have been
16 a different mix of attorneys who have appeared, and
17 so the unavailability of any particular attorney on
18 your side, I would submit, is not itself reason to
19 reschedule depositions.

20 I think that the witnesses' availability
21 is the prime consideration and the availability of
22 some involved relevant attorneys from your office, I

□
0015

1 think is the other consideration. I don't think the
2 consideration is the availability of all or a
3 particular attorney from your office.

4 MR. AMANAT: I concur in that, and let me
5 just add, it is our intention to complete these
6 depositions, and all depositions in this case, by the
7 end of July. You had indicated that you would
8 propose dates in August for some of these
9 depositions.

10 You can propose whatever you want. But it
11 is our preference, and we would be fully prepared to
12 state this preference before the magistrate judge if
13 the need to do so arises to complete these
14 depositions before the end of July.

15 MR. HELLER: Thank you. I'll just say one
16 more thing and we can move on to the other
17 preliminary matters which I think you said there
18 might be others.

19 I absolutely agree with you that by being
20 a party in a civil case, party subjects herself or
21 himself to deposition. I would note that you have
22 not taken the deposition ever about the party you

□
0016

1 represent.

2 We certainly will make the plaintiffs
3 available for depositions before the close of
4 discovery. I don't know when the close of discovery
5 will be yet. I suspect that will be determined at
6 the June 29th status conference or might be
7 determined then.

8 Obviously, we'll make them available as
9 soon as we can, as soon as they can be made
10 available. However, I don't think it's correct that
11 a person by being a plaintiff in a case subjects
12 themselves to being deposed at any time at the
13 convenience of opposing counsel.

14 MR. AMANAT: That's not what I said.
15 That's not what I said.

16 MR. HELLER: I didn't say that's what you
17 said. Other preliminary matters want to address?

mcclellan

18 MR. AMANAT: I take it you've received our
19 discovery request which we propounded on Thursday?

20 MR. HELLER: Yes.

21 MR. AMANAT: I take it you've also by now
22 received the Agency's decision on the Citizen

0017

1 Petition that is in issue in this case which was
2 issued on Friday.

3 MR. HELLER: Yes.

4 MR. AMANAT: Let me tell you as a courtesy
5 how we intend to proceed now that the Citizen
6 Petition -- now that the Agency has rendered a final
7 Agency decision on the Citizen Petition, and offer
8 proposal for future action.

9 It is our intention to move to dismiss the
10 Third Amended Complaint for lack of subject matter
11 jurisdiction on grounds that your unreasonable delay
12 claim is now moot, on grounds that you lack standing
13 to challenge the administrative proceedings with
14 regard to the SNDA, and on other jurisdictional
15 grounds as well.

16 We anticipate that one possible scenario
17 which may eventuate is that upon our filing of such a
18 motion you would file a Fourth Amended Complaint
19 challenging the final Agency decision on the Citizen
20 Petition under Section 706(2) of the APA. I may be
21 wrong in that regard but we think that is certainly
22 one possibility.

0018

1 And I want to make it clear that we are
2 not afraid of defending the substantive merits of the
3 Agency's final Agency decision on the Citizen
4 Petition, and in order perhaps to save the parties a
5 great deal of time briefing jurisdictional issues
6 which may be overtaken by an amendment to the
7 pleadings, what we would propose and we intend to
8 suggest this to The Court in fact, is that you all
9 file a Fourth Amended Complaint which does not
10 contain the claim of unreasonable delay and which
11 contains only a challenge to the Agency's final
12 Agency decision on the Citizen Petition, and does not
13 challenge any of the interlocutory decision-making
14 process in the FDA's process with regard to Plan B to
15 date.

16 If you were to propose the filing of a
17 Fourth Amended Complaint which contains that content
18 or content of that nature, we would not oppose the
19 motion to amend the Complaint, and we would be
20 prepared to move expeditiously after the amendment of
21 the pleadings to cross-motions for summary judgment
22 on the cause of action which would be asserted in

0019

1 your Fourth Amended complaint with regard to the
2 Citizen Petition response.

3 This is the course of action we intend to
4 propose to the district judge as to how the parties
5 should proceed in this case. We would like to
6 represent to The Court that we have discussed with
7 you and you all are amenable to proceeding in this
8 fashion, but before doing so we wanted to determine

mcclellan

9 whether in fact you are prepared to proceed in that
10 fashion.
11 MR. HELLER: We'll consider your proposal
12 and get back to you about it.
13 MR. AMANAT: Fair enough.
14 MR. HELLER: Any other preliminary
15 matters?
16 MR. AMANAT: No other.
17 MR. HELLER: I guess we're ready to start
18 the deposition. Is the videographer ready.
19 THE VIDEOGRAPHER: Yes, I am.
20 (End of preliminary matters.)
21
22

0020

1 THE VIDEOGRAPHER: Here begins Tape No. 1
2 in the deposition of Mark McClellan, M.D., Ph.D., MPA
3 in the matter of Annie Tummino, et al. versus Andrew
4 C. vonEschenbach as Acting Commissioner of the Food
5 and Drug Administration, pending in the United States
6 District Court, Eastern District of New York, case
7 No. 05-CV-366.
8 Today's date is June 13, 2006.
9 The time is 9:41 a.m.
10 The video operator today is Cali Day of
11 L.A.D. Reporting. This video deposition is taking
12 place at the 200 Independence Avenue, S.W.,
13 Washington, D.C., 20201.
14 Would counsel please identify themselves
15 and state whom they represent.
16 MR. HELLER: Simon Heller for the
17 plaintiffs.
18 MR. COHEN: Sanford Cohen for the
19 plaintiffs.
20 MS. STRAUSS: Nan Strauss for the
21 plaintiffs.
22 MS. LABATON: Vivien Labaton for the

0021

1 plaintiffs.
2 MS. DAY: Shelbi Day for the plaintiffs.
3 MR. AMANAT: Franklin Amanat, counsel for
4 the defendant, the Commissioner of Food and Drugs and
5 also counsel for the witness here today.
6 MR. WARSHAWSKY: Steven Warshawsky for the
7 defendant.
8 MS. SCHIFTER: Karen Schifter for the
9 defendant.
10 MS. REYES: Ana Reyes, Williams &
11 Connolly, LLP for Duramed Research, Inc. and Barr
12 Pharmaceuticals, Inc.
13 THE VIDEOGRAPHER: The court reporter
14 today is Carl Girard of L.A.D. Reporting. Will the
15 reporter please swear in the witness.
16
17
18
19
20
21
22

0022

1 MARK MCCLELLAN
2 the deponent herein, being called as an adverse
3 witness, by and behalf of the Plaintiffs, pursuant to
4 the Federal Rules of Civil Procedure, being by me
5 first duly sworn, as hereinafter certified, was
6 examined and testified as follows:

7 DIRECT EXAMINATION

8 BY MR. HELLER:

9 Q Good morning.

10 A Good morning.

11 Q How are you good?

12 A I'm good. I saw that exchange so that's
13 why I decided to go to medical school (laughter.)

14 Q You don't have those kind of heated
15 controversies over the operating table, I guess.

16 Dr. McClellan, have you ever had your
17 deposition taken before?

18 A Not in the matter like this. I've been an
19 expert witness in a case before coming into federal
20 government service and I did a deposition in that
21 context.

22 Q Basically, the process is I'm going to ask

□
0023

1 you a series of questions. I'd like to answer them
2 if you're able -- if you understand my question, give
3 me an answer to it. Your lawyer may object to
4 questions.

5 In general, we might have a short
6 discussion of the objection, but unless he instructs
7 you not to answer a question, you generally, or I
8 withdraw the question, generally you should answer
9 the question anyway.

10 A Right.

11 Q I may ask questions that you don't
12 understand. Please let me know if I do that. And
13 also it is very important, especially for the court
14 reporter, for you to give verbal responses. We tend
15 in conversations to say uh-huh or uhm-uhm, I've
16 already making a problem for him. If you can say yes
17 or no and give verbal answers whenever possible.

18 Also, if you need clarification of a
19 question, let me know. If you want to take a break
20 at any point, let me know and we can take a break,
21 you know, right then or shortly thereafter; is that
22 all right?

□
0024

1 A That's fine.

2 Q Can you tell me in general what you did to
3 prepare for today's deposition?

4 A Well, I had a couple of meetings with
5 counsel who are here at the table: One I guess about
6 a week and-a-half or so ago, and one yesterday. We
7 also had a phone conversation for an hour or so in
8 between those two meetings.

9 I looked at some of the documents that had
10 been entered into the Court record that seem from
11 discussions with counsel are likely to come up here
12 at the deposition. I think those were the main
13 things.

14 Q Have you communicated with government

mcclellan

15 officials other than counsel about this deposition?
16 A Early on, when the deposition was getting
17 set up, I talked also with counsel's office in the
18 Department of Health and Human Services about it.
19 That was Paula Stanard, who is the acting general
20 counsel and Demetrius Cazazokas who worked with her
21 as well, in the back and forth so I guess up
22 administratively, also worked through my special

0025

1 assistant, Mary-Lacey Reuther, and aside from that no
2 detailed conversation or discussions about the
3 deposition.

4 Sorry, one more thing, did talk briefly
5 with my press office and legislative director just in
6 case there were questions that we got from the press
7 or from members about what might be coming up with
8 the deposition, but, again, that was not any
9 substantive discussion of what going to be said here
10 in the proceedings.

11 Q Aside from the deposition itself, have you
12 had any discussions with anyone about this lawsuit?

13 A As a general matter or in preparation for
14 this deposition?

15 Q No, as a general matter aside from
16 preparation for the deposition.

17 A Sure. In -- about the lawsuit in
18 particular?

19 Q Yes.

20 A I think earlier on when the lawsuit was
21 filed, I probably had brief discussions, again, with
22 our press office, our legislative office about

0026

1 questions or issues that might come up. Those did
2 not get into any substantive details, just sort of
3 quick, high level, what is involved in this case,
4 what would we likely want to say if asked about it.

5 Q Okay. What sorts of questions did they
6 think or did you think would come up?

7 A Well, mainly the ones that I've seen you
8 and others talking about in the press. Whether I
9 talked or had secret meetings with people about this,
10 things like that.

11 Q What did you decide to say what you would
12 say in response to such questions?

13 A In thinking about it, we decided that what
14 I've been saying all along is the right thing to keep
15 saying because it's the truth, which is that -- this
16 matter was decided at the Agency almost two months
17 after I left the Agency; that I didn't make a
18 decision or direct a decision about Plan B; that I
19 was briefed on this decision and got information on
20 it very similarly to how done in any other important
21 issues before the Agency, and did I ask questions
22 about the science underlying the potential decisions

0027

1 or options that the Agency might consider, things
2 like that.

3 Q Okay. You received, I believe, or maybe
4 your agent received a subpoena for you to attend
5 today's deposition; is that right?

mcclellan

6 A I'm sure my lawyers did. I'm not --
7 Q You haven't seen a subpoena?
8 A I don't recall seeing -- that's not the
9 kind of thing they would have given me in
10 preparation. Much more relevant to my preparation
11 were documents from meetings I was involved in,
12 things like that.
13 Q Your lawyers provided me with some
14 documents this morning --
15 A Uh-huh.
16 Q -- that I believe are responsive to a
17 subpoena?
18 A Yes, that --
19 Q -- for certain documents?
20 A Right, a subpoena for me to appear.
21 Q There was both, a subpoena for you to
22 appear here today and a subpoena for documents, and

0028

1 these -- they gave us certain documents today, about
2 12 pages of documents?
3 A Uh-huh.
4 Q Are those documents that you provided to
5 them that you believed were responsive to the
6 subpoena?
7 A Yes.
8 Q Are there any other documents that you're
9 aware of that would be responsive to the subpoena?
10 A None that I'm aware of responsive to the
11 subpoena request as it was explained to me by my
12 lawyers. As I initially understood it, the initial
13 wording was very, very broad.
14 I think they had some further discussions
15 with you about what they -- what was requested in
16 response. And I looked through the files in my
17 office, talked with my immediate staff to see if they
18 knew of anything else that would be responsive and
19 available and that's what we provided.
20 Q What is your view, your opinion, of
21 whether individuals in the United States should have
22 a right to use contraception?

0029

1 MR. AMANAT: Objection. You can answer
2 the question.
3 A Contraception is very important for public
4 health, and it's something that's been a public
5 health priority for physicians, for government
6 agencies, for others.
7 BY MR. HELLER:
8 Q My question was do you believe that
9 individuals in the United States should have a right
10 to use contraception?
11 A I think if it's an important public health
12 goal, then it's something that we -- that the country
13 makes available, yes, it's an important right.
14 Q Do you believe that persons under the age
15 of 18 should have a right to use contraception?
16 A People should have a right to use
17 contraception when they can use it safely and
18 effectively. And providing safe and effective
19 contraception has been an important public health
20 priority for the federal government for a long time.

21 Q In general, you're familiar with the drug
22 called Plan B; is that right?

0030

1 A Yes.

2 Q What type of drug is that?

3 A It is a progesterone-only drug that, as
4 discussed in the product application, would be used
5 for what's called emergency contraception for use
6 after intercourse but within the intent of preventing
7 a pregnancy.

8 Q Is Plan B an abortive agent in some
9 circumstances?

10 A Well, that's a question that did come up
11 in some of the Agency discussions about this issue,
12 particularly back in 2002 before I arrived at the
13 Agency.

14 The Agency prepared, I think, a detailed
15 briefing memo on the background science and its views
16 about whether it was abortifacient. I asked for that
17 background memo in getting up to speed on this issue
18 when I came to the Agency and seemed to have a pretty
19 complete review of the evidence relating to this
20 question an FDA's conclusion was it was an
21 abortifacient.

22 Q Is that your own conclusion as well?

0031

1 A I didn't have any reason to question FDA's
2 about the matter.

3 Q Is it your conclusion as you sit here
4 today?

5 A What I just said, I don't have any reason
6 to question the FDA's conclusions about the matter I
7 haven't spent a long time thinking about it; I've
8 been a lot busier with issues that were actually
9 before the agencies that I've led.

10 Q Just in terms so that we get the timeline
11 right, during what period of time were you at the
12 FDA?

13 A I arrived in November of 2002 after senate
14 confirmation and then I left the Agency to move to
15 the Centers for Medicare and Medicaid Services in
16 March of 2004, so it was about a 16-month period
17 between that time.

18 Q Is that the only time you've worked at the
19 FDA, that period?

20 A Yes.

21 Q So let's see. I think there's a copy of
22 the documents you produced, or your lawyers produced

0032

1 to me this morning, that's --

2 MR. HELLER: Do you care which one we mark
3 if I want to have it attached to the deposition?

4 MR. AMANAT: They're all the same.

5 MR. HELLER: We'll mark one copy as I
6 guess --

7 MR. AMANAT: You want to mark it and have
8 the witness have a copy?

9 MR. HELLER: Yes.

10 (Exhibit 1 marked for identification.)

11 BY MR. HELLER:

mcclellan

12 Q Do you want to look those over? I believe
13 those the documents that you produced?

14 A They are. And any in particular you want
15 me the look for?

16 Q Not for the moment. I just want you to
17 tell me whether these are documents that you gathered
18 and have come to me through your lawyer?

19 A Let me double check, and I'm just be
20 looking through them fairly quickly to make sure
21 there's nothing out of line.

22 Q That's fine.?

□

0033

1 A (Witness perusing exhibit.)

2 Okay, those are the ones I provided.

3 Q Thank you. I'll come back to this a
4 little later. I want to ask you first of all, are
5 you familiar with a government entity called The
6 Government Accountability Office?

7 A Yes; I'm familiar with the GAO.

8 Q Do you have an opinion about the GAO,
9 about their work?

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

12 A The GAO has a very important function in
13 our government, address accountability issues, review
14 agency actions, answer questions for members of
15 Congress involved in oversight activities and who
16 care about the evaluation of program performance.

17 As such, I have a lot of interactions with
18 GAO in the programs that I've never seen. The FDA
19 regulates 25 percent of the U.S. economy. That's a
20 huge number of programs which generate a lot of
21 congressional interest.

22 The Centers for Medicare and Medicaid

□

0034

1 Services has a budget of over \$600 billion a year to
2 provide health insurance for more than 90 million of
3 America's neediest senior people to disability
4 children and others that have the most to gain from
5 health care, also, a program that has a lot of
6 interest from members of Congress.

7 We have frequent interactions with GAO,
8 and deal with literally dozens if not hundreds of GAO
9 reports and requests every year in both of those
10 agencies. The Agency has a important very function.

11 We don't always agree with exactly the way
12 the GAO reviews or evaluates our programs. That's
13 the way it works, and there can be reasonable
14 differences of opinions about review methods and
15 analytic methods, and whether the approach taken was
16 the right methodologic approach for the evaluation
17 issue in question, but it's a very important
18 government agency.

19 Q Thank you. If you could turn to the last
20 two pages of Exhibit 1, which are marked, I believe,
21 MBM11 and MBM12?

22 A The exhibit --

□

0035

1 Q Yeah, the exhibit you have in front of
2 you?

mcclellan

3 A (witness complied.)

4 Q This appears to a letter to you from
5 Senator Carl Levin. Is this a letter you received?

6 A Hang on one second (perusing.)

7 Yes; it's I letter that came to my office.
8 When you say received, it was formally delivered to
9 the Centers for Medicare and Medicaid Services on my
10 behalf.

11 Q And sometime after it was received, did
12 you ever read this letter?

13 A At some point after it was received I did.
14 The way that we handle congressional correspondence
15 is it usually goes into a clearance process and given
16 that we get hundreds of congressional requests every
17 month, it may be some time before a particular
18 request gets to me.

19 Q Do you know if you responded in writing to
20 this letter?

21 A I know we have not responded in writing to
22 this letter as of this time. I know there has always

□
0036

1 been some effort to develop a response to this
2 letter, because this letter pertains to, even though
3 it's directed to me at CMS, it pertains to matters at
4 the FDA, and it also pertains to matters that are
5 involved in ongoing litigation as you well know.

6 What that means from my standpoint and my
7 Agency is that there is a more sensitive review
8 process and clearance process to handle any kind of
9 response to the letter.

10 So in addition to the usual time that's
11 required to respond to a congressional inquiry,
12 because this one involved matters of litigation and
13 matters going across multiple agencies, there are
14 simple a lot of people who need the clear and sign
15 off on any official response.

16 Q I believe the letter requests that you
17 make yourself available for an interview with Senator
18 Levin's staff. Have you made yourself available for
19 such an interview up to this date?

20 A As I said, we haven't responded to the
21 letter yet, and I have not made myself available for
22 an interview yet. The letter, it appears, asks the

□
0037

1 questions about three types of issues, and, if you
2 would care to, feel free to go ahead and ask me about
3 any and all of them today. That will help me
4 circumvent the clearance process.

5 Q Maybe it will be help Senator Levin
6 shortcut what seems to be a --

7 A If we can do him a favor, that's great.

8 Q Okay. Do you know on the second page who
9 underlined the first line of text?

10 A I don't.

11 Q Have you contacted or your staff, have
12 they contacted anyone at Senator Levin's office at
13 all just to the say "we got the letter. We're
14 looking at it." Had there been any communication of
15 any kind in response to the letter?

16 A I don't have any particular knowledge of
17 that communication. I would assume that the answer

mcclellan

18 is yes, because usually when these requests come in,
19 there is a process for either letting the office know
20 that we got it, and are taking it under review or
21 sometimes members of Congress or their staffs will
22 call us to follow up to ask about the status of the

0038

1 response. So I would assume there's been some back
2 and forth.

3 They tell us not to make a lot of
4 assumptions in these depositions, but that one I
5 think is pretty safe.

6 Q If you turn to the first page of this
7 Exhibit 1, it seems to be -- actually the first two
8 pages seem to be -- a copy of e-mail correspondence.
9 And it contains what appears to be questions for you
10 or for your staff from the GAO. I guess there's one,
11 two, three, four, five questions?

12 A (Witness perusing.)

13 Q Before I get to those five questions, did
14 you ever schedule or arrange an interview with the
15 GAO regarding Plan B?

16 A Just a second, I want to make sure this is
17 pertaining to what I think it's pertaining to
18 (perusing.)

19 Okay. I'm sorry. Can you repeat the
20 question?

21 Q Sure. Did you ever arrange an interview
22 with the GAO regarding Plan B?

0039

1 A My staff had, I think, discussions with
2 the FDA staff that was lead on responding to the GAO
3 report. This is a report that was primarily directed
4 actions that the FDA, not CMS, what the staff
5 discussions led to was our providing a written
6 response to the GAO, and I am -- I think that written
7 response is at least in draft form is attached to
8 these documents as well.

9 Q My question was did you arrange for an
10 interview?

11 A Well, I think the goal was to try to
12 handle this matter by a written response first. At
13 this time, I was not only at a different agency; I
14 was at a new agency that had a very busy schedule of
15 fall activities, and I think there are also some
16 concerns on the part of the staff at both agencies
17 and perhaps at HHS that, given the fact that agency
18 heads have a lot of other current obligations, it
19 would be better if questions like this directed to
20 the agency heads could be handled in writing and
21 through the usual course of a complete response to
22 the report.

0040

1 So I'm sure that's why the staffs that
2 were working with the GAO staff wanted to handle this
3 by written response if possible.

4 Q So was it a decision -- was the decision
5 to handle it by a written response not your decision
6 but someone else's decision?

7 A I have to tell you I didn't spend a lot of
8 time thinking about this issue at the time. As I

mcclellan

9 said before, we get literally dozens of requests at
10 each agency from GAO each year and, if this is a
11 matter that could have been handled by a written
12 response, that's certainly would I prefer to do;
13 that's less time consuming and disruptive from my
14 schedule than spending more time sitting down with
15 the GAO staff when it might be possible to give them
16 all the information they need through written
17 response and dealing staff-to-staff directly.

18 Q On the first page of this document, do you
19 see in the e-mail sort of at the top --

20 A Uh-huh.

21 Q -- I don't know, tenth line down, if it
22 can arranged despite our delay, it would be helpful

0041

1 to speak with Dr. McClellan on or before August 23.
2 And that's from someone named Marty Gahart. I don't
3 know how you say that name. Do you see that?

4 A Yeah. Hang on (perusing.)
5 Okay, I see a couple of things, Marty is
6 one of my special assistant, Marty Corey as opposed
7 to Marty Gahart or Gay-heart or however that's
8 pronounced. I guess I see a couple of things. First
9 of all, GAO is saying: I apologize for taking so
10 long in getting these to you."

11 So, you know, it sounds like they have
12 been working on this report for a long time before
13 they got around to actually sending us the questions.

14 And then it looks like they're asking for
15 an 11-day turnaround and that's counting two weekends
16 for getting back to them. So it looks like basically
17 five business days to get a response. And I'm pretty
18 sure that our staff said that would be difficult
19 given everything else that was going on at the time.

20 So they didn't get this to us until later,
21 until fairly late in the process it sounds like. And
22 I'm sure they tried to be as responsive as they could

0042

1 under the limited time circumstances.

2 Q The third page of this document, I think
3 is the page that you indicated was at least a draft,
4 if not the written response, to the GAO's questions.
5 Is that right?

6 A Yes.

7 Q And who wrote this? Do you know who wrote
8 this?

9 A This would have been written by --
10 certainly with some input from me with assistance
11 from the staff that was responding at the FDA and
12 maybe some limited assistance from my staff since the
13 staff here wasn't directly involved in the issues at
14 the FDA; it was probably the FDA staff that worked
15 more closely with me on this.

16 I -- I don't have a specific recollection
17 but I would assume it probably included someone like
18 Pat Ronin at the FDA who was I think the Director of
19 Legislation for FDA at the time so he would have been
20 the point person on responses.

21 And I'm also sure that the general
22 counsel's office, probably, again, FDA lead would

0043

1 have been involved as well.

2 Q In the end you adopted this --

3 A In the end, I looked at this, probably
4 tweaked the language a little bit to make sure it
5 accurately reflected my involvement with the product
6 at the Agency, and definitely signed off on it. So
7 in the end, I absolutely take responsibility for this
8 statement.

9 Q Do you view this statement as responding
10 to the five questions, the questions that we looked
11 at before in the e-mail from the GAO?

12 A I do.

13 Q And do you view this page MBM03 as being
14 as forthcoming as you could be to the GAO?

15 MR. AMANAT: Objection. Object to the
16 form of the question.

17 BY MR. HELLER:

18 Q Do you view it as a response where you
19 were giving them as much information as you could
20 provide them with?

21 A I viewed it as giving them information
22 that was responsive to the questions asked.

□

0044

1 Sometimes in these interactions with GAO, if they
2 have a problem with the response or the information
3 they get back, they'll come back to us again and ask
4 for more information.

5 I'm not sure whether that happened in this
6 case or not. I don't think I ever heard back from
7 them again after this initial response, but it's
8 just -- just to add to that, if you have more
9 questions or want more of an expansion on these
10 points in here, I'll be happy to provide that today.

11 Q Right now I'm just inquiring whether you
12 viewed this as responsive to their questions, and I
13 think your answer was yes?

14 A My answer -- well, let me restate my
15 answer to make sure I'm clear about it. We sent this
16 response back to GAO. Often in dealing with GAO, if
17 they have further issues or concerns about the
18 response they get, they will let us know and ask for
19 further clarification or comments.

20 I did not hear back anything from the
21 staff involved in responding to the GAO about whether
22 that was the case here.

□

0045

1 Q Okay. If you turn to page 2, back to page
2 2, I guess, I'm just going to pick one of these --

3 A Back to the e-mail question?

4 Q The e-mail, yeah. If you look at question
5 4; it's a long introduction there to the question.

6 A Uh-huh.

7 Q And then 4a), it's referring to a February
8 18, 2004 meeting, and goes on a little bit and 4 a)
9 says, "what age groups were you concerned about and
10 wanted to have restricted access to Plan B?"

11 A Okay. Do you mind if I read the paragraph
12 here?

13 Q Sure. Please do read it. I want you to
14 read it.

mcclellan

15 A (witness complied.) Okay.
16 Q So 4 a) is about age groups?
17 A Uh-huh.
18 Q In the response you gave on page 3, what's
19 your -- where does that contain the response to that
20 question?
21 A The second paragraph, the response states
22 that "it is the responsibility of the FDA

0046

1 Commissioner to be informed about the underlying
2 science as it relates to the products which FDA
3 regulates. In order to achieve this, the usual
4 practice to obtain this information..." I think
5 there's a missing "is" so "in order to achieve this,
6 the usual practice to obtain this information is
7 either through routine discussions with the center
8 directors or through informational, non-decisional
9 briefings."
10 This was also Dr. McFarland's practice for
11 the Plan B product. That's what happened in that
12 briefing. There were questions about the underlying
13 scientific evidence that would form the basis for the
14 Agency's action on this product, and that's what the
15 questions and the briefing were about.

16 Q Did you at that briefing express concerns
17 about certain age groups having greater access to
18 Plan B?

19 A In every briefing I held with staff on any
20 issue before the Agency, I absolutely asked questions
21 about the underlying science that was very relevant
22 to the decision about the product.

0047

1 In it case it included questions about the
2 quality and completeness and relevance of the
3 available evidence to the use and misuse of the
4 product, the potential use and misuse by early
5 adolescent girls.

6 Q Is there some reason you didn't say what
7 you just said to me in your answer to the GAO?

8 A Well, the GAO had also received, I
9 believe, the whole packet of records related to this
10 product from FDA, which was, since I understand these
11 packets are typically dozens if not hundreds of pages
12 thick. They had a copy of the briefing memo used at
13 this briefing. They had talked to a number of the
14 staff involved at the briefing about the questions
15 that came up, and I think there were even some
16 documentation related to what was said at the
17 briefing.

18 So the GAO had full information on the
19 fact that there were discussions about the quality of
20 the evidence in age groups when they had done their
21 report. If they had thought that the my response was
22 not complete, I would have been happy to hear further

0048

1 follow-up questions from them to provide it, but my
2 guess is they looked at all that evidence and
3 concluded appropriately that there were concerns
4 about young adolescent age groups expressed at that
5 meeting.

6 Q Okay. If you turn to the first page of
7 this document?

8 A (Witness complied.)

9 Q Question 1, has two parts, two questions
10 in it. The second one is, says "Could you please
11 describe your interactions with Dr. Galson and
12 Dr. Woodcock about this issue" referring to Plan B?

13 A Uh-huh.

14 Q Where is your answer to that in your
15 statement to the GAO?

16 A Well, let me go back to my statement.
17 Again, I'll just reread the same part: "It is the
18 responsibility of the FDA Commissioner to be informed
19 about the underlying science as it relates to the
20 products which FDA regulates. In order to achieve
21 this, the usual practice to obtain this information
22 is either through routine discussions with the center

□
0049

1 directors or through informational, non-decisional
2 briefings." In looking over this more closely, I
3 probably should have said in both is pretty typical.

4 As you know, Mr. Galson was the center
5 acting center director at the time, so it is
6 definitely covered in that response that I just read,
7 and Dr. Woodcock is another senior Agency official
8 would typically be and was in this case involved in
9 the briefings and discussions about the issue.

10 Q Again, I have to ask you; they were asking
11 about interactions with Dr. Galson and Dr. Woodcock
12 and your response doesn't even mention those
13 individuals, but yet you viewed it as responsive?

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

16 A Okay. Let me reread my response again,
17 "through discussions with the center directors." Now
18 maybe I should have acting -- is it that I didn't say
19 acting center director or --

20 Q I don't know which center directors were
21 you referring to? How many centers are there?

22 A There are five, and I talked to every

□
0050

1 single one of them about every single important
2 tissue that comes up at the Agency.

3 Q But they were asking you about two
4 specific individuals and you provided them with sort
5 of a blanket statement that you talked to everybody,
6 all the center directors about all important issues.

7 MR. AMANAT: Objection.

8 A Right.

9 MR. AMANAT: You can answer the question.

10 A And that included talk to the center
11 director of the Center for Drugs about the important
12 issues like Plan B before the Center for Drugs.

13 Again, the GAO got a lot of other
14 information on exactly this issue, including they
15 talked directly to Dr. Galson and Dr. Woodcock. They
16 had information on the actual briefings that occurred
17 and what was presented and what was discussed.

18 This was all part of that overall response
19 and, again, I didn't hear back from the GAO on any
20 specific aspects of this question where they wanted

21 more information from me personally.

22 BY MR. HELLER:

0051

1 Q Then if you look further down on page 1,
2 question 2 b), do you agree with the decision to not
3 approve the application? Do you see that at the very
4 bottom of the page?

5 A (Witness perusing.)
6 Okay. Let me read the preparatory and
7 comments.

8 Q Sure.

9 A (Witness perusing.) Okay.

10 Q Where is your response to that in the
11 statement?

12 A That's in the first part my response which
13 is that the decision to issue the non-approvable
14 letter to make the Plan B emergency contraception
15 product available without a prescription was made on
16 May 7, 2004 almost two months after I left the
17 Agency.

18 So I did not express an opinion at the
19 Agency about whether or not the product -- I didn't
20 make a decision or direct a decision about whether or
21 not the product should be approved.

22 Q I think maybe I'm misunderstanding their

0052

1 questions; it's quite possible. I think they were
2 asking whether you agreed with the decision, not you
3 made the decision?

4 A I was not at the Agency when the decision
5 was actually made to -- I think determine fully
6 whether I agreed with it or not. I probably would
7 have needed to review the final decision memo
8 closely, would have needed to hear any final input
9 from the staff, and at this time in May 2004 I was no
10 longer there to do those things.

11 I was running another Agency that was
12 quite busy with some new initiatives as well. Again,
13 if you think that there's more that I should say
14 about this I'll be delighted to do it now. Just ask
15 me what else you want me to say.

16 Q We'll get to that.

17 A Or ask me what else you want me to
18 analysis, I should say. I'm not going to tell you
19 everything you want me to say.

20 Q Well, I don't expect that. If you turn
21 back to page 2 of this Exhibit 1, the fifth question
22 asks, "Did you read the application reviews written

0053

1 by staff from the Office of Drug Evaluation 3 and the
2 Office of Drug Evaluation 5 or by the director of the
3 Office of New Drugs. Did you have any comments or
4 concern -- it seems to trail off there that question.

5 It seems to me, as I read that question,
6 this is sort of yes -- the answer would be yes, I
7 read them; no, I didn't read them, or I read some of
8 them and not others.

9 Where is your response to that question in
10 your response to the GAO?

11 A Well, the answer after the fact is, no, I

mcclellan

12 didn't, because I don't think those were even written
13 at the time when I was at the Agency or certainly
14 didn't see those detailed reviews while I was at the
15 Agency.

16 But, again, in terms of my answer to the
17 question, that goes back to usual practice. It was
18 not my usual practice to read staff-level reviews
19 that had not gone through the usual Agency clearance
20 process, and certainly it wasn't my usual practice to
21 read them when they weren't written until after I
22 left the Agency.

□

0054

1 Q Okay. All right.

2 A Again, if you've got more, Simon, you want
3 to the hear about these questions, I'm happy to
4 answer them.

5 Q Did anyone outside -- did this response,
6 which is page 3, was it approved by anyone higher up
7 than you or outside the FDA or CMS?

8 A I don't know. Again, I was dealing
9 directly with the -- the FDA staff was lead on
10 providing the responses to the GAO for this
11 particular GAO analysis, and I worked -- provided
12 this response to them.

13 As I understand it, the usual process for
14 clearance, especially for something like this, might
15 involve going through the again counsel's office as
16 well, but I didn't have any direct interaction with
17 them about clearing this response.

18 Q So you don't know whether this was cleared
19 by someone else outside FDA?

20 A I don't. I think that would be a good
21 question for the FDA staff and those involved in FDA
22 who were lead on this response. CMS was peripherally

□

0055

1 involved because I was over at CMS; I had left Agency
2 at the time.

3 Q Who was lead on this response at FDA?

4 A My recollection is that it was Pat Ronin
5 in the legislative office at FDA. That's who I spoke
6 with. Whether that's the lead person or not, you
7 know, you probably have to ask them.

8 Q Do you know -- are you generally aware
9 that an SNDA was filed for Plan B to switch it to
10 over-the-counter status in 2003?

11 A I think the SNDA was -- yes, it would have
12 been April 2003, right.

13 Q I think that's right.

14 A Yes.

15 Q You're aware that happened?

16 A Yes.

17 (The following was marked protected testimony
18 and is excluded from the main transcript.)

* * * *

19

20

21

22

□

0056

1

2

3
4
5
6
7
8
9

10
11 (This concludes the protected testimony
12 portion.)
13 MS. REYES: Mark that question and answer.
14 BY MR. HELLER:
15 Q What was your involvement with the Plan B
16 SNDA?
17 A what do you mean?
18 Q what did you do? what conversations
19 meetings, people you talked to?
20 MR. AMANAT: I'm going to object to the
21 form of the question as compound and vague.
22 A Maybe we could go through some of these

0057

1 piece by piece maybe if I could start ought the
2 outset.
3 BY MR. HELLER:
4 Q Let's see, when you came to the FDA, I
5 guess in November of 2002, did someone -- was there
6 some sort of informational meeting that you got from
7 staff at the FDA about what was going on at the
8 Agency at that time?
9 A I did have a series of orientation
10 meetings, including from the Center for Drugs. The
11 Center for Drugs is handling the largest and most
12 active centers of the highest volume of activity of
13 any of the FDA centers and was handling a large
14 number of important issues at the time.
15 And much of our effort at the beginning of
16 my time at FDA was focussed on identifying ways of
17 making the review process work as efficiently as
18 possible and promoting transparency in it, so a lot
19 of our discussions were around policy processes at
20 the Center.
21 I don't recall in that initial phase of
22 briefings whether I heard specifically about the

0058

1 Plan B impending application. I would have heard
2 about it at some point before the application came
3 in. whether it was at that the initial round of
4 briefings or in one of my follow-up meetings, I met
5 very regularly with leadership of the Center for
6 Drugs for ongoing updates about the Center's
7 activity, and at one or more of those meetings the
8 topic probably came up.
9 Q So CDER -- tell me, this is probably a
10 subset of what they do?
11 A This is a small subset of what they do.
12 They handle literally, you know, 50,000 drug products
13 on the market. They were also in the process of,
14 soon after I arrived, of expanding. We had moved a
15 significant number of biologic products that had many
16 review features in common with drugs over to CDER as
17 well to take advantage of some economies of scale and

mcclellan

18 scope. There are a huge array of ongoing, regulatory
19 and oversight tasks that they're involved in.

20 Q Just focussing on the human drugs that
21 they deal with, among the things they do, am I right,
22 is they review new drug applications?

0059

1 A Yes.

2 Q Is that right? And then they would also
3 look at applications like this SNDA that seek to
4 switch the status of a drug in some way?

5 A Yes. They also review generic
6 applications, so when a patent has expired or when at
7 least the product developer for a generic drug
8 believes that the relevant patents have expired, they
9 review applications for the generics.

10 They are involved in the oversight of all
11 of the manufacturing processes for all of the drugs
12 that are on the market to make sure that the
13 manufacturers comply with up-to-date good
14 manufacturing practices.

15 They are involved in post-market
16 surveillance of drug safety issues and issues related
17 to drug utilization. They're involved in a lot of
18 communication and education activities. Sorry I'm
19 going on.

20 Q No --

21 A Big center with a lot going on.

22 Q -- I'm sure they do a lot of other things,

0060

1 but one thing they definitely do work on is new drug
2 applications?

3 A Yes.

4 Q And at any given moment, they might have
5 how many new drug applications pending? Could it be
6 a hundred or ten? What sort of typical number?

7 A You know, it varies, at various stages in
8 the process, definitely more than ten. And some of
9 them are -- let me take a step back and describe how
10 the drug development process works.

11 For most drugs the companies will bring --
12 will start having contacts with the program well
13 before they submit their application. In fact, we
14 encourage that; we encourage the earlier, in the
15 development process the product developer got in
16 touch with us, the more clear the communications
17 could be and the more clear the understanding could
18 be about getting -- about what was necessary for
19 demonstrating safety and effectiveness.

20 So for many new drugs, product developers
21 would come to us before human testing even occurs or
22 when relatively early stage, you know, so-called

0061

1 Phase I or Phase II clinical trials are going on.

2 That's all before the application is done.

3 Applications would typically come in after
4 Phase III study and then there may be one or more
5 rounds of review to address any remaining concerns
6 about demonstrating safety and effectiveness and
7 reliable manufacturing processes for those drugs.

8 So, you know, you just can't -- I don't

mcclellan

9 know exactly how many drugs were in the, you know, in
10 the application review phase, but I do know that the
11 staff was working with manufacturers on literally
12 hundreds if not thousands of compounds at any one
13 time.

14 Q Of those that the staff is working on, the
15 drugs they're working on, either in any of the ways
16 you've just described, as Commissioner how many of
17 those drug applications or processes would you
18 typically be aware of? You certainly wouldn't be
19 aware or know the whole list of 300 or whatever it
20 may be at one time?

21 MR. AMANAT: Object to the form of the
22 question. You can answer the question if you

□
0062

1 understand it.

2 A Okay. Well, let me give it a try. What I
3 think you meant was how many of those do I
4 individually get briefed up. I got general updates
5 about the times and types of developments across the
6 Agency on a pretty regular basis, so, you know, if
7 there are some compounds based on recombinant DNA
8 techniques for developing cancer vaccines, for
9 example, I'd hear about that class of products.

10 Those were some that were generally not
11 far into the application process; they're still at
12 the development stage, but, you know, for many of
13 these types of products there are novel regulatory
14 issues that come up, because they're treating
15 different kinds of problems; they're dealing with
16 preventing health problem earlier on.

17 So it raises some different kinds of
18 issues of how you evaluate safety and effectiveness
19 compared to, you know, a drug that you take when
20 something clearly goes wrong and you can see in the
21 short term what its impact is on a patient's
22 outcomes.

□
0063

1 In terms of particular drugs that were
2 further along in the process, I did get briefed on a
3 number that were coming through the Agency.

4 Also, I just add to that, remember I
5 oversee five major Centers covering essentially all
6 medical and food products, so I was also getting
7 briefed on important products under review in the
8 other Centers.

9 The Device Center, we had just right
10 around the time that this was going on, we were
11 making decisions about silicon breast implants coming
12 back on the market, going through the same kind of
13 issues there -- advisory committee, briefings for me
14 about how the Agency was planning to proceed, so
15 there was a lot of them.

16 Q Where did you get -- or who gave you your
17 first informational briefing about Plan B?

18 A That would have come from the Center
19 directors, I'm almost certain. I don't have a
20 specific recollection of it. But my recollection
21 generally is that got a basic instruction to the
22 issue from the Center.

□

0064

1 I had a few follow-up questions which I
2 think led them to send me some of the materials they
3 already prepared on issues they already resolved,
4 like issues about the mechanism of action, the Plan B
5 and so forth.

6 And they sent me that kind of information
7 and follow-up. So it would have been from the Center
8 and probably from the Center directors or deputy
9 directors.

10 Q That would have be Dr. Woodcock or
11 Dr. Galson?

12 A Dr. Woodcock or Dr. Galson in all
13 likelihood.

14 Q Why were you interested in the mechanism
15 of action?

16 A Because they gave me a review of what the
17 Agency had been doing to date. They mention that --
18 I believe, they mentioned there had been a Citizen's
19 Petition that was before the Agency, and that they
20 had already done some preliminary work on both that
21 and in working with the company that was interested
22 in submitting an SNDA.

□

0065

1 As part of that they prepared some
2 briefing material also for the then acting
3 Commissioner, that was before I arrived, and so to
4 get up to speed as quickly as possible, it probably
5 would be a good idea for them to let me know what
6 they told him.

7 Q Can you estimate for me, let's say,
8 between November of 2002 and April of 2003 when the
9 SNDA was filed, roughly how often did you talk with
10 either Dr. Galson or Dr. Woodcock about Plan B?

11 A Not very often. There would certainly
12 have been one basic orientation discussion, maybe a
13 follow-up. I think also at that time they probably
14 let me know that for small companies that have drugs
15 on the market, we had a program to exempt them from,
16 I guess it is called the facility fee or the, the
17 establishment fee.

18 So this is a smaller fee than what you pay
19 when you submit a new drug application but it is --
20 it is not a trivial amount of money and for a small
21 company that could be a hardship.

22 we had a program to provide small business

□

0066

1 exception and they probably let me know sometime
2 around the end that the company that, at the time,
3 sponsored Plan B was going to get an exemption from
4 that.

5 Q Did your --

6 A I think that's a couple of conversations
7 maybe. I just really don't recall the details. That
8 was three years ago.

9 Q Did your frequency of communications with
10 Drs. Galson or Woodcock increase after the SNDA was
11 filed or audit remain sort of that level of one or
12 two --

13 MR. AMANAT: Objection. When you say
14 frequency of communications, you mean with regard to

15 Plan B?

16 MR. HELLER: With regard to Plan B, yes.

17 MR. AMANAT: Okay.

18 A Okay. With regard to Plan B, I'm sure
19 they're around the time the application was filed,
20 there would have been an update from them on what
21 exactly came in. You know, what did they know what
22 about what was in the application, what was likely to

□
0067

1 be the course of action from there.

2 And, you know, I don't think it was
3 anything out of the ordinary that was going to be
4 reviewed -- I guess a little bit of out of the
5 ordinary, because it was reviewed by several
6 different offices within CDER. I think early on they
7 told me they expected that this one was going to have
8 an advisory committee meeting to discuss as well.

9 So around the time that the application
10 came in, whether it was, you know, the day of or a
11 days before, a few days after, I don't know, but they
12 would have been given me an update on that.

13 After that time, I don't have any
14 recollection of more frequent meetings, but, you
15 know, I was meeting with Janet and Stephen on a
16 regular basis anyway, and, if something relevant had
17 happened with the application, I'm sure they'd let me
18 know about it.

19 Q Do you know if you sent or received e-mail
20 correspondence regarding Plan B during the time you
21 were at FDA?

22 A I don't think very much, because the

□
0068

1 issues that I usual e-mail about were ones where a
2 particular decision was coming to me, or I meet
3 receive some e-mails in follow-up to questions I
4 asked at a briefing.

5 I think early on I asked is this -- what's
6 the experience of this product in other countries or
7 in the United States, in something other than
8 prescription status. I think they sent me maybe an
9 e-mail update on that.

10 I don't know that -- there's no reason I
11 would have been sending significant number of e-mails
12 on issues that were still being discussed inside the
13 Center and were still being presented to me in terms
14 of the Center's views at the briefings that I had
15 much later on in the year.

16 Q I think you said that probably you would
17 have gotten briefed by CDER --

18 A Uh-huh.

19 Q Director, acting director --

20 A Yes.

21 Q -- within a couple of days of the filing
22 of the SNDA?

□
0069

1 A If not sooner; right.

2 Q Did that also happen when other SNDAs were
3 filed?

4 A It happened every time there was something
5 in the news that I could well be asked about by

mcclellan

6 members of the press or by members of Congress or
7 others in the -- in the government. And this was, as
8 I think was the case, this did get some -- I think
9 the company announced they were filing the
10 application or some other way it made it into the
11 news, and to make sure that I looked like I know
12 what's going on at the Agency, which is always a good
13 thing, they would make sure that I knew about the
14 facts of the submission.

15 Q Did there come a time where Dr. Galson
16 conveyed to you his view that the SNDA should not be
17 approved or was not approvable?

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

20 A You know, I don't think our discussions
21 ever really focussed on that. They focussed on what
22 was the status of the review and then as the Agency

□
0070

1 staff had compiled and reviewed information not only
2 from the application but the Agency staff did some
3 extra work, went the extra mile on this one to try to
4 pull together some other literature.

5 We did the discussion the scientific
6 evidence underlying possible courses of action
7 related to the product.

8 He did express and acknowledge some
9 concerns about the quality of the evidence,
10 particularly for younger girls and for less educated
11 individuals. I don't think he ever told me that he
12 thought the application should not be approved. I
13 mean, that decision didn't happen until after I had
14 left.

15 Q The concerns you just described about
16 younger girls, I think, did you express those
17 concerns to him or did he express them to you or
18 both?

19 MR. AMANAT: Object to the form of the
20 question. Compound. You can answer the question.
21 BY MR. HELLER:

22 Q Which of those three or all three?

□
0071

1 A It probably some of both, and, again, that
2 wouldn't have been in conversations back in April
3 around the time that the application was filed; it
4 would have been conversations much later in the year
5 around the time that I was being briefed on the
6 evidence that was being discussed at the advisory
7 committee and the advisory committee's views and all
8 of the subsequent efforts that the staff had
9 undertaken to try to fill some of the gaps in the
10 available evidence.

11 Q So I guess my question was -- I think
12 you've answered it -- but did you express to him that
13 you had concerns about over-the-counter use of Plan B
14 by younger girls?

15 A The way that our discussions usually went
16 on matters that were being considered by the Agency,
17 was we discussed what concerns were and, you know,
18 what might be done to address those concerns. So I
19 definitely raised some concerns about young girls and
20 the -- about evidence on use and misuse in young

21 girls, and evidence on the findings of the label
22 comprehension study. Is that the question?

0072

1 Q Yes, that's the question. What did your
2 concerns about over-the-counter use of Plan B by
3 younger girls? What had it stem from? Had you
4 reviewed the studies that had been submitted by Barr?

5 A I had reviewed -- for the briefing that I
6 received in December, I reviewed the information
7 prepared for that briefing. It comes in what's
8 called a "Goldenrod" which is a packet of information
9 the Commissioner gets ahead of a briefing to provide
10 an overview and additional background detail on the
11 issues that are discussed in the briefing.

12 I asked questions and discussed these
13 issues with the Agency staff presenting information
14 at that briefing, and then the Agency staff did some
15 further work over the next couple of months leading
16 up to the briefing I received in February of 2004
17 where some of these concerns were discussed in more
18 detail.

19 They did, as the agency staff, always do a
20 very thorough review of all the available
21 information, so it makes for good compilation of the
22 kind of information that I'd want to look at to get

0073

1 familiar with scientific issues on particular drug
2 application or on a particular important issue before
3 the Agency.

4 Q At the time that you reviewed this package
5 of information from, I guess, from within CDER -- is
6 that the source of it, basically?

7 A Yes.

8 Q -- did any of the CDER staff who had
9 written documents in that package of information, did
10 any of them take the view that the data regarding
11 young girls was inadequate?

12 A There was some discussion about it, but,
13 you know, I didn't have a lot of direct interaction
14 with the third and fourth level down CDER staff.

15 (The following was marked protected testimony
16 is excluded from the main transcript.)

* * * *

0074

1
2
3
4
5
6
7
8
9
10
11

12
13
14
15
16
17
18
19
20
21
22

(This concludes the protected testimony portion.)
MS. REYES: I think I need to mark question and answer as confidential.

0075

1 THE WITNESS: Can I just ask on this issue
2 of -- I'm sorry, but the ones that you mark
3 confidential are ones that that end up getting
4 blocked in some way in the depositions and this is --
5 what I just discussed was all, I think is all public
6 record at this point and it is based on information
7 in the briefing.

8 BY MR. HELLER:
9 Q Dr. McClellan, I was just going to say, I
10 think Ms. Reyes is erring on the side of caution and
11 some of what she now says may be marked confidential,
12 we may return to her about later and upon review she
13 may decide it's not confidential if there comes a
14 time that we actually want to file with the Court or
15 use it in some other way that isn't secret. But for
16 know I think she's erring on the side of caution?

17 MS. REYES: Yes.
18 A The reason for the concern is that one of
19 the things that seems to happen after these
20 depositions occur is that portions of the transcript
21 make it out into public discussion.

22 I think an important part for public

0076

1 discussion on this issue is a discussion of the
2 scientific evidence relevant to the Agency's
3 decision-making process, so I guess I'm expressing
4 some concerns about that information being suppressed
5 by the process.

6 Q I actually agree with you? It's not the
7 plaintiffs who are suppressing it, nor do I think
8 it's Barr that is suppressing it definitively. Can't
9 speak for the government. But I think it's -- I
10 would like to also see all the scientific evidence
11 available to the public?

12 MS. REYES: I just like to state for the
13 record, as Mr. Heller said, stated repeatedly that I
14 would be happy to rereview any confidentiality
15 determinations that we made during these depositions.
16 No one has yet asked me to do so. When I do make
17 these confidentiality designations, I'm not just
18 doing it a whim.

19 You discuss Barr's SNDA. You discuss the
20 label study and the comprehension study. And you
21 also discussed the new study which Barr has a right
22 to keep confidential. If you all want to come back

0077

1 me after the deposition, as I said repeatedly, I am
2 happy to rereview the deposition.

mcclellan

3 THE WITNESS: I just want to add that I
4 have the tremendous respect for the importance of
5 commercial confidential information. Without it no
6 product development would ever happen; however, I
7 also think it's important to have the discussion
8 about this case focussed on what was brought up and
9 reviewed about the scientific evidence.

10 And there is a lot of this discussion
11 going on in the Agency at the time that I was there,
12 a lot of very thoughtful and intensive discussion.

13 I appreciate the point that some of this
14 may end up being rereviewed later. As you know, when
15 you talk to the press about an issue, what often
16 matters is what gets out there first -- when you talk
17 to public the issues, what gets out there first, not
18 necessarily what's complete or accurate or a full
19 representation.

20 BY MR. HELLER:

21 Q Again, Dr. McClellan, I'd be happy to have
22 all your answers be fully available to the public.

0078

1 It's not within my control?

2 A Okay. I appreciate that. Thank you.

3 Q Okay. I think you just said that there
4 was a lot of discussion at the FDA about Plan B. Is
5 that what you --

6 A Right, in the briefing -- in the briefing
7 that I had initially about, there's a lot of
8 discussion about the scientific evidence underlying
9 the application. There is a lot of it in the
10 briefing I had; there's a lot of it the advisory
11 committee meeting; there is a lot of it in the
12 follow-up briefing that I had that focussed more
13 extensively.

14 It was really designed to foster detail
15 discussion of the quality of the evidences
16 particularly in young teens in less educated
17 individuals.

18 Q Aside from Dr. Galson Dr. Woodcock in FDA,
19 who else did you communicate with within FDA about
20 the Plan B SNDA?

21 MR. AMANAT: At what point in time,
22 counsel?

0079

1 A That will be helpful.

2 BY MR. HELLER:

3 Q At any point in time.

4 A It might be -- I'm not trying to do your
5 job for you, but it might be useful the divide
6 process into several parts: There is a part while I
7 was the Agency or where I was very much involved in
8 these substantive discussions about the -- about
9 what -- or let's put that a different way -- where I
10 was briefed on the substance of the application.

11 I also had a few discussions with FDA
12 staff subsequent to leaving the Agency, like we just
13 talked about around the GAO response, and that was
14 sort of a different nature. It was kind of
15 responding to particular issues or questions that had
16 come up related to how the Agency was handling the
17 application while I was there.

18 Do you want to cover both --
19 BY MR. HELLER:
20 Q Let's take the time when you were at the
21 FDA?
22 A Okay.

0080

1 Q Aside from Dr. Woodcock and Dr. Galson,
2 who else at the FDA did you communicate with?
3 A I would have had some communications --
4 and if you're talking about all kinds of
5 communications, some communications about it with
6 people in my immediate office, ranging from my
7 personal assistants involved in scheduling a meeting
8 and making sure I got the relevant documents, to my
9 special assistance Mary-Lacey Reuther, Scott Gottlieb
10 in the Commissioner's office would have also had at
11 least limited discussions with the Press Office and
12 our Office of External Affairs, that was headed by
13 Peter Pitt at the time, and I think the relevant
14 press official was Larry Backrick, because, you know,
15 we were getting inquiries from the press and wanted
16 to make sure we were saying the right things to
17 accurately reflect what the Agency was doing at the
18 time.
19 And I probably had some discussions with
20 members of the General Counsel's office about the
21 issue and that would have been Dan Troy and, you
22 know, actually, general counsel, as you probably

0081

1 know, is not technically part of FDA, though they
2 provide us with advice. So I guess that's not really
3 responsive to your question.
4 Q Let me ask you about that last part of
5 your answer, about the discussions --
6 A Sorry. Obviously the people that I talk
7 mostly about, as you mentioned, were Janet Woodcock
8 and Stephen Galson in the context of their role in
9 overseeing and advising the Center for Drugs.
10 And I would have had discussions in the
11 course of the briefings with staff of the Center for
12 Drugs and there may have been -- I don't have the
13 names in front of me -- other people from other parts
14 of the Agency at those briefings as well.
15 Q You indicated in the last part of your
16 current answer that you might have had discussions
17 with the General Counsel?
18 A Uh-huh, yes.
19 Q About Plan B; is that right?
20 A Well, about the status of the --
21 MR. AMANAT: I'm going to instruct the
22 witness not to answer that question.

0082

1 BY MR. HELLER:
2 Q I think you said that in an answer you
3 were giving about communications about Plan B,
4 correct?
5 MR. AMANAT: You can answer the question
6 yes or no but don't reveal the content of any
7 communications you may have had with counsel?
8 A Yes. I think it's very likely that

mcclellan

9 someone from the FDA General Counsel's office was at
10 the briefings I held and would have been at the
11 morning meetings and other meetings where there may
12 have been at least passing discussion, "Hey, there's
13 an advisory committee meeting coming up. We're
14 likely to be asked by the press what's going on
15 there. What are we going to say about it?"

16 And they may have contributed something.
17 As you know, lawyers add a lot of value, I guess, in
18 terms of, you know, what we can and can't say about
19 pending applications, for example.

20 Q I guess let me ask a different question.
21 I'm not sure this will be objectionable or not. Were
22 your conversations with the General Counsel that

0083

1 related to Plan B ones in which you were seeking
2 legal advice or guidance from the General Counsel?

3 MR. AMANAT: You can answer that question.

4 A Not in any general way. The real focus on
5 the application while I was there, the focus at CDER
6 and what they were reporting in to me and what I was
7 hearing about at the briefing was on the scientific
8 evidence on safety, effectiveness of this product as
9 OTC for all of the different populations who might
10 use it.

11 BY MR. HELLER:

12 Q I understand that. What I'm trying to
13 understand is, if you were talking to the General
14 Counsel or communicating with the General Counsel
15 about Plan B in some way and it was not to get legal
16 vice or guidance, were you talking with them about
17 the scientific evidence or something else?

18 A I'm sorry, that's why I don't think I had
19 much in the way of conversations with them because
20 the main focus at the time at the Agency was on the
21 scientific evidence related to the application.

22 Q Is it typical that someone from the

0084

1 counsel's office would attend the types of meetings
2 you've described, I guess there is a December 1 and a
3 February 1?

4 A That would attend --

5 MR. AMANAT: I'm going to object. You can
6 answer the question.

7 A Would attend Commissioner briefing?

8 BY MR. HELLER:

9 Q Yes.

10 A I think it was very, very frequent. I'm
11 not sure if anyone from General Counsel attended the
12 February briefing, because that was very specifically
13 focussed on scientific evidence and scientific
14 evidence only, not any broader issues about what was
15 coming up with the advisory committee meeting and
16 what we would be talking about with the public at the
17 time and so forth.

18 But it would be pretty typical for them to
19 be in a Commissioner's office briefing on those
20 issues both because there might be legal
21 ramifications, you know, what we can and can't say
22 about pending application that we were just

0085

1 discussing a minute ago, and the fact that the
2 General Counsel needs to know what's going on in the
3 Commissioner's office and in the Agency overall for
4 purposes of providing effective counsel.

5 Q Aside from Dr. Galson and Dr. Woodcock, do
6 you recall any -- do you recall any people within
7 CDER who had communications with about Plan B?

8 MR. AMANAT: Objection. Asked and
9 answered. You can answer the question again, doctor.

10 A I do think we've already covered that.
11 About the Plan B SNDA?

12 BY MR. HELLER:

13 Q Yes.

14 A About the Plan B SNDA would have been
15 Stephen and, Stephen Galson and Janet Woodcock plus
16 the discussions with staff when they presented
17 briefings to me.

18 Q Aside from those, for example, did you
19 ever meet with Dr. Jenkins about the Plan B SNDA?

20 A No.

21 Q Did you ever meet with Dr. Ho about the
22 Plan B SNDA?

□

0086

1 A No.

2 Q I'm just trying to get a sense, aside from
3 these briefings which obviously I think probably many
4 people might have spoken at those meetings --

5 A Right.

6 Q -- whether you had any other meetings that
7 you recall with people within CDER other than
8 Dr. Galson and Dr. Woodcock?

9 A The usual course of interactions is that
10 the Center directors work with and, in fact, they're
11 responsible for overseeing their staffs and making
12 sure all the issues ongoing within the Center are
13 being handled in an effective and appropriate way,
14 and part of their responsibilities extend, also, to
15 working with the Commissioner's office on keeping us
16 apprised of what's going on in the Centers, how
17 they're meeting their statutory obligations.

18 So it would be typical for me to meet with
19 Stephen Galson, Janet Woodcock, rather than lower
20 level staff inside the Agency.

21 Q I conducted the deposition of Dr. Galson a
22 few weeks ago -- maybe it is over a month ago now --

□

0087

1 and one of the questions I asked him was whether --
2 I'll read you the question and his response and the
3 "him" here is you, Dr. McClellan. But did you
4 understand him to believe --

5 MR. AMANAT: Could you tell me what page
6 you're reading?

7 MR. HELLER: Sure. It's page 47.

8 MR. AMANAT: Bear with me one second. Let
9 me call it upon on my computer. It is Volume I page
10 47?

11 MR. HELLER: Yes.

12 MR. WARSHAWSKY: Do you have any copies of
13 the transcript for us to look at?

14 MR. HELLER: I have my own copy. You can

mcclellan

15 look at this if you want to.
16 THE WITNESS: Do you have a copy of it?
17 MR. AMANAT: On my computer screen.
18 MR. HELLER: Do you have it there?
19 MR. AMANAT: Page 47, you say?
20 MR. HELLER: Yes.
21 MR. AMANAT: What line?
22 MR. HELLER: 16.

0088

1 A Okay. I'm just going to look on.
2 Q Please do.
3 A Go ahead.
4 Q You may want to read that whole page, but
5 the question I'm referring to is the one where I
6 asked, "But did you understand him," and him here is
7 Dr. McClellan, "to believe that the application
8 should not be approved?"
9 His answer, "Yes. Yeah."
10 My question is on what basis -- do you
11 know of any basis that Dr. Galson would have believed
12 that the Plan B SNDA should not be approved, that
13 that was your belief?
14 MR. AMANAT: I'm going to object to the
15 form of the question. It calls for speculation.
16 MR. HELLER: If he knows of any basis.
17 MR. AMANAT: And I'd ask the witness to be
18 given an opportunity to review the relevant context
19 and the testimony before he answers the question.
20 MR. HELLER: Sure.
21 A I want to go back and read the question.
22 Q Please feel free to.

0089

1 MR. AMANAT: Scroll up and down if you
2 need to.
3 A (Witness perusing transcript.)
4 Okay. What was the question again?
5 BY MR. HELLER:
6 Q My question was, do you have any idea why
7 Dr. Galson would have given that response to my
8 question on line 16 through 18?
9 MR. AMANAT: Same objection. Calls for
10 speculation. You can answer the question.
11 A Okay. Let me -- I had a chance to read
12 through this part of the deposition more closely,
13 those two lines are embedded in what looks like an
14 longer exchange between you and Dr. Galson to try to
15 get a good sense of what kind of discussions were
16 taking place in the Agency and between the Center
17 director and me about the application.
18 what he said in his preceding answer was
19 that -- this is referring to those discussion --
20 "they were about the strength of the science, the
21 planning for the advisory committee, what was
22 happening with getting data from Barr -- and I think

0090

1 that was additional data from Barr in response to
2 staff questioning -- what was going on in the staff
3 analysis and how the reviews were coming out, just
4 typically updating about what was happening."
5 He was very interested in discussing

mcclellan

6 science back and forth as with many, many other
7 issues all the issues that he brought to me.

8 And then there's your two-line answer and
9 then he goes on to say, well, it was clear that it
10 was my decision and that I don't remember if he --
11 this is Dr. McClellan, I guess -- ever expressed it
12 discretely that the application shouldn't be
13 approved.

14 So that's very consistent with my
15 recollection as well, that we had a lot of
16 discussions based on the science, that there were not
17 discussions focussed on, you know, should this,
18 should this application be approved, should this
19 application not be approved.

20 The question is, what does the science
21 show about the right -- sorry, at the bottom. The
22 question is what does the application show about the

0091

1 right course of action an -- an action that the
2 Agency is going to be called upon to defend publicly
3 when it is announced. So that's what we were really
4 focussed on.

5 BY MR. HELLER:

6 Q In preparation for today's deposition,
7 what documents did you review, if any?

8 MR. AMANAT: Objection. Asked and asked.
9 You can answer the question again.

10 BY MR. HELLER:

11 Q I think you gave a general answer about
12 sort of documents.

13 A Yes.

14 Q But specifically what documents did you
15 review, if you know?

16 A Well, it would have included briefing
17 materials that were sent to me in the course of the
18 application, including that briefing that was done of
19 the prior acting Commissioner; would have included
20 calendar entries and e-mails that my counsel thought
21 might come up at this deposition; would have included
22 some of the materials related to the GAO analysis; it

0092

1 did include some -- I'm sorry, I meant to say it
2 would include; these are all did includes --
3 information from the briefings themselves, the
4 background materials and the like.

5 And where there were, you know, specific
6 statements made about me in the press; I think had a
7 copy of the depositions from the previous witnesses
8 as well, and then these documents that we found.

9 I'm not sure this is an exhaustive list
10 but I'm trying to be responsive.

11 Q Unless you had the actual documents that
12 you had in front of you, I wouldn't expect a
13 exhaustive list. You did review Dr. Galson's
14 deposition?

15 A I had access to the whole deposition.
16 That document is I think hundreds of pages long and I
17 don't have a lot of time for reading all kinds of
18 different materials, so I really tried to focus my
19 review.

20 I believe that part of Dr. Galson's -- I

21 may have skimmed through the whole thing, but the
22 part of the Dr. Galson's deposition I looked at more

0093

1 closely would have been issues related to what was
2 showing up in the press because there's a good chance
3 that the press is asking you or talking with you
4 about an issue; they're next going to come to ask us
5 about the same issue, or members of Congress will,
6 and, again, I want to make sure I've got ability to
7 be responsive and accurate if that comes up.

8 I think some of the issues that were
9 highlighted by you publicly in the press around
10 Dr. Galson's testimony had to do with Dr. Crawford's
11 decision-making process with them, so I looked at
12 that in case I was going to get asked about the same
13 thing by the press or by someone else.

14 And I think there was also maybe a press
15 story at the time that talked about my concerns on
16 the Plan B application. So it may have looked at
17 something related to that. I didn't do a detailed
18 review of the deposition, didn't have time for
19 something -- for that much preparation.

20 Q Did someone select portions of the
21 depositions for you to review?

22 A No. I got a copy of the whole deposition.

0094

1 Q How did you know where to look to find
2 these parts?

3 A Flipped through. I think the -- may have
4 had the part about Dr. Crawford, which was part of
5 your press statement at the time highlighted.

6 Q Do you know who highlighted it for you?

7 A It would have been -- it may have been
8 Mary-Lacey Reuther from my staff or -- I would have
9 asked for is "point me to what I'm likely to get
10 asked about in the press from this if there is any
11 press interest or what members of Congress or others
12 who I talked to publicly may ask about this."

13 Q Okay.

14 A I'm not sure that part that we just read,
15 I don't remember going through that --

16 Q You didn't look at that.

17 A -- through that detail.

18 Q Did you become aware at some point that
19 the FDA had issued a non-approvable letter on the
20 Plan B SNDA?

21 A I did. That was public knowledge around
22 May 5th or so or early May of 2004.

0095

1 Q Do you agree with that decision?

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

4 A Well, I mean, I think it's a bit
5 speculative, because -- I'll tell you what. If I was
6 at the Agency what would have happened is that I
7 would have been briefed on the issue, a decision
8 recommendation would have come forward from the
9 Center.

10 If I had any questions or concerns about
11 it, there would have been a follow-up question with

mcclellan

12 the Center leadership and maybe other members of the
13 staff to make sure those concerns were aired, and,
14 then in all likelihood, I'd agree with the action of
15 the Center.

16 I don't recall any time at the Agency
17 where I did not take or support the recommendations
18 of the Center. There are a lot of times where I ask
19 questions about why the Center wanted to go in the
20 direction that it did, and to make sure that we had
21 as good or bullet proof public justification for why
22 the Agency was taking action.

□

0096

1 I'm the one that is going to be publicly
2 accountable for whatever the Agency does even though
3 it's the Center staff and the professional staff, the
4 career staff of the Agency, that's actually making,
5 you know, making the decision, going through the
6 decision process. And that's what would have
7 happened here.

8 I think what I can say is I think it's a
9 reasonable decision based on everything I knew from
10 when I was at the Agency at the time.

11 (The following was marked protected testimony
12 and is excluded from the main transcript.)

* * * *

13

14

15

16

17

18

19

20

21

22

□

0097

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

□

0098

1

2

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

0099

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

0100

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17

(This concludes the protected testimony portion.)

MS. REYES: That has to be marked confidential question and answer.

A That's basically the whole scientific discussion that we had at the Agency.

BY MR. HELLER:

Q Your answer is very helpful because it really does give me a overview of the scientific discussion.

Now I want to ask more specific discussions relating to your answer. Maybe it will be confidential, maybe not; we don't know.

Isn't it true that the FDA has switched a

mcclellan

18 number of drugs from prescription to over-the-counter
19 without having any label comprehension studies at
20 all.

21 MR. AMANAT: Object to the form of the
22 question. You can answer the question.

0101

1 A I don't know the details of OTC switches.
2 when I reviewed issues that were before the Agency,
3 the focus really was on what's relevant for that
4 issue, and a lot of times what's relevant for that
5 issue was FDA's guidance or how FDA had handled
6 similar issues in the past.

7 we never handled an over-the-counter
8 switch of on oral contraception of a high dose oral
9 contraception before, so I don't know. I didn't at
10 the Agency think in those terms, I guess.

11 BY MR. HELLER:

12 Q I think you never have perfect evidence?

13 A Right.

14 Q Tell me if I understand sort of the idea
15 of that right. Let's say you're approving -- the FDA
16 is considering approving a new prescription drug?
17 They might have studies that were done, sort of
18 controlled studies but that isn't perfect evidence
19 because the only perfect evidence would really be
20 actually making it available by prescription and
21 seeing what happens?

22 A well, absolutely, and now with my new hat

0102

1 at CMS where we're really, you know -- this is, I
2 view CMS as sort of the biggest post-market program
3 in the country where we have a lot of issues related
4 to the actual use of treatments and practice.

5 There are certainly a range of issues that
6 you cannot easily study in the premarket setting that
7 are relevant in the post-market study. For example,
8 many drugs are being used in seniors today or people
9 with multiple chronic conditions or minority
10 beneficiaries where there is good reason to think the
11 response may be different and I sure would like to
12 have better evidence on how those drugs work.

13 And we're working very hard now at my
14 current Agency to try to develop better evidence so
15 that we can have effective decisions and effective
16 care for those kinds of patients.

17 Q In the premarketing decisions, like in the
18 over-the-counter switch, you can never really have
19 perfect evidence because perfect evidence would
20 consist, am I right, of making available
21 over-the-counter and seeing what actually happens?

22 A In no premarket regulatory decision, OTC

0103

1 or otherwise, can you have perfect information on
2 exactly what's going to happen when the product is
3 approved.

4 Q So to some degree or another you're always
5 extrapolating from imperfect evidence?

6 A That's right. And the Agency
7 extrapolations, and one way to view some of the
8 things that the Agency, most of the things that the

mcclellan

9 Agency does, at least with drug reviews, is make a
10 decision about the competence of the extrapolation,
11 is there good enough evidence to be confident that
12 the product is going to be used safely and
13 effectively.

14 I guess I would add to that in the context
15 of OTC, there are additional issues that come up.
16 When you're approving a product for prescription use,
17 the key statutory standard is will be it used
18 under -- when it is used under guidance of a health
19 professional, a so-called learned intermediary, will
20 it be used in accordance with the conditions on the
21 label.

22 There's a different standard for OTC

□

0104

1 switches, which is not just what is it going to be
2 used in accordance with the label, but could be
3 misused or misunderstood by individual patients who
4 will be using this product without any benefit of a
5 learned intermediary of any kind; they get it just
6 directly over the counter.

7 Q So as an example of an extrapolation one
8 might make is that, if a drug were available in some
9 other country without prescription but not in exactly
10 the over-the-counter way sense that we have it here,
11 one might try to extrapolate from that somewhat wider
12 use something about how it would -- that drug would
13 function as an over-the-counter product here?

14 A Those there are two -- the caution about
15 that is that in most other countries that have the
16 product available, this product available without a
17 prescription, it's not available purely OTC.

18 It is available behind-the-counter with
19 some kind of interaction with a health professional,
20 pharmacist or otherwise involved, that would be
21 involved in decisions about how that product would be
22 used.

□

0105

1 And that's a very important distinction
2 for true OTC switches. Because an OTC switch, you're
3 basically saying you don't need a learned
4 intermediary at all for a patient to use this product
5 and to avoid misuse of the product.

6 That's different from a behind-the-counter
7 decision. I have a lot of -- personally -- I
8 personally think -- I can say this because I'm an
9 internist and I won't offend my friends too much by
10 saying that I think there a lot of health care
11 decisions that can be made without a lot of direct
12 interaction with a physician.

13 But for many of those decision you sure
14 can get a better result if you got some interaction
15 with a health professional, whether it's a pharmacist
16 or nurse practitioner, somebody running a school
17 clinic; something like that.

18 Q I guess my question was -- and I think
19 you've answered it -- although the circumstances in
20 other countries in behind-the-counter or
21 non-prescription use are different than
22 over-the-counter status in the United States,

□

0106

1 sometimes one might be able to make extrapolations
2 from that non-prescription use in other countries
3 even though they're different?

4 A I think I answered. I think I pointed out
5 that the key further extrapolation is no involvement
6 of a learned intermediary.

7 Q As a matter of just scientific inference,
8 if you had a drug and you were concerned that making
9 it available with fewer restrictions that is, more
10 and more someone could go in and just get it without
11 any guidance from any healthcare professional, but
12 you were sort of diminishing the level of involvement
13 of a healthcare professional but you were concerned
14 that would cause problems.

15 Is it valid to say that, in your view,
16 that as you reduce the involvement of the healthcare
17 professional, if there is such a risk of bad things
18 happening, you would tend to see it as you diminish
19 the role of the healthcare professional?

20 MR. AMANAT: I'm going to object to the
21 form of the question as being convoluted and vague
22 and also as calling for speculation.

□

0107

1 You can answer the question if you
2 understand it, doctor.

3 A Let me make a stab. I think I understand
4 the speculation involved and the answer is maybe or
5 maybe not. For some decisions, if no -- let's say
6 there's no benefit at all to any learned intermediary
7 being involved in the decision-making process.

8 well, in that case going from sort of full
9 physician involvement to behind-the-counter program
10 or some more limited health professional involvement
11 wouldn't make any difference.

12 But let's say conversely the main way in
13 which a health professional would be involved is
14 making sure that you understand some basic facts
15 about the program, and -- about the product, and
16 making sure that in the case of a product that is not
17 intended to be used regularly and is not intended to
18 be used any time you have a symptom but only in
19 special cases, and only as part of a broader plan
20 of -- a plan for dealing with a health issue, then it
21 could be different.

22 You know, in particular what we found in a

□

0108

1 lot of programs that I am working on with seniors now
2 is for are an issue for -- well, seniors are
3 different than teenagers but -- let me give an
4 example from a chronic health issue that we deal with
5 CMS.

6 Diabetes care: we find that we can get
7 big improvements in outcomes for patients with
8 diabetes not by sending them to the doctor on a
9 regular basis but by having a nurse practitioner or
10 kind of clinic contact for that patient on an ongoing
11 basis, someone who they can check in with every
12 couple of weeks to see how they're doing and make
13 sure they understand the disease process, and so
14 forth. They don't need a physician at all and you

mcclellan

15 know, frankly if they were seeing a physician instead
16 of a nurse practitioner, they might even do worse.

17 Similarly, what's needed is pretty clear
18 basic public health action but does require ongoing
19 attention and ongoing involvement by the patient in
20 something like a primary plan of contraception.

21 It's a huge public health issue especially
22 for teenagers, having those teenagers involved in a

0109

1 public health clinic of some kind, talking with a
2 nurse practitioner, a school nurse, even a trained
3 counselor has the potential -- I think there are many
4 studies that show this -- for leading to much better
5 compliance with primary contraception, and much more
6 effective -- much better health outcomes in terms of
7 fewer unwarranted pregnancies.

8 So it really depends on the context. I'm
9 sorry for the long answer but there's a lot of
10 science involved in this.

11 Q I want to take a step back to a prior
12 subject and then I'll return to the science.

13 MR. AMANAT: Is this a good time to take a
14 quick break?

15 MR. HELLER: Do you want a break or does
16 the witness want a break?

17 MR. AMANAT: I'd like a quick break if
18 that's okay.

19 MR. HELLER: Maybe I can take one or two
20 more questions and then we'll take a break. Is that
21 okay?

22 MR. AMANAT: Okay.

0110

1 A I would like to break. I told my staff
2 that we'd be breaking for lunch around 12:30 or 1:00,
3 so they're planning on some interaction with them.

4 Q 12:30 is okay. We'll break at 12:30.

5 A 12:30 or 1:00.

6 Q Shorter break in a moment.

7 A Right.

8 Q Regarding your conversations about Plan B
9 with people within FDA, I think one of the people you
10 mentioned was Scott Gottlieb?

11 A Yes.

12 Q What was his -- what was the nature of
13 your communications with him about Plan B?

14 A Scott was a scientific adviser to the
15 office of the Commissioner. He's a very
16 knowledgeable clinician who has also some unique
17 experience in public communications about challenging
18 scientific issues.

19 One of my top priorities while at the
20 Agency was improving the effectiveness of our
21 communications, so if you look at what happened at
22 the time I was there, I think they were keeping stats

0111

1 on this for a while. We something like doubled the
2 number of press releases and increased the number of
3 public meetings that we held, increased the guidances
4 that we issued laying out how the Agency works.

5 So Scott, as a general matter, was

mcclellan

6 involved in providing some perspective on scientific
7 issues and helping us communicate about them
8 effectively and I expect he did the same thing with
9 Plan B.

10 Q With respect to Plan B, did he ever
11 indicate to you that he thought the data submitted in
12 support of the Plan B SNDA was inadequate for
13 approval of the over-the-counter switch?

14 A Well, a number of people indicated
15 concerns about the data, and, again, it tended not --
16 especially in December or January, most of those
17 discussions were focussed on what the data did and
18 didn't show. Getting back to how far of an
19 extrapolation were we really having to deal with,
20 because that's the question you to answer first; how
21 much extrapolation do you need to make to get to
22 approval, and, you know, how far were we from that.

0112

1 Now, the staff in the Agency was involved
2 in actually making those kinds of decisions, but for
3 purposes of public explanation about what the Agency
4 was going to do, I needed to be as clear as possible
5 as I could about what the evidence showed and do it
6 in a way that the public, the press, the Congress,
7 others who cared about this issue could understand.

8 That's my responsibility as Commissioner
9 for the Agency. So he helped me in thinking about
10 some of those issues, and so naturally, he expressed
11 some concerns about some of the -- some aspects of
12 the quality of the evidence, because, you know, there
13 had been a lot of discussions about those issues
14 inside the Agency.

15 Q Thank you.

16 MR. HELLER: Break now? How much time do
17 you want?

18 MR. AMANAT: I just need like a
19 five-minute bathroom break.

20 MR. HELLER: Okay.

21 THE VIDEOGRAPHER: This marks the end of
22 tape 1 in the deposition of Dr. McClellan. We are

0113

1 going off the record. The time is 11:16 a.m.

2 (Change tape.)

3 This marks the beginning of tape 2 in the
4 deposition of Dr. McClellan. We are back on the
5 record. The time is 11:25 a.m.

6 BY MR. HELLER:

7 Q Dr. McClellan, can you tell me, if you
8 know, what are the possible negative outcomes that
9 might occur from potential misuse of Plan B?

10 A Possible negative outcomes include failure
11 to have an effective primary method of birth control.
12 This is intended to be an emergency products, not
13 relied on for usually contraception.

14 Failure to use effective primary methods
15 of birth control can also result in complications
16 like pregnancy, increase incidence of sexually
17 transmitted diseases, things like that.

18 Use of high-dose progestins on an ongoing
19 basis may also create some health issues. I don't
20 think those are very well defined at this point

mcclellan

21 because we don't have much evidence on it.

22 Q Do you know of any scientific evidence

0114

1 supporting the proposition that, if Plan B were
2 available over-the-counter, women would use it as a
3 routine method of contraception?

4 A What I heard from the staff in the
5 briefing was that there were some concerns expressed
6 about that, and that for adults where literacy and
7 comprehension were good, they did not think there was
8 much basis of those concerns.

9 For younger individuals, while there was
10 some recognition that label comprehension studies was
11 lower about specifically this issue of, you know, the
12 fact that Plan B should be an emergency form of
13 contraception, I think some of the staff felt that
14 the data could be extrapolated to the younger
15 population.

16 On the -- so I think there's a lot of
17 discussion going on about that issue. And one of the
18 other issues that came up related to this was the
19 price of the product.

20 I recall in both the staff discussions and
21 I think this may have come up at the advisory
22 committee meeting, too, the argument that, "Well,

0115

1 this won't be used as a primary method of
2 contraception because the price is too high."

3 It was \$30, but, you know, you could --
4 now speaking as economist where I have substantial
5 expertise, specifically on health economics, when
6 there is a significant market for a product, there
7 are often more than one company that will enter that
8 market, and when more than one company enters a
9 market, you end up with significantly lower prices
10 than where you started.

11 Also, for frequent use, could be several
12 times a month, I think we have no evidence directly
13 on whether progestins are safe in long-term use,
14 several times a month or more. At least the evidence
15 is pretty limited, oral high-dose progestins.

16 Q The issue you raised about price?

17 A Uh-huh.

18 Q As an economist, looking at it just as a
19 question of economics, let's assume that there is a
20 woman who, an adolescent, 16 years old, who is having
21 intercourse ten times per month.

22 As a matter of economics, it certainly

0116

1 more expensive for her to rely on an over-the-counter
2 product that costs \$30 for each use than it would be
3 to rely on a contraceptive product that might cost a
4 dollar for each other, like a condom?

5 MR. AMANAT: I'm going to object to the
6 form of the question. You can answer if you
7 understand.

8 A Yeah, I think it's hypothetical and I
9 don't know of any studies that have been done on
10 comparing different methods of birth control for the
11 price responsiveness or the substitution elasticity,

mcclellan

12 but, getting back to the earlier point, this is not
13 meant to be a primary form of birth control.

14 For people who are planning ahead and
15 thinking carefully about their contraception,
16 obviously, there are far less expensive choices that
17 they would rely upon more regularly. That doesn't
18 necessarily describe all teenagers or early teens or
19 others in the population.

20 Q But from an economics perspective, isn't
21 it true that the price of \$30 per use is an economic
22 disincentive to relying on that routinely --

□
0117

1 MR. AMANAT: Object to the form of the
2 question, again. You can answer.

3 BY MR. HELLER:
4 Q -- compared to con Dons?

5 A Sure. But again, condoms require -- there
6 are different -- there are multiple aspects of a
7 product that -- let's take a step back. When an
8 economist approaches an issue of modeling how people
9 think about decisions, they try to include in the
10 model all of the key aspects of a product that may
11 have value to an individual.

12 Other things equal, having the plan ahead
13 to use something may be -- may be more of a problem.
14 You see some of the ads on TV now for some of the
15 different kinds of stomach acid blockers, and they
16 compete on, you know, "you can wait until the last
17 minute to take ours, or "you can wait until after you
18 have symptoms to take ours. With those other guys
19 you got to think about it 12 hours before or 24 hours
20 before."

21 So people are clearly willing to pay
22 something not to have to wait, and there may be other

□
0118

1 dimensions of this decision that are important as
2 well.

3 In addition, I think the other point I was
4 trying to make is that we have been trying to foster
5 in this country a lot of competition to bring drug
6 prices down, and one way that you foster competition
7 is when you got a product in a class where there are
8 multiple competing available as is the case with oral
9 contraceptive pills, you often see competition
10 working to drive down those costs over time.

11 And that could well happen here. Just
12 because a price starts out with a price of \$30,
13 there's no guarantee that's where it's going to stay.
14 In fact, it's probably going to come down. That's
15 what we've seen with a lot of products after they had
16 been on the market and competing drugs enter in the
17 same kind of class.

18 Q I want to get back to my earlier question
19 which is whether you know of any scientific evidence
20 supporting the proposition that, if Plan B is
21 available over-the-counter, adolescents will use it
22 as a routine method of contraception? Is there any

□
0119

1 sign civic evidence supporting that proposition that
2 you're aware of?

mcclellan

3 MR. AMANAT: Objection. Asked and
4 answered. Also object to the form often question.
5 You can answer the question if you --

6 A Well, maybe I can try.

7 BY MR. HELLER:

8 Q Is there scientific study that you know of
9 that supports that proposition?

10 MR. AMANAT: Objection. Asked and
11 answered. You can answer it again.

12 A Let me try it a different way on this.
13 When drug product is up for
14 over-the-counter review, the question isn't, you
15 know, is there a lack of scientific evidence as a
16 basis for moving forward.

17 Q I understand that. My question is --

18 A The question is what is the evidence on
19 this question. You know, I want to go back to my
20 earlier formulation which is the way that I and I
21 think a lot of the people in the Agency think about
22 the issue. You're always making some kind of

□
0120

1 extrapolation, how much of an extrapolation are you
2 making?

3 And the evidence relevant here is on girls
4 who tended to be older, using the product in settings
5 that were different from the OTC use in several
6 important respects, including amount of access to
7 products and availability of learned intermediaries.
8 And those are the kind of discussions we had.

9 I just want to reiterate since we're going
10 around and around on is because we have these
11 discussions doesn't mean the Agency's got a foregone
12 conclusion about the product. I think it's very
13 important every time an issue comes before the Agency
14 that the staff are encouraged to fully discuss and
15 vet the scientific evidence.

16 I was very impressed with the staff work
17 in this case in particular of going and trying to
18 really dig out as much evidence as possible, went
19 well beyond what had been submitted in the initial
20 application. So all we were doing, in the context at
21 the Agency, was discussing the available evidence and
22 what it meant in terms of the kinds of extrapolations

□
0121

1 needed to reach a conclusion about the product.

2 BY MR. HELLER:

3 Q I understand that. My question was, was
4 there is any evidence available, scientific evidence,
5 that supported the proposition that, if Plan B were
6 available over-the-counter, adolescents would indeed
7 use it as a routine method of contraception if there
8 was -- I'm not saying that you needed to have such
9 evidence or you didn't have need to have it.

10 Was there such evidence? Are you aware of
11 such evidence?

12 MR. AMANAT: Objection. Asked and
13 answered at least three times. You can answer it
14 again if you want.

15 BY MR. HELLER:

16 Q Either a yes or no?

17 A Well, it's --

18 Q Or maybe --
19 A Again, as you pointed out in your
20 questions, the evidence that we need to make
21 decisions directly on point is just not available.
22 So you should never have the expectation that you're

0122
1 going to have exactly on-point evidence to a question
2 related to a major switch in product availability.

3 Q Tell me the evidence --
4 A That was your comment, not mine.
5 (The following was marked protected testimony
6 and is excluded from the main transcript.)
7 * * * *

8
9
10
11
12
13
14
15
16
17
18
19
20
21
22 (This concludes the protected testimony

0123
1 portion.)

2 MS. REYES: Why don't we mark that part of
3 the discussion confidential.

4 A Probably do it with this one, too, but go
5 ahead and try; the Raines study -- Raines, Haines,
6 one of those studies.

7 THE WITNESS: Sorry, I just can't provide
8 clues, can you?

9 A One of those studies showed quantitative
10 difference in many aspects of responses by the
11 patients. The pregnancy rate, the repeat use of
12 emergency contraception rate, you know, which it
13 would be in line with more regular use of the
14 product.

15 The differences were not statistically
16 significant because they had a relatively small
17 number of people, but I think the pregnancy rate was
18 twice as high, there's maybe a 40, 60 percent
19 difference in some of these other important
20 behavioral responses that we talked with.

21 Those are just numbers though. They're
22 trends; they don't necessarily mean there's a real

0124
1 difference there. You just don't know because the
2 sample size isn't large enough. That's one important
3 area where the Agency would look for more evidence.

4 A second important area involves the
5 circumstances of use in the study.

6 As you said before, you're not going to
7 get two conditions of actual use on a large scale in
8 a U.S. population before you actually made this

mcclellan

9 decision, so that's not going to be available. So
10 the question is how close can you get.

11 And factors that go into that issue
12 include things like what was the extent of
13 involvement by a learned intermediary, a health
14 professional, a pharmacist, something like that.

15 Things that would tend to make the
16 extrapolation larger, meaning harder to draw the
17 policy conclusion with a strong level of confidence
18 would be things like, you know, only studying
19 patients who were already in health clinics where, if
20 you're going -- if you're a teenager going to a
21 health clinic, the number one thing they ought to be
22 talking about is a regular method of birth control if

0125

1 you're sexually active.

2 Other issues that might come up would be
3 things like how much is the product actually
4 available. You know, if you, in a study it would be
5 a lesser extrapolation. There would be access, more
6 or less unlimited access to the product or maybe pay
7 something each time you get it. You wouldn't have
8 to, you know, fill out a questionnaire or necessarily
9 go back to the clinic and make an appointment to get
10 the product.

11 And in many of the studies that were done,
12 the girls involved, or the young women involved, had
13 access only one or few courses of treatment, so that
14 makes for a better kind of extrapolation as well.

15 Another area of importance is how long the
16 follow-up occurs. In a four-week study, you can't
17 learn anything directly about the long-term patterns
18 of use or the, you know, the socialization to use of
19 a product that's available. So none of those kinds
20 of questions were addressed in many of the studies
21 that were available.

22 And that's -- that's fine in the sense

0126

1 that's what the state of the evidence was, and
2 that's -- I think the main thing that I wanted to see
3 for the Agency was that they had fully discussed all
4 these issues, which we tried to do in every single
5 case that the Agency dealt with.

6 Q In the time after you left -- since you
7 left the FDA, have you spoken with people within the
8 FDA about Plan B?

9 MR. AMANAT: Objection. Asked and
10 answered. You can answer the question again.

11 A Okay. The main interactions I've had with
12 the FDA are involved in responses to issues that have
13 come up in, from either public policy standpoint or
14 press standpoint. That would include the GAO report
15 and Congressman Waxman's own special interpretation
16 of that report, and the subsequent press that has
17 happened over the last few weeks, when you, or
18 someone from your team, has made a statement in the
19 press that implicates me directly or indirectly.

20 And in a few of these cases I've talked
21 about legislative staff or the press staff at FDA
22 about their activities. So those are the FDA

0127

1 interactions.

2 Q Let's talk about now interactions outside
3 the FDA if you've had any. During the time you were
4 at the FDA, did you have any interactions with people
5 outside the FDA about Plan B?

6 MR. AMANAT: When you say outside the FDA,
7 you mean anyone in the world?

8 MR. HELLER: Yes, in the world.

9 MR. AMANAT: Okay.

10 A Well, let me start with the ones that
11 might be of most interest or relevance to you. I had
12 occasional updates, informational updates, on what
13 was going on in the Agency with some of the staff in
14 the department and relevant policy staff at the white
15 House.

16 And I had probably some interactions or, I
17 definitely had some, at least one meeting with
18 members of Congress about this and probably heard
19 occasionally -- I'd have to go back and look at the
20 hearing transcripts -- but, you know, this issue may
21 have well come up in one of my numerous appearances
22 from Congress.

□

0128

1 There may have been others through casual
2 conversations or interactions with reporters, but
3 those would probably be the main ones.

4 BY MR. HELLER:

5 Q Who did you have interactions with at
6 department. I assume you mean the Department of
7 Health and Human Services?

8 A Department of Health and Human Services,
9 yes. It would have been Ladd Wiley who was kind of
10 the department liaison or I think his former title
11 was Counselor who was overseeing FDA and other public
12 health issues; Scott Whittaker, who was the Chief of
13 Staff at the time. At least a basic brief update on
14 Plan B probably came up in one or few of my briefings
15 with the Secretary. I met with him from time to time
16 about important issues at the Agency.

17 We were really focussed on some major
18 regulatory actions like taking ephedra off the market
19 as the first time ever that anyone had used the
20 Dietary Supplement Act to remove a product from the
21 market on safety grounds.

22 And it was another issue where there's

□

0129

1 some very interesting points that come up about how
2 you reach conclusions about safety and effectiveness
3 based on limited available evidence.

4 So in the course of updating him on those
5 other major issues, where we were in the process of
6 making some real -- and we made some real policy
7 decisions that the Department certainly got asked
8 about, I may have provided a brief update on this.

9 I don't have a specific recollections of
10 it but it would be in keeping with my usual course of
11 doing business with the Department of HHS.

12 Q So would the update have been something
13 like this: "We're reviewing the evidence?"

14 MR. AMANAT: Object to the form of the

mcclellan

15 question. You can answer the question.

16 A Let me maybe characterize the updates a
17 little bit more.

18 BY MR. HELLER:

19 Q That will be helpful.

20 A When the application came in to the Agency
21 and there were some press around that, I would have
22 let the Department know, if they had asked, and I

0130

1 expect they did, that we're reviewing the
2 application.

3 And since they were not experts
4 necessarily on what exactly the processes were at the
5 FDA, I would have let them know that it was going to
6 be reviewed by a number of relevant offices inside
7 the Agency, that there would, in all likelihood, be
8 eye advisory committee meeting on it; that the Agency
9 would take the information from that advisory
10 committee meeting and the internal staff review and
11 use it to make a conclusion about the action on the
12 product based on the scientific evidence available
13 and that would take place over some course of time,
14 maybe a year or close to a year or something like
15 that.

16 And then later on in the process, might
17 give them an update if something significant
18 happened; like we scheduled a advisory committee
19 meeting. There will probably be some press attention
20 around it. Or the advisory committee met; here's
21 what some of their main findings and issues were;
22 something like that.

0131

1 Q Did you ever indicate to one of these
2 people at the Department of HHS, did you ever
3 indicate to them, "well, the direction we're heading
4 in is this" or similar direction?

5 A I indicated very clearly that the
6 direction we were heading in was a scientific review
7 of the evidence, and that would determine the
8 Agency's ultimate action and that there were, you
9 know, as the review proceeded, would have probably
10 given them a little bit of an update about what kinds
11 of scientific issues were coming up, that, you know,
12 the evidence seemed very strong for adults. There
13 were some questions and extrapolating to younger age
14 groups, things like that.

15 Q What about at the White House? Who did
16 you have contact with there?

17 A The domestic policy staff would have been,
18 I think Jay Lefkowitz initially and then Kristen
19 Silverberg, and it would have been in the same nature
20 of occasional updates when there was something new
21 happening with the application, and just to let them
22 know that we were handling it and how we were

0132

1 handling it.

2 Q Let's start with Jay Lefkowitz. What
3 other FDA processes were you updating him about?

4 MR. AMANAT: Object. You can answer the
5 question as long as it does not reveal any trade

6 secret or confidential or commercial information
7 about unapproved products.

8 A There were are very number of very
9 important FDA initiatives ongoing at the time, in
10 early 2003; it was just after I had gotten to the
11 Agency. The Agency had been without a confirm, a
12 senate-confirmed full Commissioner for, you know, two
13 and-a-half years, three years at that point.

14 And so there was a lot of business that we
15 needed to start really moving forward on. That's not
16 to take anything away from the leadership staff that
17 had been there before. It's just easier to get
18 things done when you're the Commissioner, when you've
19 gone that process of confirmation by the Senate and
20 in that confirmation process I highlighted a number
21 of areas I think I thought were very important for
22 the Agency, such as implementing a new level of food

0133

1 security in the United States. We just got some
2 funding to do that and needed to put it in place
3 effectively, such as implementing some important
4 reform in our premarket review process, some
5 important reforms in collecting more comprehensive
6 information routinely in the post-market setting.

7 And then from time to time there would be
8 issues that come up, because this is the FDA, that
9 are going to be of major importance to the public.

10 It was later on in the year but we
11 experienced the first case of bovine spongiform
12 encephalopathy or "mad cow disease" in this country
13 late in the year 2004 -- early, late 2002 and early
14 2003 -- you know, it's funny, I guess not funny, but
15 being Commissioner you kind of hope that at some
16 point there's going to be a break in the action, a
17 little bit of a break, and the first holiday season I
18 was there around the end of 2002, that's when the
19 Iranians announced they cloned a human, so that led
20 to a lot of Agency meetings and updates for the white
21 House and what was going on here. Is there -- is
22 this true? Are the regulatory implications in this

0134

1 country?

2 And then the next holiday season was busy
3 because we pulled ephedra, we announced we were
4 pulling ephedra off the market and also have that
5 first case of BSE. So there were always issues like
6 that coming up, and I'd have to go back and look. I
7 don't have any notes or anything in front of me so I
8 can tell you what exactly happened when, but those
9 are the kinds of things that would be discussed.

10 Q Going back to your updates for HHS about
11 Plan B, I think you indicated that those updates
12 would basically include the information that you were
13 evaluating the scientific evidence?

14 A Yes.

15 Q But wouldn't always be true? Why would
16 you have to tell me them that? Wouldn't that be
17 always the case?

18 A It is always true, but, you know, it's
19 important to give them context for what the
20 scientific evidence means, so in this case it would

21 be reviews of the ability -- the reviews of evidence
22 relevant of extrapolating from the prescription use

0135

1 of the product to the use in over-the-counter status,
2 and you know what the -- the difference --
3 Different applications have different
4 particular scientific issues that are relevant, and
5 so that was -- I think it was important to give them
6 the specific kind of context of the scientific issues
7 that were relevant for this application.

8 Q So you were not just telling them it was
9 under scientific review but also the issues that were
10 under review?

11 A Give them a flavor of the issues. That's
12 right. I mean, this was not the kind of discussion
13 that we had just a few minutes ago and it was
14 certainly not the kind of discussions we had with the
15 staff about what the numbers show and, you know,
16 issues of statistical power and reviews of specific
17 studies and the like.

18 But it was kind of a high-level discussion
19 of look, when you're doing over-the-counter switch, I
20 remind them about why that's different and in many
21 ways harder than a prescription drug approval, or at
22 least in many ways different from prescription drug

0136

1 approval and what kinds of studies are relevant, so,
2 you know, for an initial prescription drug approval
3 evaluation, label comprehension may not be as
4 important as it is in an over-the-counter product,
5 because, you know, in the former you've got much more
6 involvement of the learned intermediary, things like
7 that.

8 Q In your contacts with the white House, did
9 they ever tell you, did the people you talked to
10 there ever tell me you, anything about their views
11 about the Plan B?

12 A The conversations really didn't go to that
13 in that they were about an update about on where the
14 applications were and, you know, that's where I
15 wanted to keep the discussions focussed and that's
16 pretty much what we talked about.

17 Q Is the White House sort of your boss when
18 you're Commissioner of the FDA?

19 A The President is the head of the executive
20 branch of the government of the United States, and
21 every Agency in the executive branch is part of, in
22 some way, the overall structure of the executive

0137

1 branch and the way that the President's office
2 interacts -- the executive office of the President
3 interacted with me on issues like this was I had
4 their vote of confidence.

5 I was the person the President had
6 nominated to run the Agency at a very critical time
7 with lots of safety and security and drug and other
8 medical product development issues ongoing, and I
9 kept them apprised about what we were doing on major
10 issues.

11 And if there as a major policy initiative,

mcclellan

12 I would try to work with them on making sure there
13 was a good understanding and ideally
14 administration-wide support for those kinds of
15 initiatives.

16 For example, in our response on BSE, we
17 would only respond effectively if we were working in
18 concert with the other federal agencies ranging from
19 Customs and Border Protection, dealing with food
20 imports and exports; since this was a Canadian cow
21 that had some potential implications for further
22 exchange of animals with Canada; with USDA, because

0138

1 the Department of Agriculture has important
2 regulatory oversight responsibilities for meat, and
3 with other agencies, Commerce and others, that would
4 be feeling some of the fallout of the potential
5 market or economic implications of the decisions we
6 were making and the actions we were taking.
7 we can do a much better job of serving the
8 public when we were well coordinated, when the
9 leadership of the executive branch knows what we're
10 doing.

11 Q With respect to Plan B were there other
12 federal agencies or entities that would be involved
13 in the Plan B OTC switch other than FDA in the way
14 you just described these others?

15 A No. That was a single-Agency issue. But,
16 yeah, there were a lot of Agency issues that
17 pertained just to HHS or just to the FDA where the --
18 where regular updates for the white House were
19 appropriate. Giving you another example was --

20 Q I want to us to get to lunch.

21 A Okay.

22 Q Were there any other OTC switches that you

0139

1 updated the white House about?

2 A Yes. The earlier in the -- I think it was
3 earlier in 2003, I believe Prilosec went
4 over-the-counter; that's a H2 blocker, which was, I
5 think at the time, not being No. 1, one of the number
6 one drugs in the United States, so it going
7 over-the-counter and having the resultant reduction
8 in healthcare costs because, you know, No. 1 it's
9 cheaper and, No. 2, you don't have to go see a doctor
10 in order use it was of considerable interest to the
11 administration and the general public.

12 Remember, this was a time when there was a
13 very high level concern of concern about drug costs
14 and we were doing all we could do to get drug costs
15 down.

16 Q So you updated the white House regularly
17 about Prilosec?

18 A I probably gave them one update when the
19 Agency had made its decision about taking it to OTC
20 status. This wouldn't have been in the course of a
21 separate meeting. Probably it would have been in the
22 course just letting them know along with update on

0140

1 any other issues or any other reasons that we might
2 have for meeting.

mcclellan

3 Because there were so many regulatory
4 activities ongoing at the Agency that were in the
5 public eye, there was on a fairly regular basis, I'd
6 say ever several weeks or so, a reason for me to let
7 them know about the Agency status of a particular
8 issue.

9 Q So with respect to Prilosec that you just
10 mentioned, when you gave them that update, it had
11 over been switched over-the-counter by the Agency; is
12 that right?

13 A Well, the Agency was about to announce the
14 switch. And, again, let me tell you, this is just an
15 example. I don't have a specific recollection of
16 that conversation. I'm just trying to give you a
17 flavor for the kinds of interactions that I had with
18 the White House.

19 Q How many updates did you give the white
20 House about Plan B?

21 A I don't recall more than -- I don't recall
22 any conversations specifically. I don't recall more

0141

1 than several updates. There would have been one
2 around the time when the application came in, maybe
3 in response to a press report or something like that.

4 There would have been probably another one
5 around the time of the advisory committee meeting and
6 then maybe after the advisory committee meetings of
7 several of so. It's conceivable, though again I
8 don't have any recollection of it, that sometime
9 along the way there, Jay or subsequently Kristen may
10 have asked, you know, "are things still moving
11 forward on the Plan B application?"

12 It would have been, "Yes. Here's where we
13 are in the process"; something like that.

14 Q During these updates in general when you
15 would give the white House updates, would the people
16 you're talking to at the white House ever express a
17 view about the updates sort of, "Oh, that's great."
18 Or "I don't like the way that sounds?"

19 MR. AMANAT: Object to the form of the
20 question. You can answer the question if you
21 understand it.

22 A Not so much. I don't think it would have

0142

1 had a big impact on what I was telling them anyway,
2 even if they did. I certainly don't have any
3 specific recollections about strong objections being
4 raised on this issue.

5 I -- you know, I can tell you about -- I
6 certainly was a little alarmed and concerned, for
7 example, when I let them know about the BSE case.

8 Q So if I've understood you correctly, you
9 don't recall any objections raised by the people
10 you're talking to at the white House about the way
11 FDA was dealing with Plan B?

12 A They certainly didn't direct me to take
13 any actions or not take any actions related to how
14 the Agency was handling the product.

15 Q Did they express their approval of the way
16 you were handling it?

17 A I don't remember. They didn't express

mcclellan

18 disapproval. Maybe that's a better way, because
19 that's something I probably would have remembered.

20 Q Do you think they would remember it,
21 whether they expressed approval or disapproval?

22 MR. AMANAT: Objection.

□

0143

1 A I doubt it. I mean, you would have to ask
2 them but I doubt it since these are only -- we are
3 talking about several or so conversations over the
4 course of a year in the context of brief updates
5 along with many other issues.

6 BY MR. HELLER:

7 Q Did any of the white House people, I think
8 you mentioned two people, Jay Lefkowitz and someone
9 named Kristen?

10 A Kristen Silverberg.

11 Q Did either of them ever express to you the
12 white House's views about Plan B?

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

15 A Not that I recall. Not specifically on
16 Plan B. Remember, what I was doing in these
17 conversations was providing a specific factual update
18 and, you know, kind of reminding them about the
19 course -- the course of action when the Agency
20 handles a product.

21 It's not something where there's a lot of
22 room for strong responses one way or the other. It's

□

0144

1 just laying out a factual update.

2 BY MR. HELLER:

3 Q Did you convey to them the concerns that
4 you had about Plan B being switched to
5 over-the-counter status, the concerns about data, the
6 scientific concerns?

7 MR. AMANAT: Object to the form of the
8 question. You can answer the question.

9 A Early on, because, you know, we wouldn't
10 have reviewed any of the evidence. No, that wouldn't
11 have come up. It would have been just an update
12 about the fact that the application was in and what
13 the course of action is when the Agency gets an OTC
14 application.

15 Later on, around the time of the advisory
16 committee meeting, as with the Department, again, I
17 don't have any specific recollections of the specific
18 conversations, because these were just sort of
19 regular updates that I do as a matter course.

20 I probably mentioned that the scientific
21 discussion was focussing on issues in certain areas,
22 because that's what it should do when an application

□

0145

1 is being reviewed.

2 BY MR. HELLER:

3 Q Is that because you wanted their
4 scientific feedback or just to give them an update?

5 A Just to give them an update. As you said,
6 as you said, the Agency is always making decisions
7 based on the science and should always make decisions
8 based on the science and just another way to put that

9 in context.

10 Q Did the White House, the people at the
11 White House ever express to you that they wanted to
12 continue to get updates on Plan B, or conversely "we
13 don't need to hear about that any more." Did they
14 express one way or another?

15 A I don't remember either of those two
16 things happening.

17 Q In the initial contact you had with Jay
18 Lefkowitz we have a calendar entry for you on April
19 21st, 2003 of a conference call with Jay Lefkowitz
20 regarding Plan B submission?

21 MR. AMANAT: Are you going to show the
22 document to the witness, Mr. Heller?

0146

1 MR. HELLER: Sure.

2 MR. AMANAT: Do you have copies of the
3 binder for the witness or for counsel today?

4 MR. HELLER: The binder, no. I have
5 copies of the calendar page.

6 MR. AMANAT: Do you have copies of the
7 calendar page for counsel?

8 MR. HELLER: Yes. I will give you two
9 pages actually, one is marked at the bottom 509 and
10 the second is 510 (proffered.)

11 MR. AMANAT: Are you going to mark these
12 for identification as an exhibit, Mr. Heller?

13 MR. HELLER: We don't need to. They are
14 marked as part of the discovery you gave us. I think
15 that's enough.

16 Q So 509 is frankly very hard to read, but I
17 think around 5:00 or 5:30 slot there's a notation
18 about a conference call with Jay Lefkowitz regarding
19 Plan B submission I think?

20 A Yes.

21 Q On the second page a more legible
22 reference to the same conference call, I believe.

0147

1 Do you see that?

2 A Yes.

3 Q Did you review these two pages or either
4 one of them before today's deposition?

5 A I did see these pages in the packet that I
6 got, and the main reason for that was that I believe
7 you told some reporter that there was a secret
8 meeting of Dr. McClellan with the White House.

9 Q I never used the word "secret."

10 A That's -- that was a headline and maybe
11 the reporter made it up, so this was brought to my
12 attention, yes.

13 Q Was there such a conference call, do you
14 know?

15 A I don't have any specific recollection of
16 the conference call. But I can tell you several
17 things from reviewing the documents that you just
18 gave me. And this is because -- first of all, you
19 see a lot of black space. My calendars are usually
20 fully booked, and in some cases they were double
21 booked, and that was like what happened here at this
22 530 time slot I actually got another call scheduled

0148

1 right at the same time, and that's something that my
2 staff would do fairly often when it was expected to
3 be a very brief call.

4 So, you know, they didn't want to schedule
5 one at 5:30 and the other at 5:37 but they knew that,
6 you know, reasonably within the next 20 minutes or so
7 I'd be able to get through both calls.

8 So they double book them. That's what
9 they did here. What that tells me is this was a
10 short call which means it's likely by nature just a
11 brief update.

12 Second thing is from the other page, page
13 510, it says, it says, "Call with Jay Lefkowitz re:
14 Plan B submissions" so that suggests it's about the
15 submission of the application. And I don't have the
16 specific dates in mind. But my guess is that this
17 was either at or around the time that the news of the
18 Plan B application was made public.

19 And then as a third thing from looking at
20 the calendar is in parenthesis it says "schedule with
21 Lauren on 4/21." So this was 4/21, so it was not a
22 meeting that was planned far ahead. It was something

□

0149

1 that just came up that day and, in fact, it was late
2 in the day means, you know, it was something that
3 needed to be handled timely that it was not super
4 urgent that it needed to interrupt one of the earlier
5 meetings that I had scheduled during the day, and
6 5:30 is probably about the first time that he or I
7 had a open slot for a brief discussion.

8 So putting that all together, short call
9 added that day on the Plan B submission, probably in
10 response to news about Plan B that day to give him a
11 brief update. And I don't have any more specific
12 recollection than that.

13 Q Perhaps to refresh your recollection, do
14 you recall whose ideas the call was? Was it his or
15 yours?

16 A No. It may well have been his. Sometimes
17 when issues show up in the newspapers for the first
18 time, and there's some speculation in the papers
19 about, you know, this being important or this being
20 something that administration needs to address, I
21 would get calls from the White House or the
22 Department just so they knew what they were dealing

□

0150

1 with, so in case they got asked about it, they'll be
2 able to say, "well, the application came in today and
3 the Agency will be reviewing it in due course over
4 the coming months."

5 So it may well have been something they
6 saw in the papers; just wanted to get a basic sense
7 of what was going on at the Agency.

8 Q Okay. And you believe it was probably a
9 short call because there was another call scheduled
10 for the same time?

11 A Yes, another call scheduled at the same
12 time, and the two calls collectively were only
13 scheduled for 30 minutes.

14 Q Did that happen a lot when you were at

15 FDA -- by that --

16 A Double booked? Oh, yes.

17 Q Not double looked.

18 A A lot.

19 Q But you would schedule a call with the
20 white House for the same day?

21 A Yeah. It definitely happened, and it
22 would happen -- I mean, a lot -- I don't know about a

0151

1 lot, but, you know, if there was a new issue that
2 came up. You know, I can guarantee you when the
3 first case of BSE occurred or when there was some
4 other food safety threat or some other major event,
5 we probably had a quick update call.

6 Q Did you view the filing of the Plan B SNDA
7 as a major event in some way?

8 A Not in the sense of the course of handling
9 the application, since at least everybody at the
10 Agency -- I think everybody who cared about this
11 issue in the public knew this was coming. It was a
12 discrete milestone or landmark, though, that you know
13 led to some further public interest in the issue.

14 I don't recall myself being, you know,
15 surprised by this or, you know, changing my views
16 about the issue or anything like that as a result of
17 the filing itself. My recollection is that it was
18 quite expected.

19 Q I think you indicated that this was a
20 discussion call, your testimony?

21 A An update call.

22 Q I think you also said discussion?

0152

1 A Maybe.

2 Q What I'm trying to get a sense of is when
3 this type of call took place. First of all, am I
4 right from the calendar it seems that it was only
5 addressing Plan B and not a number of other issues as
6 well?

7 A That's right, because it was a brief call,
8 scheduled at the same time as another call that also
9 needed to get to in the next few minutes. So it
10 would have been short and that would have given us
11 the opportunity to discuss only a few items.

12 Given that this occurred on April 21, I
13 think the main topic of discussion would be the
14 Plan B submission and what the usual course of action
15 with the submission is, what the white House could
16 expect.

17 Q Wouldn't the white House always know what
18 the usual course of action would be at the FDA?

19 A No, not if they don't focus on this issue
20 at the same time as the million other issues that are
21 going on at the white House on domestic policy. And
22 I think they probably, before they were to say

0153

1 something public about it, if they were asked about
2 it, would like to make sure they know what the Agency
3 is thinking about it, just for confirmation if
4 nothing else.

5 They may not know -- you know, I'm sure

mcclellan

6 they didn't off the top of their heads -- what the
7 usual time of review is for an application like this,
8 when the Agency might be expected or whether the
9 Agency might be expected to have more public
10 discussion about the issue; things like that.

11 Q Do you recall any other update calls of
12 this nature with the white House about the filing of
13 any other SNDA?

14 A I do recall other update calls with the
15 white House when there was news on some kind of event
16 happening. You know, maybe another example would
17 be -- actually, I think from this, around this time
18 period, was the death of a baseball pitcher
19 associated with ephedra. They made the news.

20 Q With regard to the filing of the SNDA, not
21 some news just in general. Do you recall the filing
22 of an SNDA that then was followed shortly thereafter

□
0154

1 by a call with the white House?

2 A First of all, I was only at the Agency for
3 16 months, so there were not that many filings that
4 came into the Agency. Second, when many companies
5 file their SNDA, they do it quietly I. They view
6 that as a commercial activity and they don't want
7 their competitors to know that the application is
8 even with the Agency, so there wouldn't be any news
9 about it.

10 Again, the way I tend to think about these
11 issues is it something that is in the news that the
12 white House would want to be aware of how the Agency
13 is handling it just in case they get asked or just
14 because the Office of the President, you know, needs
15 to know what's going on in the executive branch of
16 the government.

17 Q Why would the Office of the President want
18 to know about Plan B?

19 MR. AMANAT: Objection.

20 BY MR. HELLER:

21 Q Do you know why they would want to know
22 about that?

□
0155

1 MR. AMANAT: You can answer the question.

2 A Beyond what I already said, again, the
3 discussion that I had in the several updates over or
4 thereabouts over the course of the year were only
5 informational about what the Agency was doing with
6 the product.

7 One reason that the white House tends to
8 be interested in issues is, if they are going to be
9 in the press because, if they're in the press,
10 there's a good chance that they, the President, his
11 advisers, are going to be asked about it either by
12 the press or by members of Congress or by members of
13 the public.

14 I think in this case in particular there
15 were letters of from members of the Congress and the
16 public going to the executive Office of the President
17 about Plan B.

18 what makes an issue of interest to the
19 press, well, lots of things: Controversy does, you
20 know, major change of other types might, and this fit

21 in with the kinds of things that generated press
22 interest and kinds of things that I would have given

0156

1 this kind of brief update about.

2 Q You also had subsequent updates about
3 Plan B that were over the succeeding months?

4 A Time I was at the Agency, right.

5 Q Is it your testimony that as far as you
6 know, the only reason the White House was interested
7 in what was going on with Plan B was that it was in
8 the news?

9 A well --

10 Q As far as you know?

11 A Look, this is -- anything involving
12 contraception, birth control, these types of issues
13 is, in this country inherently controversial. That
14 also makes its inherently newsworthy. You know, if
15 you've dealt with the press then you know you can get
16 a lot more press attention if you say something
17 explosive or extreme or, you know, concerning in some
18 way and controversies are good for generating press
19 attention.

20 wrapped up with the ongoing interest of
21 the press, is certainly some controversy about these
22 larger issues but, again, the discussions I had with

0157

1 the white House -- and I would remember if it was
2 otherwise -- were focussed on what we were doing with
3 the application and that was mainly it.

4 Q Do you know what the positions of the
5 white House are with respect to contraception?

6 MR. AMANAT: Objection. It assumes a fact
7 not in evidence. You can answer the question if you
8 know.

9 MR. HELLER: I'll ask it differently.

10 Q Do you know if the white House has any
11 positions on contraception?

12 A I know that the President wants to reduce
13 the number of abortions. I know that the white House
14 has some positions, some well known positions related
15 to abortion. I don't know that extends to certain
16 specific types of contraception.

17 Q Do you know whether the white House has
18 any positions on contraception?

19 A Offhand -- well, not would have come into
20 the issues that we were dealing with at the FDA. I
21 think there's some issues about federal funding for
22 contraceptive programs overseas or elsewhere. Those

0158

1 don't directly involve or didn't directly involve the
2 FDA so there's no reason I would know about the
3 details.

4 Q Do you know if the white House has any
5 position on emergency contraception specifically?

6 A I don't know of any specific position on
7 the issue. I don't think I've seen a policy paper or
8 anything like that.

9 Q I don't necessarily mean a written policy
10 paper. Did anyone from the white House ever express
11 to you orally anything about their views about

12 emergency contraception?

13 A I don't have any specific recollections of
14 any particular individual expressing concerns.

15 Q So it's possible that somebody did express
16 something like that to you but you just don't
17 remember?

18 MR. AMANAT: Objection.

19 MR. HELLER: What's the objection?

20 MR. AMANAT: You can answer the question.

21 A I guess it's possible. I'll tell you what
22 I would have remembered, though. If I was being

□

0159

1 given any direction on how I should act on this
2 application, I would have remembered that because
3 that never happened.

4 If I was being told that I should look
5 at -- the Agency should look at the scientific
6 evidence in one way versus another; I would remember
7 that. But that never happened. I don't know if
8 that's helpful for your question.

9 Q It didn't really answer my question but
10 that's all right. So do you know if you -- if your
11 successor, Dr. Crawford, he was acting Commissioner
12 after you left; is that right?

13 A Yes.

14 Q Do you know if he had these regular --
15 continued to give regular updates to the White House
16 about Plan B?

17 A I don't know.

18 Q Did you tell him --

19 A Just you characterize this as regular.
20 Again, I wouldn't characterize it that way.

21 Q Updates?

22 A When there was a significant event,

□

0160

1 especially something that made news or was likely to
2 make news, then I would make sure -- either they
3 would ask about it. This may have happened on this
4 April 21st call or it may come up in the course of
5 discussion of other issues which are of -- would be
6 of more interest and more focus for the White House
7 because there would have been --

8 Over the course of the year there are all
9 kinds of issues that come up at the FDA that lead to
10 high levels of public attention, requires us to take
11 new actions. And I meant mentioned some of them,
12 like ephedra and silicon breast implants and Prilosec
13 going over-the-counter, and mad cow disease and human
14 cloning.

15 In the course of talking to the White
16 House about new actions that we're taking, we might
17 occasionally provide updates on some of the other
18 issues or I might occasionally provide update on some
19 of the other issues that are going on.

20 This was not sort of a regular planned set
21 of activities and there was never any kind of request
22 for regular updates on Plan B or anything like that.

□

0161

1 Q Did you tell -- when you were sort of
2 transitioning out of the FDA to CMS, did you inform

mcclellan

3 Dr. Crawford regarding what you had been providing
4 information to the White House about the sort of
5 subject you had been talking to them about?

6 A Not really, because it was the kinds of
7 things that we've been talking to them about would be
8 pretty much common knowledge inside the leadership of
9 the Agency. Even if he wasn't following issues
10 closely, he knew that, you know, Plan B was under
11 review.

12 He knew there would be a an Agency
13 decision coming in the months ahead and so forth, and
14 that's about the level of the updates that the white
15 House would have gotten; these occasional updates
16 with the white House have gotten into.

17 Q I meant something a little bit
18 differently. Is there somehow you would have
19 conveyed to him, you know, these are the six things
20 or whatever it was, ten things, that "over my tenure
21 here I have updated the white House about. You might
22 want to the continue update them about it as things

0162

1 progressed?

2 A I see. This wouldn't have made a top six
3 list. The things that made that list were things
4 like how were we responding to BSE, where less was
5 already very much involved and up to date, but I did
6 have some views about some important next steps for
7 the parts of the issues that I had been handling with
8 them with some of the others agencies and how we were
9 talking about it in the public.

10 We were in the midst of a new initiative
11 on reducing the costs and the uncertainty in the drug
12 development process, our critical path initiative
13 which had just been launched, so I spent a good deal
14 of time making sure that Les was up to speed on that
15 issue.

16 There were no device user fees that we had
17 just implemented in the Agency, which were coming
18 with expectations of improved performance in handling
19 our medical device review.

20 So things like that made my list of top
21 issues for Les and top issues for that transition.

22 You also must keep in mind that the

0163

1 transition I had was, you know, an undesirably brief
2 one. It went from being at the Agency to being over
3 at CMS just in a matter of, you know, a few weeks or
4 so between when I was nominated for the position and
5 when I had to move over.

6 In the ideal world I would have stayed at
7 the FDA a lot longer. I loved the Agency; it's a
8 great place to work. There's a unique combination of
9 being able to work on issues of interest to the
10 public and science and a very dedicated staff.

11 But because, you know, I was moving over
12 to implement the new Medicare drug law, I had to go
13 fast. So we had only a very limited amount of time
14 for any kind of transition issues and, you know, this
15 definitely did not make the cut of things that we
16 were focussed on in the transition.

17 Q Did you tell Dr. Crawford about, or maybe

mcclellan

18 he knew all along -- did you tell him about your
19 practice of giving the white House occasional updates
20 on a range of issues?

21 A Well, he was probably involved in some of
22 those. You know, if it was -- if we were going over

0164

1 to the white House for a meeting on BSE, for example,
2 he would attend. I would probably attend as well as
3 the Agency head, but he was my point person on a lot
4 of the implementation steps that we were taking and
5 certainly on our interactions with other governments
6 and other agencies.

7 So, you know, the end of those meetings we
8 might spend a couple of minute on updates on other
9 issues.

10 I don't think he would have been there for
11 a particular Plan B update just because those didn't
12 happen very often. There may be several, like I
13 said, or so over the course of the whole year. So, I
14 don't think we discussed it particularly beyond that.

15 He was just -- I guess what I'm trying to
16 say is that he was familiar enough with some of the
17 ways in which I interacted with the white House from
18 briefings and meetings that he attended with me or
19 from calls that he would have been on with me to
20 provide updates on these many other important issues
21 before the Agency.

22 Q When you would provide updates to the

0165

1 white House, did you have any kind of written
2 documents or "this is what we're going to update the
3 white House about" that would you work of or was it
4 just off the top of your head, so to speak?

5 A For quick updates like the ones we're
6 talking about here, it would be off the top of my
7 head because it was basic information that I had at
8 hand.

9 For the specific substantive issues that
10 we were updating on, like, you know, the death of an
11 individual related to ephedra or the details of a BSE
12 case or something like that, sure, I probably have
13 some written notes in front of me for that.

14 Q What happens with those notes? Do you
15 keep them, do you destroy them?

16 A They are part of the FDA's recordkeeping
17 process. As you probably know, the FDA has an entire
18 office, Executive Secretariat set up to maintain
19 records. Also have a number of people working in my
20 immediate office who help manage the correspondence
21 in and out of the immediate office of the
22 Commissioner, and then we also have a records process

0166

1 that's integrated with what the rest of the Agency
2 does.

3 So each of the centers, including CDER,
4 have their own records management process for keeping
5 track of all of the required records for specific
6 issues before -- before their center, so that's all
7 part of the support available to make sure that
8 appropriate records are retained.

mcclellan

9 Q Do you know if you ever had notes or sort
10 of written, anything in writing, that would have
11 indicated that Plan B was the subject of an update to
12 the white House?

13 A I really doubt that I would have had notes
14 for this call that we mentioned on April 21st,
15 because this looks like, again, a short double-booked
16 call that was added that day, and similarly, there
17 wasn't that much to tell them at other times during
18 the course of the review.

19 The time when we would have had a lot more
20 to say is when the Agency had reached a decision and
21 when we were about to make that decision public and
22 at that point we would have had, if it was like any

□
0167

1 of the other issues that were of considerable public
2 interest when I was at the Agency, we would have
3 prepared so-called rollout materials, you know, press
4 release, a summary of the technical information that,
5 you know, because most people in the press and public
6 won't read the whole file or the whole response
7 letter, summary the key points, something like that.

8 But that didn't happen while I was there.
9 That decision was made on Plan B months after I left
10 the Agency, and I -- so there wasn't anything, you
11 know, in more detail to update them about.

12 Q Do you know if before you became
13 Commissioner of the FDA whether it was the regular
14 practice, or the practice of your predecessors, to
15 also update the white House about important matters
16 that the Agency was involved with?

17 A I don't know offhand. I, you know, do
18 know that -- well, I don't have much direct knowledge
19 bearing on that. I guess the closest I could come to
20 telling you about that is that when I worked in the
21 previous administration, I was a political appointee
22 in the Clinton Administration as well, the Department

□
0168

1 of the Treasury, one of the issues we were dealing
2 with at that time was 1989 to 1999 was taxation and
3 regulation of tobacco.

4 And this was following on the time when
5 the FDA had sought to regulate tobacco as a drug and
6 there was a lot of legislative discussion about how
7 FDA -- how tobacco taxation might be imposed. It
8 actually got pretty close to passing the Senate.

9 In my job at Treasury, one of the things
10 we did was run the economic models underlying what
11 the likely responses to an increase in tobacco taxes
12 would be. In the course of doing that analysis, we
13 worked with the FDA substance experts and we all
14 reported in to a process led by the, you know, white
15 House Domestic Policy team on how the Administration
16 was working to get the -- to work to get the
17 legislation enacted.

18 And I do think that the FDA Commissioner
19 at the time was very much involved in talking
20 extensively with the white House about that. I was
21 certainly involved in extensive interactions with the
22 white House about making sure that policy was pursued

□

0169

1 effectively with the Congress.

2 Q Going back to the updates you gave the
3 white House from time to time, did those
4 interactions -- were they usually by telephone or in
5 person or both?

6 A Again, I don't have any specific
7 recollections about the several or thereabouts Plan B
8 brief updates that would have occurred. They could
9 happen either way. If we were downtown for a
10 meeting, if there's a -- I remember occasional issue
11 meetings about issues ranging from generic drug price
12 initiative; that was another big one that we were
13 undertaking in 2003 that the white House was very
14 concerned about and actually very helpful for us on.

15 We had requested some additional funds
16 from Congress to increase our ability to review
17 generic applications quickly, which was very
18 important to get low cost safe drugs to Americans.
19 So in the course of working with Congress to get that
20 legislation passed, there probably was a meeting at
21 some point with the white House.

22 On the tail end of that I might provide

□

0170

1 brief updates on one or a few issues that were moving
2 along at the Agency.

3 I don't have any recollections about doing
4 that with Plan B. It could also happen by phone. We
5 did a lot of work by conference calls. The Agency is
6 based up in Rockville and I tried to spend as much
7 time out in the general vicinity of my staff as
8 possible which means I couldn't really do a whole lot
9 of in-person work in close contact with the agencies
10 downtown like the Executive Office of the President.

11 Q incidentally, like, for example, this
12 conference call that listed with Jay Lefkowitz, would
13 it literally be just you and he on the phone or, if
14 it was a conference call, or would there be other
15 people either the FDA or at the white House who were
16 also listening to what was going on?

17 A It would depend. Longer call that got
18 into more substance may well have other people on it.
19 I think for something like this, you know, if it's a
20 brief update on Plan B or brief update on our user
21 fee legislation or something like that, it might just
22 be me talking with him for a few minutes.

□

0171

1 This looks like a call that was not a big
2 production; it was just a brief update type of call
3 and especially since it was scheduled at the same
4 time as something else I had to get to quickly, I
5 doubt that we would have -- I can't think of any
6 information at that time where I would need a lot of
7 additional technical experts.

8 On the other hand, if we were doing, you
9 know, a more substantive update, "Okay, we're two
10 weeks in the first BSE case" or we're about to
11 announce that we are removing ephedra from the
12 market, that would probably be the subject of a
13 longer briefing with more technical experts available
14 to make sure that we could answer any questions that

mcclellan

15 arose about the actions that we were taking.

16 Q I think you said earlier -- but I don't
17 want to mischaracterize what you said -- that you
18 would expect that when the FDA took some action on
19 Plan B, that the white House would at least updated
20 about that?

21 A Would be informed about it, yes; when we
22 were taking the action, so...

0172

1 Q Not before -- around the time of the
2 action?

3 A Right, and that was pretty typical, you
4 know, when -- in fact, recently, right before --
5 before the advisory council for this, or a few weeks
6 before, we had taken action on an application for
7 silicon breast implants where we went against the
8 recommendation of the advisory committee and gave the
9 company a non-approvable letter, and there was a huge
10 amount of press interest in that issue.

11 I think all the major networks covered it.
12 That's the kind of thing that is probably better for
13 the white House to know and the Administration to
14 know, the Department to know, that it's coming rather
15 than just tuning in on the television.

16 So would have given them a brief update on
17 "here's what we're doing. Here's why we're doing it;
18 here's why we didn't go along with the advisory
19 committee recommendation, and here's the course
20 forward for the company, here's what the press is
21 likely to focus on; something like that.

22 Q while you were at the FDA, there was never

0173

1 that kind of call with the white House about Plan B,
2 was there?

3 A No, because it was --

4 Q Was it?

5 A No, because the decision about Plan B was
6 not made while I was at the Agency. It was made
7 months after I left the Agency.

8 Q I just have a couple of questions and I
9 think we should take a lunch break if that's all
10 right with everyone?

11 MR. AMANAT: Sure.

12 BY MR. HELLER:

13 Q From your description of the white House
14 updates that you gave, it sounds like it was
15 primarily a process where you were providing them
16 with information. I'm trying to get a sense of were
17 there other meetings or perhaps no meetings at all at
18 which they gave you sort of feedback on your work.

19 They said, you know, "Thanks for this
20 information. Here's what we think of it." Did such
21 meetings ever take place? Were they combined with
22 the update meetings?

0174

1 A Not for something like this, for a drug
2 application. The kinds of cases where more that sort
3 of thing would come up is when we want to make new
4 policy or get new legislation. So, an example of it,
5 as I mentioned before, was we decided -- I decided it

mcclellan

6 was very important for us to get more funding for
7 generic drugs.

8 So to get a new budget request approved
9 you need to get the approval of the Office of
10 Management and Budget; that's the budget arm of the
11 White House that oversees the spending in the U.S.
12 government.

13 If we were issuing a new regulation, that
14 goes through PMB clearance as well, to make sure that
15 there are not any other departmental concerns or that
16 it's inconsistent with overall Administration policy.

17 So on those kinds of issue I very often
18 get feedback like, "what the heck are you thinking?"
19 and hopefully after while, if I got that kind of
20 feedback, I could convince them that this was the
21 right way forward, and that was the case with the
22 regulations that we went forward with like the

□
0175

1 regulatory action on ephedra.

2 Q So there is a sort of forum in which the
3 White House can express its disagreement or agreement
4 with work that the FDA is doing?

5 A When there is a new -- when the FDA --
6 when any agency in the federal government issues a
7 new regulation, that has to go through a clearance
8 process; first, with the relevant department, then
9 with the Office of Management and Budget representing
10 the Executive Office of the President, and at that
11 point there may well be feedback or guidance from the
12 White House about the new regulatory policy issue.

13 When the administration proposes new
14 legislation, there would similarly be a process to --
15 especially if it has budget implications associated
16 with it to go through Administration level clearance
17 of the new initiative.

18 So those kinds of things definitely got
19 feedback. That wasn't the case for a new drug
20 application. Those were, you know -- while I was
21 there, those were handled inside the Agency.

22 Q But it could be the case with a new drug

□
0176

1 application if the White House had some special
2 interest in it?

3 A Well, you know, I guess technically, since
4 the authority for approval or denial of an
5 application is delegated all the way down from the
6 Secretary who reports, you know, at least on paper
7 and constitutionally to the President of the United
8 States, there were no cases when I was at the Agency
9 where I did anything other than to support the
10 decision of the relevant career staff at the Centers
11 for the specific actions that they took in terms of
12 project -- product approvals.

13 Q Just as an example, if the FDA were about
14 to approve a new drug that would induce abortion,
15 elective abortion for women, do you think that would
16 be the sort of thing that you would want to update
17 the White House about?

18 MR. AMANAT: Objection. Calls for
19 speculation.

20 A Didn't happen while I was there. That did

mcclellan

21 happen with Mifiprex in the previous administration,
22 and I do believe there was some -- that was a very

0177

1 high level decision by the FDA. I think actually the
2 Commissioner of the FDA signed that approval decision
3 herself or certainly made up much higher in the
4 Agency than staff level review. But that was in the
5 prior Administration and not something I was directly
6 involved in.

7 MR. HELLER: Let's take a lunch break. Do
8 you have a preference about how long you'd like to
9 have?

10 THE WITNESS: An hour could be good for
11 me. If we could start at 1:30.

12 MR. AMANAT: Want to come back like 1:30
13 or 1:35.

14 THE VIDEOGRAPHER: We're going off the
15 record. The time is 12:32 p.m.
16 (Luncheon recess taken at 12:32 p.m. and
17 reconvened at 1:41 p.m.)
18
19
20
21
22

0178

1
2
3
4
5 AFTERNOON SESSION
6 THE VIDEOGRAPHER: We're back on the
7 record. The time is 1:41 p.m.
8 BY MR. HELLER:
9 Q Good afternoon. Before we had our lunch
10 break, you had described to me two categories of
11 people outside FDA who you had been in communication
12 with about Plan B, and I think one category was
13 people at the white House, office the white House and
14 the other was the Department of HHS?

15 A Right.

16 Q Are there any other -- were there any
17 other people outside FDA who you were in
18 communication about?

19 A Not that I recall aside from, you know, my
20 wife occasionally asking about what's going on,
21 colleagues in passing; no specific or detailed
22 conversations, though.

0179

1 Q Then after --

2 A Then, and I guess I'm just trying to think
3 of anybody else. Some members of Congress where, you
4 know, I had one meeting with several members of
5 Congress, and there may have been some brief
6 discussion of Plan B around other meetings I had with
7 members or testimony that I gave on the Hill, you
8 know, other interactions as part of my job then, or
9 subsequently Congressman Waxman asked me about this
10 issue subsequent to the time I was at FDA.

11 Q Okay.

mcclellan

12 A That sort of thing.
13 Q And then after you left the FDA, I think
14 you had said that -- maybe you didn't say this --
15 after you left the FDA, you had some communications
16 about Plan B around the GAO inquiry?
17 A Yes.
18 Q Aside from those communications, did you
19 have other communications about Plan B after you left
20 FDA?
21 A There were some related to the GAO inquiry
22 and that was not so much -- it was partly the GAO

□
0180

1 inquiry itself and then Congressman Waxman's letter
2 and the press coverage around that where we had a few
3 press inquiries, and I followed up with some of the
4 FDA staff as to how they were responding to make
5 sure, you know, I was aware of anything they were
6 going to be saying publicly about this.
7 Subsequent to that, I had some occasional
8 interactions with them around publicity for these
9 depositions. So when you said something to the press
10 and, you know, there's something reported on me about
11 it in the press, the FDA staff that would have
12 probably the most information on that.
13 Q Incidentally, going back to your contacts
14 with the White House, I think you indicated that one
15 of the reasons that you gave them updates about
16 Plan B was that it was in the news and they might
17 want to know information about what was going on, so
18 they might be able to, among other things, respond to
19 press inquiries?
20 A Yes.
21 Q Do you know if they had press inquiries at
22 the White House about Plan B?

□
0181

1 A I don't know of any, and if there were
2 press inquiries on issues that we dealt with they
3 didn't feel equipped to handle, we wouldn't often
4 hear about that. I didn't get any -- I didn't get
5 any follow-up like that on Plan B.
6 Q Exhibit 1 which I think you have still in
7 front of you, pages 4 through 10 appear to be
8 testimony you gave in front of some sort of, I guess,
9 House of Representatives body. Is that right?
10 A Yes; The Energy and Commerce Committee of
11 the House of Representatives.
12 Q Do you know whether you were under oath
13 when you gave those statements?
14 A I don't recall offhand.
15 Q Have you read over this recently, over
16 these pages?
17 A Not very recently.
18 Q Do you know when you last read over them?
19 A Probably at some point I looked back
20 through them in preparation for the deposition,
21 but --
22 Q Do you recall whether there was any

□
0182

1 statements that are recorded in here that you would
2 now disagree with or contradict?

mcclellan

3 A I don't recall anything offhand. I need
4 to look more closely.

5 Q Maybe we can do that a little bit later.

6 A Okay. But if you have any questions about
7 it, I'd be happy to answer them.

8 Q Returning to the time you were
9 Commissioner of the FDA and Plan B was under
10 consideration, after the SNDA was submitted, other
11 than Dr. Galson and Dr. Woodcock, were you aware of
12 the opinions of other scientists, career scientists,
13 in CDER about whether the data supporting an OTC
14 switch was adequate?

15 A Yes.

16 MR. AMANAT: Sorry. At what point in time
17 are you asking about particularly?

18 MR. HELLER: When it was -- I just said
19 when it was under consideration after the SNDA was
20 filed until he left the Commission.

21 A I was about to clarify after the briefings
22 that I had received from the staff, some of the staff

□
0183

1 made clear that they thought that the evidence was
2 adequate, that, you know, making those kinds of
3 extrapolations that I mentioned before was -- would
4 be appropriate.

5 BY MR. HELLER:

6 Q Are you aware of anyone other than
7 Dr. Galson and Dr. Woodcock within CDER who thought
8 that those extrapolations were not appropriate?

9 A In -- at the time I don't think that I
10 was. I mean, I have -- I don't recall exactly what
11 Dr. Woodcock and Dr. Galson characterized in terms of
12 the exact use of the staff at the time, and in
13 preparation for the deposition and in some of the
14 materials made reference to, you know, one or more of
15 the staff who had concerns about -- or who felt that
16 the application was not -- was not supported for
17 over-the-counter status.

18 Q Who was that?

19 A I believe it was Dr. Chen.

20 Q Anyone else?

21 A I don't recall any specific names, no.

22 Q So is it fair to say that you were aware

□
0184

1 within CDER as between Dr. Galson and Dr. Woodcock
2 and the other career scientists that there was a
3 disagreement about the adequacy of the data?

4 A That certainly became more apparent over
5 time. I'm not sure I was, you know, fully aware of
6 it in the December briefing that I had, but
7 definitely by the February briefing it was clear that
8 some or many of the staff had a different view or
9 different level of concern about the gaps in the
10 evidence. I think everybody agreed that the evidence
11 wasn't ideal, but they had reached different
12 conclusions or had different levels of confidence
13 about the adequacy of the evidence that was
14 available.

15 Q Can you tell me what would be some of the
16 benefits, if any, of making Plan B available
17 over-the-counter?

mcclellan

18 A One benefit would potentially be reduced
19 pregnancy in women, particularly unwanted
20 pregnancies; that does have health consequences.
21 Other benefits might be lower cost, overall access to
22 effective birth control.

0185

1 Remember as we talked about before this
2 was not meant to be a primary form of birth control
3 but just an emergency source of contraception, and in
4 the absence of an over-the-counter program, you'd
5 have to see a physician, and pay the added cost
6 associated with that to get access to the drugs.

7 There are some other ways to address that
8 issue, like some of the very impressive evidence from
9 some of the advanced provision programs and
10 clinic-based programs which are kind of sort of
11 win-win in the sense you get easier access and it's
12 lower cost and less burdensome than seeing a
13 physician.

14 Also, I understand since the time of the
15 application there's been a substantial increase in
16 the use of advanced provision form of people asking
17 for, at least a course of treatment, well before they
18 might need it, getting counseled by a physician and
19 getting a prescription filled so they have it handy
20 when they need it at the time. That goes to the
21 convenience issue.

22 The point is there are some clear benefits

0186

1 from making emergency contraception available OTC.
2 Some of those benefits you can achieve at least in
3 good part through other steps than going all the way
4 to OTC status but that is -- there are important
5 benefits.

6 Q Would one of the benefits be avoiding
7 abortions --

8 A Yes.

9 Q -- unwanted pregnancies?

10 A Potentially to the extent that abortions
11 carry important health risk, health risk for the
12 mother.

13 Q Earlier in your testimony I think you
14 indicated there were other countries or you knew of
15 some other countries --

16 A Yes.

17 Q -- where Plan B -- I'm not even sure it's
18 necessarily called Plan B in each of these other
19 countries; it may have a different name, but that
20 it's available without a prescription in some other
21 countries but that they have -- it isn't like
22 over-the-counter in the United States.

0187

1 Do you know which countries those are?

2 A I think Plan B is unique to the United
3 States. In fact, that was another area of
4 disagreement within CDER as to what this product
5 should be called that predated my arrival at the
6 Agency. In terms of where the product is available,
7 like which countries?

8 Q Yes. Do you know?

mcclellan

9 A I think it's Norway and Sweden,
10 Scandinavian countries where it's purely OTC. There
11 is a larger number of countries where it is available
12 in some kind of behind-the-counter form or with some
13 more limited involvement of a health professional
14 required in order to use the product.

15 And there are a lot of countries, probably
16 the largest number of countries, where it is still a
17 prescription status.

18 Q Norway and Sweden if you have those
19 countries right?

20 A I should add, too, that my level of
21 awareness of this issue is a little bit dated at this
22 point. Those were the countries that were mentioned

0188

1 in the briefings that I had a couple years ago.

2 Q I've asked you a whole lot of questions
3 today so far.

4 A That's okay. That's what I'm here for,
5 you should ask me all of them you want to answer.

6 Q -- about the Plan B SNDA. I want to try
7 to capture a lot of information with one or two
8 questions, which is, there was also a Citizen's
9 Petition that was recently denied by the FDA to
10 switch Plan B to the over-the-counter. Were you
11 aware of that Citizen's Petition?

12 A Yes.

13 Q Were you aware it was denied on Friday?

14 A I did find out about that late on Friday.
15 I wasn't aware of it beforehand.

16 Q How did you find out about that?

17 A It was mentioned to me by someone from the
18 General Counsel's office just in passing. I think
19 Paula Stanard actually.

20 Q In terms of the communications you've
21 described that you had around Plan B, both with the
22 White House, HHS, within FDA, are there -- is there a

0189

1 separate set of communications that you had regarding
2 the Citizen's Petition?

3 A No.

4 Q So sort of what you testified about today
5 so far would encompass all the communications you had
6 about the Citizen's Petition, when the -- in your
7 description of those communications?

8 A Yes. Yes, I did not have any other
9 conversations about the Citizen's Petition. I think
10 they're internally -- and you're asking about
11 internally within the Agency or externally?

12 Q Both.

13 A Okay.

14 Q I'm trying to -- I prefer not to go
15 through all those same questions with you about the
16 Citizen's Petition?

17 A Okay.

18 Q So I want to see, are there any
19 conversations, either external or internal, internal
20 being within the FDA, that dealt only with the
21 Citizen's Petition?

22 A External, no. Internal, yes, especially

0190

1 early on as part of some of the introduction to the
2 general issues around Plan B.

3 Q Okay. The question I asked you about
4 avoiding abortions as a possible benefit of
5 over-the-counter access to Plan B, can you compare
6 for me which presents more of a problem for a woman,
7 having an abortion or carrying a pregnancy to term in
8 terms of health risks?

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

11 A Not offhand. I'm not a Ob/Gyn specialist
12 and I'm sure that given some proper informations to
13 review, I could get back up to speed on this issue.
14 They both present important risks to the mother.

15 BY MR. HELLER:

16 Q Okay.

17 A Obviously risks to the baby, too.

18 Q What are the risks to the baby?

19 A Well, with a term pregnancy, there are
20 some -- the risks of adverse outcomes for the infant
21 or the neonatorum are order of magnitude larger than
22 the risk of outcomes for the mother, and for preterm

0191

1 pregnancies higher risk for the baby.

2 Q I'm going to show you a document if I can
3 find it (perusing.)

4 while we're trying to locate this
5 document, do you know if the data about Plan B showed
6 that the sooner after unprotected intercourse that
7 it's used properly the more likely it is that it will
8 be prevent pregnancy?

9 A Yes.

10 Q That would be one reason, also, that in
11 making available over-the-counter might reduce
12 unwanted pregnancies because the process might be
13 faster if a woman can just go buy it as opposed to
14 having to go to a doctor and get a prescription; is
15 that right?

16 A That's right. Faster access definitely
17 improves effectiveness but, you know, by that
18 argument the most effective approach is advanced
19 provision where the woman who is getting regular
20 health professional counseling about an effective
21 contraception method would get a prescription for
22 this in advance in addition to whatever counseling

0192

1 she received about her regular contraception, so
2 she's got it available right then, if the other birth
3 control fails.

4 Q Especially if that option is available to
5 her, that advanced provision option?

6 A Well, it does take some effort. It does
7 thinking about your contraception method ahead of
8 time, having a plan and having a discussion with your
9 physician and the physician giving you an advanced
10 prescription.

11 But, you know, anyone, I think, can get,
12 who has a prescription filled -- you don't have to
13 actually have had intercourse in order to get
14 prescription for Plan B and many more people in the

mcclellan

15 last several years are doing just that.

16 Q There are people, though, aren't there,
17 who have no health insurance and therefore try to
18 minimize having to pay for healthcare themselves and
19 therefore might not have regular contact with a
20 physician?

21 A Well, and that's why it is so important to
22 have a cost effective or inexpensive ways for people

0193

1 to get effective contraception counseling. There are
2 lots of ways to do it besides the standard office
3 visit -- school clinics in some cases, other
4 community health clinics, planned parenthood, other
5 groups are involved in providing lower cost access,
6 not just to Plan B, which is not by any means a
7 complete plan for reproductive health but for a whole
8 coherent plan for contraception management.

9 So that's absolutely an important policy
10 priority is making those less expensive, effective
11 alternatives available. The Plan B alone, you know,
12 access to Plan B alone, doesn't provide that kind of
13 effective planning support for contraception.

14 Q Do you know if the Department of Health
15 and Human Services supports complete contraceptive
16 education in schools?

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

19 A I don't know offhand. That's outside of
20 the purview of the -- while I have had direct
21 experience in overseeing much of what HHS does,
22 educational grants are not part of my portfolio.

0194

1 BY MR. HELLER:

2 Q But you don't know anything about it?

3 A Not offhand.

4 Q But you would support that?

5 A Well, I am in favor of some -- I am in
6 favor of an effective approach to contraception, and
7 whether it's through federal funding or through other
8 means, I think there are lots of different tools
9 available that can help us achieve that goal.

10 Q Okay. I found the document I think.

11 A Okay.

12 MR. AMANAT: You gave me a copy. Do you
13 have a copy for the witness?

14 MR. HELLER: I think I have -- I don't
15 know what I have. Yes, I have a copy for the
16 witness.

17 Q This is a document that is at bottom
18 marked 30393 and it ends with 30396. It's at least
19 four pages that I want to call your attention to.

20 First of all, I want to ask you if you
21 reviewed this document recently in preparation for
22 this deposition?

0195

1 A Yes, I reviewed it briefly. And you
2 should know the binder of records related to the
3 Agency's action on Plan B -- well, you probably do
4 know -- it's a really thick set of documents and I
5 have not had time to review any or all of these

mcclellan

6 documents very closely but this is the, as it says,
7 the "Executive Summary" of briefing that was held for
8 me on December 10th so I'm basically familiar with
9 the event.

10 Q You did attend this event?

11 A Yes.

12 Q Do you know who requested this event?

13 MR. AMANAT: Can you give the witness an
14 opportunity to read the document, please, before you
15 ask him about the document?

16 MR. HELLER: I'm not asking about the
17 document.

18 Q Do you know who requested the December
19 10th 2003 meeting?

20 A I'm just seeing if there's any information
21 on here that would be relevant to helping my memory
22 (perusing.)

□
0196

1 I don't. My expectation is that the
2 Center put forward at least the suggestion of having
3 a briefing ahead of the advisory committee.

4 This is something that happened on other
5 occasions as well while I was Commissioner. For
6 example, we were talking earlier about the silicon
7 breast implant Agency decision which was I think in
8 October or maybe November of 2003.

9 There, too, there had been a high profile
10 advisory committee meeting and there, too, the Center
11 had briefed me beforehand on the issues that were
12 expected to arise at that briefing and afterwards on
13 how they were planning to proceed in dealing with the
14 application.

15 So this was -- it wouldn't be surprising
16 to me if the Center requested it. I don't have any
17 more specific recollection of it.

18 Q You described, I think, the advisory
19 committee meeting as high profile. Can you tell me
20 what that means to you?

21 A That means that it was expected to and did
22 generate a significant amount of media attention and

□
0197

1 other congressional and advocacy group and public
2 attention.

3 Q Do you know someone named Jennie Embrey at
4 FDA?

5 A The name sounds familiar but I don't know.
6 I don't know who she is offhand.

7 Q When there is a OTC switch -- I mean, you
8 weren't at the FDA for 20 years, but during your
9 tenure there, when there was an OTC switch that was
10 going to be considered by advisory committee, was it
11 typical to have this sort of
12 office-of-the-Commissioner meeting?

13 A When there was a high profile issue for an
14 advisory committee, it absolutely was typical for
15 there to be a briefing or some other kind of formal
16 way of informing the Commissioner's office about it.

17 As you said, I was only at the FDA for 16
18 months, there are only a limited number, a lot, but
19 still relative to a longer timeframe at FDA, a
20 limited number of issues that came before me.

mcclellan

21 And, you know, just another example was
22 the silicon breast implant case where I did get

0198

1 briefed beforehand about the issues that the advisory
2 committee was going to deal with and got an update
3 afterwards from the Center about what they found and
4 the issues that they were considering in determining
5 how to proceed.

6 Q This wasn't the first time you had heard
7 about the OTC switch for Plan B? You had known about
8 it since at least April of that year or earlier
9 before that?

10 MR. AMANAT: This being what, you mean
11 December 10 --

12 BY MR. HELLER:

13 Q This wasn't now for the first time they're
14 informing you that this was underway because you had
15 known about it for quite some time?

16 A That's right. This was a good
17 opportunity, though, for the staff to pull together a
18 lot of the information they had compiled in the
19 course of their review and subsequent discussions
20 with the company about the product, so one --

21 The way the Agency typically works is that
22 the staff and the office or offices that are

0199

1 immediately responsible for the review will take a
2 first passthrough the application, review any
3 questions, concerns, any incomplete aspects of the
4 application, take steps to fill in those gaps with
5 the company, and then they'll start compiling sort of
6 a summary of what kind of information they had have,
7 what the major issues or what the evidence is bearing
8 on those issues.

9 That all typically happens in some detail
10 inside the Center, and then on -- in preparation for
11 the briefing, they'll pull that all together in a way
12 to let the Commissioner's office know about what it
13 is, you know, where the analysis stands; what it is
14 they found.

15 This thing is also part and parcel of
16 getting ready for a high profile advisory committee
17 meeting where the same kind of thing happens there.
18 I don't have the particular slides or attachment here
19 but my guess is that much of the same information
20 that the Center staff presented to me at this
21 briefing was what they presented to the advisory
22 committee soon after.

0200

1 So it's part and parcel of preparing in an
2 organized way for an advisory committee meeting and
3 the next step in the review process for a drug
4 application.

5 Q On the first page of this document, 30393
6 there is a heading, bullet point discussion, and then
7 on the other side it says "all". Does that mean that
8 everyone was essentially was invited to participate
9 in that portion of the discussion?

10 A Well, that's the way I usually like to
11 run -- run business at these briefings is there is a

mcclellan

12 lot of back and forth and discussion of the issues
13 that had been brought up.

14 Now, that doesn't mean that everybody
15 actually said anything. As you can see from the list
16 of invitees there were people there from the Center,
17 people there from various parts of the Commissioner's
18 office, our Office of Science, our Office of Policy
19 and Planning, our Office of Women's Health, Chief
20 Counsel's office, Press Office, so lots of different
21 people with lots of different perspectives on the
22 information being discussed.

0201

1 And it wouldn't -- it wouldn't be unusual
2 for many of them to ask questions or make comments.
3 And I think one constant feature though of all these
4 briefings is I would ask questions particularly about
5 the science and getting to these issues of what kind
6 of extrapolations are people thinking about, and how
7 confident are they about them.

8 Q Do you recall any of the questions you
9 asked at that meeting?

10 A Not specifically, but I'm sure just
11 because of the concerns I had about the
12 extrapolations that were being done, they pertained
13 to issues like the level of understanding that Plan B
14 is not meant as a primary or usual method of birth
15 control particularly among less educated women,
16 issues related to extrapolating from the information
17 observed in limited studies for limited timeframes in
18 settings where women had ongoing access to healthcare
19 and health professionals, to the over-the-counter
20 setting, and particularly related to young girls.

21 Q When you say "young girls," I realize we
22 were both using that term earlier. What do you have

0202

1 in mind?

2 A Young adolescents and preadolescent girls.
3 As you know the age of menarche in this country has
4 come down. I think the average age is around 12 now,
5 so that means there will be some girls who will be
6 post menarchal well before age 12; so that kind of
7 age range on up to 16, 17.

8 Q Okay. I'm going to show you a different
9 document. This is has a number 512?

10 A Am I done with this one?

11 Q Yes. I can take that back.

12 A (Witness proffered.)

13 Q Thanks.

14 MR. AMANAT: Are you going to show 511
15 with it, too, or is it just 512?

16 MR. HELLER: I found 511 so unreadable
17 that I thought I would start with 512?

18 A Do you have 511 handy?

19 Q I could give you 511 as well if it would
20 help, but it's a -- let me ask you a question first.

21 A Okay.

22 Q Do you recall talking with someone named

0203

1 Dr. Carmona about Plan B?

2 A I know Dr. Carmona well. I talked with

mcclellan

3 him frequently while I was at the FDA because we both
4 dealt with broad range of public health issues facing
5 the nation. I do not recall this specific brief
6 call.

7 Q How can you tell me that it's a brief
8 call?

9 A Because on the subject line of the
10 document you just handed me, it says "short call,
11 during this time," and this time is 8:30 minute
12 window -- short call during this time with
13 Dr. Carmona.

14 Q It also says there "SG wants to discuss
15 recent ruling on Plan B." SG would be Surgeon
16 General?

17 A Yes.

18 Q Do you recall that he wanted to discuss
19 some Plan B ruling with you?

20 A No. I do recall that, you know, fairly
21 often -- and I can try hard to think about how often
22 if that's very important, but fairly often -- he

□
0204

1 would call to ask about some issue that FDA was
2 dealing with that had a potential impact on the
3 public health.

4 Remember he's the most visible spokesman
5 in the Administration on the public health issues.
6 He's the Surgeon General and he spends a lot of his
7 time out on the road talking to groups, talking to
8 reporters, intermixing with the public, around many
9 of the public health issues facing the nation.

10 In that context, he can be virtually
11 guaranteed that he's going to be asked about whatever
12 the public health issues of the day are going to be.
13 So we would talk from time to time about things like
14 the Administration's action on ephedra.

15 I expect that I gave him an update or gave
16 his staff an update on or our staff gave his staff an
17 update on issues like breast implants and certainly I
18 discussed the BSE case with him.

19 Remember he's got a major role for sort of
20 communicating to the public in plain English about
21 things that they are -- they need to know and about
22 things they might ask about. And, again, I think

□
0205

1 this was the day -- was this the day after the
2 advisory committee meeting?

3 It would have been -- I don't have the
4 dates, but they probably would have been given this
5 around the advisory committee time, a fair amount of
6 press coverage about that issue, and I expect he
7 wanted to know what we were saying about it, what he
8 ought to say about it.

9 I have the same discussion with my own
10 press staff so that we were all on the same page
11 speaking clearly and appropriately about what the
12 advisory committee was doing.

13 Q Did anyone else participate on that call,
14 do you remember, besides yourself and the Surgeon
15 General?

16 A I don't remember.

17 Q Do you recall a letter that David Hagar

18 sent to you about Plan B?

19 A Yes. That's been mentioned in press
20 reports and in some of your publicity around these
21 deposition proceedings and so forth. So I am
22 familiar with the letter.

0206

1 Q Do you know if he decided to write that
2 letter spontaneously himself or whether someone asked
3 him to write a letter expressing sort of the
4 dissenting view of the advisory committee?

5 A I know from press reports that he said, I
6 think, that someone had asked him to bring the
7 letter.

8 Q Yes, but do you know if someone asked him
9 to write that letter or a letter like that?

10 A No.

11 Q Just to be clear, you don't know whether
12 someone asked him or nobody asked him?

13 A I don't know whether anybody asked him
14 and, you know, I know I didn't ask him and I don't
15 know of anybody else who would have.

16 Q Okay. I'm going to show you a copy of the
17 letter. On the bottom it is 13 and 14, and 15, there
18 are some other pages?

19 A Are we done with the Surgeon General
20 (proffered.)

21 Q Thanks. Some of the concerns he raises in
22 this letter -- and I'm going to point out a few of

0207

1 them. First of all, I think he actually uses the
2 word concerns. He says he has major concerns
3 especially about adolescents. Do you see that in the
4 second paragraph?

5 MR. AMANAT: Will you give the witness an
6 opportunity to read the document?

7 A Are we going to go through the whole
8 letter or do you want me -- is it worth it?

9 BY MR. HELLER:

10 Q Probably not.

11 MR. AMANAT: I still rather him have an
12 opportunity to read the document.

13 A I'll read quickly. Just a minute.
14 (Perusing exhibit.) Okay.

15 BY MR. HELLER:

16 Q You would agree with me he expresses a
17 number of concerns about making Plan B available
18 over-the-counter in this letter?

19 A He does express, as he says, in this
20 letter great concerns.

21 Q Tell me if I'm right about this: One of
22 them, one of the concerns that he expresses is that a

0208

1 very small number of the women in the actual use
2 study were between 14 and 16 years of age, or 14 to
3 16. I'm looking at the top of page 2.

4 A Okay. Okay. I see that.

5 Q That was also one of your concerns, wasn't
6 it?

7 A Well, it was one of the concerns that was
8 noted in the advisory committee meeting and noted in

mcclellan

9 the documents used to prepare for the advisory
10 committee meetings as well, so, yes, I mean, he
11 mentions it as well but this was a concern that came
12 up in many other sources.

13 Q I'm asking if it was one of your concerns?

14 A Oh, right. As we've already talked about,
15 the small numbers of younger women and girls makes it
16 harder to competently extrapolate from other parts of
17 the population.

18 Q Later on as sort of the third full
19 paragraph on the second page, he talks about a great
20 concern about women of low socioeconomic and
21 educational status. You also, I think, earlier in
22 today's deposition mentioned a concern about label

□
0209

1 comprehension among less educated women.

2 was that also from you?

3 A Yes, but just reading his paragraph, his
4 concern sounds different than what I said earlier
5 today and what we discussed at the time. He had
6 concerns about women in lower socioeconomic status.

7 This is somewhat different from what I
8 said earlier in that he says, "I have a great concern
9 about those women of low socioeconomic and
10 educational status" and then at the end of the
11 paragraph "will this," this meaning pricing, "will
12 pricing exclude lower socioeconomic women from the
13 availability of the drug."

14 Now, when we were talking earlier it was
15 about the pricing being a potential barrier to repeat
16 or, you know, more frequent use of the drug than
17 very, very rarely on emergency occasions. So that's
18 different.

19 (The following was marked protected testimony
20 and is excluded from the main transcript.)

21 * * * *

22
□
0210

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

0211

1
2
3
4
5
6
7

(This concludes the protected testimony portion.)

8

MS. REYES: I ask that be marked confidential, question and answer.

9

10

MR. AMANAT: I'd like to hold to this one because I may ask him about it.

11

12

BY MR. HELLER:

13

Q I'd like to show you a document that's marked --

14

15

A want these back (proffered.)

16

17

Q -- Tummino 288 and it is -- it's a calendar page I think from your calendar that's mostly been blacked out but the one thing that is readable is a "1:15 p.m. to a 1:45 p.m. conference call with Galson/Woodcock regarding Plan B."

18

19

20

21

22

□

0212

1

Do you see that notation?

2

A Yes.

3

4

Q Do you have any idea what this conference call was about?

5

6

A I don't have any specific recollection of the call. It was soon after the advisory committee meeting so it may have been to provide me with an update on that meeting and the next steps that the Center intended to take.

7

8

9

Q Was there such a call or meeting at which they advised you about the next steps they intended to take after the advisory committee meeting?

10

11

12

A Well, over the -- I don't have any specific recollection of this call but over the ensuing weeks I did hear more from the Center about the further steps they were taking to look at all evidence possible related to lower education groups and younger women and girls.

13

14

15

16

17

18

And at some point in this, you know, in the weeks after the advisory committee meeting they discussed having a follow-up briefing to go over the more detailed scientific information that the staff

19

20

21

22

□

0213

1

had gathered following on the initial advisory committee the meeting.

2

3

So I don't know whether it came up on that call or subsequently.

4

5

Q Thank you.

6

7

MR. AMANAT: It would be more efficient if you just gave us a copy of the binder.

8

9

MR. HELLER: Maybe in discovery. Will you give us a copy of all your binders?

10

11

MR. AMANAT: I don't use any binders in also deposition.

12

13

MR. HELLER: Or anything you have in your office on this case.

14

Q The next document I'm showing you now is

mcclellan

15 marked 30666 through 30670, and it appears to be
16 meeting minutes from a January 15th 2004 meeting
17 chaired by Dr. Galson and if you would turn to the
18 second page of this document?

19 A (Witness complied.) I'm just reading over
20 who --

21 Q who was there?
22 MR. AMANAT: Again, I'd like the witness

0214

1 to have an opportunity to read the whole document,
2 please.

3 MR. HELLER: I'm not going to ask him
4 about the whole document.

5 MR. AMANAT: Well, I'd still like him to
6 read --

7 MR. HELLER: He can read it later.

8 MR. AMANAT: It is only three pages long
9 and to read the whole document before you ask him
10 about it.

11 MR. HELLER: why don't you see what my
12 question is first.

13 Q If you'd look at the second page?

14 A Okay.

15 Q There is a line that says "meeting
16 objective to inform ODE3 and ODE5 of the office of
17 the Commissioner's position on the acceptability of
18 the application. Do you see that?

19 A Yes.

20 Q My question is by January 15th 2004 had
21 the Office of the Commissioner formulated a position
22 on the acceptability of the Plan B SNDA?

0215

1 A Not to my knowledge, but the Office of the
2 Commissioner is a large group and it's entirely
3 possible that someone somewhere in the Office of the
4 Commissioner had a position on the acceptability or
5 the application, certainly not from an overall
6 standpoint, or a standpoint of any particular
7 direction.

8 Q So you had never, prior to January 15th
9 2004, informed Dr. Galson about your position on the
10 acceptability of the Plan B SNDA?

11 A Let me -- do you mind if I read through
12 the rest of this?

13 Q Sure, if you need to answer that, go
14 ahead.

15 A This is just a meeting that I was not -- I
16 had not participated in this meeting and am not, you
17 know, very familiar with what happened then
18 (Perusing.)

19 Okay. Let me go back to the question,
20 again, or you can read it back if you want.

21 MR. HELLER: Could you read it back?
22 (The following question was read:

0216

1 "QUESTION: So you had never, prior to
2 January 15th 2004 informed Dr. Galson about your
3 position on the acceptability of the Plan B SNDA?")

4 A No. At this stage I would have informed
5 him about some concerns I had based on the briefing

mcclellan

6 and the advisory committee meeting and, you know,
7 would have come up in our subsequent discussion as
8 well, and, you know, if you look down at the action
9 items from this meeting what it says is that they
10 were planning to meet with the Commissioner to
11 discuss Office of Commissioner concerns and, you
12 know, that can include someone like Janet Woodcock as
13 well; she was detailed over to the Commissioner's
14 office at the time, and present more data on the use
15 of adolescents girls and that this meeting was going
16 to take place in early February and the staff were
17 going to gather available data.

18 Again, I think at this time staff was
19 doing some very diligent follow-up to identify all
20 available evidence related to younger girls and
21 understanding of -- understanding of the label in
22 less educated populations and they were proceeding

□
0217

1 with their review.

2 So that's -- those action items are very
3 consistent with what I understood the status of the
4 application to be. In my discussions with Dr. Galson
5 I don't recall him telling me that the -- either his
6 staff or he were making a final recommendation or
7 decision on the product.

8 BY MR. HELLER:

9 Q I think we need to stop for a moment for
10 the videographer, am I right, to switch tapes. So if
11 we can go off the record or a few minutes?

12 THE VIDEOGRAPHER: This marks the end of
13 tape 2. We are going off the record the time is
14 2:29 p.m.

15 (Change tapes.)

16 This marks the beginning of tape 3 in the
17 deposition of Dr. McClellan. We are back on the
18 record. The time is 2:36 p.m.

19 BY MR. HELLER:

20 Q Dr. McClellan, we were looking at a
21 document before the break and this document indicates
22 or talks about some concerns and issues regarding the

□
0218

1 data submitted in support of a Plan B SNDA.

2 Do the concerns and issues described
3 here -- are they, in fact, the concerns and issues
4 you had with the Plan B SNDA at that time?

5 MR. AMANAT: I'm going to object to the
6 form of question. Are there specific -- it's a
7 compound question unless you identify which specific
8 concerns you're referring to.

9 BY MR. HELLER:

10 Q Are they all your concerns or are there
11 some that are not your concerns?

12 A Some of these are my concerns about the
13 label comprehension and lack of evidence from actual
14 use studies on younger -- on the younger age group.

15 The recommendation of a non-approvable
16 letter is not something I had heard from the Center
17 at that time, and I didn't know anything about, you
18 know, it's not -- there wouldn't be any reason I
19 would, but I didn't know anything about labeling
20 negotiations or anything like that.

mcclellan

21 Q with respect to the point that you just
22 mentioned, a non-approvable letter is recommended,

0219

1 could that have been recommended by someone else at
2 the Commissioner's office?

3 A I think it's -- aside from Janet Woodcock,
4 I don't think there was anyone who was really
5 following the scientific issues closely, and, you
6 know, again the discussions that I had with
7 Dr. Woodcock and Dr. Galson by way of updates on what
8 the Center was doing with the review of the
9 application, indicated that they had not reached a
10 decision about the product at this time, or, really,
11 even while I was at the Agency.

12 I mean the whole point, I think, of having
13 the follow-up meeting the next month, and that was
14 like, I think of the meeting, the next briefing I had
15 in mid-February was to go over some of the concerns
16 raised here to help -- I gather inform me and maybe
17 discuss with the Center director the further work
18 that the Center had undertaken on these issues
19 related to safety.

20 So the Center didn't usually waste my time
21 on issues where the conclusion was already
22 determined, and to have a follow-up briefing it was a

0220

1 good indication they wanted to have some further
2 discussion and, again, from my discussions with
3 Dr. Galson, Dr. Woodcock, they certainly seemed very
4 open and interested to further discussion of the
5 science.

6 Q This document on the page marked 30668
7 uses the term "FDA upper management," sort of in the
8 last sentence of the page. Do you see that?

9 A (Witness perusing.) Yes.

10 Q Do you have an understanding what that
11 means? What is "FDA upper management?"

12 A I don't know, that's not a formal FDA term
13 and I don't think I've seen that in many other
14 official documents.

15 Q Do you know at what point Dr. Galson
16 decided that the decision on the Plan B SNDA would
17 not be made at the ODE level?

18 MR. AMANAT: Objection.

19 MR. HELLER: What's your objection?

20 MR. AMANAT: Assumes a fact not in
21 evidence. You can answer the question.

22 A No.

0221

1 BY MR. HELLER:

2 Q Do you know if he decided at some point
3 that it would not be made at the ODE level?

4 A I do know that when the decision on this
5 initial application came out of the Agency in May, he
6 disagreed with the ODE level recommendation.

7 I do know that subsequent to that, the
8 company filed an amended application that was
9 responsive to the concerns raised, and I think he
10 supported that application.

11 Q The next document I'm going to show you is

mcclellan

12 marked 30719 to 30722 (proffered.) This seems to be
13 meeting minutes of a February 18, 2004 meeting that
14 was chaired by Dr. Galson which you attended.

15 Do you remember this meeting?

16 A Yes.

17 Q If you turn to the second page of this
18 document -- by the way, did you review this document
19 recently in preparation for your deposition?

20 A It was in the document packet but, if you
21 don't mind, I could probably use a couple of minutes
22 to look through it now.

□

0222

1 Q Go ahead.

2 A (Witness perusing.) Okay.

3 Q All right. If you turn to the last page
4 of the document I handed you, did you concur in these
5 meeting minutes?

6 A No, I did not see these meeting minutes
7 while I was at the Agency.

8 Q So when it says concurrence M. McClellan
9 on the last page, what does that mean?

10 A I don't know. You know, there's not a
11 date next to it, so I don't know why it would have --
12 I don't know if the others just concurred with no
13 date. I know I did not review these minutes while I
14 was at the Agency.

15 Q Do the minutes accurately reflect what you
16 recall having happened at the meeting?

17 A Well, they accurately reflect many of the
18 issues that we discussed related to the status of
19 scientific evidence and the additional evidence that
20 the review staff had pulled together, I think, from
21 reviewing further studies, from further contacts with
22 external experts on these very important questions of

□

0223

1 scientific evidence.

2 In terms of the characterization of my
3 comments, I don't think that's quite -- I don't think
4 that's the way I would put it, and certainly on the
5 characterization of the action items, I'm not sure
6 that fully or accurately captures my perspective at
7 the meeting.

8 Q Let's start with the first one.

9 A Okay.

10 Q What did you say at the meeting that
11 differs from what is recorded in these minutes?

12 A Well, I think a lot of the discussion, and
13 I don't have -- there was a hand out they prepared
14 along with it and some other documents as well. I
15 don't have that in front of me now.

16 But, you know, "a trend toward a potential
17 difference in various parameters," I think I would
18 characterize that much more in the context of the
19 specific items earlier in the list, so earlier in the
20 discussion they note a whole series of important
21 elements for making safety and effectiveness
22 determination here like impacts on sexual and

□

0224

1 contraceptive behavior, label comprehension data and
2 the like.

mcclellan

3 This is all summarized as sort of one line
4 of a potential difference in various parameters?

5 I think in a number of those studies there
6 were some reasons for concern. Now, the reason it
7 says potential difference is I wouldn't have
8 characterized it that way; I would have characterized
9 it as the study was underpowered to detect a
10 potentially important difference because of the small
11 sample sizes involved, and just to give -- we talked
12 earlier about, I guess, it's the Raines study -- I
13 don't know if it is Raine or Raines -- but the Raines
14 study did show some numerical differences that could
15 be of policy importance in a number of results
16 related to contraceptive behaviors in the younger age
17 groups.

18 There was another study that, if I recall
19 correctly -- and again I don't have it in front of
20 me, so this is just from memory -- that showed a
21 difference in sexually transmitted diseases rates.

22 These were not statistically significant

□
0225

1 differences but they were differences of a magnitude
2 where, if you had a decently powered analysis, you
3 would have been able to see a statistically
4 significant result.

5 So I think the trend towards a potential
6 difference doesn't quite do justice to the more
7 extensive discussion that we had about the issues and
8 the level of evidence in the information that was
9 presented.

10 As another example, we talked, you know it
11 by "counseling by a learned intermediary may be a
12 benefit." I think what we talked about more in the
13 discussion was that many of these studies were done
14 in populations where the young girls and young women
15 involved had access to some kind of ongoing health
16 professionals or learned intermediary interaction.

17 They were patients in a health clinic or
18 they obtained the Plan B product on a limited basis
19 through some kind of study protocol or protocol
20 involving a checklist with health information and the
21 like.

22 So I would probably characterize my

□
0226

1 response as being more, rather than not convinced,
2 you know, convinced by a study is -- I hardly even
3 know what that means. What you do is you review
4 actual evidence and then you make inferences about
5 how to go beyond that.

6 The discussion that we had, had to do with
7 how the studies did not have either not sufficient
8 power but how you could make inferences from studies
9 about one type of setting to a study that differs in
10 important respects, the over-the-counter setting;
11 that's not really captured in those bullet points,
12 either.

13 Q In the bullet points under action items I
14 want to ask you specifically about some of them.

15 A Okay.

16 Q The first says, "CDER was directed to
17 continue work with the sponsor on a marketing plan to

mcclellan

18 limit availability of the product over-the-counter,
19 and to consider the most appropriate age groups to be
20 restricted from access to the product.

21 Did you direct CDER to do that?

22 A I don't think what I would characterize my

0227

1 action at the meeting -- I don't think I would
2 characterize my action at the meeting as direction.
3 Again, I don't have real detailed memories of this,
4 but I expect that, as you pointed out in the last
5 document you saw, that some CDER was doing some work
6 with the sponsor on a limited marketing plan or on
7 some alternative ways of marketing the product.

8 I expect they let me know they were doing
9 that, and I didn't say about not doing that. I
10 agreed, okay, that seems like it is not an
11 unreasonable thing to do.

12 Q Did you direct them to consider the most
13 appropriate age groups to be restricted from access
14 to the product?

15 A I don't have any particular recollection
16 of telling them to or not to work on a specific age
17 group restriction. Again, I think that's something
18 that the Center was already doing some work to
19 address, based on, you know, some of the differences
20 of opinion that you mentioned started to emerge or
21 were apparent back in January.

22 Q The second point here under action items,

0228

1 did you express that restricted distribution would
2 deserve another discussion in a public forum before
3 implementation?

4 A I'm almost sure that's at least a
5 mischaracterization of what I said. We've talked a
6 lot today about the importance of an Agency being
7 transparent and providing information to the public
8 about the foundations for its actions and
9 particularly the underlying science.

10 In this case, over the past month, the
11 CDER staff had, in fact, been working with experts
12 outside the Agency on issues like whether there was
13 supplemental evidence that would be relevant to the
14 kinds of policy decisions about young girls that were
15 at issue here.

16 I found that getting public input in one
17 form or another, and it doesn't necessarily have to
18 be formal, can be very helpful in breaking logjams
19 and finding win-win solutions for it, in addressing
20 what seems like gaps or difficult problems in the
21 Agency's existing approach to an issue.

22 So while I'm sure I -- as I did in many

0229

1 briefings raise the issue of would it be useful to
2 get further public input on how to address these
3 kinds of concerns, or how to -- how to address some
4 of the evidence issues raised, you know, I don't
5 think that necessarily means, you know, some people I
6 think jump to the conclusion that that meant another
7 advisory committee meeting or some other formal
8 regulatory process.

mcclellan

9 It doesn't have to be like that. And
10 again, I think the staff had been getting some useful
11 input during this time from other external experts
12 about the application.

13 Q You mentioned that -- I think you
14 mentioned that the Agency consulted with experts
15 outside the Agency. Who?

16 A I don't remember the names, but the staff
17 came back with this -- at this briefing to tell me
18 about a lot of the further work that they've been
19 doing to shore up the available evidence on younger
20 girls and less educated women, so I think you have to
21 talk to them about who they spoke with. I assume
22 they didn't generate all that evidence on their

0230

1 own -- I did, in terms of this last bullet --

2 Q I wasn't asking about.

3 A I was going to say, when the action I
4 requested was for the Center to come forward with
5 their recommendation in a timely way. I think at the
6 briefing, some of the staff there did specifically
7 ask me what I thought they should do with the
8 applications.

9 I specifically told them that I wanted the
10 Center to come forward with their recommendation and
11 with their decision, actually, about how to proceed.

12 Q If they had done that, you would have
13 accepted their decision no matter what's it was?

14 A Well, that's one of these hypotheticals.
15 I have to tell the whole time I was at the Agency,
16 there weren't any cases where I disagreed with
17 conclusion of a Center about an action on a product.

18 Q Do you recall a meeting that you had in
19 early 2004 with Congress, members of Congress, Smith,
20 Welden and Manzullo?

21 A Yes. I do recall that briefing, that
22 meeting.

0231

1 Q Was that here or at the Capitol. Where
2 was the meeting held?

3 A I believe it was held in one of the member
4 offices. I couldn't tell you which one, so it
5 wouldn't have been in the Capitol but one of the
6 house of rep office buildings.

7 Q Was it with the members themselves or
8 their staff or both?

9 A It was the members themselves and I
10 believe some of their staff was present. I believe
11 some FDA staff was present as well. That's the usual
12 way we would do these meetings with members. And
13 this was one of the, you know, the -- one of the
14 listening meetings that we did where we would have
15 been clear that since the Agency was in process, it
16 was -- had a regulatory process underway, this was an
17 opportunity for them to ask us about where we are in
18 the process, what are we thinking so forth.

19 It's an opportunity for us to listen to
20 them because they had some concerns that they wanted
21 to make sure that the Agency had heard.

22 Q So it was sort of two parts of the

0232

1 meeting: One was where they expressed their views
2 and the other was where you would update them on --

3 A No, not the latter.

4 Q Not the latter?

5 A Just the former. That's right. When the
6 Agency had a regulatory process underway, so it was
7 really about giving them an opportunity to let us
8 know they're views.

9 Q Do you know if that meeting was recorded
10 or whether minutes were taken of that meeting by
11 someone in Congress?

12 A I don't know.

13 Q Were minutes taken by someone from the
14 FDA?

15 A I don't know. I'm sure, if there were
16 action items from the meeting, that the legislative
17 staff would have made a note of them are. We had
18 lots of members with members of Congress. They have
19 a lot of interest, obviously, in many of the issues
20 before the Agency, and part of my job is to provide
21 kind of a buffer between the members and their
22 concerns, which they often feel very strongly about,

□

0233

1 often in completely diametrically opposed direction,
2 but they often feel very strongly about. I had to be
3 a buffer between those kinds of concerns and the
4 staff activity inside the Agency.

5 If there were specific action items from a
6 meeting -- an informational meeting like this one
7 generally wouldn't have any -- the staff would make a
8 note of that. Sometimes, though, the members might
9 request some follow-up information or to be updated
10 again at some time in the future when there was, you
11 know, a new action from the Agency, things like that
12 that we make a note of.

13 Q Going back to the document that I think
14 you still have in front of you that ends with 30722,
15 on the last page, again, there are these names listed
16 concurrence and some have dates after them and some
17 don't. Do you know if the date means anything?

18 A You have to talk to the people in CDER
19 involved in document management here. As I said, I
20 didn't see this document while I was at the Agency
21 which was really just a couple of weeks after this
22 meeting, and, you know, I wouldn't hazard a guess.

□

0234

1 It is maybe when they reviewed the minutes. I don't
2 know.

3 Q After you left the FDA, did you have
4 any -- did you, for example, were you able to follow
5 the process that was going on with Plan B or for that
6 matter -- let's say, for Plan B, between the time you
7 left and the time that the Agency publicly announced
8 the non-approvable letter? Were there any contacts
9 you maintained with the Agency so you certainly knew
10 what was going on?

11 A Not really. They may have let me know
12 when they were taking action because, again, that may
13 be something I would get asked about given the high
14 level of interest and the fact I was there for a good

mcclellan

15 part of the time that the product was under review.
16 But, you know, as you know, a lot of
17 things have happened since then, and a lot of things
18 have happened at my new Agency as well.

19 So I probably heard something about the
20 application when decision on the initial, you know,
21 the initial non-approvable letter went out in May. I
22 do recall hearing, I guess later on in the summer,

0235

1 that Barr had resubmitted an application intended to
2 be responsive to the concerns raised in the initial
3 letter.

4 And subsequent to that, that, you know,
5 the Agency had taken a further regulatory action this
6 past year but not -- I didn't have any, you know,
7 sort of detailed updates or ongoing involvement in
8 that process.

9 Q Have you ever read the non-approvable
10 letter that Dr. Galson signed as to Plan B in May of
11 2004?

12 A That was included in the deposition prep
13 materials that I received ahead of today's
14 activities.

15 Q So you're aware that Dr. Galson himself
16 signed that letter?

17 A Yes.

18 Q Do you know if it's typical for the
19 Director of CDER to sign an OTC switch action letter?

20 MR. AMANAT: Object to the form of the
21 question.

22 A It is certainly not unprecedented for more

0236

1 senior managers to sign letters. I think, you know,
2 most probably are signed at the -- at lower levels in
3 the Agency.

4 BY MR. HELLER:

5 Q In general, what would be the situations
6 in which someone at a higher level would sign such a
7 letter. I mean, what are the things that motivate
8 that occurring?

9 A Well, in this case, I don't think there's
10 any mystery. I think the staff reviewers came to a
11 different conclusion about safety of the product for
12 all women than the Center Director did.

13 I think other cases may be different. I
14 think Dr. Woodcock has overruled CDER in the past on
15 issues like, you know, generic versions of hormone
16 therapy. So I think it would depend on the specific
17 circumstances. But differences of opinion, which
18 arise any time people review scientific data and
19 often they can be worked out but not always.
20 Differences of scientific opinion can lead to the
21 differences in who signs the letter is one reason.

22 Q Did you have a concern that approving an

0237

1 OTC switch for Plan B would lead to increased unsafe
2 sex by adolescents?

3 A That really wasn't a major focus of the
4 discussions we had, I think in part because there's
5 really no way to get conclusive reviewable evidence

mcclellan

6 on it. That's the kind of very potentially --
7 potentially it's a very important question, but it's
8 not one that you can easily design a study to address
9 and it's not one that was viewed generally as within
10 the scope of a lot of the review activities that were
11 underway.

12 You know, certainly if you had more
13 confidence or if the evidence was stronger about
14 whether young girls and adolescents would use the
15 product as intended without any intervention from a
16 learned intermediary, then you might have more
17 confidence that there wouldn't be such responses,
18 but, again, that's an area where the evidence we had
19 to review was quite limited.

20 Q Did you have a concern that
21 over-the-counter availability of Plan B would lead to
22 increased sexually transmitted infections among

□
0238

1 adolescents?

2 A That was a very important question that a
3 number of the studies tried to address, however,
4 indirectly. And I recall there was one where it
5 wasn't a statistically significant difference in
6 sexually transmitted infection rates between the
7 younger girls and the older adolescents, but there
8 was a numerical difference. And that gets back to
9 what we were talking about earlier about a potential
10 trend where the statistical power of the analysis is
11 just too weak to determine if there really is any
12 differential -- any real difference in behavior.

13 Q Do you know if there was studies that
14 showed no difference?

15 A Well, there were studies over all in the
16 populations being reviewed that showed no difference
17 with a high degree of statistical confidence.
18 Showing no differences, I mean that's no fete to be
19 proud of by itself. You can show no difference in a
20 study of three people even if the effect in one
21 person is a hundred percent and the effect in the
22 other two is zero percent, because you don't have

□
0239

1 enough of a sample size to make a statistically
2 significant conclusion.

3 what you really want to know is whether
4 you can reject the hypothesis that there is no
5 difference -- that there is a difference between two
6 groups with a high degree of statistical certainty.
7 In order to do that you need more statistical power
8 than most of these studies had.

9 Q Is it feasible to conduct, for example,
10 actual use studies over-the-counter use for 12 year
11 olds?

12 A That's a very good question that we had
13 some discussion about, in the course of this
14 application being reviewed, and there are a number of
15 challenges there.

16 I think the staff particularly emphasized
17 the fact that IRBs, the local review boards for
18 whether a study was "ethical" or not might have real
19 trouble in approving such a study basically to
20 conduct an experimental analysis on, involving a

mcclellan

21 12-year old. You need to get permission from the
22 parent because 12-year olds generally aren't viewed

0240

1 as being able to make informed decisions like that on
2 their own, so it would have required getting parental
3 consent for involvement in the study and that
4 presented some issues.

5 I think there were also some concerns
6 raised about, "well, gee, if the IRBs have problem
7 with this kind of analysis, shouldn't that mean that
8 we ought to be able to be careful in reviewing it?"

9 But I think the questions were more just
10 practical and logistical that we actually discussed.
11 But, you know, you could see potential ways to do it.

12 For example, some of the staff noted that
13 in some states, Washington and California as well,
14 the Plan B product is already available behind the
15 counter in pharmacy, so it's only an incremental step
16 from there to have it available in the pharmacies
17 without any guidance or intervention from the
18 pharmacist.

19 And in fact I think one small element of
20 the -- one of the studies, I think it was the actual
21 use study -- included a pharmacy component but they
22 didn't include very many pharmacies in the effort;

0241

1 they didn't include all the California pharmacies,
2 which is a lot of pharmacies. In my new job, I talk
3 to a lot of those pharmacists myself; there are
4 thousands of pharmacies in California.

5 So while there would be some challenges,
6 it is something I think there is some discussion
7 about and would be interesting to know how -- would
8 be interesting to think further about how it could be
9 pursued.

10 Q Haven't there been a number of OTC
11 switches that have been approved by FDA over the
12 years in which no actual use data for adolescents at
13 all has been submitted?

14 A That's true. Kind of couple of things
15 about that: One is that over the years, the FDA has
16 been moving to paying more attention to differences
17 in responses by children and adolescents.

18 In fact, one of the first things I did at
19 the Agency was work with the Administration and with
20 Congress to get codified into law our so-called
21 "pediatric rule" which gives the Agency the ability
22 to compel more studies of the differences in effects

0242

1 of treatments in younger population, children and
2 adolescents, and accomplishment I'm very proud of
3 from my tenure at the FDA.

4 In addition, the FDA had been doing, had
5 been collecting more information through studies that
6 it funded of differential effects in children. So
7 definitely there's been a trend towards recognizing
8 that children are not little adults; they do respond
9 differently and handle medications differently in
10 many cases.

11 Q You would agree, wouldn't you, there are a

mcclellan

12 lot of drugs available over-the-counter in the United
13 States right now as to which there was never an
14 actual use study done for 12-year olds?

15 A Well, there are also -- those are also I
16 think drugs where there were not the same types of
17 concerns as might arise here, and this is -- these
18 are hormones that have systemic effects if they're
19 used in high doses for prolonged periods of time or
20 irregularly but significant over a long time. I
21 think the evidence is pretty limited.

22 Not only that, this is an over-the-counter

□
0243

1 product that isn't just for use whenever you have a
2 symptom; it's for use as part of a more comprehensive
3 forethought plan of contraception, so unlike an
4 antihistamine, which is basically find the use
5 whenever you have serious hay fever, as long as it
6 doesn't happen too frequently, and you could, you
7 know, three, four times a month, no problem.

8 This was a product designed to be used
9 much less frequently than that and in conjunction
10 with an effective contraception plan.

11 Q Okay.

12 MR. HELLER: Can we take a five-minute
13 break?

14 THE VIDEOGRAPHER: We're going off the
15 record. The time is 3:11 p.m.

16 (Recess taken.)

17 we're back on the record. The time is
18 3:17 p.m.

19 BY MR. HELLER:

20 Q Dr. McClellan, I think you talked about
21 Plan B containing hormones. What hormones?

22 A It's a progesterone compound,

□
0244

1 levonorgestrel.

2 Q Does that compound cause systemic
3 symptoms?

4 A It can. It's a compound, a hormone that's
5 released in high levels in pregnant women so it can
6 cause, at a minimum, symptoms related to those that
7 many women experience pregnancy -- nausea, bloating,
8 breast tenderness, things like that.

9 Q By the way, I would actually like you to
10 take few minutes to read pages 4 through 10 of that
11 Exhibit 1 which is the testimony, or the things you
12 said at the congressional committee, and just let me
13 know if there's something in there you'd like to
14 correct or that you now disagree that you said?

15 A Okay. Do you want me to do that now.

16 Q Yes, I think we should do it now, because
17 I don't want to use up your break time.

18 A Okay. (Witness complied.)

19 I assume you're not asking me whether I
20 want to revise or expand on my remarks about medical
21 liability or physician payments.

22 Q Just your remarks about Plan B.

□
0245

1 A On a couple of things that we've already
2 talked about here -- I don't think I have much -- I

mcclellan

3 don't have anything in the way to change what I said
4 in my responses here, but just a couple of
5 clarifications.

6 We talked a lot earlier about
7 communications that I had with certain individuals in
8 the White House and the Department of Health and
9 Human Services and the nature of those conversations
10 and so forth. I hope you got a good understanding of
11 those.

12 That's more extensive than the level of
13 detail that we were able to get into in this exchange
14 in the hearing.

15 And then second thing I just want to be
16 clear about is, you know, Congressman Waxman has a
17 very -- what's the word I want to use -- effective
18 way of asking questions, and he will start out with
19 sort of the, "Why did you refuse to talk to the GAO?"
20 which I didn't do, and I tried to make clear in my
21 response that I would -- did want to make sure they
22 had the information they need.

0246

1 He goes on to ask about why wouldn't you
2 make yourself available for an interview? And I
3 guess I would clarify that next remark to be that we
4 had provided -- as we talked about earlier today, we
5 had provided the GAO with written responses relevant
6 to the questions.

7 We had provided the GAO with a whole set
8 of other materials and, if they had further issues or
9 questions or the questions they wanted to address, I
10 would assume they'd come back to me with them.

11 If you got any questions about the
12 response that I gave to GAO here or more generally in
13 this testimony, I hope you'll go ahead and ask me
14 about that right now just to make sure that I'm as
15 clear as possible about all of these important
16 issues.

17 Q Okay. I'm just going to show you one more
18 document somehow here?

19 A Okay.

20 Q Which is marked Tummino 270 through 272?

21 A We done with this one (proffered.)

22 Q Which seems to be an e-mail from Jane

0247

1 Axelrad to a group of people. Have you ever seen
2 this document before?

3 A (Witness perusing.)

4 Let me take a minute. It doesn't look
5 familiar offhand but do you mind if I read through
6 it?

7 Q No. Go ahead.

8 A (Witness perusing.)

9 The question again?

10 Q Have you seen this document before?

11 A I don't think so. This was -- just
12 looking at the date on the e-mail, this was, you
13 know, weeks after I had left the Agency and I don't
14 recall reviewing it in preparation for the
15 deposition.

16 Q One of the questions the GAO asked and
17 it's actually on page 2 of Exhibit 1 that you still

18 have there?

19 A Okay.

20 Q Question 3 at the top of page 2?

21 A Yes.

22 Q If you could please read that over?

□

0248

1 A The whole question 3?

2 Q Yes, just that question 3 at the top

3 there.

4 A (Witness complied.)

5 Okay.

6 Q So would you mind giving me your answer to

7 that question now?

8 A Not at all. If I had the materials that
9 we actually were discussing at those meetings in
10 front of me, that would be helpful, too. But I can
11 just give you a general -- a general sense of the
12 comments.

13 The comments had to do with the fact that
14 there were a very small number of young girls and
15 young adolescents involved in the study, and, the
16 studies that were reviewed, and for some of the
17 studies that were reviewed there were differences in
18 the use rates of repeat emergency contraception, the
19 use rates of "effective" forms of contraceptions, the
20 pregnancy rate that was observed in the study, and
21 in, I think in one of the studies the sexually
22 transmitted infection rate.

□

0249

1 None of these were statistically
2 significant as we talked about before because the
3 sample sizes were too small that expect that you'd be
4 able to see statistically significant differences
5 unless they were just truly vast differences and even
6 then you've only got 10 or 20 people in the study.
7 It's hard to detect these kinds of effects.

8 One source of my concern was the sample
9 sizes in the studies. Another source of concern was
10 the conditions of use in the study, since most of
11 these studies were conducted in health clinics or in
12 settings where there was some interaction with a
13 health professional behind the counter, on the phone
14 or otherwise, the girls could get some important
15 health advice from health professional about
16 appropriate use of the treatment, and, also, many of
17 the studies included limitations on how much of the
18 product was made available.

19 All of those were different than the
20 settings in which the OTC product would be used, and
21 so my questions went to from making these
22 extrapolations from the available evidence, evidence

□

0250

1 that's not ideal either in terms of number of
2 subjects or length of follow-up or conditions of
3 analysis for replicating or being very similar to
4 what would occur in the OTC setting.

5 what do we know? what inferences can we
6 confidently make and how confidently can we make
7 them? Those were the kind of questions that came up,
8 and, again, some of the concerns stem from, if you

mcclellan

9 just looked at some of the raw numbers. Again, they
10 are not statistically significant differences but
11 they're trends towards differences in some of these
12 important outcomes.

13 Q Do you know why it is that many of the
14 career scientists at CDER did not develop those same
15 concerns when they themselves also looked at the data
16 in the studies that had been done?

17 A I think they believed that the studies
18 could be extrapolated. Some of them noted that some
19 members of the advisory committee had felt that the
20 studies could be extrapolated. Other members of the
21 advisory committee felt otherwise, and, you know, a
22 number of them, weren't presented with the full range

0251

1 of -- well, there may have been other ideas that the
2 staff developed in the course of reviewing the
3 application that might have been helpful after the
4 fact for the advisory committee to know.

5 But different scientists can come to
6 different conclusions about extrapolating from data,
7 and Dr. Galson, Dr. Woodcock, I think, came to, based
8 on their own experience, which was very broad in
9 reviewing drug applications and other types of
10 regulatory processes, came to a bit more cautious
11 conclusion about the extrapolation of this kind of
12 data to conclusions about safe use of oral -- of
13 emergency contraception in young women.

14 Q The FDA, though, does from time to time
15 extrapolate from data, for example, about adults --
16 data about adolescents? I'm sorry.

17 A Absolutely. Again, you always have to
18 extrapolate when you're making decision about a new
19 kind of product. It's a matter of degree and the
20 nature of the extrapolation that, I think, determines
21 the degree of confidence that the FDA has in its
22 ability to make certain kinds of regulatory

0252

1 decisions.

2 Q I think one of the things you indicated
3 earlier in your testimony is that one might be able
4 to make some valid extrapolation about
5 over-the-counter use by looking at information from
6 California and Washington state?

7 A States that had --

8 Q Broader access?

9 A Right.

10 Q Is that right?

11 A That's right, or it would be easier to
12 design study to more closely replicate OTC conditions
13 in those settings because in some ways you're
14 incrementally closer to OTC.

15 The products available through pharmacy
16 access, you still have to have an intervention of a
17 learned intermediary, one that might even be more
18 effective than a physician in some cases, if it's a
19 health clinic with someone who specializes in helping
20 women with their contraceptive planning.

21 But it's less of an extrapolation than
22 from a setting where the product is only available by

0253

1 prescription.

2 Q Thank you, Dr. McClellan.

3 MR. HELLER: Your turn.

4 CROSS-EXAMINATION

5 BY MR. AMANAT:

6 Q Dr. McClellan, many of your answers to
7 Mr. Heller's questions made reference to statistics
8 and kind of statistical terminology, or the
9 terminology that statisticians would use.

10 Do you have any special training or
11 experience in statistics in the manipulation and
12 interpretation of statistical data?

13 A I do, in addition to my medical background
14 and master's degree in basically public policy
15 analysis, I also have a Ph.D. in economics from MIT
16 and economics known to many as a fuzzy science, I
17 think as being a science of applied statistics.

18 When you're doing economics you can almost
19 never do the kind of randomized controlled trial that
20 is viewed as the gold standard in many medical
21 sciences.

22 You'd like to know how people change what

□

0254

1 they eat or which cars they buy as the prices change
2 or as other features of products change. You can't
3 ever easily do experiments on that or it's very hard
4 to do experiments on that.

5 So economists do a lot of work with
6 statistical techniques and with these issues related
7 to making inferences that go beyond the actual
8 non-experimental settings they observe to reach
9 conclusions about differences in effects of the
10 impacts of certain policies.

11 That's the something before coming in the
12 government that I spent most of my professional
13 career addressing is doing research, publishing
14 papers, participating in academic dialogue around
15 these kind of applied statistical issues.

16 Q You know when you came to FDA in the
17 capacity as head of the Agency as the Commissioner,
18 and when you served in the role of Commissioner, did
19 you bring your knowledge of statistics and economics
20 to bear in the course of your policy-making and
21 decision-making activities as Commissioner?

22 A Very much so. Some of the initiatives

□

0255

1 that we launched and expanded while I was at the
2 Agency involved ways of using cutting edge and
3 recently developed statistical techniques to help the
4 Agency with reaching its policy conclusions.

5 For example -- and this is just one
6 example -- we undertook an expansion of activities
7 related to so-called Basion statistical techniques.
8 These are techniques where you try to bring in prior
9 evidence, again may not be perfect evidence but prior
10 evidence, on a problem to pair it up with additional
11 studies that may be done in somewhat different
12 settings and do it in an analytically rigorous
13 fashion.

14 The Agency held a workshop and conducted

mcclellan

15 some further activities on integrating these kind of
16 Basion approaches and some of it review work and some
17 of the oversight work related to post-market
18 monitoring, and particularly in our device review
19 procedure. That is one example but there are lots of
20 discussions around how we can best bring statistical
21 as well as other cutting edge sciences to help the
22 Agency improve its regulatory processes.

0256

1 Q As you were being briefed about Plan B
2 with the various briefings that you testified to in
3 response to Mr. Heller's questions and you were kind
4 of listening to the various presentations that some
5 of the staffers within CDER and within FDA were
6 making to you about Plan B, did you bring -- or to
7 what extent did you bring your knowledge of
8 statistics and economics and those theories to bear
9 on your own kind of thought process and
10 decision-making process?

11 A It is certainly relevant. I can't really
12 remember any briefing where I didn't ask a question
13 about the underlying statistical analysis because
14 it's so important in helping the Agency, solid
15 statistic Agency is so important in helping the
16 Agency reach effective policy conclusions.

17 Q While we're on the subject of your
18 training and background, let me just briefly ask you
19 a couple of questions about your training and your
20 kind of experiential background as a general matter
21 if I may.

22 I believe you testified earlier that

0257

1 you're an internist?

2 A Yes, internal medicine doctor.

3 Q So you did your residency in internal
4 medicine?

5 A Right. Did my residency in internal
6 medicine and got board certified in internal medicine
7 and before --

8 Q Where did you do your residency?

9 A My medical degree was in a joint program
10 of the Harvard Medical School and Massachusetts
11 Institute of Technology that was really geared
12 towards quantitative approaches to medical practice
13 and medical research.

14 My residency was at the Brigham and
15 Women's Hospital in Boston, one of the Harvard
16 teaching hospitals.

17 Q You said, I believe, that you got your
18 Ph.D. in economics from MIT?

19 A From MIT, yes.

20 Q So you spent a good deal of time in
21 Cambridge, I take it?

22 A Yes, as my wife kept complaining to me

0258

1 about.

2 Q Did you also say you had another master's
3 degree of some type?

4 A I did. I have a master's in public
5 administration from the Kennedy School of Government.

mcclellan

6 A lot of the course work that I was taking related to
7 my work in applied economics and health policy
8 overlapped with some of the courses offered at the
9 Kennedy School and I have had a longstanding interest
10 in public policy, and so I fit in with those other
11 degrees I was doing. Didn't have a whole lot of
12 extra time.

13 Q Did you ever practice medicine in a
14 patient care setting?

15 A I did. Obviously as a resident I
16 practices practicing medicine with a license in
17 Massachusetts. After moving to Stamford in 1995, I
18 was on the faculty initially just the Department of
19 Economics at Stamford and added affiliation with the
20 Department of Medicine, and I'm actually on leave now
21 from those jobs.

22 As part of that, I practiced part-time in

□
0259

1 our residence training clinic at Stamford.

2 Q In your capacity as a practicing
3 physician, did you ever prescribe contraceptives to
4 any of your patients?

5 A Yes; I would have done some prescribing.
6 I can't recall any specific cases, but definitely.

7 Q So you didn't have any kind of moral
8 objection to prescribing contraceptives for patients
9 who requested and needed it?

10 A And where it was medically appropriate and
11 indicated, yes.

12 Q Now, I think you mentioned in your
13 testimony, if I'm not mistaken, that you served for a
14 time in a position in the Clinton Administration; am
15 I correct?

16 A That's right, from mid-1998 to mid-1999, I
17 was a Deputy Assistant Secretary of the Treasury for
18 Economic Policy in the previous Administration.

19 Q So was that a political appointment?

20 A Yes.

21 Q How long did you serve in that capacity?

22 A About 13 months, I think.

□
0260

1 Q Now, in his questioning, towards the very
2 end of his questioning, Mr. Heller asked you some
3 questions about, if you recall, he made reference to
4 the fact that some of the lower level staffers within
5 CDER had in their reviews of the Plan B application
6 apparently not come to the same conclusions as you
7 had based on your review. Do you recall that line of
8 questioning?

9 A I do, and just to clarify, I think my --
10 the issues that I raised were more at the level of
11 concerns, you know, when the Agency did reach -- did
12 reach a final decision on any product, I'm the one
13 who is going to be called upon to explain that
14 decision to the public, defend it with the public,
15 and so I want to make sure that I'm very familiar
16 with the issues involved in the application that may
17 be of interest to the public. And here those issues
18 go to the safety of use without learned intermediary.

19 Q Let me ask you a question about that. You
20 said you were Deputy Assistant Secretary of Treasury

McClellan

21 in the Clinton Administration and you headed FDA and
22 you now head CMS and you served in other capacities

0261

1 in government as well?

2 A Yes.

3 Q You have essentially held high level
4 positions in government for sometime; is that
5 correct?

6 A Yes.

7 Q Based on your experience as a high ranking
8 government official, Dr. McClellan, would you say
9 that, that lower level career civil servants look at
10 problems and policy issues in the same way as higher
11 level government officials do?

12 A Well, I think they all have the same basic
13 goal in mind, which is implementing policy
14 effectively, but people at more senior levels of
15 management generally have more experience to draw on,
16 a wider breadth of experience. They may have
17 perspectives and input that is not possible from, you
18 know, a more narrow position, a position with a more
19 narrow range and a more narrow perspective inside the
20 Agency that can help them in considering more --
21 considering effectively the consequences of
22 particular policy decision by the Agency.

0262

1 And, you know, in particular in that at
2 FDA I was repeatedly very impressed with Dr. Woodcock
3 and Dr. Galson's level of experience and
4 effectiveness in addressing a difficult, constantly
5 changing and very challenging range of public health
6 issues involving drugs.

7 Janet Woodcock is probably the most
8 experienced drug regulator in the world, and also is
9 one of the most effective and committed people I know
10 on promoting effective contraception.

11 Dr. Galson had experience not only broadly
12 at the FDA but also in the Environmental Protection
13 Agency, including a lot of experience related to
14 issues involving pediatrics and issues involving
15 extrapolations of data on potential risks, including
16 potential long-term risks.

17 So both because of their scientific
18 experience and their effectiveness in bringing
19 together different perspectives, perspectives that
20 didn't always agree in an orderly presentation of an
21 inner, I depended on them a lot.

22 Q I ask you please to take a peak at what

0263

1 was earlier marked as identification as McClellan
2 Exhibit 1. It's the collection of documents that you
3 produced to the Plaintiffs this morning.

4 We talked about a number of these
5 documents during the course of your earlier
6 testimony. Let me draw your attention particularly
7 to the first two pages here, this set of e-mails,
8 e-mail correspondence that was exchanged between the
9 Government Accountability Office, I almost called it
10 the General Accounting Office, the Government
11 Accountability Office and members of your staff.

mcclellan

12 Now, as you recall from your testimony
13 from Mr. Heller's questioning earlier, the e-mail
14 that starts kind of in the middle of page 1 and
15 continues on to page 2 consists of a set of questions
16 which the Government Accountability Office was posing
17 to you in connection with their engagement that they
18 had undertaken with regard to Plan B, is that
19 correct?

20 A Yes.

21 Q Now, Mr. Heller, during his questioning of
22 you, skirted around these questions to some extent

0264

1 and you invited him on several occasions to pose the
2 questions to you and to get your answers and he did
3 so, I believe, with regard to question No. 3 but not
4 with the others.

5 So let me just take a moment or two and
6 just ask you the questions that GAO posed to you in
7 this e-mail, and I call upon you to provide answers
8 to these questions in whatever level of detail you
9 think is appropriate.

10 The first question it says, "In general,
11 what was your role in the review of the Plan B switch
12 application? Could you please describe your
13 interactions with Dr. Galson and Dr. Woodcock about
14 this issue?"

15 A We've covered this issue a lot already
16 today. My role in the review as was -- as my role
17 was in many other decisions in the Agency, which was
18 to get briefings on a regular basis, so I'd be
19 informed about the issues before the Agency, to have
20 the opportunity to ask questions and probe on the
21 justifications for the Agency action so that I would
22 be comfortable and help make sure the Agency was

0265

1 strong in being able to defend actions that it took,
2 and fully justified based on the science what those
3 actions were and any limitations of the science as
4 well. That's what I did in this case.

5 I had ongoing interactions with Dr. Galson
6 and Dr. Woodcock in their capacities as leaders of
7 the Center for Drugs and in a senior position in the
8 Office of the Commissioner on an acting basis for
9 Dr. Woodcock as well. That included ongoing updates
10 about activities before the Center, including
11 occasional updates about Plan B.

12 Q Okay. Question 2 has a preamble which
13 says, "During the course of our interviews we
14 received conflicting information regarding when and
15 who made the decision to not approve the
16 application." That's not exactly English but that's
17 what it says.

18 Section 2A, "Do you know who made the not
19 approvable decision and when this decision was made?"

20 A My understanding is that the decision was
21 made by Dr. Galson and that's reflected in the
22 administrative record of the Agency's action. There

0266

1 were certainly a lot of discussion about the
2 scientific evidence and what that might mean for

mcclellan

3 different courses of action the Agency could take
4 before that decision was actually made, but that's, I
5 think, entirely appropriate and a sign of an Agency
6 that's having the healthy discussion of scientific
7 evidence that should be part of the FDA's ongoing
8 actions.

9 Q Now, when you say that Dr. Galson made the
10 decision. Did he make the decision as far as you are
11 aware, did he make the decision on his own or based
12 on directions and instructions which you had given
13 him?

14 A I am sure he made the decision based on
15 all kinds of information that he had gathered from
16 other sources, but, as I said in my response to -- as
17 I said in my response to Congressman Waxman before, I
18 did not make a decision on this product and I did not
19 direct Dr. Galson to act in any particular way about
20 the product.

21 Q During the time when you were the
22 Commissioner of food and drugs and Dr. Galson was, I

□
0267

1 guess, acting director of CDER during your time, were
2 you his direct first-line supervisor?

3 A I did work very closely with the Center
4 directors. I didn't have a chief of staff or a whole
5 lot of layers between me and the Center Directors
6 what I found in government the more you can rely on
7 the career staff, especially the senior career staff,
8 the more you're going to get done and the more
9 effective and consistent the work of the Agency will
10 be, so he did in that sense report directly to me.

11 Now, I had a lot of other people that I
12 needed to supervise across this very vast Agency, so
13 I didn't get -- he made, ended up making a lot of the
14 decisions within the Agency and certainly the
15 decisions within CDER but with input from me along
16 the way.

17 Q Did you put any kind of pressure on
18 Dr. Galson of any kind with regard to how or when he
19 should decide the Plan B application?

20 A No. All I asked him to do was make sure
21 they do a thorough review of the science as they do
22 in every case.

□
0268

1 Q Did you make any statements to him at any
2 point in time which he might have understood as
3 suggesting that there would be repercussions of any
4 kind if he took action of one kind or another with
5 regard to Plan B?

6 MR. HELLER: Objection. Calls for
7 speculation.

8 BY MR. AMANAT:

9 Please answer the question.

10 A No. I should add we had regular contacts,
11 including regular opportunities for me to provide
12 feedback to him on his job performance and for him to
13 let me know if he thought there were any areas of
14 concern or directions in which the overall Agency was
15 going that he thought we could do better, and both --
16 no issues like that ever came up.

17 Q So in those discussion of that nature that

mcclellan

18 you just described having had with Dr. Galson, did
19 Plan B come up in those discussions at any point in
20 time?

21 A No. The only time we discussed Plan B was
22 in the context of the updates on the review status

0269

1 and the scientific evidence that the Agency was
2 considering.

3 Q Okay. Question 2b) I believe Mr. Heller
4 did actually ask you and you did answer that during
5 the course of your testimony?

6 A Yes.

7 Q whether you agreed with the decision to
8 not approve the application and he also asked you
9 question 3. Let's look at question 4.

10 It says, "According to FDA's minutes of
11 the meeting..." this is also -- 4 also has a preamble
12 first before it asks the questions, so 4 -- the
13 preamble says, "According to the FDA's minutes of the
14 meeting you also attended a meeting held on February
15 18th 2004."

16 we looked at those minutes, I believe, in
17 the course of your testimony. Attendees at this
18 meeting included Dr. Woodcock, Dr. Galson,
19 Dr. Jenkins, Dr. Kweder K-W-E-D-E-R and review staff
20 from the Office of Drug Evaluation 3 and the Office
21 of Drug Evaluation 5.

22 "The objective of the meeting was to

0270

1 inform and update your office on the staff's
2 positions on the 'acceptability of the Plan B switch
3 application' after reviewing numerous studies on
4 adolescents."

5 "In addition the minutes note that there
6 was particular emphasis on adolescents in order to
7 address concerns that had been conveyed to the review
8 staff from senior management regarding the timing of
9 doses, safety, and behavior changes that might result
10 if product access increased."

11 Now, the first question that asks, this is
12 4a), "what age groups were you concerned about and
13 wanted to have restricted access to Plan B."

14 What's your answer to that question?

15 A That's a bit of a leading and presumptive
16 question. What age groups were concerned about was
17 something that we definitely discussed at the
18 meeting. It's from that is a leap to say what age
19 groups did I want to have restricted access to Plan B
20 since the main point of the meeting was to discuss
21 what the status of the evidence was on some of the
22 younger age groups.

0271

1 As Mr. Heller asked earlier, we did have
2 discussions that focussed in particular on age,
3 younger girls' ages under 16 as well as some of the
4 limited evidence on 17-year olds and other young
5 adults, so that was the main focus of the discussion.

6 I think it's a presumption. I'm not quite
7 sure why GAO made the presumption to ask that
8 compound question in a leading way about wanting to

mcclellan

9 have restricted access to Plan B.

10 The point of meeting was to discuss the
11 studies on adolescents and the evidence that provided
12 to provide confidence level about extrapolation from
13 the studies that were done to the conditions that
14 might be observed over-the-counter.

15 Q Okay. Then question b) says "one of the
16 action items listed in the meeting minutes was your
17 comment that restricted the distribution would
18 deserve another discussion in a public forum before
19 implementation." This was the subject that you
20 testified about to some extent in your testimony?

21 A Yes.

22 Q They ask specific questions which you did

0272

1 not directly address in your testimony. The first
2 one is, why did you feel the need for another
3 advisory committee meeting?

4 A Again, this is either a leading question
5 or a leap based on information that certainly wasn't
6 in what I said and wasn't in the minutes which I had
7 some concerns about as well.

8 There are lots of ways to get public input
9 besides advisory committees meetings and, if I make
10 suggestions like that in the course of a discussion,
11 it doesn't mean, and the staff knows it doesn't mean,
12 that's what the Agency absolutely needs to do; it's
13 just another idea to try to contribute to the goal of
14 having effective Agency action and action that the
15 Agency can effectively publicly defend when it takes
16 action.

17 Again, I'm the person who is going to be
18 up there defending the Agency's action and, if we can
19 get feedback along the way to make sure we haven't
20 missed any studies or missed any opportunities to
21 gather more evidence or present our conclusion more
22 effective, the Agency is going to be more successful

0273

1 in its work and it's going to develop better
2 confidence from the public. So to leap from that to
3 saying I was asking for another advisory committee
4 meeting is a bit of a stretch.

5 Q And the last part of question 4 b) says
6 "what was your response when told by staff that they
7 felt advisory committee members had 'already clearly
8 stated that members did not support restricted
9 distribution, including on the basis of age'."

10 A That was part of the discussion at the
11 meeting, to make sure that we had -- that I had an
12 opportunity to ask questions about the evidence on
13 the -- that the staff had developed and the
14 discussion at the advisory committee meeting.

15 In particular the staff did a good job of
16 pulling together some additional studies related to
17 age and that was the main focus on the meeting as I
18 recall. We didn't have extensive discussion about
19 particular restricted distribution plans. That was
20 not one of the main focus of discussion of that we
21 had on -- or rather the main focus of our discussions
22 was on the scientific evidence related to younger

0274

1 girls.

2 Q Finally question 5 listed here says, "Did
3 you read the application reviews written by staff
4 from the Office of Drug Evaluation 3 and the Office
5 of Drug Evaluation 5 or by the Director of the Office
6 of New Drugs and did you have any comments or
7 concerns?"

8 A And Mr. Heller did raise that issue. And
9 I did not specifically review those, read those
10 reviews. I think my impression of at least some of
11 them were completed after I had gone, but I certainly
12 had the opportunity to hear from the staff and
13 discuss with the staff some of the concerns they
14 raised and we talked about here today.

15 We talked a lot about the studies that
16 were included in the analysis and this used with
17 statistical power, duration follow-up, setting of the
18 studies, IRB issues, you name it, related to these
19 populations.

20 Q Okay. Let me ask you to turn to the very
21 last page of this exhibit; it is marked MBM12?

22 A (Witness complied.)

□

0275

1 Q Do you recall we looked, this is the
2 second page of a two-page letter --

3 A Yes.

4 Q -- that you received from Senator Levin in
5 his capacity as ranking minority member on the
6 senate's Permanent Subcommittee on Investigations. I
7 believe you said you received this in your capacity
8 as Administrator at CMS; is that correct?

9 A Yes, though obviously it's a letter that
10 bears on issues of import to the Food and Drug
11 Administration and because there's ongoing litigation
12 here as well that the General Counsel was concerned
13 about, too.

14 Q And here Senator Levin poses three very
15 specific questions to you, which he says would assist
16 him in gaining an understanding of FDA's
17 decision-making process related to Plan B.

18 If I remember correctly, you invited
19 Mr. Heller to pose these questions directly to you
20 and he declined your invitation. So let me do so.
21 Let me pose these questions to you one by one and ask
22 you again to please answer each of these questions in

□

0276

1 whatever level of detail and specificity you think is
2 appropriate.

3 The first question Senator Levin poses to
4 you is one he asks you to "identify the persons you
5 communicated with during the process leading up to
6 the May 6th Plan B decision, including persons inside
7 and outside the FDA, and the dates, participants and
8 circumstances of such communications and what was
9 said?"

10 A We did have a lot of discussion about
11 these issues with Mr. Heller where he had asked about
12 persons in the Department of Health and Human
13 Services -- I'm sorry, where he had asked about
14 persons inside the Agency, persons in the Department

mcclellan

15 of Health and Human Services, and persons in the
16 Executive Office of the President, and we went
17 through in some detail that the short phone update
18 that I had with -- that was on my schedule with Jay
19 Lefkowitz as well as I talked about subsequent
20 occasional conversations, probably several or so over
21 the course of the year that I was at the Agency until
22 I left in the first part of March of 2004 in all

0277

1 those areas.

2 And I don't think I have any more persons
3 to add at this time but I do want to come back and
4 make sure Mr. Heller doesn't have any more questions
5 related to this.

6 Q Did there ever come a time, Dr. McClellan,
7 where you received any kind of specific instructions
8 or directions from the white House with regard to how
9 FDA was expected to handle the Plan B application?

10 A No.

11 Q In the course of your review and
12 evaluation and consideration of the various briefings
13 and material that your subordinates within the Agency
14 were provided to you on the subject of Plan B, and
15 the subject of -- in the course of formulating the
16 concerns that you articulated earlier and testified
17 about earlier, were you articulating those concerns
18 on the basis of your understanding of what the white
19 House's expectations was?

20 A No.

21 Q Now, it goes on in part 2 asks a similar
22 questions Senator Levin asks you to "identify any

0278

1 contact you on your immediate staff had within any
2 person within the Executive Office of the President
3 with regard to Plan B and if such contact occurred
4 the dates, participants and circumstances of such
5 communications and what was said.

6 Now you did testify to some extent about
7 this. Is there anything you want to add about in
8 response to this particular question?

9 A No.

10 Q One thing I wanted to ask you about this
11 was, at one point Mr. Heller asked you about your
12 contacts with the white House, and you were
13 describing -- well, you gave some testimony about how
14 it was certainly not uncommon to discuss with the
15 white House matters which cut across multiple
16 agencies and then he asks you, well, did Plan B cut
17 across multiple agencies or did it only deal with
18 FDA? And you testified I believe that it only dealt
19 with FDA.

20 Can you think of any other examples during
21 your tenure as Commissioner of Food and Drugs when
22 you might have given the white House an update on a

0279

1 matter that really only affected FDA from the point
2 of view of policy other than like, you know, other
3 than budget issues?

4 A Sure. There are a couple of updates that
5 I had mentioned earlier. "One is when Prilosec went

McClellan

6 over-the-counter since that was either the No. 1 drug
7 or one of the top used drugs in the country, would
8 have a substantial impact, you know, hundreds of
9 millions of dollars of impact on cost of drugs and
10 that was a high profile public issue in 2004 and is
11 today as well.

12 Another would be our decision about the
13 application for return to market of silicon breast
14 implants where the Agency went against the
15 preponderance of its advisory committees and issued
16 an non-approvable letter on that decision.

17 Another would be an update about ephedra
18 where there was a regulatory action that we were
19 taking there first ever regulatory action under the
20 Dietary Supplement Health and Education Act to remove
21 a product from the market on safety grounds. Those
22 are some examples.

0280

1 Q Dr. McClellan, when you had contacts with
2 people at the Executive Office of the President, such
3 as Mr. Lefkowitz and Ms. Silverberg, did you try to
4 hide those contacts, those communications?

5 A No.

6 Q Was there anything sinister about those
7 communications?

8 A No.

9 Q Was there -- I mean, when you were -- when
10 you were having communications with domestic policy
11 advisers in the White House staff, was that some kind
12 of conspiracy to set policy from the White House?

13 A No.

14 Q Did it violate any FDA regulations or
15 protocols for you to be consulting with or briefing
16 Executive Office of the President personnel on
17 matters before the Agency?

18 A No.

19 Q Is it unusual for -- I mean, you served in
20 several different agencies, right?

21 A Yes.

22 Q You served in the Department of Treasury;

0281

1 I believe you served on the Council of Economic
2 Advisers, right?

3 A Yes.

4 Q Now you are head of CMS, right?

5 A Yes.

6 Q CMS is -- how large an Agency is it,
7 again?

8 A CMS has close to 5,000 employees and we
9 oversee healthcare financing for close to 90 million
10 Americans and that's more than \$600 billion worth of
11 health care spending a year. We've got a lot going
12 on.

13 Not only that, the whole reason I came
14 over to the Agency when I did despite the fact that I
15 really enjoyed the work I was doing at FDA was
16 because we faced a unique time, passing the most
17 important legislation in 40 years in Medicare, the
18 biggest expansion of Medicare benefits ever in a
19 different way intended to keep benefits up-to-date
20 and deliver them at a lower cost.

mcclellan

21 Since that time we've also passed some
22 very important legislation on Medicaid reform that's

0282

1 leading some major changes, improvements in the
2 Medicaid program to give people with disabilities
3 more control over how they get their services, to
4 give people more up-to-date options on their health
5 care if they're having trouble affording health
6 insurance, so lots going on at CMS.

7 Q In your capacity as head of CHS, do you
8 from time to time meet with or talk to personnel from
9 the Executive Office of the President?

10 A Yes.

11 Q Is that inappropriate?

12 A No. It's I think part of doing the job
13 effectively, to make sure that they're informed about
14 important steps that the Agency is taking, to make
15 sure that they know and aren't surprised by and
16 therefore can be, you know, effective part of our
17 efforts to improve coverage if there's, you know, a
18 new announcement or news related to the Agency's
19 action. Things like that.

20 Q Do you try to hide or somehow make opaque
21 these communications and consultations you have with
22 the white House?

0283

1 A No.

2 Q Is there anything sinister about them?

3 A No.

4 Q When you -- let me ask the third question
5 that Senator Levin asks here. He asks about whether
6 as part of the FDA decision-making process you ever
7 offered your opinion as to whether Plan B should or
8 should not be sold over-the-counter and, if so, the
9 dates, the participants and circumstances of such
10 communications and what was said.

11 A I did not make a decision about the Plan B
12 over-the-counter status. I didn't direct anyone to
13 make a decision about Plan B's over-the-counter
14 status.

15 As always when I have briefings on an
16 important issue before the Agency I ask questions
17 about the underlying science and try to support
18 effective action by the Agency's professional staff
19 and the Centers.

20 Q Now, while we're on the subject of Senator
21 Levin, let me ask you another couple other questions
22 about Congress if I may. You testified in response

0284

1 to some questioning that --

2 A By the way, I'd like to thank you for
3 helping me complete a clearance process that
4 otherwise might have taken more time.

5 Q You testified in response to some
6 questions that you got from Mr. Heller that you had a
7 meeting at some point in the winter of 2004 about
8 meeting with Congressmen Smith, Welden and Manzullo
9 with regard to Plan B. Do you recall that testimony?

10 A Yes.

11 Q If I'm not mistaken one of two of these

mcclellan

12 congressmen are physicians, am I right?

13 A Yes, Congressman Welden is a physician.

14 Q You described this in response to
15 questioning from Mr. Heller, as I believe, a
16 listening session? Is that the terminology you used?

17 A Yes.

18 Q Now, listening in my experience can take
19 several different forms. You can listen politely to
20 somebody but not really be influenced by what they
21 say and you can also listen and actually be
22 influenced by what you're hearing.

□

0285

1 So can you elaborate on that meeting and
2 in particular let me ask you this: Did anything that
3 Congressman Smith say at that meeting influence in
4 any way or change in any way your perspective on
5 Plan B and whether it should be made available
6 over-the-counter?

7 A No. The members of Congress made some
8 points that were important to them. We definitely
9 wanted to listen, but Agency at that point was
10 already well along in its review process, had already
11 identified and was working very hard to address a
12 number of scientific issues and that was the main
13 factor.

14 I think certainly the main factor that
15 impacted my own thinking and by my going to these
16 meetings it helps make sure that the staff don't have
17 to face any direct pressures from members of Congress
18 on regulatory issues before the Agency.

19 Q Let me ask you about that word pressures
20 that you use. Did you feel that Congressmen Smith,
21 Welden and Manzullo were trying to pressure the
22 Agency to decide in a particular way?

□

0286

1 A They had strong views about what they
2 thought the Agency action should be, but they
3 understood that we were going to take the action that
4 we thought was scientifically appropriate and did not
5 put any undue pressure on us in that regard.

6 And I didn't feel pressure that I had to
7 make some kind of decision, and I didn't feel
8 pressure that I didn't do anything else than what I
9 was going to do anyway, which is help the Agency make
10 a decision based on the science.

11 Q Let me go back to the question I asked you
12 earlier: were your views, your opinions, your
13 thoughts, your analyses of the Plan B OTC issue
14 influenced or changed in any way by anything that
15 Congressmen Smith, Welden or Manzullo said to you?

16 A No.

17 Q Were they influenced or changed in any way
18 by any of the other staffers said to you at that
19 meeting?

20 A No, and I don't recall any particular
21 comments from their staffers.

22 Q The reason I asked if one of these

□

0287

1 Congressman was a physician -- and you said that
2 Congressman Welden is a physician -- when they were

mcclellan

3 making the presentation to you, were they making the
4 presentation essentially on what they understood or
5 characterized as scientific grounds, or were they
6 making essentially political presentation?

7 A Well, I think they definitely -- my
8 recollection is that they raised some issues related
9 to science. They also raised some issues, as I
10 recall, that went beyond the usual scope of
11 scientific review at the Agency and were not things
12 that we considered in the review process.

13 Q Like what?

14 A I don't have the records or notes or
15 letter that they wrote in front of me, but they did
16 send a letter along with some other members of
17 Congress which very closely tracked with my
18 recollections of what was discussed in that meeting.

19 That letter identified some, I think,
20 broader social concerns about availability of oral
21 contraceptives without a prescription for women in
22 this country. And those are not issues that were the

□
0288

1 focus of our discussions at the Agency.

2 Q When you say they were not the focus of
3 your discussions at the Agency, did those concerns
4 factor into your own thought process at all?

5 A No. Though there were definitely views on
6 both sides of the issue where, you know, sort of the
7 social concerns, you know, may have come in. I don't
8 think it influenced the Agency's course of action,
9 but, you know, in addition to the Congressmen's
10 concerns about social implications, on the other
11 side, I recall some of the advisory committee members
12 who favored OTC availability with no restrictions,
13 making comments like "we should support women and
14 particularly adolescents becoming more
15 independent." You know, I think that family, the
16 parents of these girls would want this product to be
17 available without restriction over-the-counter.

18 Those kind of social concerns that went
19 beyond the scientific evidence that we had available
20 was not where the Agency's review was focussed. The
21 Agency addressed the scientific evidence on safety
22 and effectiveness of the OTC product switch.

□
0289

1 Q You mentioned a letter that you had
2 received from Congressmen Smith, Welden and Manzullo.
3 Did you receive any correspondence from Congress --
4 members of Congress on the other side of the aisle?

5 A Oh, yes. This was an issue that had
6 strong supporters on both sides.

7 Q Okay. So would you say that this was an
8 issue that was of interest to many members of
9 Congress of varying political perspectives?

10 A Yes. But that's not unusual for the
11 Agency. There were any number of issues that we were
12 dealing with at the time that generated a range of
13 opinions from members of Congress on both sides of
14 the issue.

15 For the silicon breast implants I recall
16 speaking to democratic members of Congress who were
17 urging not to follow the advice of the advisory

mcclellan

18 committee; for ephedra there were strong views on
19 both sides about whether we should take action there
20 and whether we were using the statutory authority in
21 an appropriate way and on and on and on.

22 The Agency gets literally hundreds of

0290

1 letters from members of Congress every year about the
2 issues before it.

3 Q Does the FDA make its decisions based on
4 this kind of political input or pressure to use a
5 word used earlier from members of Congress of varying
6 political perspectives?

7 A No. What's important for the Agency is
8 that it is able to build a complete record of the
9 relevant scientific facts and have carefully
10 considered scientific analysis to make appropriate
11 inferences about policy decisions based on those
12 facts.

13 I would assume that on occasion letters
14 from members of Congress, just like letters from any
15 other source, can bring important facts to light that
16 the Agency should consider in its review process, but
17 that is a very different than being driven by
18 political considerations or bowing to the views of
19 particular members.

20 One of the things that you learn in being
21 a Commissioner, if you're around long enough, you're
22 going to tick everybody off and there certainly were

0291

1 some opinions that came out while I was at the Agency
2 that made some republicans happy, others that made
3 democrats happy, and some that made nobody happy but
4 were still the right thing to do.

5 Q In the course of formulating your own set
6 of -- your own analysis of the Plan B OTC issue in
7 your own kind of concerns -- let's call them that --
8 as you described them earlier, concerns about the
9 Plan B OTC application and the presentations that
10 were being made by CDER staffers, was there any
11 identification ideological component to your
12 concerns?

13 A No.

14 Q Was there any political component to your
15 concerns?

16 A No.

17 Q Was there any component to your concerns
18 that was based or predicated on moral views about
19 sexual behavior?

20 A No.

21 Q Let me ask you, you were asked about this
22 letter from Dr. Hagar, do you recall this?

0292

1 A Hand it to me. Yes. That came up earlier
2 in the deposition.

3 Q I believe Mr. Heller identified a couple
4 of passages from this letter which he described as
5 being similar to -- as expressing concerns similar to
6 concerns that you testified about. Do you recall
7 that testimony?

8 A Yes.

mcclellan

9 Q In formulating your concerns or coming --
10 developing those concerns in your mind, were you
11 influenced or affected by this letter in any way?

12 A I don't think I had even seen this letter
13 at the time that we were having the, certainly the
14 initial briefing and the time we were having some
15 discussions about the concerns on the scientific
16 evidence related to the OTC switch.

17 This letter did get some press attention
18 along the way, but, you know, I testified a minute
19 ago that the Agency gets literally hundreds of
20 letters from members of Congress every year.

21 We get thousands of letters from members
22 of the public including experts in the public on the

0293

1 issues the FDA is dealing with. Those letters don't
2 come the me. I don't have time to read each and
3 every piece of correspondence that comes into the
4 Agency.

5 Part of the Executive Secretariat process
6 of the Agency is to route correspondence like this to
7 the appropriate area of expertise in the Agency for
8 dealing with it, making sure that we've registered
9 and taken note of the concerns raised and proceeding
10 in an orderly way with our regulatory processes.

11 This didn't make it to me at the time. I
12 think the first time I may have heard about it was
13 from some of the staff telling me, based on press
14 reports or their own look at the letter -- because
15 I'm sure it was routed to CDER for response and
16 action -- what it said and how and why that was or
17 wasn't a concern.

18 But I really don't recall any specific
19 discussion of this letter at all in my briefings.

20 Q You said a moment ago that you said "I'm
21 sure it was routed to CDER for a response." Do you
22 know specifically what happened to this document when

0294

1 it arrived at FDA addressed to you?

2 A Off the top of my head, I don't, but I
3 expect that you can find response in the record from
4 the relevant officials in the Center for Drugs.

5 Q Let me show you a document that was
6 produced by the Plaintiffs. I'm sorry, I don't have
7 it in hard copy but it is Bates No. Tummino 295 that
8 was produced in discovery of the Plaintiffs.

9 Let me ask you to take a peak at this
10 letter here, Dr. McClellan, and tell me if that
11 refreshes your recollection as to what happened to
12 this letter from Dr. Hagar upon its arrival in the
13 Agency?

14 A Yes, this is a response letter to
15 Dr. Hagar from an official in CDER, noting that "we
16 have received a letter" and it looks like there was
17 some delay in actually getting this response out to
18 Dr. Hagar. Sometimes there is some processing time
19 required in handling the volume of correspondence
20 that comes in to FDA.

21 And the letter notes -- it says, "Thank
22 you for writing expressing your thoughts and concerns

0295

1 regarding this important issue." Notes that the
2 letter will be entered into the public docket, which
3 we had -- I don't know what the number was. I'm sure
4 it's a large number of public comments related to
5 this Agency proceeding, and that looks like the
6 disposition of the letter within the Agency.

7 Q Was it the practice of the Food and Drug
8 Administration during the time you were Commissioner
9 to request minority reports or minority opinions from
10 members of advisory committees who did not agree with
11 the recommendations of the majority of the members of
12 an advisory panel?

13 A No.

14 Q Do you have any reason to believe that
15 practice was deviated from in the context of Plan B?

16 A No. I didn't request it. Nobody that I
17 know -- I don't know of anybody else in the Agency
18 requesting it.

19 Q Do you know Dr. Hagar personally?

20 A No. I don't think I've ever met him. I
21 certainly don't know him and I never discussed any
22 Plan B-related issues with him.

□

0296

1 Q Now, you -- at one point during your --
2 well, at one point during his questioning of you,
3 Mr. Heller asked you whether in connection with prior
4 OTC switch applications FDA had requested data
5 specifically relating to adolescent sub-populations.
6 Do you recall that question he asked you?

7 A Yes.

8 Q Now, for lawyers, precedent is important,
9 how things were handled in the past is an important
10 consideration in determining how things should be
11 handled now at least for lawyers.

12 Is that also true in the drug application
13 context? I mean, is the Agency -- is FDA bound by
14 how it treated previous drugs and drug applications
15 in making a decision on a particular drug product?

16 A Well, science definitely progresses and,
17 as we learn more, the Agency has updated its approach
18 to dealing with various scientific issues. And I
19 talked about that earlier in, even in my response to
20 that question from Mr. Heller or some other related
21 question.

22 In some areas of product review where

□

0297

1 there is a -- the Agency has a lot of experience with
2 very similar products, we can develop guidances and,
3 you know, that kind of predictability can be helpful.

4 However, for a product like this one,
5 where we really had never had an OTC switch like this
6 where there were concerns about potential systemic
7 effects of high-dose oral contraceptives and specific
8 concerns related to how adolescents and young girls
9 would use the product without any supervision from a
10 health professional. Those were not issues that had
11 been dealt with in prior applications. That's why I
12 think the Agency took a closer look.

13 Q Okay. At another point in your testimony
14 in response to Mr. Heller's questions, he asked you,

mccllellan

15 I believe, and I'm paraphrasing his question, but he
16 asked you about the challenges that would be posed by
17 an effort to conduct an actual use study that
18 involved more younger adolescents and you, I believe,
19 testified that there indeed would be some challenges
20 posed by ethical considerations and IRBs and so forth
21 and so on. Do you recall that testimony?

22 A Yes.

0298

1 Q Okay. And your testimony suggested -- and
2 if I'm mischaracterizing or misparaphrasing your
3 testimony, please correct me -- your testimony
4 suggested that although there were challenges in
5 conducting an actual use study of that nature, you
6 did not believe that those challenges were
7 insurmountable? Am I correct stating your testimony?

8 A Yes. And I've come to become an optimist
9 as some people might be surprised by that after as
10 much experience, after a number of years of
11 experience in government, but there are a lot of
12 innovative approaches out there for developing
13 evidence and a lot of statistical and data problems
14 that creative researchers have found ways to solve.

15 Now it's not the FDA's job to come up with
16 all of those; it's the requirement under the statute
17 is on the drug manufacturer to prove safety and
18 effectiveness and that there would not be misuse of
19 an OTC product.

20 Q Let me flesh that out with you a little
21 bit more with you, Dr. McClellan. Let's say that the
22 challenges you described actually were

0299

1 unsurmountable. Let's say that all the great minds
2 at Barr Pharmaceuticals and the lawyers as well after
3 scratching their heads and sitting down and trying to
4 figure out, well, how can we come up with a design of
5 an actual use study that overcomes these challenges,
6 that can't figure anything outing. Okay.

7 what's the consequence of that from the
8 point of view of FDA's responsibility towards the
9 drug application?

10 A Well, the statute requires FDA to not
11 approve OTC application unless the statutory
12 conditions are met, and there's not really room for
13 exceptions to that. But I do continue to -- that's
14 the short answer.

15 I do continue to believe, though, that
16 there's lots of ways to develop more evidence on
17 products, and, you know, I think one -- if there were
18 steps to make Plan B available more widely, whether
19 it's through education about advanced provision,
20 which women can get now if they talk to their
21 physician, or if it's through behind-the-counter
22 programs which are being used in limited areas of the

0300

1 United States already, or through other means, those
2 kinds of developments make it incrementally easier to
3 learn more about questions that have not yet been
4 answered.

5 And much of scientific progress is

mcclellan

6 incremental. And, you know, many of the policies
7 that FDA has implemented in the past have led to
8 incremental improvements in medical care and medical
9 technology. You keep learning as you're going along.

10 Q Let me just follow up on that with one
11 more question. If the drug sponsor were to come back
12 to FDA and say, "we just can't figure out how to do
13 this. We obviously don't think there is any way we
14 can design a study that meets these concerns." Under
15 that circumstance is that a circumstance where the
16 Agency should just go ahead and approve the
17 application?

18 A No. But the Agency does try to work very
19 hard to find a path forward when there is a potential
20 value for a product that's under review. And as I
21 understand Dr. Galson's letter in May, it not only
22 identified some issues with young age groups; it also

□
0301

1 invited the company consider another path forward
2 besides developing the scientific evidence and that
3 was to resubmit an application that focussed on the
4 older age groups where the evidence was very clear.
5 And that's exactly what the company did.

6 Q You were asked during Mr. Heller's
7 questioning about a conference call or telephone call
8 that you had on the afternoon of April 21, 2003. Do
9 you recall that with --

10 A Yes, I recall the earlier discussion about
11 it, right.

12 Q -- Mr. Lefkowitz?

13 MR. AMANAT: Let me ask you please to mark
14 this document as McClellan Exhibit 2.

15 (Exhibit 2 marked for identification.)

16 BY MR. AMANAT:

17 Q Let me ask you, Dr. McClellan, you don't
18 need to read this carefully but just look at it
19 briefly, if you might?

20 A Okay (witness perusing.)

21 Q I've handed you what's been marked for
22 identification as McClellan Exhibit 2 which, for the

□
0302

1 record, consists of two news articles both dated
2 April 21, 2003, the first from the Washington Post of
3 that day, which was a Monday, and the second which
4 begins on the third page of the document, an article
5 from the United Press International, also April 21.

6 Now, you said that there were some
7 questioning as to what might have prompted you to
8 have this call with Mr. Lefkowitz on April 21, 2003,
9 and you said that you didn't have a crystal clear
10 recollection as to what might have but you thought
11 that maybe there was some press coverage?

12 A Yes.

13 Q Upon seeing these news articles, does that
14 refresh your recollection as to what might have
15 prompted that particular telephone call to take place
16 on the afternoon of April 21, 2003?

17 A Yes. There was definitely some press
18 coverage as the Washington Post and the wire article
19 show on Monday April 21, 2003. Now, these articles
20 would have been out in public that morning, so again

mcclellan

21 we didn't just jump to a call but did -- we did
22 catch-up briefly later in the day about the

0303

1 application being in and given the news.

2 Q During your time at FDA, which I
3 understand was relatively short, only 16 months, do
4 you recall any other drug applications of any kind
5 which were filed with the Food and Drug
6 Administration which were reported in major national
7 newspapers on or shortly after their date of filing?

8 A Well, many manufacturers don't seek or
9 encourage or actually try to suppress any press
10 around the time that they actually file the
11 application initially, so, there may have been some.
12 None come to mind right now.

13 What does come to mind is that there were
14 other occasions when because of an advisory committee
15 meeting or an action of the Agency on a drug, that
16 led to press coverage and that could lead to, you
17 know, calls or need to provide an update or something
18 like that as well.

19 Q My question specifically was, are you
20 aware of any other drug application of any kind in
21 which there was substantial national press coverage
22 of the drug application either on or very shortly

0304

1 after the drug application was filed?

2 A Offhand, I don't.

3 Q Now, Mr. Heller asked you during your
4 earlier testimony whether you had any conversations
5 specifically about the Citizen Petition as opposed to
6 the SNDA which had been filed by the sponsor. Do you
7 recall that line of questioning that he asked you?

8 A Yes, we didn't -- we didn't pursue it very
9 far, but, yes, I recall it.

10 Q Let me flesh that out with you a little
11 bit and just talk to you about the petition
12 processes. In your view -- first of all, does CMS
13 have a Citizen Petition process as well?

14 A No. We don't have the same kind of
15 regulatory structure as FDA does. It is a different
16 law and different regulatory procedures. Our
17 coverage decisions have -- do have a public notice
18 and comment process but it's not in the same fashion
19 as a Citizen's Petition.

20 Q So what did you understand the role or
21 purpose of the Citizen Petition process was within
22 the context of the Food and Drug Administration?

0305

1 A Well, it was a means for the parties and
2 the public to request regulatory action on products
3 that the FDA regulates. The more common course of
4 action is that a product developer will take action
5 or the FDA may take action on some of them based on
6 safety concerns or new information, but members of
7 the public are able to suggest or recommend courses
8 of action as well.

9 Q Now, in Mr. Heller's questioning of you
10 with regard to the Citizen Petition, he asked you
11 whether you had had any conversations specifically

mcclellan

12 about the Citizen Petition and you testified, I
13 believe, and again if I'm misstating your testimony,
14 please do correct me -- you stated that the subject
15 of the Citizen Petition might have come up in one or
16 two of your conversations but that you did not have
17 any conversations specifically about it. Am I
18 correct in stating it that way?

19 A That's about it right. Early on in my
20 time at the Agency when is was getting oriented to
21 this issue, I believe that the Center let me know
22 that there was a Citizen's Petition in but that

0306

1 because of concerns that the professional staff had
2 about the lack of evidence to back up the recommended
3 action the Citizen's Petition, plus the fact that one
4 of the product manufacturers involved was expected to
5 submit an SNDA soon, because of those facts, the
6 Agency was concentrating its limited resources on
7 working with the company on its SNDA submission
8 which, you know, addressed the same issues as, the
9 same kind of issues in the Citizen's Petition.

10 Q There was also discussion during your
11 testimony about the fact that the Citizen Petition
12 had now been decided?

13 A Yes.

14 Q In your experience and in your experience
15 as Commissioner and experience in government in HHS
16 more generally, was the amount of time that the
17 Agency took to decide the Citizen Petition in this
18 case unusual?

19 A Well, the amount of time to deal with a
20 Citizen's Petition can vary a lot, and certainly I
21 know of others that are still around, that have been
22 around longer than the this Citizen's Petition.

0307

1 Here I think some of the factors that may
2 have contributed to the time included the fact that
3 the Agency shifted its focus to the SNDA given the
4 one of the resources available, and that may have
5 been a contributing factor, but it's certainly not
6 very unusual.

7 Q Now, I do have a few more minutes of
8 questions for you but I'm informed by the
9 videographer that we're almost out of tape. So
10 should we take a breather now --

11 A Yes, and I'd also like to be sure that,
12 especially with these questions that have come up
13 from GAO, Senator Levin that if Mr. Heller has any
14 further clarifications or details that he wants to
15 ask me about on them, that we cover then.

16 Q He'll have an opportunity but why don't we
17 take a break to change the tape, and I then have
18 maybe like three or four more minutes.

19 THE VIDEOGRAPHER: This marks the end of
20 tape 3 in the deposition. We are going off the
21 record. The time is 4:36 p.m.

22 (Change tape.)

0308

1 This marks the beginning of tape 4 in the
2 deposition of Dr. McClellan. We are back on the

mcclellan

3 record. The time is 4:43 p.m.

4 BY MR. AMANAT:

5 Q Dr. McClellan, the Plaintiffs have raised
6 a number of allegations in their complaint about
7 Plan B and about the FDA's actions with regard to
8 Plan B.

9 I'm going to read a few of the allegations
10 from their Complaint -- this is from their Third
11 Amended Complaint -- and ask if you believe that the
12 allegations set forth in the Complaint is a truthful
13 statement and why or why not. Okay?

14 A Okay.

15 Q You can read over my shoulder if you want.

16 Paragraph 76 of their Complaint they state
17 "the administrative record compiled by the Agency
18 confirms that as early as January 15th 2004 upper
19 level management at FDA had decided that the OTC
20 switch for Plan B would not be approved, and that
21 this decision was made before the scientific review
22 of the OTC application was complete."

0309

1 Is that a truthful statement,
2 Dr. McClellan?

3 A No, not to my knowledge. And as I
4 understood at the time the Center was still gathering
5 additional evidence that had a bearing on the
6 response of the application. Dr. Galson and
7 Dr. Woodcock noted that they would have, even be
8 willing to have a further briefing with me on that
9 evidence as well. So I think they were developing
10 the evidence, they were reviewing it, and the Agency
11 was still involved in decision-making.

12 As you approach a decision, you need to be
13 ready for the different options that the Agency might
14 take, and so the Center, as I understand it, may have
15 been taking some steps towards being ready for a
16 range of options -- a range of decisions, but I don't
17 think the decision was made. And Dr. Galson
18 certainly didn't communicate that to me.

19 Q Paragraph 78 of the Complaint says in part
20 "documents show that both the Commissioner of the FDA
21 and the Deputy Commissioner of Operations played an
22 unusually active role in the decision to issue an

0310

1 non-approvable letter as well as subsequent Agency
2 action on Plan B."

3 Is that sentence a truthful statement?

4 A Well, it is not even correct. I think
5 they're referring to Dr. Woodcock, who at that time
6 was not the Deputy Commissioner of Operations but was
7 on a detail to the Commissioner's office to help us
8 with a range of issues, including effective review
9 and approving review processes in the Agency. So I
10 don't think it's correct even in the description of
11 who was in the Office of the Commissioner.

12 In terms of the role, it's absolutely
13 typical for me to be briefed on important issues
14 before the Agency and it's absolutely typical for me
15 to ask questions about the quality and completeness
16 of the scientific evidence, so, no, I don't think
17 that's correct.

mcclellan

18 Q Paragraph 83 of the Complaint alleges as
19 follows: "The FDA applied a different and higher
20 standard to Plan B's OTC switch than it has applied
21 to OTC switches of other drugs."

22 Is that a truthful statement,
□

0311

1 Dr. McClellan?

2 A No.

3 Q Now, let me just explore this with you. A
4 few minutes in response to one of my questions you
5 gave a lengthy response in which you talked about how
6 the scientific process that is implicated in the drug
7 approval process is not a static process but that it
8 evolves over time?

9 A Right.

10 Q And I believe you testified at the end of
11 that answer you used the words "closer look" and you
12 stated that the Agency may have taken a closer look
13 because the science had evolved.

14 When you were testifying and you made the
15 statement "closer look" was that the same as saying
16 that the Agency applied a higher standard to Plan B's
17 OTC switch than it applied to OTC switches of other
18 drugs?

19 A No. The standard that the Agency applies
20 is, does the scientific evidence support that the
21 product could be used safely and appropriately
22 without misuse by consumers without intervention from
□

0312

1 a health professional.

2 What I meant by the science evolving and
3 also the specific areas where the Agency is going to
4 look closely in a particular application is that
5 depends on the particular application.

6 Each application raises distinctive
7 issues, especially this one. This was the first time
8 we had an OTC application for this kind of product, a
9 product with systemic effects that is not intended to
10 be used on a regular basis any time you might have a
11 symptom and where there was even some evidence that
12 some people, particularly younger individuals and
13 those of limited educations, might not fully
14 appreciate that this was intended to be only an
15 emergency form of contraception as part of an overall
16 effective contraception plan.

17 So it was the science and the evidence on
18 the particular case that dictated where the FDA
19 focussed its efforts; that's what I meant.

20 Q Let me go on -- you partially answered the
21 next question, but the next allegation I want to draw
22 your attention to paragraph 84 where it says, where
□

0313

1 it is alleged, "There is no medical or scientific
2 basis for the FDA's application of a different and
3 higher standard to Plan B's OTC switch."

4 Let me ask you, do you consider that to be
5 a truthful statement?

6 A No. Again, the FDA review focuses where
7 the scientific evidence indicates that it should
8 focus and that's what happened in this case.

mcclellan

9 Q Okay. Finally, paragraph 85 of the
10 Complaint alleges as follows: "The FDA's failure to
11 approve Plan B for OTC use is based in part on
12 outmoded stereotypes of women and girls."

13 Is that a truthful statement,
14 Dr. McClellan?

15 A No, absolutely not.

16 Q Do you want to elaborate on that at all?

17 A Well, it's just not the kind of standard
18 that the Agency uses in review, and I can tell you
19 from talking with Dr. Woodcock on a number of
20 occasions about this application while I was at the
21 Agency, she is a very strong believer in finding
22 effective ways to provide medical support for women

0314

1 and young girls.

2 I think that's been evident throughout her
3 career and it was certainly evident in her approach
4 to the Plan B product. She is probably one of the
5 most effective scientific advocates that women and
6 girls can have in federal government.

7 Q Actually, there is one more allegation I
8 want to ask you about; paragraph 86 of the Complaint
9 alleges, "The FDA's application of a different and
10 higher standard to Plan B's OTC switch was a result
11 of factors that fall outside the FDA's statutory
12 mandate, including impermissible ideological
13 factors."

14 Is that a truthful statement,
15 Dr. McClellan?

16 A No.

17 Q Now, let me wrap up, sir, by asking you,
18 are you aware of the regulation that governs FDA's
19 consideration of OTC switches which says -- which
20 describes the standard as follows: "Any drug limited
21 to prescription use shall be exempted from
22 prescription dispensing requirements when the

0315

1 Commissioner finds such requirements are not
2 necessary for the protection of the public health by
3 reason of the drug's toxicity or other potentiality
4 for harmful effect."

5 Are you familiar with that regulation?

6 A Yes, generally.

7 Q For the record that's 21 C.F.R.
8 Section 310.200(B). The regulation makes reference
9 to other potentiality for harmful effect. Okay.

10 What in your experience does that phrase
11 mean or what does it subsume?

12 A Well, it subsumes a very broad range of
13 public health concerns. The OTC switches involve in
14 some important ways a broader range of public health
15 considerations than prescription drugs switches
16 because the issue isn't just whether or not a product
17 can be used in accordance with conditions on the
18 label and under a physician's supervision, safely and
19 effectively, but whether an individual will be able
20 to use the product effectively, not misuse the
21 product on their own with no intervention of a health
22 professional.

0316

1 That can be a pretty broad range of issues
2 to consider and it certainly goes to some of the ones
3 that we've discussed at length today, like issues
4 related to contraception behavior which can have
5 public health consequences; sexually transmitted
6 diseases and the occurrence or prevention of
7 pregnancy.

8 Q Thank you Dr. McClellan. I have no
9 further questions.

10

REDIRECT EXAMINATION

11

BY MR. HELLER:

12

Q Dr. McClellan, let me ask you is your
13 current presidential appointed?

14

A Yes.

15

Q And your prior position was presidential
16 appointed?

17

A Yes.

18

Q So people in your position who might seek
19 to advance their career, unlike career scientists at
20 agencies, don't you think they would be more subject
21 to political influence simply because the next step
22 in their career is going to may well be a desire to

□

0317

1 have another presidential appointment?

2

A Maybe. My own experience was in
3 government first time when I was appointed by a
4 democratic president that the best way to advance
5 your career, certainly the only way that I'm
6 comfortable with, is by doing your job effectively
7 and that means making good policy and supporting the
8 Agency that you work for and represent and lead in
9 making the most effective policy possible.

10

Q Without impugning what you just said about
11 yourself, isn't that exactly the answer you'd expect
12 every political appointee to give whether or not --

13

MR. AMANAT: Objection.

14

BY MR. HELLER:

15

Q -- no, I mean -- let's just be frank.

16

Nobody is going to say, you know, "well, I do sort of
17 keep my finger in the wind and try to see what the
18 higher-ups want." Nobody says that, though, right?

19

A No. But I can just tell you, I can
20 appreciate your not wanting to believe everything
21 that I say.

22

Q I specifically say I don't want to cast

□

0318

1 down what you're saying. There are people like that,
2 also, who are more prone perhaps than yourself to
3 political influence?

4

A I suppose. But in terms of my work at the
5 Agency, and the people that I've dealt with on this
6 issue, Dr. Woodcock, Dr. Galson, in particular, I can
7 tell me you that they're not politically motivated at
8 all.

9

Q They are also not presidential appointed,
10 right?

11

A That's correct; they're career staff.

12

Q You also gave some testimony about, you
13 know, I think he asked you -- read you some stuff
14 from our Complaint about, for example, FDA decision

mcclellan

15 was based on outmoded stereotypes of women and girls?

16 A Yes.

17 Q I think you said that did not play a role
18 in the FDA's decision-making. Am I also right that
19 you don't really know what played a role in the FDA
20 decision-making after you left?

21 A I guess I should be clear. That's
22 correct. I left the Agency in early March of 2004.

0319

1 I was only involved in the Plan B application process
2 for the first phase -- not even the complete first
3 application. I wasn't even there when the decision
4 was made on the first application.

5 So since that time, as you note, Barr has
6 resubmitted a second application. The Agency has
7 taken some action on that and in the further
8 processes I haven't been involved.

9 Q So you don't really know what factor -- of
10 course, you would hope that it was based on the
11 science and good analysis of science?

12 A Absolutely right. I should be clear that
13 the discussions that I had and the points I was
14 making were related to my direct experience with the
15 Agency.

16 Q Thank you. I have no additional
17 questions.

18 A Just to make sure the questions from GAO,
19 Senator Levin, nothing else there that you want to --

20 Q I have nothing else. I can't speak for
21 them.

22 A I just want to make sure we got those

0320

1 completely addressed here for all the purposes that
2 you need.

3 Q For all the purposes I need. Again, I
4 can't speak for Senator Levin and I think the GAO has
5 concluded its investigation, so probably they don't
6 care at this point anyway. Thank you.

7 A Thank you.

8 THE VIDEOGRAPHER: This marks the end of
9 the deposition of Mr. McClellan. Total number of
10 tapes used today was four. We are going off the
11 record. The time is 4:56 p.m.

12 (Signature reserved.)

13 (Deposition concluded.)

0321

1 C E R T I F I C A T E
2 District of Columbia)
3 I, Carl W. Girard, Registered
4 Merit Reporter, and Notary Public within and
5 for the District of Columbia, duly commissioned and

6 qualified, do hereby certify that the within named
7 witness MARK McCLELLAN, M.D. Ph.D. MPA was by me first
8 duly sworn to testify the truth, the whole truth and
9 nothing but the truth in the cause aforesaid; that the
10 testimony then given by him was reduced by me to
11 stenotype in the presence of said witness, subsequently
12 transcribed into English text under my direction, and
13 that the foregoing is a true and accurate transcript of
14 the testimony so given.

15
16 I do hereby certify that this
17 deposition was taken at the time and place as
18 specified in the foregoing caption and was
19 completed without adjournment.

20 I do hereby further certify that
21 I am not a relative, counsel, or attorney of either
22 party or otherwise interested in the outcome of

□
0322 this action.

1
2
3 In witness whereof, I have
4 hereunto set my hand this 19th day of June, 2006.

5
6
7 _____
8 CARL W. GIRARD, R.M.R.

9 My commission expires
10 October 14, 2009

11
12
13
14
15
16
17
18
19
20
21
22
□
0323
1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE EASTERN DISTRICT OF NEW YORK
3

4
5 _____)
6 ANNIE TUMMINO, et al.,)
7 Plaintiffs,)
8 v.) Civil Action No.
9 ANDREW C. vonESCHENBACH, as Acting) 05-CV0366(ERK/VVP)
10 Commissioner of the Food and Drug)
11 Administration,)
12 Defendant.)
13 _____)

14 I, MARK McCLELLAN, M.D. Ph.D. MPA, do hereby
15 certify that the foregoing transcript of my testimony
16 in the cause aforesaid is true and accurate, with
17 corrections, so given by me at the time and place
18 specified in the heading herein.

21
22
□

mcclellan
MARK MCCLELLAN, M.D. Ph.D. MPA