

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

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FOOD AND DRUG ADMINISTRATION

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RISK COMMUNICATION ADVISORY COMMITTEE

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THURSDAY, APRIL 30, 2009

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The meeting convened, at 8:00 a.m., in Room 1066, at 5630 Fishers Lane, Rockville, Maryland, Baruch Fischhoff, Ph.D., Chair, presiding.

COMMITTEE MEMBERS:

BARUCH FISCHHOFF, Ph.D., Chair
CHRISTINE M. BRUHN, Ph.D., Member
JACOB DELAROSA, M.D., Member
ANNAMARIA DESALVA, Member
SOKOYA FINCH, M.A., Member
MICHAEL GOLDSTEIN, M.D., Member
SALLY GREENBERG, Member
PRERNA MONA KHANNA, M.D., M.P.H., Member
MADELINE Y. LAWSON, M.S., Member
MUSA MAYER, M.S., M.F.A., Member
JOHN E. PALING, Ph.D., Member
ELLEN M. PETERS, Ph.D., Member
BETSY LYNN SLEATH, Ph.D., Member
MICHAEL S. WOLF, Ph.D., M.P.H., Member

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C-O-N-T-E-N-T-S

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P-R-O-C-E-E-D-I-N-G-S

8:36 a.m.

CHAIRMAN FISCHHOFF: Let me welcome you.

I'm Baruch Fischhoff, the Chair of the FDA's Risk Communication Advisory Committee.

I would like to welcome you all to our fifth meeting.

Let me turn it over to Dr. Lee Zwanziger, the Designated Federal Officer.

DR. ZWANZIGER: Thank you, Dr. Fischhoff.

Good morning to the members of the Risk Communication Advisory Committee, members of the public, press, and the FDA staff. Welcome to this meeting.

The following announcement addresses the issue of conflict of interest with respect to this meeting and is made a part of the public record to preclude even the appearance of such at the meeting.

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1 Today and tomorrow, the Risk
2 Communication Advisory Committee will discuss
3 points to consider regarding the FDA's Draft
4 Risk Communications Strategic Plan and risk
5 communication research needs.

6 Based on the submitted agenda for
7 the meeting, as announced in The Federal
8 Register, and all financial interests reported
9 by Committee participants, it has been
10 determined that no interests in firms
11 regulated by the Food and Drug Administration
12 present potential for conflict of interest or
13 appearance of such at this meeting.

14 Should the discussion turn to any
15 area of possible conflict or any area not
16 already on the agenda, participants are aware
17 of the need to identify any conflicts
18 pertaining to them and refrain from
19 participating, and their statements and
20 exclusions would be noted for the record.

21 We do have a period set aside for
22 open public comment each day that is listed in

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1 the agenda. If anyone is not already signed
2 up to speak and now wishes to request time,
3 please see one of my colleagues at the sign-in
4 table outside.

5 This entire meeting is being
6 transcribed, and the transcript will be posted
7 on the FDA's website. But it will only
8 contain what the transcriber hears, so let me
9 just remind us all to turn on and speak into
10 the microphones every time you are recognized
11 to speak, and turn them off when you are not
12 speaking.

13 Also, I would suggest that we turn
14 cell phones and other devices to a silent
15 mode.

16 Finally, I note that one of our
17 members, Dr. Andrews, is unable to be present
18 today, due to just a schedule conflict, but
19 should be here tomorrow.

20 And thank you very much.

21 CHAIRMAN FISCHHOFF: I'm, again,
22 Baruch Fischhoff.

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1 Let me ask the members of our
2 Committee to introduce themselves. Let's
3 start over here with Christine.

4 MEMBER BRUHN: Good morning. I'm
5 Christine Bruhn. I'm with the University of
6 California at Davis. I do consumer research
7 on attitudes toward food safety and quality,
8 and I address ways to communicate more
9 effectively with the public regarding food and
10 food choice and food-handling behavior.

11 MEMBER DeLaROSA: Good morning.
12 I'm Jacob DeLaRosa. I'm a cardiac surgeon in
13 Idaho at Idaho State University. Good
14 morning, everyone.

15 MEMBER MAYER: Good morning. I'm
16 Musa Mayer. I'm a breast cancer advocate from
17 New York City. I work with patients who are
18 living with metastatic breast cancer and their
19 families primarily. As the author of several
20 books on breast cancer, I have a particular
21 interest in clear communication to patients
22 and the public about the risks and benefits of

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1 treatments.

2 CHAIRMAN FISCHHOFF: I'm Baruch
3 Fischhoff. I'm a professor of social and
4 decision sciences in Engineering and Public
5 Policy at Carnegie Mellon University, and I
6 head our decision sciences major.

7 If anybody has an inquisitive high
8 school junior, come and see me at the break.
9 If you want to do a college tour in
10 Pittsburgh, we would be happy to help you.

11 MEMBER SLEATH: I'm Betsy Sleath,
12 and I'm a professor of pharmaceutical outcomes
13 and policy at the University of North
14 Carolina, Chapel Hill. My research interests
15 are primarily in how providers and patients
16 talk about medications.

17 MEMBER PALING: Good morning. I'm
18 John Paling. I organized a group called Risk
19 Communication Institute. My interest is
20 helping healthcare professionals understand
21 the importance of risk communication and to
22 increase its visibility and its importance in

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1 their mind.

2 My goal, if I were to be really
3 simplistic about it, is to convince healthcare
4 professionals and all those that work in this
5 field that risk communication is not a gray
6 responsibility, but instead should be seen as
7 a golden opportunity.

8 MEMBER PETERS: Good morning. My
9 name is Ellen Peters. I'm a senior research
10 scientist at Decision Research in Eugene,
11 Oregon. I'm a psychologist by training. I
12 study how people make decisions.

13 In particular, I'm interested in
14 how people process affective and emotional
15 information, and how that influences their
16 decisions, but, also, how individual
17 differences, like numeracy or number ability,
18 as well as age, influence how we process
19 different sources of information.

20 MEMBER WOLF: My name is Michael
21 Wolf. I'm from Northwestern University, and I
22 direct the Center for Communication in

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1 Healthcare. A lot of my work has been around
2 health literacy, issues of medication safety
3 and the like.

4 MEMBER FINCH: Good morning. My
5 name is Sokoya Finch, the Executive Director
6 of Florida Family Network, an advocacy
7 organization that deals with education,
8 health, and income of low and middle families
9 throughout the State.

10 In terms of health, we do a focus
11 on health disparity, which very much often
12 played a link between academicians' research
13 and communities as it relates to community
14 health.

15 CHAIRMAN FISCHHOFF: Thank you.

16 Let me introduce -- hi. Would you
17 like to introduce yourself?

18 MEMBER LAWSON: Good morning. My
19 name is Madeline Lawson. I'm the President
20 and CEO of the Institute of the Advancement of
21 Multiculture and Minority Medicine, based in
22 Washington, D.C. The primary focus of the

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1 Institute is on addressing health disparities.

2 CHAIRMAN FISCHHOFF: Okay, thank
3 you, Madeline.

4 As you can see, we have really
5 quite an excellent and unusual Committee in
6 terms of the diversity, the academic
7 backgrounds as well as the non-academic
8 backgrounds of people. It is really quite a
9 remarkable Committee.

10 What I thought I would do, by way
11 of opening, for those of you who haven't been
12 at all of our meetings or read all of the
13 excellent transcripts that -- actually, let me
14 say that the website for this Committee, once
15 you find it, it is really kind of a treasure
16 trove.

17 We have the excellent verbatim
18 transcripts that we have here. After each
19 meeting, Lee has produced a terrific narrative
20 summary, which is then sent around to the
21 Committee members.

22 For some of our meetings, we have

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1 had recommendations that you can find there.
2 There have been presentations. You could
3 probably do a course in this topic just based
4 on the slideshows that are posted there.

5 So what I thought I would do is
6 just take a few minutes to give you a flavor,
7 a little bit of the history of the Committee,
8 just with some of my own personal impressions
9 of it. Since they are personal impressions, I
10 wouldn't make a slideshow.

11 So this Committee is purely
12 advisory. That is, if we have to make the
13 case to the FDA staff that we have good ideas,
14 if we don't make that case, they don't have to
15 do anything. So that is our challenge then.

16 Each of our meetings has had some
17 measure of education by FDA staff in terms of:
18 what are the problems that they have? What
19 are the constraints under which they work?
20 Where do they think that we could be most
21 helpful? Where do they hope that there is
22 some science available to solve their

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1 problems?

2 We have had, this will be our fifth
3 meeting. Our first meeting was at the end of
4 February last year, where we had a day's
5 education. We were good enough to have the
6 Commissioner von Eschenbach come and speak to
7 us at that time, as well as people from
8 different divisions.

9 Then we had our first challenge,
10 which was to say something useful about how
11 FDA could deal with the communications
12 regarding food recalls. FDA, the staff that
13 brought it to us, had realized, had come to
14 the conclusion that there was a need for
15 standardization in the recalls, so that you
16 would be sure you got the right information
17 out and the audiences would know what to
18 expect when FDA talked to them.

19 So we brought some of the research
20 that was relevant to that and talked about
21 some of the issues of how to test the messages
22 with something like the diverse -- people like

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1 those in the diverse audiences that FDA needs
2 to address, so that you have some evidence
3 that your best guess at what will work with
4 people actually does.

5 We have heard back from FDA that
6 they have adopted some of our suggestions and
7 have found a way of doing some kind of testing
8 within FDA's own very heterogeneous workforce
9 to do rapid testing for messages.

10 We also got our first dose of
11 something which I assume we will be hearing
12 about a lot today, the constraints under which
13 FDA operates in terms of its ability to
14 collect evidence from people under the
15 Paperwork Reduction Act, which requires OMB
16 clearance and a very complicated procedure.

17 A recurrent theme that I think came
18 out first in that meeting is that FDA is often
19 expected to do the impossible by the public.
20 The public thinks that FDA has a staff --
21 well, what people expect FDA to do might
22 require a staff of ten times larger than what

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1 it actually has and may also require
2 regulatory authority that it does not have,
3 say in terms of requiring recalls.

4 So a recurrent theme has been, how
5 can FDA, in the context of communicating about
6 very specific issues, give people realistic
7 expectations of what FDA can and can't do?

8 Our second meeting in May of last
9 year, we dealt with two items that were, I
10 guess, assigned to the Committee under the FDA
11 Amendments Act of 2007, which was to look at
12 two aspects of direct-to-consumer
13 advertisement for pharmaceuticals.

14 One was how to ensure that those
15 advertisements reach the diverse audiences
16 which are, in effect, all Americans who are
17 affected by that information.

18 And secondly, how FDA could develop
19 a study to look at the usefulness of adding an
20 800 number, so that people who thought that
21 they had a problem with drugs that were so
22 advertised could phone in their problems.

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1 So, again, I think we had some
2 recurrent problems. We wrestled with the
3 issue of how FDA could do studies in a timely
4 fashion. A number that stuck in my mind is
5 that it would take perhaps two years to
6 complete an evaluation study for an 800
7 number, and then another two years to go
8 through any sort of regulatory sort of
9 proceeding. And that's four years, and the
10 world can change a lot in four years.

11 One of the presentations that we
12 had had from the FDA staff was from some of
13 the partnerships that various offices had here
14 with activist organizations. Somebody said,
15 "Well, why don't we just do that? It won't
16 take us four years." If we thought that this
17 800 number were useful, then -- they have a
18 number that exists now. It is just not widely
19 known to the public. "If we thought it was
20 useful, we'll just do it. Nobody can stop
21 us." I don't know if they did. If they did,
22 it didn't reach me. But it was a creative

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1 response.

2 Another theme that came up there
3 during that meeting was how inseparable
4 communications were from the product. So a
5 drug that goes through testing, part of the
6 testing protocol is the information that is
7 given to patients when they sign up, as part
8 of their continuing care, if they have
9 problems in finding out what the benefits are.

10 A pharmaceutical that is then made
11 available to the general public will have a
12 different communication package associated
13 with it, and it may, in effect, have somewhat
14 different risks and benefits, as a function of
15 how people use it, who decides to use it and
16 how they deal with potential problems, how
17 they take advantage of benefits that are not
18 immediately perceived.

19 The third meeting that we had was,
20 in a sense, an attempt to I guess not turn the
21 tables, but we felt that, in consultation with
22 the staff, we thought that maybe we had

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1 understood enough about FDA that we could tell
2 FDA what we knew from our various perspectives
3 that might be relevant to its problem.

4 So you will find at the website
5 presentations about what the science and
6 practice is of communication. The way we
7 divided that day was into the science and
8 practice that is available about what we
9 called persuasive and non-persuasive
10 communications.

11 So there are situations in which
12 FDA's mission is to persuade people to do
13 something, like not eat contaminated food, and
14 there are situations in which FDA's mission is
15 to facilitate people making their own
16 independent decision and, hence, the
17 communications need to be non-persuasive.

18 It's not unpersuasive, that is,
19 it's not trying to persuade people and
20 failing, but trying to present a reasonable,
21 balanced, authoritative perspective regarding
22 the risks and benefits of various actions, so

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1 that people can know what decisions that they
2 are making. If things go wrong, they won't be
3 surprised. You know, their expectations
4 should be in line with what we're capable --
5 "we" as a professional community -- are
6 capable of bringing to them.

7 We also dealt with issues of crisis
8 communication, which are in a way
9 organizational issues, getting on one page,
10 getting the information to the people who need
11 it, but also a way of taking advantage of the
12 science in high-pressured situations. So
13 sometimes you will know in advance what the
14 nature of your message is going to be. You
15 could stockpile prepared messages and then
16 tweak them for the conditions that you have.

17 So, if we had a stockpile of field-
18 tested messages regarding avian flu, we might
19 have been able to have tweaked them into some
20 rapid-testing for what we are dealing with
21 now.

22 Something that came out of that

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1 meeting, in our recommendations there, which
2 you will see in the materials that were
3 circulated here, was a recommendation from the
4 Committee, I think to a welcome audience, that
5 FDA should view communications as a strategic
6 activity.

7 There are people who view
8 communications as an end-of-the-pipeline
9 activity. People decide what to do, and then
10 you give it to the public. The consensus of
11 the Committee was that, for an agency --
12 probably the same thing would apply to a firm
13 -- that hopes to serve the public, that one
14 needs to begin by listening to the public to
15 find out what its needs are, what information
16 it already has, correct or incorrect
17 information, to design data-gathering
18 procedures that are relevant to the decisions
19 that people need to make; to summarize them in
20 terms that will be relevant to them.

21 We recommended that FDA view
22 communications as a strategic activity, as a

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1 way of -- somebody said sort of preserving,
2 not preserving, as they're representing the
3 FDA brand.

4 So the idea when you listen to
5 people, when you speak to them, that is a
6 statement about who you are, whether it is a
7 parent or it is a federal regulatory agency.
8 What you say, what you feel, the diligence you
9 do in presenting your information and ensuring
10 that it is understood is part of your
11 commitment.

12 We recognize that FDA is trying
13 very hard to do this, and there would be
14 value, we have said there would be value in
15 thinking about that in a strategic way, which
16 is what we are here for today.

17 Then, finally, we met about two
18 months ago to talk about an activity that is
19 mandated to FDA, although I think not mandated
20 to consult with the Committee, which is to
21 look at the usability of consumer medication
22 information. I guess I shouldn't be

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1 describing this to an FDA audience. But in
2 case somebody is not an FDA audience, those
3 are the things you get at the pharmacy.

4 We heard some results from
5 evaluations as well as some alternatives. The
6 conclusion that I came away with, it was an
7 incredible technological accomplishment that
8 you get that piece of paper, that it gets into
9 most people's hands, with a very heterogeneous
10 pharmacy system. We were told some pharmacies
11 still have dot matrix printers.

12 Yet, it seemed to be clear that,
13 based on the evidence that was presented to
14 us, and then what we all understand about
15 communication, that what ends up in people's
16 hands does not serve the needs of allowing
17 them to make informed choices.

18 So we heard several talks about the
19 science of making informed choices. We
20 reached some recommendations suggesting that
21 -- we had heard a presentation about the drug
22 facts box that has been developed by the

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1 Dartmouth group, and came up with a
2 recommendation that the basic elements in that
3 box, without endorsing that specific
4 representation, that the drug facts box that
5 was presented to us had several elements that
6 any solution needed to have.

7 That is, people needed quantitative
8 evidence because verbal quantifiers, verbal
9 expressions of the kind of risks and benefits
10 you get from things are well-known not to
11 communicate as well as they need to in order
12 for people to make informed choices. But
13 people need that information about both the
14 risks and the benefits, and they need that
15 information in a comparable form, so they know
16 what are the risks and benefits of alternative
17 treatments.

18 Other recommendations that we had,
19 which, again, you could find at the website,
20 was a recommendation that came from a
21 realization that making information available
22 -- that no standard representation of

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1 information will reach all of the
2 heterogeneous audiences that may take a
3 particular product.

4 A realistic expectation might be
5 make it available in a form that 50 percent or
6 60 percent of motivated adults could get
7 access to. They can understand the few
8 numbers. They can read the information. But
9 then we need to worry, to ensure that our
10 healthcare system broadly-defined connects the
11 links with people for whom that information
12 doesn't work.

13 So one could think of, if the
14 information is not available anywhere, then we
15 are really lost. But, once it is available,
16 you would like everybody to be within one or
17 two degrees of separation from somebody who
18 can interpret that information for them, and
19 that we have a collective responsibility to
20 ensure that degree of access.

21 One of the people who spoke to us
22 at that time was a former member of the

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1 Committee, David Moxley, who has worked with
2 a large group; I think he said 500 or 600
3 homeless, older African-American women in
4 Detroit. He gave a very effective
5 presentation about the circumstances under
6 which the women that he works with live. One
7 needs to imagine that every other population
8 has lives that are similarly complicated, some
9 with more assets and some with more problems.

10 But if you thought of any of our populations,
11 their lives, like ourselves and yourselves,
12 are just as complicated.

13 He thought in terms of the
14 particular group that he was working with, he
15 said there are typically women who are not
16 innumerate, who are not illiterate, who often
17 have been important players in their
18 communication, but something happened in their
19 lives, an accident, a house burnt down, they
20 lost work, and they were in a situation where
21 they, my interpretation, they just couldn't
22 concentrate. Their life was so burdensome,

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1 they couldn't understand the information.

2 They wanted to, and they had made
3 decisions on their own. They were capable of
4 making this decision if you could just
5 structure the interaction.

6 He suggested that his group had
7 just completed writing, producing a guide for
8 faith-based organizations interested in
9 working with the homeless. He suggested that
10 he could imagine a situation where somebody
11 would come in and say, "Here's my meds. These
12 are the ones that I have been able to keep
13 track of in these difficult situations."

14 And a worker could say, "Here's the
15 drug. Here's the fact sheet on that drug,"
16 and say, "Do you have arthritis? And if you
17 don't have arthritis, you probably shouldn't
18 be taking this drug."

19 Then to structure it, and then get
20 into a situation where somebody who wasn't a
21 healthcare professional could kind of do the
22 preliminary organization, and then transfer

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1 this to healthcare professionals.

2 So, as a society, some of this goes
3 far beyond what FDA is chartered or has the
4 resources to do, but we felt that, as a
5 society, we need this responsibility, and that
6 what FDA can do, which is to use its kind of
7 unparalleled expertise to identify, see that
8 the information is produced, to characterize
9 it in authoritative ways, so that something
10 can be made directly available. Then the rest
11 of society can pick up the baton and take it
12 from there.

13 Anyway, so we are very grateful to
14 have been listened to, I think, to become part
15 of half of the rest of the Committee. Up
16 until now, I think we could not have been
17 happier to have seen that we provided some
18 additional impetus to processes within FDA
19 that were already going on.

20 As you will see in the strategic
21 plan, there is a reference or an
22 acknowledgment to our recommendations from our

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1 August meeting and asking for the strategic
2 plan. We know that FDA staff on many levels
3 has been working on these issues for a very
4 long time. But if we provided a little extra
5 push, we are very grateful.

6 Let me say one final thing, which
7 is that I think that FDA is fortunate in
8 having within it such a professionally-diverse
9 staff. I chair another advisory committee.
10 EPA has a Homeland Security Advisory
11 Committee.

12 We met last week to talk about
13 there is the revision of the incident
14 commanders' guidebook for handling an anthrax
15 attack. There was a 2003 version. It was
16 slightly updated in 2005. So we have learned
17 a lot since then.

18 This multi-agency task force, where
19 EPA has the lead, was trying to figure out
20 what to do about this guidebook. So the 2005
21 guidebook had nothing, essentially nothing,
22 about the public or communication. And if you

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1 think about anthrax, I mean of the various
2 biohazards, the one where the -- I hate to say
3 it -- sort of the psychological versus the
4 physiological are in -- the psychological
5 certainly is a big part of that.

6 One of our five charge questions
7 was on communications there. But it became
8 apparent, at least to me in the meeting, that
9 the task force had just no capability. It
10 recognizes the issues were out there, but had
11 no capability.

12 It was a multi-agency task force,
13 none of whose members had any expertise in the
14 social, behavioral, and decision sciences, had
15 no resources for dealing with anything, and
16 was not, personal opinion, was not even in a
17 position that, if they were given resources,
18 that they would know how to spend them.
19 Because you need a certain level of expertise.

20 There is always somebody willing to
21 take your money, whether it is for
22 communications or therapy, or whatever. If

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1 you don't have internal expertise, then you
2 won't get very much for it.

3 So they had some tentative thoughts
4 of spending money on messaging sessions, which
5 is where you get a group of self-appointed
6 people around the table who decide what their
7 audience needs to know, how they need to know
8 it, and then gives it to somebody to work it
9 up with good production values. In my
10 opinion, you are better off not doing it than
11 doing a messaging session.

12 So FDA is in the remarkable
13 position of having a kind of corporate culture
14 whereby it is able to undertake a kind of
15 strategic initiative that we have here, and
16 having expertise like Lee Zwanziger and Nancy
17 Ostrove and others who know the science and
18 can help to do these bridging activities.

19 So I'm really very grateful to be
20 working with FDA. I hope that we can help you
21 with this important work.

22 Okay, so maybe we will go first to

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1 -- our first speaker will be Malcolm Bertoni,
2 the Assistant Commissioner for Planning.

3 Excuse me. We have two people. Go
4 ahead and introduce yourselves, Michael and
5 AnnaMaria.

6 MEMBER GOLDSTEIN: Yes, I
7 apologize for my tardiness.

8 I'm Michael Goldstein. I'm a
9 physician and work at the Providence Veterans'
10 Administration Medical Center in Providence,
11 Rhode Island. I'm a professor of psychiatry
12 also at the Alpert Medical School at Brown
13 University. My area of expertise is in
14 clinician/patient communication and helping
15 clinicians to work with their patients to
16 address risk communication in this setting.

17 Thanks.

18 MEMBER DeSALVA: Good morning.
19 I'm AnnaMaria DeSalva. I lead the Global
20 Healthcare Practice at Hill and Knowlton,
21 which is a global public relations and public
22 affairs firm. So we have client organizations

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1 all throughout healthcare, both on the
2 industry side and also on the public sector
3 side, who are always addressing how to more
4 effectively communicate risk.

5 CHAIRMAN FISCHHOFF: Thank you,
6 AnnaMaria.

7 Okay, Malcolm, welcome.

8 MR. BERTONI: Good morning,
9 everyone.

10 My name is Malcolm Bertoni. I am
11 Assistant Commissioner for Planning in the
12 Office of Policy Planning, in the Office of
13 the Commissioner at FDA.

14 Thank you very much for this
15 opportunity to address you this morning, and
16 thank you, Committee members, for your time,
17 helping FDA out. We really appreciate it.

18 The purpose of my talk this morning
19 is to really provide a broad context for the
20 discussion that we will have later on about
21 the specific Risk Communication Strategic
22 Plan.

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1 It is an opportunity to talk about
2 something that most people don't engage in
3 very often, and that is strategic planning.
4 So I thought I would start fairly broadly.

5 There's a lot of different
6 literature out there, a lot of different
7 approaches to strategic planning. We thought
8 it would be a good idea to set that context.

9 In fact, it is so broad. It is a
10 jungle out there. So one of the things we
11 will do is take a brief safari through some of
12 the strategic planning literature.

13 Then we will focus in a little bit
14 more about strategic planning in public
15 organizations, because most of the literature
16 really is about the private sector and
17 corporate strategic planning. We will talk a
18 little bit about a couple of models that are
19 used in the public sector.

20 Then we will talk specifically
21 about some of the requirements for strategic
22 planning within the federal government and get

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1 specific about what FDA has done in this area,
2 and some of the mechanisms that we have in
3 place for doing that.

4 Finally, we will talk a little bit
5 about how we got to where we are now in terms
6 of the development of the Risk Communication
7 Strategic Plan.

8 So we will start with some
9 definitions. I think it is worthwhile to talk
10 a little bit about what do we mean by
11 strategy.

12 Professor Henry Mintzberg, who is
13 at McGill University in Canada, is one of the
14 more thoughtful and prolific authors in the
15 area of strategic management. He has talked
16 about strategy in terms of five different
17 perspectives. They all start with "P".

18 The first one is plan. That is
19 sort of the classic way of thinking about it.

20 It is really a consciously-intended course of
21 action. It tends to sort of come out of the
22 military planning tradition, and a lot of

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1 large corporations undertake this kind of
2 approach.

3 There's another way of thinking
4 about strategy as well, however, that is
5 strategy as a pattern of consistency in
6 behavior over time. You can think of strategy
7 that emerges.

8 Another way of thinking about
9 strategy is strategy as a position. So think
10 of that as a particular product within a
11 niche. So if you think of, say, wristwatches,
12 Rolex has a very different position than
13 Swatch in that particular market.

14 There's another way of thinking
15 about it as well. That is strategy as a
16 particular perspective. So that has to do
17 with the way that you perceive yourself as an
18 organization, the way you respond to your
19 environment, the way you perceive your
20 environment.

21 I sometimes think that, if you look
22 at, say, the personal computer business and

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1 think about Dell versus Apple, you would think
2 of very different perspectives on how they
3 approach things.

4 Then there is also strategy as a
5 ploy. That is where you introduce the concept
6 of artifice or stratagem and the idea of
7 competition and faking people out, or
8 something like that. Of course, there is
9 another military reference there.

10 So just a few different ways of
11 thinking about what do we mean by strategy.

12 Then let's talk a little bit about
13 what we mean by strategic planning as a
14 process. Professor John Bryson at University
15 of Minnesota is also a person who has done a
16 lot of talking about strategic planning in
17 public organizations. So we will turn to him
18 for our particular definition.

19 That is, strategic planning is a
20 disciplined effort to produce fundamental
21 decisions and actions that shape and guide
22 what an organization is, what it does, and why

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1 it does it.

2 So here I think it is important to
3 look -- the emphasis is on decisions and on
4 actions. So to deliver the best results,
5 strategic planning requires broad, yet
6 effective, information-gathering, development,
7 and exploration of strategic alternatives, and
8 an emphasis on future implications of present
9 decisions.

10 I think some authors would also
11 introduce the concept of resource allocations,
12 since choosing among these alternative futures
13 really involves conscious choices, or
14 sometimes unconscious choices, about what you
15 are going to do and where you are going to
16 invest, and also where you're not going to
17 invest, and perhaps where you are going to
18 retrench.

19 So I mentioned it's a jungle out
20 there. In fact, Professor Mintzberg and his
21 colleagues have written a nice book that kind
22 of pulls together and does an analysis of the

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1 different ways of thinking about strategic
2 planning. They used a taxonomy that places
3 the literature into these 10 different
4 schools.

5 So we will briefly just cover some
6 of these, because I think it is interesting to
7 look at the different ways people have
8 approached and thought about strategic
9 planning and how it has evolved over time.

10 The design school is sort of the
11 classic approach that you have probably
12 encountered in your organizations or you have
13 heard people talk about. It is this process
14 of conception, but this is really the place
15 where you hear about the SWOT analysis, the
16 strengths and weaknesses of your organization,
17 the opportunities and threats of the business
18 environment or the marketplace, and how you
19 bring those things together, formulate a
20 strategy, and then execute on a plan.

21 Now the planning school is
22 something that you might consider as the

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1 design school on steroids with a very rigorous
2 workout regimen. It is the kind of thing that
3 happened in, say, the 1960s and 1970s in some
4 of the large corporations, where there was a
5 highly-formalized process, a lot of effort to
6 bring information of various types together, a
7 lot of analysis, large strategic planning
8 staff offices in headquarters of the
9 corporations. There has been a movement away
10 from that approach in the last 25 years or so.

11 Then, of course, there's the
12 positioning school, which relates back to that
13 analytical approach of where does our
14 particular set of products or services fit
15 within a particular marketplace. I think of
16 it as a market niche.

17 Now there's also an entrepreneurial
18 school that looks at strategic planning more
19 from the perspective of, say, the iconic
20 visionary leader. It is about a process of
21 coming up with that vision of the future and
22 figuring out how to get there.

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1 Of course, so far we have been
2 talking about some of the information that
3 feeds into the process. There is really only
4 one school here that tries to open up the
5 black box of the mind and look at the actual
6 thinking processes going into the formation of
7 strategy, and that is the cognitive school,
8 where you would be looking into the cognitive
9 psychology aspects of how people pull these
10 things together and actually come up with a
11 plan.

12 Now the next set of schools begin
13 to look at things a little differently. The
14 learning school is more of the pattern type of
15 approach, where we are looking at strategic
16 planning as an emergent process and thinking
17 that we don't control the environment. Just
18 as they say no battle plan ever survives
19 contact with the enemy, here you can think of
20 that as a strategic plan surviving contact
21 with the marketplace or competitors. So there
22 is an acknowledgment that you must have a

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1 learning approach and an adaptive approach.

2 Then the power school looks at
3 strategic planning in terms of the power
4 relationships, the political processes,
5 negotiation among the different actors.

6 The cultural school looks at it a
7 little bit differently in terms of
8 organizational culture and the collective
9 process, buy-in, participation of the people
10 and stakeholders potentially.

11 Then the environmental school is
12 really on the opposite end of the spectrum
13 from the design or planning, from the
14 standpoint that there's an acknowledgment that
15 the environment dominates, and really the
16 strategy emerges from reaction to the
17 marketplace and the environment.

18 Then the configuration school is
19 something that pulls together a lot of
20 different aspects of these other ways of
21 thinking about strategic planning, in that it
22 views strategic planning really as an

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1 organizational transformation process. It may
2 go through cycles and different times of
3 tumult, or whatever, but it's really viewed in
4 that more organization development type of
5 framework.

6 So, if you are interested in those
7 kinds of things, I have given a few references
8 to some good books here. This one, it's the
9 Strategy Safari. It's still available and in
10 print.

11 There's a more recent book that has
12 just within the last year or so come out
13 that's called Tracking Strategies. Professor
14 Mintzberg has looked at some of these same
15 ideas and talks about some of the case studies
16 and other research that he has done to put
17 some of these ideas to work.

18 So, if we could come up with a
19 strategic plan, it is no good if it sits on a
20 shelf. We want to look at how it's actually
21 being implemented. To do that, we need to
22 think about, how do we know that? What kind

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1 of measurement do we put in place? So that is
2 an important link in with strategic planning.

3 One area that I thought I would
4 highlight here is the work of Kaplan and
5 Norton regarding a balanced scorecard. A lot
6 of corporations have taken on this approach,
7 and government, in fact, has taken on this
8 approach in the last 15 years or so.

9 It's, I think, a very interesting
10 way of thinking about it. It's an
11 acknowledgment that, in fact, financial
12 metrics are not the only metrics that matter
13 to a corporation. Particularly if you are
14 looking at long-term health and growth, that
15 you need to look at things more from a
16 customer perspective, from the internal
17 processes that build value and capability over
18 time, and learning and growth not just within
19 the corporation, but within its environment.

20 So the thought here is that you
21 develop some very performance- and outcome-
22 oriented metrics along these different lines,

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1 so that you have a true balanced scorecard by
2 which you are grading the organization, how
3 well it is doing.

4 You try to develop these that apply
5 to a group more so than an individual. What
6 it does is, because it talks about outcomes or
7 results that you are trying to achieve and not
8 how to achieve to them, you kind of free up
9 the creativity and innovation of the workforce
10 to achieve the objectives that the
11 organization wants to achieve.

12 We have seen some of this in the
13 federal government, particularly through the
14 last Administration's President's Management
15 Agenda and some of the scorecard approaches
16 that we have had there.

17 Bringing this sort of into a
18 framework that is more common within the
19 federal government, I thought we would talk a
20 little bit about measurement along what you
21 might call a strategic value chain. The boxes
22 along the bottom of this diagram, which talk

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1 about inputs, activity, and outputs, and then
2 intermediate outcomes and ultimate outcomes,
3 really is sort of the elements of a logic
4 model that we often use when we are thinking
5 about, what are we really trying to achieve
6 and what is it going to take to achieve them?

7 Then, what kind of measures should we be
8 putting in place to gauge how well we are
9 accomplishing those?

10 So we can certainly measure inputs.

11 What are the resources that we are obtaining?

12 A lot of measurement goes on around
13 activities and what things are we doing,
14 counts of things like inspections or the kinds
15 of activities.

16 Then there's a lot of measurement
17 about outputs because those are the things
18 that we control. But if you go further to the
19 right, paradoxically, you talk about things
20 that are much more important to the public and
21 to the public servants who are working for you
22 and on your behalf. Yet, they are much more

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1 difficult to measure. In fact, they are much
2 more difficult to attribute to the actual
3 activities that are going on.

4 That's just a fact of life. It
5 doesn't mean we don't try to measure outcomes,
6 but we try to come up with strategies for
7 developing decent measurements that are
8 telling us how well we are doing that.

9 And while we do measure the
10 ultimate outcome, say, the incidence of food-
11 borne illnesses or the outcomes regarding
12 cardiovascular disease, we know that there are
13 many different contributing factors to those
14 outcomes. So what we try to do is identify
15 some intermediate outcomes where we can
16 establish a stronger causal link or influence
17 from what we are doing, and then kind of the
18 stepping stone to the ultimate outcome.
19 Because that gives us a little bit better
20 gauge about whether or not our program
21 activities are actually having their intended
22 effect.

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1 We are also going to see, I think,
2 a lot of emphasis, a lot more emphasis on
3 transparency and accountability in this new
4 Administration. So I think, in addition to
5 efficiency measures that really are just
6 looking at the relationship between the
7 outputs that you produce versus the inputs
8 that you have, I think we are going to look at
9 like getting back to trying to measure
10 productivity, which is really trying to get at
11 the measure of the actual outcomes that we're
12 producing versus the inputs. That is a
13 challenge, but it is a kind of challenge that
14 we should be taking on.

15 So I'm not expecting you to see or
16 read this complicated diagram here from
17 Professor Bryson's book, but I did want to
18 just point out that strategic planning can be
19 a fairly elaborate process, particularly in
20 complex organizations like the federal
21 government.

22 Basically, what this is talking

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1 about -- this is a wonderful little tune that
2 we have going here, isn't it?

3 (Laughter.)

4 But what we have is on the lefthand
5 side of this diagram, you essentially have the
6 components of a SWOT analysis, if you will,
7 looking at the strengths and weaknesses of the
8 organization, and what kinds of information do
9 you want to gather and pull together to
10 evaluate that; and what kinds of opportunities
11 and threats you are trying to address, and
12 what kind of stakeholder input and buy-in
13 within your own organization, in order to
14 identify strategic issues. So that is sort of
15 the complicated lefthand part of this diagram.

16 In the very center, we have
17 strategy formulation in one box, and then sort
18 of on the righthand side you have the planning
19 for the execution of that strategy.

20 So I guess many of you have seen
21 this cartoon before. I think it characterizes
22 the strategy formulation step. It is where

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1 two men are at the blackboard, lots of
2 complicated equations, and in the middle it
3 says, "Then a miracle happens," and one says
4 to the other, "I think you should be more
5 explicit here in step two." I think that
6 describes often that strategy formulation step
7 in strategic planning.

8 Yet, it is something that good
9 leaders do naturally and strong organizations
10 have developed the capability to do. It is
11 studied a lot. It is certainly not an
12 engineering or a scientific discipline so much
13 as it is an art.

14 There's another model for looking
15 at this that I think also helps with that
16 strategy formulation. For anyone who has had
17 the good fortune to take any of the executive
18 education courses up at the Kennedy School of
19 Government at Harvard, you probably will have
20 encountered this particular model.

21 I think it is a very astute model
22 of thinking about strategy formulation in

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1 public organizations, in the public sector.
2 Because when you think about it, what's
3 different -- there are many similarities
4 between strategy formulations, but what is
5 different is you don't have that profit motive
6 or the fiduciary responsibility to increase
7 shareholder value. It is a little bit
8 different.

9 So here what Mark Moore has
10 formulated is a very robust framework for
11 thinking about this, where instead of profit,
12 you have a public value proposition, in
13 essence. So, of course, in the case of FDA,
14 most broadly stated, it is science-based
15 protection and promotion of public health.

16 Then, of course, you can translate
17 that into more specific terms in each one of
18 the regulatory programs, whether it is drug
19 safety, more therapies, or whether it is food
20 safety, things of that nature.

21 Of course, in order to deliver that
22 public value, you have to have some operating

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1 capacity, some operational capacity. That can
2 be expressed in terms of the structure of how
3 you organize yourselves, what kinds of
4 resources, both human resources as well as
5 infrastructure and equipment.

6 Then you have systems. You have
7 the information that you can collect, that you
8 can process. You have the standard operating
9 procedures that you have, and all those things
10 combined.

11 Of course, in our connected world,
12 an organization has never been completely
13 independent, but today it seems the
14 connections outside the organization just are
15 getting more strong and complex.

16 In the case of the federal
17 government, a lot of the things that we do are
18 done through contractors. So you have to
19 consider that when you are thinking about your
20 operational capacity.

21 Then we also, of course, have
22 consultants who advise us on how we should do

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1 it. We might consider advisory committees
2 somewhat like that.

3 But we also have some other
4 partners, whether it be other government
5 agencies or non-profits, other organizations.

6 In fact, when you think about it, labor
7 unions certainly help structure the
8 interactions and procedures, and state and
9 local governments, in fact, are a special type
10 of partner for the FDA. We do a lot of food
11 inspections through contract with many of the
12 states.

13 But then you also see this other
14 bubble on the righthand side. That is very
15 important because we get our resources not by
16 going out and finding venture capital or
17 selling shares of stock. We get it through
18 appropriations. We also get it through user
19 fees, but those user fees have to be
20 authorized by Congress and appropriated as
21 well. So the authorizing environment is
22 critically important to allowing and

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1 supporting our operational capacity.

2 Also, of course, courts determine
3 whether our authorities are legal. The
4 Administration, the Executive Branch has the
5 sort of command-and-control responsibility
6 around how we do our job. So that is
7 critically important, and if they don't see
8 the public value in what we are doing, then we
9 may not see the resources flow and that sort
10 of thing.

11 Then, of course, what you have on
12 the righthand side is a stakeholder analysis
13 of who is influencing that authorizing
14 environment. It is a very diverse set of
15 people. We have the press. We have academia,
16 patients, and consumers, regulated industry,
17 healthcare providers and payers, in addition
18 to the labor unions and the state and local
19 governments that I mentioned before.

20 So you can take any particular
21 issue that you are wrestling with, and you can
22 kind of overlay this particular way of looking

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1 at things. It can be, I think, very helpful
2 in trying to understand what the key strategic
3 issues are and how to formulate strategy
4 within the government.

5 So that's kind of some general
6 theory. I appreciate your indulgence there.

7 What we will talk about now is some
8 more specific requirements within the federal
9 government. It has been some time now since
10 the Government Performance and Results Act of
11 1993, but that is still a very important law
12 on the books.

13 It was put in place during the
14 Clinton Administration. The Bush
15 Administration embraced it as well. They put
16 their spin on it with the President's
17 Management Agenda. We expect to see more of
18 the same going through with the Obama
19 Administration.

20 It is not something just here in
21 the United States. It is a trend throughout
22 the world and throughout the United States in

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1 state governments and others, to take a very
2 performance-oriented view of how our tax
3 dollars are being spent and how government
4 services are being provided.

5 So what this does require in terms
6 of strategic planning, it requires all
7 essentially Cabinet-level departments and
8 independent agencies to develop a strategic
9 plan. There are some elements that are laid
10 out that describe what it needs to address.

11 The planning horizon that must be
12 addressed is six years, basically the current
13 year and then five years out. These plans
14 have to be refreshed every three years.

15 Now FDA is not required to have a
16 strategic plan under what we affectionately
17 call GPRA because we are part of Health and
18 Human Services. Health and Human Services is
19 really the Cabinet-level agency that is
20 required to have this.

21 Yet, all of the operating divisions
22 of HHS have strategic planning as part of

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1 their management, and they may or may not have
2 formal strategic plans. We will talk a little
3 bit about FDA's strategic action plan that we
4 have.

5 The other aspect that the
6 Government Performance and Results Act
7 requires is annual performance plans and
8 reports on how we did the previous year on
9 particular goals and objectives and targets.

10 During the Bush Administration,
11 that performance plan and report was
12 integrated with the annual budget submission
13 to Congress. So what you have is an
14 integrated performance budget. Typically, a
15 lot of the details are put into an appendix of
16 that, but there is an attempt for most
17 agencies to actually integrate the information
18 and try to tie resources to the performance.

19 You can see that on FDA's website.

20 We have our performance budget up there, like
21 all of the agencies do.

22 In terms of how this is actually

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1 implemented throughout the federal government,
2 the Office of Management and Budget has a
3 Circular A-11 that sets forth all these
4 requirements. Of course, you can read these,
5 if you were so inclined. They are available
6 on the public OMB website.

7 Another thing that the Bush
8 Administration introduced was the Program
9 Assessment Rating Tool, or PART. What this is
10 is basically it is a government-wide program
11 evaluation tool. They went around to all the
12 different departments and the key operating
13 divisions of those departments, and they went
14 through a program assessment. Strategic
15 planning was one of the key areas that was
16 assessed.

17 They took a kind of scorecard
18 approach. There are results that you can see.

19 There's a website called expectmore.gov that
20 has all of that information for all of the
21 departments.

22 This is some of the kind of general

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1 guidelines that we have to follow.

2 So the question is, how do we do it
3 here at FDA? Well, first of all, it is
4 important to think about how do we relate to
5 the Department of Health and Human Services,
6 because they're the sort of parent
7 organization.

8 We do try to align our strategic
9 planning with the Department. The last time
10 the HHS strategic plan was updated was in
11 2006. So we are due for another update. Of
12 course, we just have a Secretary as of Tuesday
13 evening, and Secretary Sebelius is now on the
14 job and helping deal with the 2009 H1N1 virus.

15 It is not the swine flu. It is the 2009 H1N1
16 flu virus.

17 So we can, hopefully, see a path
18 forward, and we are very hopeful that we will
19 see a confirmation hearing very soon for Dr.
20 Peggy Hamburg, who is the Administration's
21 choice for the next Commissioner.

22 So the Department has laid out a

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1 strategic plan with four goals. Really, FDA
2 aligns with three of them. Healthcare,
3 improving the safety, quality, affordability,
4 and accessibility of healthcare, including
5 behavioral healthcare and long-term care.

6 Then public health promotion and
7 protection, disease prevention, and emergency
8 preparedness. Preventing and controlling
9 disease, injury, illness, and disability
10 across the lifespan. And protect the public
11 from infectious, occupational, environmental,
12 and terrorist threats.

13 Now the human services goal:
14 promote the economic and social well-being of
15 individuals, families, and communities. We
16 have a more indirect effect there. So we
17 don't typically try to align with that goal.

18 Then the fourth is scientific
19 research and development. Advance scientific
20 and biomedical research and development
21 related to health and human services.
22 Certainly, a lot of the clinical trial work

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1 that we oversee, as well as some more
2 regulatory-focused applied research and
3 development that we undertake applies there.

4 So, talking a little bit more about
5 the process of strategic planning at FDA, as
6 you can imagine, every Commissioner has a
7 different perspective on this. So the process
8 is going to be a little bit different with
9 each Commissioner.

10 Of course, FDA, unfortunately, has
11 had a history of a lot of turnover in that
12 position over the last several years, but we
13 did have a period there where Dr. von
14 Eschenbach was in place for a couple of years,
15 a little more, and Dr. von Eschenbach did
16 engage in the strategic planning that resulted
17 in the current Strategic Action Plan that we
18 have currently. The previous long-term
19 Commissioner, Dr. McClellan, also had a
20 Strategic Action Plan in place.

21 So we have a number of different
22 forums in which we engage the senior

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1 leadership of the agency in there. There's a
2 senior leadership team that's primarily
3 composed of the Deputy Commissioner level and
4 sort of senior staff within the Office of the
5 Commissioner that sets the policy from sort of
6 the more political leadership perspective.

7 But there's also the Management
8 Council that engages the Center Directors as
9 well as other administrators. That is a very
10 robust forum for talking about the direction
11 of the agency.

12 There's sort of a smaller working
13 group that reports into the Management Council
14 that we call the Strategic Planning Council.
15 That really focuses more directly on the
16 development of strategy and also how strategy
17 relates to the annual budgeting process.

18 There's also a planning group
19 called the Bioinformatics Board that looks at
20 the information management needs of the
21 agency. It is composed not only of the
22 technical information technology folks, but

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1 also of key business process owners, folks who
2 are intimately familiar with the way that we
3 do our regulatory and public health business,
4 and they participate in helping shape how we
5 are going to plan the sort of information
6 architecture of the 21st century for the
7 agency, and moving from many paper-based
8 operations to fully electronic standards-based
9 and modern computing capabilities.

10 There's also a lot of strategic
11 planning that happens within the operating
12 business units of the agency, the centers,
13 where the real regulatory and public health
14 work on the ground is done. So each one of
15 the product centers has a senior management
16 team. Some of them have actual planning
17 operations within their center that engage
18 with the rest of their leadership.

19 Pretty much all of the product
20 centers also have various forums in which they
21 engage with the stakeholder community, whether
22 they are the public consumer or patient groups

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1 or whether they are the regulated industry
2 groups. They have some way of having dialog
3 with them.

4 If you look at the actual Strategic
5 Action Plan that we have on our website, you
6 will see that its framework is constructed of
7 four high-level strategic goals. I will tell
8 you, the way that those are structured is
9 significant from the standpoint that three of
10 the goals actually address sort of the core
11 mission responsibilities of our agency that
12 cut across all the different product centers.

13 So it is really looking at the
14 agency more as a functional perspective and
15 looking at the pre-market review
16 responsibilities we have, looking at sort of
17 the oversight of the supply chain, of
18 production and manufacturing of products and
19 its distribution, and then looking at the
20 post-market surveillance, safety surveillance,
21 and information products that we produce. You
22 can see there's a little bit of a life cycle

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1 there.

2 Then, of course, there's a fourth
3 goal that deals with the overall
4 infrastructure and human resource aspects of
5 the agency, and those supporting and enabling
6 capabilities.

7 Those categories came out of a very
8 detailed study that we did across the agency
9 looking at our business processes a number of
10 years ago. So it is built on a lot of
11 detailed work and information-gathering.

12 In terms of how we measure our
13 progress, the actual Strategic Action Plan is
14 a very high-level document. It contains a
15 number of action items that are sort of
16 projects, more milestone type of things that
17 we put in there that weren't a very long-term
18 timeframe. They are typically within the next
19 18 months of the time it was published.

20 So, if you want to look at more of
21 the day-to-day operational things that we're
22 doing, you have to sort of turn to the annual

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1 performance budget and look at the performance
2 plan. Those annual performance goals do align
3 with these strategic goals and the strategic
4 objectives.

5 But what we are doing, as we move
6 toward our next round of strategic planning,
7 is we are trying to develop some better
8 outcome measures that are associated with the
9 strategic objectives. So we will see how far
10 we get with this next round of planning and
11 how much of those will be public, but that is
12 a long-term effort that the agency is doing.

13 I can tell you, with the incoming
14 Administration and leadership of the agency,
15 particularly Dr. Joshua Sharfstein, who is
16 already at the agency as our Principal Deputy
17 Commissioner and Acting Commissioner, and Dr.
18 Hamburg, who we hope will be coming to the
19 agency soon, they both have a public health
20 background, both having served as public
21 health officers in major cities. So this idea
22 of public health outcomes I believe will be an

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1 important emphasis for the agency.

2 So here, in a graphical format, you
3 see the actual structure of the FDA Strategic
4 Action Plan. You can see the four goals sort
5 of on the lefthand side.

6 Strategic Goal One is strengthen
7 FDA for today and tomorrow. You are going to
8 see there are four objectives under that.

9 There's Strategic Goal Two:
10 improve patient safety and consumer safety.

11 Strategic Goal Three is increase
12 access to new medical and food products.

13 And Strategic Goal Four is improve
14 the quality and safety of manufactured
15 products in the supply chain.

16 And if you were to look at each one
17 of these objectives -- I won't read through
18 all of them -- but the objectives really get
19 at particular facets of those core mission
20 requirements.

21 We have, in fact, down at the next
22 level of detail in this hierarchy, we have

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1 strategies that aren't stated explicitly in
2 this plan, but in terms of the internal
3 management structure that we have, we have
4 more details below that.

5 So it's at these objective levels
6 that we are going to be, and have been,
7 developing outcome-oriented, long-term
8 measures to chart our progress toward these
9 particular goals.

10 Of course, when we get to the next
11 round of strategic planning, some of this may
12 change. Every new leadership team, of course,
13 needs to have the opportunity to make their
14 own assessment and decide where they want to
15 take the agency.

16 I suspect that, no matter where we
17 end up, we will be able to relate the new
18 strategic plan back to some of these areas
19 because these are fundamental to our core
20 mission.

21 So now, at long last, let us talk a
22 little bit more about how we got to the actual

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1 strategic plan for risk communication that is
2 in draft form that we will talking about the
3 rest of the day.

4 So a little bit of history: it was
5 really the Institute of Medicine's "Future of
6 Drug Safety Report" that crystallized some of
7 the thinking, or maybe provided some of the
8 impetus that we were talking about before, to
9 raise the issue of risk communication. They
10 had evaluated some of the experience that FDA
11 had, particularly around Vioxx and some other
12 drug safety issues, and recommended that we
13 really elevate risk communication to this more
14 strategic function.

15 We responded by saying, well, let's
16 develop this Risk Communication Advisory
17 Committee as a result. Now, of course,
18 Congress helped us along with a little bit of
19 a push. The FDA Amendments Act of 2007, a
20 major, major piece of legislation that not
21 only reauthorized some user fee programs, but
22 also made many other changes in directing the

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1 agency, actually required the establishment of
2 this Committee and made a few things easier
3 for us in the process. But we were already
4 well on track.

5 Then, of course, this was mentioned
6 before, the Committee itself made some
7 recommendations last summer. Here one of them
8 was to actually establish a Risk Communication
9 Strategic Plan, do some strategic planning.

10 We did get some additional
11 resources through a 2008 budget supplemental
12 that we were allowed to spend through fiscal
13 year 2009. Some of that money went toward
14 risk communication activities. One of the
15 commitments that we made as part of that was
16 to develop a strategic plan to improve risk
17 communication. So that is sort of how we got
18 to where we are at this point.

19 In terms of how did we come up with
20 the draft, well, as good public servants, we
21 formulated a cross-agency working group --
22 within the agency, I should say. We pulled

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1 together experts from around the different
2 centers and offices and within the Office of
3 the Commissioner to come up with an outline,
4 vetted the outline, developed the actual draft
5 that you see.

6 We had a number of forums where we
7 brought this plan to. There was the Strategic
8 Planning Council that I mentioned before.
9 There's a Communication Council that has been
10 formed sort of in parallel with the Advisory
11 Committee that helps pull together folks from
12 around the agency and all the centers to talk
13 through a number of different communications
14 issues. They were very instrumental in
15 staffing and helping develop and vet the draft
16 that you see.

17 We also brought this to the Food
18 Management Council. So the top levels of the
19 agency have had an opportunity to look at the
20 draft and weigh-in.

21 Then, of course, where we are now
22 is we are undertaking this review by the

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1 Advisory Committee. As we have been so far,
2 we will continue going forward to integrate
3 this planning effort with the agency-wide
4 strategic planning effort.

5 I think the next round of strategic
6 planning will await until we get the new
7 Commissioner in place, but we expect that,
8 once the Commissioner gets here, that that
9 will be on the agenda.

10 The actual goals that we will be
11 talking about in much more detail are broken
12 down into three areas: strengthening the
13 science that supports effective risk
14 communication, expanding FDA's capacity to
15 generate and disseminate and oversee effective
16 risk communication, and optimize FDA's
17 policies on communicating product risks and
18 benefits.

19 So where do we go from here?
20 Certainly, we want to hear feedback and
21 suggestions on the plan at the current
22 Advisory Committee meeting.

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1 We also have the Draft Research
2 Agenda that we are looking for feedback on.
3 It is very important to us. So that will
4 inform our revisions for -- we call it a Final
5 Plan, final from the standpoint of delivering
6 something to Congress by the end of the fiscal
7 year. So that would be the end of September
8 of 2009.

9 But, as we view strategic planning
10 as a process, we can think of it as just a
11 particular milestone that we will continually
12 revisit over time and integrate it in with the
13 strategic plan more generally at the agency.

14 Of course, what we need to do in
15 terms of executing, we will have to establish
16 some vehicles for strengthening the science.
17 We will definitely be working with FDA centers
18 and offices as part of the overall strategic
19 planning process to develop these outcome
20 measures and specific action steps. If you
21 have looked at the document, you see that it
22 is still fairly high-level in trying to set

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1 the framework and the more detailed planning
2 about commitments. I mean we have some ideas
3 in each one of these areas, some of which we
4 will talk about, but those haven't been
5 committed to explicitly on paper at this time.

6 I believe that is all we have on
7 this presentation. So thank you very much for
8 your attention. I am happy to engage in any
9 dialog, questions and answers.

10 CHAIRMAN FISCHHOFF: Thank you
11 very much.

12 From the panel?

13 Could you go back three or four
14 slides where you have the FDA's mission and
15 vision? Yes, that's the right one.

16 So where do you see this fitting
17 into that?

18 MR. BERTONI: A good question, and
19 I probably should have highlighted that.

20 In Strategic Goal Two, improve
21 patient and consumer safety, first of all, let
22 me say at one level it cuts across all of

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1 these objectives. It comes out a little bit
2 more explicitly in a couple of areas.

3 One of them would be in Objective
4 2.4, "Provide consumers with clear and timely
5 information to protect them from food-borne
6 illness and promote better nutrition," and
7 2.3, "Provide patients and consumers with
8 better access to clear and timely risk/benefit
9 information for medical products."

10 So here you see very explicitly
11 this part of our mission that involves
12 empowering patients and consumers with better
13 information to make better choices, and here
14 it has just been split up between the medical
15 products and the food area.

16 But, if you think about other areas
17 here, Strategic Goal Three, where we're really
18 talking about the pre-market functions, and
19 where so much of our regulatory authority is
20 really around the labeling and making sure
21 that the information is accurate, that is
22 critically important.

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1 Then, of course, in Strategic Goal
2 Four, where we are talking about oversight of
3 the supply chain and the inspection process,
4 but also, you know, recalls, things of that
5 nature, where the communications are
6 absolutely critical in making sure that people
7 know what to do with their bag of pistachios,
8 or what have you, which is interesting
9 because, in one case here, we were talking
10 about for pistachios, as an example, a lot of
11 activity and discussion around, well, do I
12 need to throw them all out or do I need to
13 just hold onto them and wait to determine
14 whether or not that particular bag is likely
15 to be contaminated or not? Some very
16 challenging and complicated messages can be
17 part of the equation.

18 CHAIRMAN FISCHHOFF: Let me just
19 try one hypothesis. One thing that has been
20 on my mind is viewing the communications as
21 part of the product. So, as I mentioned
22 earlier, if you think about pharmaceuticals,

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1 the communication package is different during
2 the trial than it is during actual use. It is
3 easy to imagine getting more risk because
4 people don't know what to look for, but also
5 getting less benefit because people don't know
6 how to monitor, to assess the value that they
7 are getting from a product.

8 So, if one could think of how to
9 improve that, the communications associated
10 with the product, then you would
11 improve -- you know, that might be a Strategic
12 Goal Three, if we knew how to articulate that.

13 MR. BERTONI: Yes, and I will say
14 that there's a couple of areas, risk
15 communication is one, information technology
16 is another, sort of preparedness -- are three
17 areas that we have identified over the last
18 couple of years where we need to make sure
19 that they cut across all of the goals.

20 Risk communication definitely is
21 one area, particularly now that we have a
22 strategic plan, we have a Communications

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1 Council, we have a focal point, we have the
2 Advisory Committee. We're planning to make
3 sure that that is an important aspect of
4 delivering, doing the planning for the next
5 agencywide plan.

6 CHAIRMAN FISCHHOFF: I mean I like
7 the cross-cut because you don't know what
8 questions to ask. You sense that the
9 communication is --

10 MR. BERTONI: Yes.

11 CHAIRMAN FISCHHOFF: But if you
12 don't have somebody to articulate it for you,
13 then it's a --

14 MR. BERTONI: Yes, and it could
15 show up as a strategy under each one of these
16 objectives that has something around risk
17 communication aspects of what we are doing.

18 CHAIRMAN FISCHHOFF: Yes, thank
19 you.

20 So Ellen and then Michael.

21 MEMBER PETERS: I was curious to
22 hear your thoughts on how it fits into the

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1 Strategic Goal One here in terms of the
2 infrastructure.

3 So we have heard that you guys have
4 -- and I apologize. Can everybody hear me
5 okay? Is there rattling? Okay, I can hear a
6 little feedback here.

7 But one of the things that you guys
8 have done, which I think is a great idea, is
9 you have developed this internal FDA panel to
10 start to work with some of your employees and
11 test some of these risk communications.

12 But there are other things that
13 could be done from an infrastructure
14 standpoint. I am curious what your thoughts
15 are about where you see the infrastructure
16 heading in terms of data collection, for
17 developing messages and testing messages.

18 There's this internal panel. There
19 perhaps could be other internal ways for the
20 FDA to collect data and start to build the
21 sort of collection of messages that Baruch
22 talked about that could be developed, for

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1 example, for one outbreak, and then can be
2 used later strategically for some other type
3 of outbreak, like the current flu.

4 MR. BERTONI: Yes.

5 MEMBER PETERS: And there are some
6 models for that in some of the other federal
7 agencies, like the National Cancer Institute.

8 It could be that you want to be
9 working outside, doing contracts with other
10 people outside the FDA.

11 It could be that you think that
12 this should be happening at the pharmaceutical
13 company level.

14 I'm curious what your thoughts are
15 around this strategically.

16 MR. BERTONI: Excellent points. We
17 are going to have an opportunity to talk about
18 that in a lot more detail because one of the
19 goals for the Risk Communication Strategic
20 Plan is to improve our capacity and in aspects
21 of research as well.

22 But you've correctly pointed out

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1 that we also need to make sure we are
2 addressing it in Goal No. 1. It is really
3 talking about strengthening the FDA.

4 There is one explicit objective
5 there about enhancing partnerships in
6 communications, Objective 1.3. So a lot of
7 the things that you talked about could be
8 incorporated there.

9 You think of strengthening FDA's
10 base of operations talks about a lot of the
11 systems and things. I mean look at Web 2.0
12 and social media. There's all kinds of things
13 that we could be thinking about there. That
14 is going to also have some physical
15 infrastructure implications for the agency.
16 We are in the process of trying to improve our
17 information technology infrastructure, so that
18 we could handle that kind of thing.

19 When it comes to just the people
20 that we are hiring and the training that we
21 are doing, all those kinds of things are
22 absolutely essential.

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1 But you put your finger on a really
2 important one about partnerships, about
3 engaging with others. That we will have, I
4 think, an opportunity to talk about in a lot
5 more detail as we get into the details of the
6 Risk Communication Plan today.

7 Our expectation would be that we
8 would find ways of incorporating these good
9 ideas, and more that we will hear from you,
10 into the overall agency plan and try to
11 interweave those throughout.

12 CHAIRMAN FISCHHOFF: Thank you
13 very much.

14 Yes?

15 MEMBER GREENBERG: Hi. I'm Sally
16 Greenberg. I'm Director of the National
17 Consumers League.

18 CHAIRMAN FISCHHOFF: And, Mona, I
19 didn't see you come in.

20 MEMBER KHANNA: Dr. Mona Khanna.
21 I'm a physician, board-certified in public
22 health, internal medicine, and occupational

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1 medicine. Also, a lieutenant colonel with the
2 Texas State Guard and full-time medical
3 journalist.

4 MEMBER GOLDSTEIN: So thank you
5 very much for the overview of the strategic
6 planning process and where you have come so
7 far, and how we can help.

8 I think my mantra over the next
9 couple of days is going to be also aligned
10 with what Dr. Peters said about partnerships
11 and collaboration.

12 As you outlined the process and
13 talked about the strategic planning process
14 for FDA, and alignment with HHS goals, I'm
15 just wondering, to what degree the process
16 itself could be collaborative? So, to what
17 degree can FDA involve members or
18 representatives of these from some of the
19 other key agencies like NIH, like CDC, like
20 AHRQ, who have similar alignment with these
21 same goals, to help in the process of
22 strategic planning, not just once you've done

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1 yours and once they've done theirs, to find a
2 way to make it work?

3 MR. BERTONI: Yes, excellent
4 question. Thank you.

5 I'm hesitant to make too definitive
6 a remark before the Commissioner gets here and
7 not knowing, hopefully, what her approach will
8 be, but I would be very surprised if it wasn't
9 along the lines that you did describe.

10 That is, try to gather input and
11 feedback from a broad array of stakeholders.
12 Within the federal government, certainly we
13 have many other public health agencies, both
14 within the Department of Health and Human
15 Services and other agencies.

16 I mean I'm involved right now in
17 some work with not only CDC, but also the Food
18 Safety Inspectorate at the USDA, who has
19 responsibilities for meat and poultry and egg
20 products. We are looking at measures for
21 long-term health in food safety.

22 So there's a lot of collaboration

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1 that does go on. I absolutely agree that it
2 is necessary to incorporate that into this
3 strategy formulation process.

4 Exactly what that will look like, I
5 don't know yet. Then not just with other
6 federal agencies -- certainly, gathering input
7 from stakeholders. You know, the FDA
8 Modernization Act of the mid-nineties told the
9 agency we need to engage with our stakeholders
10 in a number of areas. I think you will see a
11 more concerted effort in this round to engage
12 directly in those.

13 CHAIRMAN FISCHHOFF: Yes,
14 AnnaMaria, please.

15 MEMBER DeSALVA: Good morning.

16 It is definitely exciting to see
17 the plan and see how far everything has come
18 since we started working together.

19 I just have a basic question about
20 how you all identified these particular
21 strategic goals. A related question would be,
22 if the plans started with a behavioral

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1 outcome, if you were, for instance, to frame
2 this entire plan around the concept that risk
3 communication from the agency should
4 ultimately mitigate risk, and actually drive
5 risk behaviors that mitigate risk by a range
6 of different stakeholders under a range of
7 different circumstances, do you think that
8 would have any material impact on the
9 strategies and tactics in the plan?

10 MR. BERTONI: Taking the last one
11 first, yes, I think having that more outcome-
12 oriented focus does influence how you think
13 about what you do within your program. Many
14 of us are really trying to drive the agency
15 toward that approach.

16 I happen to sort of ascribe to the
17 configuration school, that we need to look at
18 a strategic plan as a process of organization
19 transformation. Because if it is just a plan
20 with some metrics that are hoops that the
21 operating groups have to jump through, "Aw,
22 that's the GPRA stuff," we're not taking full

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1 advantage and really integrating all that we
2 do as management.

3 So it is a 100-year-old agency. We
4 have a lot of ways of thinking that are fairly
5 ingrained. We have to learn and grow and
6 change.

7 This idea of thinking about
8 outcomes and thinking about partnerships is
9 not necessarily the place where everyone
10 started from. So it is a matter of trying to
11 figure out, how do you do that when your
12 mission is not only public health, but also
13 regulation, and we have regulatory authority.

14 So there is, to some degree, these
15 different mindsets that come together in an
16 agency like FDA. But, having said that, I see
17 some progress and I see new ways of thinking
18 about it. So we are engaged in a number of
19 different activities across the agency right
20 now to try to engage people in thinking about
21 outcomes. So I do see that having an impact
22 on how we approach that.

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1 I'm not sure if I hit the first
2 part of your question, though.

3 MEMBER DeSALVA: The first part
4 was, why did you start here --

5 MR. BERTONI: Yes.

6 MEMBER DeSALVA: -- or why did you
7 define these goals?

8 MR. BERTONI: There was a lot of
9 analysis that went in. Of course, you never
10 start with a completely clean sheet of paper.

11 One thing that influenced how we
12 approached this was that Program Assessment
13 Rating Tool that the Office of Management and
14 Budget was doing across the agency that
15 occurred in, I guess it was the 2002-2003
16 timeframe.

17 The first time they did the
18 evaluation of FDA, they kind of dinged us for
19 not being able to demonstrate that we were
20 achieving certain objectives, and they noted
21 that we really didn't have long-term outcome
22 goals. So there was a lot of work that went

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1 into figuring out what those long-term
2 outcomes should look like.

3 It was around that time that we
4 were also doing this business process analysis
5 of the agency, to try to look at the
6 commonalities about what we do, rather than
7 the differences within each one of the product
8 centers.

9 So these two different streams of
10 thinking, the outcome-oriented review to
11 develop these long-term outcome goals in
12 response to this program evaluation that was
13 happening government-wide, as well as this
14 sort of analysis of the commonalities in the
15 business processes, sort of came together in
16 this framework.

17 The objectives sort of lay out
18 along the core responsibilities as the leaders
19 and managers of the agency viewed them.

20 But I will say that it was an
21 internal view. It was largely an exercise
22 that we were undertaking within the agency.

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1 A lot of this work had already
2 taken place when I joined the agency in the
3 summer of 2004. But, as we kind of took it
4 into developing the plan, I was around and
5 involved in many of those discussions.

6 I will say that the engagement with
7 the public and with the partners happened in
8 lots of other forms. It didn't happen
9 directly as a part of this strategic plan.
10 But I don't want to give the impression that
11 we shut out the outside world because the
12 agency does engage in a number of different
13 forums with the regulated industry, patients,
14 consumer groups, other agencies, and various
15 task forces. So, from that standpoint, those
16 experiences informed the discussion
17 specifically around the strategic plan.

18 MEMBER DeSALVA: Thank you.

19 MEMBER DeLaROSA: One comment that
20 I have is that, like everything in big
21 government, FDA has gotten bigger and bigger,
22 and there's so many more things over this

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1 timeframe, that it is something to consider if
2 FDA needs to be broken up into pieces, into
3 FDA regulatory, FDA in promotion, et cetera.

4 From this side, I see progress, but
5 from the consumer side, from the regulatory,
6 waiting for product to get to devices, et
7 cetera, to get to market, it is longer and it
8 is taking a long time. Have we gotten too big
9 in the FDA? Just something to consider.
10 Should it be the new mission, the new vision,
11 that we do need to break up FDA into different
12 pieces?

13 MR. BERTONI: Okay. I guess I
14 should comment on the comment that there are
15 different viewpoints on that, of course. I
16 think a lot of people at the agency look at
17 some of the downsides of fracturing what we
18 do. I know there is a lot of talk about a
19 single federal food agency. I guess we see a
20 lot of the connections between food and
21 nutrition and medical, science, and health.

22 So we tend to want to take a good

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1 crack at properly resourcing these functions
2 and looking at other management issues rather
3 than necessarily reorganizing things. Because
4 a good root cause analysis may not point us in
5 the direction of splitting things up; it may
6 be just fixing some other areas.

7 I guess, also, perception and data
8 are sometimes not always in agreement in terms
9 of the time it takes to get things through the
10 system. I know, with the user fee programs in
11 medical products, whether it is devices or
12 drugs, the trend has been toward improving
13 those processes and shortening the times,
14 which is not to say that we don't have some
15 issues, particularly in the generic drugs
16 area, where we have an incredible increase in
17 the number of applications. We have really
18 struggled to keep up with that, but we have
19 made a lot of process improvements. I'm not
20 as familiar with some of the medical device
21 numbers, but the numbers are out there.

22 We have performance reports on the

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1 web regarding medical devices as well as
2 animal drugs and human drugs and biologics.
3 Certainly, the folks in those programs can
4 address it.

5 But I think the general point is
6 well taken that we have to be careful about
7 how we manage those different functions. That
8 is the kind of thing, I think, that the
9 incoming Administration is going to have a
10 fresh look at. They are very concerned about
11 it.

12 So I appreciate the feedback.

13 MEMBER MAYER: I have almost an
14 opposite point to make. That is, that having
15 lived through an era where there was a lot of
16 attention given, and resources given through
17 PDUFA to hastening drug approval, and devoting
18 energies there, and not a commensurate
19 attention paid to looking at issues of drug
20 safety, I know how important it is to have a
21 unified vision.

22 That's what I really like in what I

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1 am hearing today, is this idea, this real
2 focus in all of FDA's missions being
3 addressed, and addressed carefully and
4 specifically in this way. So I thank you for
5 that.

6 MR. BERTONI: Thank you.

7 MEMBER GOLDSTEIN: While we're
8 being broad and visionary this morning, and I
9 think it is great to start that way, I have to
10 ask about the degree to which FDA has been
11 included in any of the discussions so far
12 about the broader healthcare reform plans.

13 Getting back to the collaboration
14 and partnership, and the importance of FDA
15 within the whole context of a healthcare
16 system, to what degree is FDA at the table and
17 sharing perspectives on issues of risk and
18 regulation, as well as dissemination, which is
19 a key function in the strategic plan?

20 So if you could shed some light on
21 that, that would be useful.

22 MR. BERTONI: Sure. I will share

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1 what I can, what I know. I believe we are at
2 the table. I think we are a key member of
3 Health and Human Services.

4 Anybody who, for example, happened
5 to catch Secretary Sebelius' press conference
6 yesterday about the H1N1 flu might have
7 noticed that Dr. Sharfstein was behind her,
8 just as the Acting Director of CDC and others
9 were.

10 I know the American Recovery and
11 Reinvestment Act, the stimulus bill that was
12 passed, contained a major provision on health
13 IT. That was viewed partly as stimulus, but
14 partly as laying the groundwork for healthcare
15 reform.

16 FDA is most definitely at the table
17 on various work groups there. We didn't
18 directly get any money out of that particular
19 bill, but there are a number of pools of money
20 where we are discussing with the Department,
21 with the other agencies, particularly around
22 comparative effectiveness and prevention,

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1 nutrition, and on health IT specifically when
2 it comes to how our information is going to be
3 relevant, and how we are going to use some of
4 the information from electronic health
5 records, and all that. We've got a number of
6 initiatives that are very much in the mix.

7 CHAIRMAN FISCHHOFF: Sokoya?

8 MEMBER FINCH: As we talk about
9 being broad, I'm just curious to know if there
10 are goals within -- I'm looking at Strategic
11 Goal Two, if you're looking at -- well, let me
12 back up a second.

13 As we look at our country and we
14 see that the minority group is becoming the
15 majority, how diverse are you with information
16 coming out in a way where it is culturally-
17 relevant as well as clear in terms of the
18 language of the major minority cultures in the
19 United States?

20 MR. BERTONI: Yes, an excellent
21 question.

22 I can say that, specifically around

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1 language, we have a number of ways in which we
2 try to reach out to make sure we have
3 translations done of some information.

4 But, really, getting deeper to your
5 point of how do you develop the message, how
6 do you look at the different target audiences,
7 I think that's an area that we are going to
8 have an opportunity to talk about a lot more
9 today because that is an essential part of the
10 risk communication plan.

11 I wouldn't say that in this
12 particular strategic plan there is a whole lot
13 of material you will find in there explicitly,
14 but they're in the strategic goals. You will
15 see some inklings of that.

16 But we recognize that that is
17 absolutely critical. Because when you think
18 about what FDA's mission is, yes, it is to get
19 the science right and to make the right
20 decisions. But if we don't communicate it --
21 and this has been said before -- if we don't
22 communicate it effectively to the people who

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1 need to know it, then all that work is not
2 having the impact it is supposed to have.

3 Clearly, there are different
4 communication needs of different communities,
5 different situations that they face, different
6 kinds of information that may be relevant for
7 them to make well-informed decisions. That's
8 part of us getting smarter and getting better
9 at outreach and kind of extending that one
10 diagram that talked about our operational
11 capacity out to partners and others. That is
12 an absolutely critical way for us to deliver
13 the public value.

14 MEMBER PETERS: Just to sort of
15 continue on this idea of the potential for FDA
16 impact, we have seen, as a Committee over the
17 past year and a half, the incredible people
18 and the capacity of the FDA to promote as well
19 as to protect human health with really what
20 oftentimes seem to be very limited resources.
21 It is amazing the job that can often be done.

22 Part of the FDA's ability to

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1 communicate effectively, though, depends also
2 on perceptions of the FDA and trust in the
3 FDA. I'm curious, going back, there's a slide
4 you had. I think it was your slide seven
5 about measurement along the strategic value
6 chain.

7 I'm curious if you know what
8 influences perceptions of the FDA and trust in
9 the FDA in terms of the outputs and the
10 outcomes there.

11 And are perceptions of the FDA
12 currently one of the intermediate outcomes,
13 for example, that are included here? And if
14 not, should they be?

15 MR. BERTONI: Yes, thank you for
16 that question.

17 This, to some degree, for some of
18 us, it is a little bit of a frustration and a
19 sore point for us, because you are making some
20 excellent points.

21 When you think about it, our
22 effectiveness as a public health agency is

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1 partly determined on whether or not people
2 view us as credible and as having accurate
3 information, so that people act on that
4 information.

5 It turns out, when you go and you
6 dig a little deeper into the data, perhaps our
7 credibility isn't as battered as some in the
8 mainstream media would like to believe or the
9 way they at least spit out, to be quite frank.

10 Because, oftentimes, the first
11 thing you hear in an article when FDA comes up
12 is, you know, the battered agency, this, that,
13 and the other. When you poll doctors or other
14 folks about who do they really trust for the
15 information, FDA is near the top of the list.

16 But, having said that, there's no
17 doubt that the agency did suffer some problems
18 in terms of the perceptions over the last
19 several years. There's a number of reasons
20 for that. You can look at them.

21 You know, we're not perfect. The
22 public's perception of safety and the amount

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1 of risk that they are willing to accept, and
2 things like that, are part of the equation as
3 well.

4 We try to communicate that no drug
5 is perfectly safe. There are always risks and
6 benefits that we have to weigh. So it is
7 partly managing expectations while we are
8 trying to always improve that safety.

9 In terms of the measurements that
10 we have, we track some things. I don't think
11 you will find in the strategic plan any
12 specific metrics, but it is something that I
13 think we should definitely look at. It is
14 something that we will be looking at broadly
15 around the risk communication area.

16 I think it is something you've got
17 to be careful about how you measure it. I'm
18 not sure how we would go about doing that.

19 But credibility and perception of
20 others is clearly an important area.
21 Educating the public about what the agency
22 does, and what our mechanisms are, is clearly

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