

1 important as well, because they may be
2 pointing to us for a problem that really we
3 need to work with Congress to give us the
4 authority to do something that you thought we
5 were able to do, but we really can't.

6 MEMBER PETERS: If I can just
7 follow up for one second, I mean I would
8 suggest that you might want to think about
9 this in terms of your Goal No. 1 around the
10 infrastructure, and that understanding where
11 might you get negative impacts on the FDA's
12 credibility and people's trust in the FDA.

13 Sometimes I think you are right
14 that you guys are just going to have to take
15 it.

16 MR. BERTONI: Yes.

17 MEMBER PETERS: But to understand
18 where that is might help you be more effective
19 risk communicators down the road.

20 MR. BERTONI: Yes, that's right.
21 If you are going to survive long in this
22 agency, you've got to have a tough skin

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1 because we are always kind of in the middle.
2 Some people think, if we are not being
3 criticized by both sides, we are not doing our
4 job right. But, still, I think it is an
5 excellent point.

6 Part of my job is to try to improve
7 the kinds of measures that we are making to
8 diagnose, check the status and trends of how
9 we are doing, and there's a lot of work to do
10 to improve how we do that. I am hopeful that
11 the incoming Administration is going to
12 recognize the value of that.

13 Just like we are improving our
14 information technology infrastructure, which
15 enables a lot of that information-gathering,
16 we will also have a renewed focus on getting
17 the right kinds of measures in place in a very
18 broad, diverse portfolio of different types of
19 measures, including things around risk
20 communication perception of the agency, et
21 cetera.

22 As long as it is not perceived as

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1 just a PR thing, though, that it is
2 superficial -- we want it to really have
3 fundamental public health, science-based
4 validity.

5 MEMBER PALING: I would like to
6 say, first of all, that whoever put this
7 together, the many people, the many
8 departments, have done a fabulous job.

9 When I read this, I was enlightened
10 and surprised and delighted or, in last
11 night's word, enchanted -- (laughter) -- to
12 see that there was a spirit of inclusion, of
13 wisdom, and reality. Taking our Chairman's
14 word, we might have been part of the impetus
15 for this, but it is you people in FDA, whoever
16 they all are, who have done this. And it's
17 just wonderful.

18 I did want to say that, but I was
19 wanting to pick up on your comments about
20 trust and credibility. This may not be the
21 most appropriate place to say this right now,
22 but it keeps resonating through what you say

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1 and what's in this report.

2 Long ago, when I started
3 questioning our professional friends about who
4 in the U.S. -- and I am an American citizen --
5 is responsible for communicating risks and
6 benefits to the public, it transpired that
7 basically it does sit on the FDA's shoulders
8 as the primary source.

9 What the public, what patients,
10 what doctors want to give to patients, most of
11 all, is something that none of us, including
12 the FDA, can give, which is certainty.

13 One of the huge frustrations,
14 however good the data, however thorough the
15 research, is that in the end it may not apply
16 to me or I can't plan because of uncertainty.

17 When I discuss with doctors how to
18 deal with uncertainty of their patients, and
19 there are far better authorities than I am, I
20 suggest to them that it is very rare to trust
21 an agency or a company. You can trust people
22 or your perception of people or the

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1 sensitivity of an agency as revealed by
2 people, but you don't trust the Army or Pfizer
3 or even FDA.

4 My own opinion is that, to be of
5 best service to patients, as well as the
6 benefit to you as an agency for being more
7 credible and getting better scientific basis
8 for your advice, if you could reach out to
9 help patients most of all, it would be to
10 increase your sensitivity to what patients
11 should really do when there are still huge
12 uncertainties at the end of the day.

13 To that degree, taking Ellen's
14 point, which sparked me to comment, I think
15 there are ways, some very basic, that the FDA
16 might increase its perceived sensitivity to
17 being really concerned for caring about
18 patients' uncertainty.

19 Among them is something as simple
20 as this: we in this Committee, and you as
21 professionals know this better, come to the
22 issue of -- some of the words that are used by

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1 the FDA to communicate are, in fact, used in
2 either legally meaning or nuance meaning that
3 does not, in fact, mean what the public thinks
4 they do mean. Recalls, you know, we've had
5 that one.

6 You, yourself, said, well, the
7 agency is well aware that, although we would
8 like to hope that our products are safe and
9 effective, and everyone knows that, in my
10 submission, everyone does not know that. If
11 there were a single way, in my very limited
12 perspective, in which the FDA might increase
13 trust and serve everyone's interest the
14 better, it would be to not only appoint senior
15 leadership that are primary communicators, as
16 well as knowledgeable scientists, which I know
17 is being done, but also to make an active
18 policy to distinguish between when a word is
19 being used in its legalistic or traditional
20 context and when it is being used simply to
21 communicate with the public. In those times,
22 there should be a default assumption that you

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1 will be using words which mean what the
2 general member of the public uses.

3 That is not good advice, but it is
4 an area of intended help and in some way
5 discomfort, not to diminish the huge value of
6 this document.

7 MR. BERTONI: Thank you very much.

8 I know we have had some discussions
9 within the agency about how to handle the
10 spokesperson role, about the use of language
11 and standardizing language perhaps a little
12 more than we do across some of the centers,
13 where maybe it is used a little bit
14 differently.

15 I appreciate those comments. I
16 also would like to express my appreciation for
17 your acknowledgment of the work of the agency.

18 I know Nancy and Lee and many others, some of
19 whom are in this room, did a tremendous job
20 putting together this Draft Risk Communication
21 Plan in what is, to a government agency, a
22 very short amount of time. It is very much

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1 appreciated.

2 CHAIRMAN FISCHHOFF: Madeline and
3 then Mike.

4 MEMBER LAWSON: Good morning.

5 I think the document is really an
6 outstanding document. A tremendous amount of
7 work, I can see, has gone into it.

8 I just wanted to know that, once it
9 has gone through the full clearance process
10 and internally distributed, do you have a plan
11 in mind for making certain that the public,
12 our stakeholders at large, is fully aware of
13 the document and the new direction?

14 MR. BERTONI: Our intention on just
15 about anything that we would send to Congress,
16 we would probably have on our website. I
17 guess the question is, what are our plans for
18 rollout and promotion of that? I don't know
19 that we have anything explicitly down on paper
20 yet, but that's generally on our timeline, is
21 to figure out how to roll it out.

22 So thank you for the comment. We

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1 will make sure that we get a little bit more
2 explicit now that we are getting further along
3 in the process.

4 MEMBER GOLDSTEIN: Just a couple
5 of things that have been said, particularly
6 the comment Ms. Finch made: I do think we
7 want to keep in mind, as we think about
8 priorities particularly, that there are
9 vulnerable populations that are in most need
10 of attention with respect to communication.

11 It is going to be really important
12 as we consider those limited resources that
13 may be available, so that, again, working
14 together with other HHS agencies, and even
15 broader agencies within the federal
16 government, that we make sure that we set as a
17 priority those that are socially and
18 economically disadvantaged, those that have
19 lower levels of education, who need the
20 translation, the layering of information even
21 more than perhaps other members of our
22 society.

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1 right, if FDA can do it right for its
2 problems, then having something that works,
3 other agencies will be able to adopt for their
4 own purposes rather than to have kind of a
5 one-size-fits-all.

6 I'm not sure what Mike meant, but
7 you don't have to comment. Anyway, that is my
8 thought, whether or not you meant that.

9 So, if we are thinking -- this may
10 be meta-strategic, but you had suggested
11 earlier that bioinformatics and communication
12 might be cross-cuts that have implications all
13 the way through the system. It might be
14 interesting to look at the cross-cut of
15 bioinformatics and communication. So just a
16 couple of different things.

17 So one is, if we are going to make
18 information available through various
19 technologies, that technology can be more or
20 less usable. It is not always clear that you
21 have sort of human/computer interaction
22 informed by -- that stuff is really usable in

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1 the minimal sense, much less in the sense that
2 it addresses the decision-making needs of the
3 various people that are going to use it.

4 And thinking in advance of, you
5 know, if you designed a system that would
6 ultimately be usable by a wide variety of
7 users with intermediaries, one could avoid
8 wasting an opportunity and wasting a lot of
9 money.

10 I have been working with a
11 physician on a decision-making project. She
12 was describing just how hard it is to use
13 MedWatch, that even if you want to take the
14 time out of your busy day to input
15 information, she said she just gave up on
16 something where she thought she had something
17 valuable to do. Somebody got a lot of money
18 for designing a system that has frustrated
19 this one committed, talented individual.

20 So just I am thinking both,
21 conceptually, what are we asking for, and then
22 the technical parts of the design.

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1 A second thing is that, if we are
2 changing the technology, then we can
3 anticipate, if we put our minds to it, we
4 could anticipate the change in the kind of
5 signal that we are going to get.

6 So imagine that there were a
7 readily available MedWatch 800 number, like we
8 discussed a couple of meetings ago, and the
9 public is going there, and some people,
10 however well it is designed, some people are
11 going there to look for medical advice, and
12 other people are using it for a variety of
13 different things.

14 From a signal detection theory
15 perspective, the quality of that information
16 is going to be different than what you get
17 when physicians are using it, the thresholds,
18 the d-prime and beta signal detection theory.

19 So one could do studies that would
20 enable you to make better value of the
21 information that the technology can provide,
22 so that we are hearing from the public through

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1 these various channels. We are hearing them
2 better because we know how they are speaking
3 to us.

4 Then the third thing was that every
5 profession has its norms for the kinds of
6 information it provides, the way it summarizes
7 it, the level of precision. They always want
8 more precision.

9 If one thinks about these
10 information systems in terms of the decision-
11 making needs of various users, it may at the
12 simplest have implications for what the
13 formatting is. People are interested in
14 effect sizes, not just statistical
15 significance.

16 But, also, if you applied decision
17 science to it, what is the level of precision
18 that we need from different parts of the
19 operation? We may be getting way more
20 information than we need about some things and
21 way less on others.

22 So it might be interesting to visit

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1 that cross-cut and intellectually-stimulating.

2 It may be useful.

3 MR. BERTONI: Yes. It sounds
4 really good.

5 A couple of quick comments about
6 the first area, in particular. FDA has been
7 looking at redesign of its website and using
8 some evidence-based approaches to testing how
9 we approach that. It will be rolled out -- I
10 don't know how much is public, so I won't say
11 -- in the coming, within a month or two, you
12 may see some more about that.

13 In particular, we have a project
14 with MedWatch to pull together all the adverse
15 event reporting and collaborating with NIH on
16 a new way of gathering information using a
17 rational questionnaire approach, more like
18 Turbo Tax. It's not an endorsement of any
19 particular product, but that kind of rational
20 questionnaire.

21 So that is not quite out there, but
22 within the next year that, in fact, will be

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1 something that is coming forward.

2 I think the points you raise about
3 changing the system and changing the
4 information and the signal detection issues
5 are very, very important. Folks, that's on
6 their radar screens.

7 I know we are a little over with
8 this.

9 MEMBER WOLF: I will again, like
10 everyone's comment, nice plan. It is well-
11 framed.

12 I have just very simple, well,
13 maybe not simple, but two comments or
14 questions for you.

15 How far have you drilled down?
16 Each of these objectives is quite lofty. How
17 far have you drilled down to get at how you
18 will be accountable for each of these
19 objectives, or at least how you have made
20 progress toward them?

21 Also, are there opportunities -- or
22 I guess, how have you laid out opportunities

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1 for feedback, as you lay out this new plan?

2 MR. BERTONI: And you're speaking
3 to the Risk Communication Draft Plan or are
4 you talking to the --

5 MEMBER WOLF: I'm talking about the
6 largest strategic plan.

7 MR. BERTONI: Okay.

8 MEMBER WOLF: I mean, I think we
9 could either talk a lot about more
10 specifics -- I have a lot of questions on that
11 later, but just right now on the larger issue
12 for FDA.

13 MR. BERTONI: Yes. Well, we track
14 how we are doing against the action items that
15 are listed in there. But the action items to
16 me don't get at some of the core issues. So
17 we are in the process of putting together a
18 more robust set of outcome measures that line
19 up with the strategic objectives. We are not
20 there yet in terms of having those outcome
21 measures arrayed across all of them, but we
22 have identified potential areas. We are

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1 continuing to work through that.

2 A lot of times, outcome measure
3 development can be expensive, and we have to
4 build in the resources to measure them
5 properly. Of course, you get what you
6 measure. So you've got to be careful what you
7 measure. But we have an ongoing process
8 within the agency to do that.

9 We certainly have aligned our
10 annual performance goals against these
11 strategic goals and objectives. Some have
12 more measurement associated with them than
13 others. Things in the pre-market area about
14 our review process are very well-measured and
15 managed.

16 Other areas around post-market
17 safety surveillance are improving greatly. We
18 are starting to put in place comparable
19 systems.

20 We are still looking for some of
21 the right kinds of outcome measures. Some of
22 these things are very difficult.

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1 The areas of inspections and
2 compliance and enforcement are very
3 challenging areas to measure because you can
4 imagine all kinds of perverse incentives that
5 you could put in place with the wrong measures
6 if you don't have the right countervailing
7 metrics.

8 But we are coming up with some
9 ideas that we are going to be testing and
10 thinking through how better to do that. So we
11 can talk offline if you would like to hear
12 more about some of these efforts.

13 Right now, at the most visible
14 level, we have been tracking against the
15 action items that are public. The GAO, the
16 Government Accountability Office, I guess they
17 call themselves now -- change their name, but
18 don't change the initials. They are doing a
19 study of strategic planning and management at
20 the agency.

21 So, at some point, they will be
22 coming out with their report that will detail

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1 not only how we are doing this at the
2 agencywide level, but within the centers and
3 the connections and all. So there will be a
4 lot more information I think that will be
5 public in their report to talk about that in
6 some detail.

7 CHAIRMAN FISCHHOFF: Let me thank
8 you for inviting us and thank you for
9 addressing us.

10 We will take a break for 15 minutes
11 now.

12 (Whereupon, the above-entitled
13 matter went off the record at 10:00 a.m. and
14 resumed at 10:17 a.m.)

15 CHAIRMAN FISCHHOFF: Welcome.
16 Almost everybody is back.

17 So we are now going to begin the
18 detail, having seen the strategy, going to
19 begin the discussion of the individual goals.

20 We are fortunate to have Susan
21 Winckler, who is the Chief of Staff of FDA.
22 Thank you.

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1 MS. WINCKLER: Good morning.

2 I'm going to walk through a couple
3 of slides and get us a little more in-depth
4 into the capacity goal and some of the
5 strategies we are going to pursue on that,
6 answer questions that you have.

7 Then I am going to go join the
8 table, so that we have good discussion among
9 the Committee members, where I will still be
10 available, but it is more about what you are
11 talking about than me standing up here,
12 because that is far more interesting to the
13 rest of the world.

14 I'm going to talk about the
15 capacity goal. What I really like about
16 starting with the capacity goal is that I see
17 the entire strategic plan as enhancing the
18 agency's capacity to better communicate and to
19 do better at our job for risk communication.

20 So it is only fair, then, that we
21 start with the one that will be important, but
22 then as we look at policy and science, that

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1 drives and supports what we want to do in the
2 capacity goal.

3 I have also thought about this,
4 that as we are talking about expanding FDA's
5 capacity, the strategies that we have proposed
6 could really be categorized in three ways.

7 That it is expanding and making
8 sure that we have the right expertise. That
9 we become more efficient and then, at the end,
10 we are more effective.

11 So I will tell you how I have
12 categorized these strategies, as well as
13 update you on some things that we are pursuing
14 at the agency to already implement and pursue
15 some of these areas. We are really looking
16 for your feedback on how we can better do
17 that, as well as how we can expand what we
18 have in the plan.

19 The first strategy here, where we
20 talk about streamlining and coordinating the
21 development of our messages, is a fundamental
22 challenge to the agency. When we go to

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1 communicate, we have a number of subject
2 matter experts in the science of what it is
3 that we are talking about. Then we have the
4 experts in the regulatory structure under
5 which we are operating.

6 Then we have the experts who are
7 looking at communication and who it is that we
8 want to reach, which, if you look at one of
9 the lists early in the strategic plan, it
10 talks about our stakeholders. I think the
11 list has at least 15 different categories of
12 people mentioned.

13 That starts to create problems, you
14 might imagine, when we say, well, healthcare
15 professionals will interpret this phrase in
16 one way, and consumers will interpret it
17 another; what do we do? How do we move
18 forward?

19 So the strategy where we are
20 looking to streamline and coordinate
21 development is really trying to get the agency
22 to be more efficient in developing our

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1 messages, which will then be more effective.
2 But we see this as a strategy where we are
3 more efficient. This is probably one where we
4 are focusing on processes within the agency.

5 The second strategy is looking at
6 our planning for crisis communications. For
7 all of you who have done crisis
8 communications, or tried to communicate
9 something in a crisis, the last time -- well,
10 the worst time to be trying to figure out
11 precisely what word will convey what it is
12 that you want to say is when you have a
13 situation you need to communicate 12 minutes
14 from now, and you still have subject matter
15 experts debating whether you want people to
16 postpone eating something, stop eating
17 something, or we just want you to know that
18 we're a little concerned about something.

19 We shouldn't be having those
20 debates in the middle of the crisis, but we
21 hope, rather, to have some planning in place
22 where we have some structure for what words

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1 would be used when, and then getting agreement
2 among the subject matter experts as to where
3 we are in the process, which helps us choose
4 what words that we would use.

5 So the planning for crisis
6 communications is one that I would put in our
7 efficiency category, where we do the work
8 ahead of time, rather than being faced with a
9 specific situation.

10 The strategy on streamlining
11 research and testing is looking at our
12 understanding that we need to do more research
13 and testing, but we also need to streamline
14 that so that it is done efficiently and that
15 we can use the results of that, and will use
16 the results of that, in our work.

17 So the capacity here that we expand
18 is that we do that research and testing
19 efficiently. Then it will help our results.
20 When we incorporate that into our message
21 development and our communication work, that
22 will be more effective.

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1 The fourth one that we list here on
2 clarifying the staff roles and
3 responsibilities and creating messages is
4 another one that I would categorize in
5 efficiency.

6 This is a challenge. As many of
7 you, I'm sure, have seen when you bring a
8 group of people together to agree on anything,
9 you have many different thoughts. Part of
10 what you want to do in that process is to
11 understand what role it is that people are
12 playing.

13 So that if our subject matter
14 expert is speaking to the science of the
15 issue, but then wants to engage and provide
16 the legal interpretation of our regulatory
17 structure, that is not the right role for the
18 science and the subject matter expert.

19 So the fourth bullet here in the
20 strategic plan, the strategy where we clarify
21 the roles and responsibilities is very helpful
22 in helping us streamline and coordinate the

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1 development of the communication messages and
2 activities.

3 I will give you an example of
4 something that we have implemented in the last
5 four weeks that has helped us with these two
6 strategies and might just be a good
7 illustration of how the agency sees the idea
8 of streamlining development and clarifying
9 roles and responsibilities.

10 About four weeks ago, we set up a
11 structure called a rapid response team, where
12 if we needed to communicate something, we
13 needed to develop a communication within four
14 hours, that we would bring together the
15 subject matter experts. We would bring them
16 physically to one room. The people who are
17 assigned and come to the room come not as --
18 they come as a person, but they come with a
19 role.

20 So, when I am there, I am there as
21 the Chair and the facilitator. So my job is
22 to get everyone to input and to be done. So I

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1 am not engaging in the content of the
2 communication.

3 From our Legal Counsel's Office, we
4 have someone who is there in the legal role;
5 someone who is there in the content and
6 subject matter expertise role; someone who is
7 there in the policy role, because there may be
8 policy implications for what's being said.
9 Their job is to assure that we have the policy
10 consistency, that what it is we are saying
11 here is consistent with other agency
12 messaging.

13 There is a risk communication role.

14 Nancy, in fact, joined our team the last time
15 that we had to convene such a group. I think
16 there's nine roles when we lay it all out.

17 Their job, when we convene, is to
18 settle on the message as well as the
19 communication plan. So we are using their
20 expertise to talk about, is this a message
21 that should be pushed out in a news release?
22 Is it a nationwide issue? Is it a local press

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1 issue? Is it something that requires
2 coordination with other agencies, with other
3 stakeholders? Are there folks who we need to
4 talk to first? Is this one where we want to
5 have a specific spokesperson, and what is that
6 they would do?

7 Decide on that plan, and then we
8 spend about the next hour and a half creating
9 and signing off on the foundational statement
10 that is used for all subsequent
11 communications.

12 So those individuals are deputized
13 from their areas. It gets the content all in
14 one place, the clearance in one place, and has
15 been a fairly effective tool when we have used
16 it.

17 Now we have used it four times in
18 four weeks.

19 (Laughter.)

20 We have found that it just helps
21 us, and we have a lot of rapid communicating
22 to do.

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1 (Laughter.)

2 But it has been an interesting
3 exercise because each of those groups has
4 involved different people. It involved
5 different centers. Some had to do with
6 medical products. Some had to do with food.

7 We are evolving, obviously. We are
8 learning from what worked well in the first
9 instances and what is working well moving
10 forward.

11 But that is just an example where
12 we are trying to take these ideas and change
13 how the agency operates in real-time.

14 I should have acknowledged that I
15 am happy to have interaction as we go through
16 these slides. So why don't we just go ahead
17 and talk about these strategies, if folks
18 would like to? Then I just have a very few
19 number of slides. So we can talk about this.

20 I was planning to stay up here for about 30-
21 35 minutes and then join you at the table.

22 MEMBER DeLaROSA: I think that is

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1 excellent.

2 In hospitals, the traditional code
3 blue was when things went bad and somebody is
4 dying. Now the hospitals have gone to this
5 rapid response team. The rapid response team
6 is to prevent the code blue.

7 So it is great to see that the FDA
8 has moved that way. One of my comments was in
9 our first meeting that we ever had here a year
10 and a half ago, that was brought up,
11 specifically to have a group, a point person,
12 someone to go out, get the information, and
13 disseminate the information.

14 So it is good. I don't know if it
15 was from our meeting that this has come out,
16 but it is good to hear.

17 MS. WINCKLER: Okay. Why don't I
18 run through some of the other strategies that
19 we have?

20 I should say that it was certainly
21 in listening to the discussions of the
22 Advisory Committee and what it is that we

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1 could incorporate, I know that that drove the
2 development of the strategic plan, and then
3 our thinking we really need to pursue this.
4 So it wasn't just frustration with really slow
5 clearance processes.

6 Yes?

7 MEMBER PETERS: If I could just ask
8 one question? So, actually, the result of the
9 rapid response team is to decide how to
10 communicate and to send out communications, I
11 believe?

12 MS. WINCKLER: It's both. For that
13 situation, specifically how that will be
14 communicated, as well as to settle on the
15 foundational statement.

16 Let me explain, what would
17 typically happen, as an FDA statement moves
18 through a clearance process, it may go through
19 the subject matter experts, then through the
20 leadership of that product center, then to the
21 Office of the Commissioner for communication,
22 policy review, coordination review, consumer.

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1 That is where you build in some more of the
2 communications expertise, building on what the
3 center has done, and then finally the legal
4 review.

5 When you get through all of those
6 steps, the end product may not resemble what
7 left the center. It may be better. It may be
8 wrong. But, in every situation where it has
9 this sequential clearance, the people who were
10 earlier in the clearance process don't know
11 why something has evolved.

12 So not only does it take more time
13 to do that sequential clearance, but we don't
14 learn from the process. You just know it is
15 different, but you don't know why and think,
16 why would I then incorporate it, and do we
17 want to start with different words the next
18 time around?

19 MEMBER PETERS: Yes. So, with the
20 rapid response team then, are you guys -- do
21 you have someone who is a communications
22 expert on the team? And are you working off

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1 of tested prior messages?

2 MS. WINCKLER: We're doing the
3 first. We're not yet doing the second. That
4 is what we aspire to.

5 MEMBER PETERS: So, sort of like
6 with pharmaceuticals, the FDA is now starting
7 to do more post-marketing surveillance. Are
8 you going to start to do that on the messages
9 as well, so that you can learn from the
10 effectiveness of the messages that you're
11 developing, so that that can then get rolled
12 back into the next rapid response team?

13 MS. WINCKLER: We certainly want
14 to. I think part of what we will be
15 discussing the rest of today is how to do that
16 within some of the constraints we have,
17 including ideas that we use current staff to
18 react to some of those messages because of the
19 limits on getting more than nine people to
20 react to something that we are proposing, as
21 well as doing much of that testing in a way
22 that it is relevant more broadly than simply

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1 just to the situation, which would be true in
2 most instances.

3 But, as an agency, we could do
4 better at learning from all that we do, rather
5 than putting out fire after fire after fire,
6 and moving from one communication to another.

7 I will go over, then, a few of the
8 other strategies that are in this capacity
9 goal within the plan that you have.

10 The first bullet here is really
11 about getting the right expertise into the
12 agency. So that when we are talking about
13 capacity, we do also mean more people.

14 We need more people who have this
15 expertise in behavioral science. Then making
16 better use of them in the message development.

17 This is really an integration, not only with
18 -- it might be obvious that we would say we
19 want to integrate that with our Office of
20 Public Affairs, who interacts with the media.

21 But we also need to integrate them with the
22 offices that deal with the website and our

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1 consumer communication, as well as the center
2 level, just in how we communicate it all and
3 recognizing that much of what the agency does
4 is communication, but we haven't necessarily
5 focused -- we spend a lot of time on the
6 science and the decisionmaking, and then
7 communicating that result hasn't been as
8 structured as it should be, and hasn't
9 involved the experts that we need to.

10 So this strategy is very much so
11 about getting the right expertise and then
12 using that expertise at the right stage in the
13 process.

14 The second strategy here, talking
15 about improving the effectiveness of the
16 website, the very good news is that the
17 website transition, where we have a fully-
18 revised website with a different web content
19 management system, should be coming to you and
20 every other member of the American public in
21 the next five weeks.

22 So that now you have a very

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1 different front page to the FDA, to fda.gov.
2 We have said that we have a very nice front
3 door. Then you step through the front door
4 and it is the same old building that we have
5 had. Now we will have a building and an
6 interior that matches the front door.

7 That will be up and running in the
8 next five weeks or so. It has taken much
9 longer than we thought, but you might imagine
10 that we have a lot of information on the
11 website. So it has involved a lot of staff to
12 help transition to the new content management
13 system and will allow us to maintain and have
14 that better not only visual presence, but
15 organization of the information and being able
16 to locate things on the site.

17 Yes?

18 MEMBER MAYER: This may not be
19 relevant right at this moment, but in light of
20 the problems you have of doing external
21 studies and how complex that is, and your
22 need, then, to use your staff, has anybody

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1 explored the idea of using SGEs for that
2 purpose?

3 And more specifically, not expert
4 SGEs, but SGEs like myself or others whose
5 work it would be to be ongoing respondents on
6 a rapid response basis, like focus groups that
7 could be quickly assembled, that had already
8 received clearance, but that were surrogates
9 for the public that you are trying to reach.

10 MS. WINCKLER: I think that is a
11 great idea.

12 Nancy, I don't know if you can
13 speak to whether we have pursued that. I know
14 that some of our offices have focus groups
15 that are readily available, but that is a
16 great idea, to pursue more.

17 DR. OSTROVE: We have nothing
18 formal that I am aware of. At least certainly
19 at the Commissioner's level, I'm not even -- I
20 know that the SGEs have been kind of limited
21 generally to those people who are on the
22 committees.

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1 As you know, Musa, there are very
2 few who represent the general public. We've
3 got a lot of people who would represent
4 healthcare providers but not the general
5 public. That is something we really do need
6 to think about and look into.

7 MEMBER MAYER: Well, since 2001,
8 actually, I have been one of the exceptions.
9 That is the Patient Representative Program,
10 which has grown and grown, and has been
11 enormously effective.

12 We still have to go through the
13 usual clearance and training, and so on, than
14 any other SGE would be.

15 But it just struck me, as you were
16 speaking about experts and communication, that
17 experts often, though they understand all the
18 research, have a distance from, let's say,
19 public awareness, and especially I'm thinking
20 of vulnerable populations and special
21 populations.

22 It is one thing to know

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1 theoretically what's needed. It is another to
2 actually be the recipient of the communication
3 and be able to give that direct feedback.

4 I am wondering if there is a
5 barrier really for FDA to actually have like a
6 cadre of people, maybe a large group of
7 people, that they could instantaneously test.
8 Given the web tools that we have, you could
9 turn something like that around within a short
10 space of time if people were -- and I know
11 there are people who would love to do this and
12 feel honored to be a part of a program like
13 this.

14 MS. WINCKLER: That is a great
15 idea. In fact, it reminds me that much of
16 some of the evolution of the things we do,
17 particularly on the web, is supported by,
18 occasionally driven by, reaction, where we
19 hear that doesn't make any sense.

20 Or, say, we have a Salmonella
21 contamination in certain products, and the
22 visual on the home page is Salmonella. We

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1 heard from a lot of people that that was just
2 scary.

3 At some level, there was debate,
4 well, is that perhaps what we want, but not?
5 If it meant scary, they didn't look for the
6 information? Or scary, important?

7 So we did some evaluation of what
8 it is that we should do there and those
9 reactions. So it is maybe even more a better
10 way of institutionalizing and seeking that
11 feedback.

12 But I think that fits in these
13 strategies where we want to streamline that
14 research and testing. That fits right into
15 that idea of streamlining the research and
16 testing.

17 MEMBER SLEATH: I just had a quick
18 question about your thoughts on increasing the
19 behavioral science expertise. Do you plan to
20 do that like across the centers or in a
21 central office? I just wonder what the agency
22 was thinking about that.

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1 MS. WINCKLER: That is, I know, an
2 area where we like your feedback on where we
3 should. My personal opinion is that, wherever
4 we can, we should, without setting up boxing
5 matches between experts at different levels in
6 the process. But that, in particular, I
7 think, is a place where we would appreciate
8 your input on what types of people should be
9 where within the agency.

10 MEMBER PETERS: Just to follow up
11 on what Musa was saying, one of the things
12 that I thought about a lot as I was going
13 through reading the strategic plan is it would
14 be great if you guys could have some kind of a
15 longitudinal panel of people that you could go
16 to in order to do research. If that could be
17 done with special government employees, where
18 you had 500-600 SGEs who are paid minimal
19 amounts of money every little while, as some
20 new, emerging risk comes out, and you can go
21 back to them over time and look to see how
22 things are working, and people who vary in

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1 ability, who vary in medical conditions. You
2 know, there's a variety of things that could
3 be done. I mean that would be an incredible
4 resource, if that is doable.

5 MS. WINCKLER: And that would help
6 us with a challenge we sometimes see. As an
7 agency, we are good at doing what we call
8 lessons learned processes, where we say,
9 "Okay, what could we have done differently?"
10 We're not so good at learning those lessons
11 and incorporating them.

12 We recognize that. I think a
13 longitudinal panel would remind us that
14 perhaps they have told us something before and
15 we could have learned the lesson.

16 MEMBER DeSALVA: I have lots of
17 comments, but I'm formulating them.

18 (Laughter.)

19 MEMBER WOLF: I'm just going to
20 comment on this. I mean I have some mixed
21 feelings on it.

22 I think the idea of using SGEs for

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1 feedback, and that means likely bringing in
2 new SGEs that represent more of a lay public
3 perspective, not being communications experts,
4 is a great idea.

5 The idea of having them -- like you
6 would almost have to have kind of a short
7 stay. I don't know how much the longitudinal
8 piece of it is, because I would be worried
9 about, once you have been involved in the
10 process, you become like a professional
11 consumer, and your feedback might no longer
12 reflect who you are talking about.

13 But I think a good model -- is it
14 the CARRA program through NCI, the way they
15 used it with grant reviews? It is a different
16 context, but the idea of using consumer
17 advocates to be involved and have a voice is a
18 good one.

19 Actually, even given the other
20 topic about centralizing or spreading out
21 behavioral sciences and communications is
22 another good model I think NCI has kind of

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1 forged ahead. So that might be a group to
2 look at.

3 MEMBER BRUHN: I want to reinforce
4 Michael's comments about, after a while, your
5 panel of the lay people become trained because
6 of the type of questions that they are
7 addressing.

8 The concept of having that panel is
9 wonderful, but their tenure needs to be
10 limited to what's an appropriate number. I
11 guess it depends on how often they are called
12 upon. But certainly they don't remain in that
13 panel for a long time. Three years perhaps?
14 Or a certain number of instances where you
15 have asked their comments on? Because pretty
16 soon they begin to think like an expert.

17 CHAIRMAN FISCHHOFF: AnnaMaria?

18 MEMBER DeSALVA: Thanks.

19 It was remarked earlier in the
20 introductory discussion about the
21 possibilities, broadly speaking, for FDA to
22 collaborate more with industry with respect to

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1 risk communication.

2 This discussion around research and
3 panels I think is a very relevant one because
4 the industry, of course, is immersed not only
5 in the risk/benefit profile of their products,
6 but also in understanding to whom they are
7 speaking and how to effectively reach those
8 people.

9 There's a lot of knowledge there,
10 and there are a lot of mechanisms and channels
11 that have already been established, so that
12 questions can be addressed quickly in a
13 commercial setting.

14 So I can assure you I realize that
15 it is a difficult thing for the agency and the
16 industry to work together in certain respects.

17 However, I can assure you from conversations
18 I have had in my own professional life that
19 there is an interest and commitment in sort of
20 sharing those assets and getting to the right
21 outcome, really in the spirit of getting to
22 the right outcome.

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1 MS. WINCKLER: And if I could react
2 a bit, especially on the industry side, the
3 other helpful dynamic of interaction with the
4 industry is that it also helps us focus on the
5 specific aspects of the product about which we
6 might be talking.

7 MEMBER DeSALVA: That's right.

8 MS. WINCKLER: There's a difference
9 if we are talking about in the food context a
10 problem with something that is an ingredient
11 in thousands of things with very long shelf
12 lives versus something that is a discrete
13 product with a very short shelf life, and the
14 different communication dynamics that
15 presents.

16 Similarly, with the medical device
17 that is implanted versus a drug that you can
18 stop using, or something else.

19 So it helps the agency have that
20 very up-to-date information and understanding
21 of consumer and patient behavior as the
22 industry understands it.

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1 MEMBER DeSALVA: Right.

2 MEMBER GOLDSTEIN: I would just
3 second the recommendations that are being made
4 about the behavioral scientist involvement in
5 the process. I mean it is great that you have
6 these different layers of responsiveness.

7 And I think in building the
8 capacity, it gets back to what I said earlier
9 about collaboration. Because there are
10 scientists, professionals who are already
11 working at government agencies like CDC and
12 AHRQ focusing on how we best frame messages
13 and how we test whether those messages are
14 being utilized the way we are hoping they are.

15 So some of those folks that may be
16 on these rapid response teams may also be in
17 positions where they are doing similar work
18 for the other agencies, as well as figuring
19 out the broader standards and systems that you
20 want in place in order to enhance
21 dissemination.

22 So, in thinking about behavioral

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1 science expert staff, you want to think about
2 not just the core behavioral sciences who
3 might be studying the content and the framing
4 of messages, but also the dissemination
5 scientists who are looking at how information
6 gets used.

7 For instance, I am thinking about
8 how AHRQ studies the use of guidelines by
9 practitioners. So the audience in that case
10 are the professionals who are out there who
11 are also communicating these core messages to
12 patients, and how you can speed their use of
13 effective messages, the right messages, the
14 information that you want to deliver.

15 And there are networks out there.
16 For instance, AHRQ has the network of primary
17 care-based research groups. PBRNs, they are
18 called. They are already set up to do
19 dissemination research. That is their
20 mission. They are around the country.

21 Also, AHRQ has pods, if you will,
22 of research scientists who are involved in

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1 dissemination research and identifying the key
2 principles that influence how clinicians adopt
3 behaviors.

4 Those evidence-based review
5 organizations are studying not only how to
6 look at the evidence and make sense of it, but
7 also how to disseminate that evidence
8 effectively.

9 So, again, I'm thinking just about
10 that collaboration, identifying key people who
11 might either be shared with FDA as a resource
12 or even come to FDA to help you do this work.

13 MEMBER WOLF: I want to get back to
14 a point that AnnaMaria made, this building out
15 capacity through the partnerships that you
16 have, engaging with the industry as well.

17 I'm the new guy on the Committee.
18 So I may have a very naive question.

19 How much does the FDA dig into or
20 get access to the information, the data, that
21 is being gathered by industry? In the
22 comprehension testing they actually use

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1 assessments of a product as it is going out,
2 as to understanding whether it be labeling
3 issues -- I'm thinking, again, on
4 communications, what you can be learning about
5 the nature of misunderstanding or how the
6 process for getting that information, the
7 labeling, that gets developed, because that
8 could be a resource where you are getting that
9 information, rather than you having to go out
10 and get it.

11 MS. WINCKLER: My understanding is
12 that we do get access to a fair amount of that
13 information.

14 But, Nancy, do you want to respond
15 to that?

16 DR. OSTROVE: Well, certainly, when
17 it comes to label comprehension studies for
18 over-the-counter drugs, especially those that
19 are going on a switch from prescription to
20 over-the-counter, there's like required
21 studies.

22 We do work with the industry on the

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1 protocols for those. We review the results
2 that come in. So we are getting information
3 about those for certain.

4 I don't know -- I'm not saying that
5 we couldn't get the information in terms of
6 what industry did with regard to labeling for
7 prescription drugs or for other products. I
8 don't know to the extent to which we are
9 currently doing that.

10 MEMBER WOLF: Could it be that the
11 process could be informed, that if you know
12 that they are having to do those activities,
13 that you could provide further guidance as to
14 what they should be looking for or what you
15 might want to be offering up in return, if
16 there was value?

17 DR. OSTROVE: Well, certainly, if
18 you look at kind of the REMS programs from
19 FDAAA, I think there's kind of an
20 encouragement for standards to be set up and
21 effectiveness to be measured. So there is
22 probably work that is being done in the

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1 center, certainly in the Centers for Drugs and
2 Biologics on that now. I think that is an
3 important point that we should be looking at.

4 MS. WINCKLER: And it does touch on
5 the last little bullet on this slide in
6 talking about how we can enhance our
7 partnering to improve that two-way
8 communication. Because it is more than just
9 the information that is developed as product
10 maybe going through the approval and then the
11 ongoing regulatory process.

12 The industry may well have
13 information that would be helpful to us in
14 communicating that is not related at all to
15 the regulatory process or the regulatory
16 action.

17 We have pursued some efforts to
18 have more dialog with industry to get access
19 to that information because it helps their
20 messaging and our messaging, and how it is
21 that we communicate what we want to say. But
22 that, from my observation, is perhaps a bit

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1 untapped, particularly when we look at, what
2 do we want to say, to whom, and when?

3 CHAIRMAN FISCHHOFF: In the data
4 collection, the thing we have been working
5 around is the constraints that OMB has imposed
6 on FDA. I don't know what you are allowed to
7 say as a federal employee.

8 But are there some thoughts about
9 what might be kind of some reasonable
10 strategic requests from OMB that would fulfill
11 the legitimate obligations of the Paperwork
12 Reduction Act, that limits our ability to
13 require people to do things? Are there some
14 specifics?

15 We have had a former head of
16 OIRA -- I assume that this goes to them -- who
17 was familiar with behavioral research and had
18 done some of it. We may have another head of
19 OIRA who is familiar with the science here.

20 So have you thought of what -- is
21 there some thought about what a well-
22 formulated request might be?

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1 MS. WINCKLER: There has been
2 thought and discussion in that there are those
3 types of questions, and we seek your input on
4 these.

5 What are the questions that we
6 should ask through that process? Just because
7 it is burdensome doesn't mean that it
8 shouldn't be used. It just means we shouldn't
9 use it when we are trying to figure out how to
10 communicate a new safety warning about a
11 device, that that is the wrong time.

12 So what are the questions that
13 could be asked in that context? Then what are
14 other mechanisms that comply with the OMB
15 requirement that we can use in more time-
16 sensitive situations?

17 Then there's the whole span of in
18 between where we have more time and should be
19 thinking more about the communication and the
20 messaging, and what should we be asking then?

21 So we have thought about it, and
22 thought about some of the things that should

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1 be asked, but really that is an area where it
2 would be great if we get in-depth reaction
3 from the Committee about, if you were in this
4 situation -- you are now advising us. What
5 questions would you ask in the robust, long-
6 term, but burdensome process? What would you
7 ask in that? And how would we do the interim?
8 And what would you look for in the very short-
9 term and what could we use?

10 CHAIRMAN FISCHHOFF: So, for
11 example -- and again, I don't know what you're
12 allowed to say and not say. But imagine, you
13 know, there's an issue with a medical device
14 and you want to communicate to people about
15 that. Then the industry wants -- I mean
16 everybody wants to communicate.

17 It is burdensome on the people who
18 have the device to get a badly-worded message.

19 It might be considered burdensome to test
20 your message on people like those who actually
21 have the device unless you say, well, I'm
22 going to test my communication on you and then

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1 give you full individual counseling of a sort.

2 So one could think of a protocol
3 that one could say: here's how we are going
4 to do the study. Here's the people we are
5 going to ask preliminarily, who are people
6 with not the device, but the same sort of
7 diverse population groups. Then we're going
8 to do some sort of testing with -- I'm making
9 this up, but that we are going to then do some
10 testing with people who have the device, but
11 as part of a clinical setting, so they will
12 read our standard message, but then we will
13 make certain that they absolutely understand
14 what's happening in case the message doesn't
15 do it. And these are the performance
16 standards that we are going to be looking at.

17 I could imagine a standard protocol
18 for doing that kind of testing that would then
19 be adapted to specific problems that would be
20 scientifically-sound, would serve all of the
21 public interests, which is not just not having
22 to fill out needless paperwork, the only

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1 public interest.

2 And that a scientifically-sound
3 case could be made, and one could imagine
4 somewhat different protocols for dealing with
5 medical devices or for ensuring that direct-
6 to-consumer advertising is appropriate. So
7 the people producing direct-to-consumer
8 advertising, they spent a lot of money on
9 testing. FDA might come up with its own
10 protocol on its impact, which they could have
11 the data collected at the same price, you
12 know, at the same time, with some kind of
13 audit ability so it is honest stuff.

14 It would perhaps be welcomed by
15 industry, who is trying to second-guess what
16 FDA's judgments are going to be on FDA's
17 issues.

18 I just wonder whether one could
19 envision a set of things that would go to OMB
20 and that they might welcome.

21 MS. WINCKLER: I think it is
22 definitely a possibility. Where we run into

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1 challenges, too, is on product-specific
2 issues, you know, limitations on what
3 information we can share when, as well as if
4 it is something that we need to communicate,
5 should we communicate it to everyone at the
6 same time?

7 That speaks, then, to the idea of,
8 in your hypothetical, is it about a specific
9 device or is it about implantable devices?
10 And there would be research done on the
11 uniqueness. You know, what is the difference
12 of a message that is going to someone with an
13 implantable device versus a different device,
14 a diagnostic test? And how might we
15 communicate those differently?

16 So I think the protocol opportunity
17 is one that should definitely be -- and the
18 agency is interested in how we might do that
19 and what we should pursue. What are some
20 priorities within that? What are questions
21 that we should ask? What are things that we
22 should be looking for in that area?

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1 Let me talk a little bit about the
2 new web tools on the website. This is just to
3 share with you some of the things that have
4 been happening, as well as some of the new
5 dilemma that it creates.

6 In the recall of the peanut
7 products contaminated with Salmonella
8 typhimurium, we created a searchable database
9 that then you could -- and I don't understand
10 the technicalities of this, to even spell the
11 words that I'm about to use. But in putting
12 it on our website, there was also then the
13 Twitter -- there was a widget so that it could
14 appear on other websites. Then you could get
15 the recall, you can get our recall updates by
16 Twitter. So that it provides this consistent
17 update.

18 That was very widely used. Tens of
19 thousands of sites posted that widget to
20 expand access to it, which helped us with the
21 reach.

22 Then we get to another warning

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1 about nut-based products and say, okay, do we
2 build that into the same feature, so that you
3 now get warned about all problems that might
4 happen to relate to FDA's food products or
5 just the nut ones?

6 And do we start to create
7 challenges for ourselves if you could get a
8 Twitter every time there is a recall of an
9 FDA-regulated product, which there are a lot
10 of, some for important safety reasons where
11 the agency would have spoken proactively, and
12 some that is information that we would have
13 posted on our website so it is there for
14 awareness, but we aren't backing it up with an
15 additional message.

16 So I offer that just as things to
17 think about, that we are exploring the new web
18 tools. The new website will support that and
19 will drive much of this, but it also creates
20 questions for us and dilemmas back to what do
21 we use when, and when do we start annoying
22 people?

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1 CHAIRMAN FISCHHOFF: So this is a
2 Twitter to look at my widget?

3 MS. WINCKLER: Yes.

4 (Laughter.)

5 CHAIRMAN FISCHHOFF: Thank you.

6 MEMBER MAYER: So this is an old
7 web tool or not even a web tool, but years ago
8 when I signed up with CDER to receive
9 notifications of alerts on products, I want to
10 tell you the amount of emails that I receive
11 is tremendous. I can no longer take the time
12 to read them, just the sheer volume of
13 information.

14 I don't imagine a widget or
15 Twitter, whatever, is going to help this. It
16 is just going to be the same thing in a
17 different form.

18 There has got to be a way to help
19 people really tailor the information that they
20 wish to receive, unless, in fact, they want to
21 receive all of that.

22 MEMBER DeSALVA: You know, I feel

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1 as though some of the things that we are
2 beginning to discuss are sort of a downstream
3 symptom of what I think is a fundamental issue
4 or opportunity related to this draft of the
5 strategic plan.

6 I raised it earlier in a question
7 format with Mr. Bertoni when he presented.
8 But it would be more helpful if I were more
9 direct about my bias, I guess.

10 That is, I feel like the plan isn't
11 adequately outcomes-oriented. I appreciate
12 what he said in response to my question, that
13 that is kind of a sea change and maybe too
14 radical a shift.

15 But, from my own experience in
16 building strategic plans, and in doing that in
17 the communications environment, if you are
18 laser-focused on the intended outcome, it has
19 such a profound downstream effect on your
20 strategies and tactics. I realize that is
21 obvious.

22 But I think there is a big

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1 opportunity at this particular point in time
2 for the agency -- it's a pain point because so
3 many things have changed, and you are trying
4 to deal with that change. You are trying to
5 deal with all these new demands that you now
6 have.

7 But, at the same time, you are able
8 to see the new patterns that are emerging. If
9 this were a different sort of session and we
10 were, I don't know, just having like an
11 informal working session, and I had a
12 whiteboard, I might try to sketch for you or
13 ask you to help me sketch for you, what are
14 the emerging patterns in risk communication
15 for the agency?

16 Even though there isn't formal risk
17 categorization, what's the continuum of risk
18 in which you are constantly operating, all the
19 way from the standard sort of adverse events
20 that are associated fundamentally with a
21 product's risk/benefit profile, all the way to
22 the other end of the spectrum, where there is

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1 life-threatening, urgent and immediate risk?

2 And if there are four or five
3 categories of risk, and you are thinking about
4 the outcome, intended outcome, for each of
5 them, what is the risk mitigation behavior?
6 You need doctors to pursue. You need
7 consumers to pursue and patients who are
8 taking that drug or have that device. You
9 begin to see those kinds of patterns.

10 I feel as though, if that becomes
11 the north star for the plan, how do we
12 communicate in a way that actually mitigates
13 risk and drives certain types of behaviors in
14 certain types of these situations?

15 All of a sudden, I think some of
16 the tactical flow becomes much more clear.
17 And from a policy standpoint, some of the
18 principles and guidelines you can provide all
19 your stakeholders also become more clear.

20 Sorry, that's long-winded.

21 MS. WINCKLER: If I may, Nancy,
22 that is precisely what we are looking for in

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1 this session.

2 I don't think there is a Federal
3 Advisory Committee Act prohibition on
4 whiteboards. So we could probably arrange for
5 that.

6 That is what often drives, when you
7 have people saying, "Well, what should we say
8 when? How should we do this?", it does have
9 to come back to, what is it that we want to
10 happen? If this is for consumers, what is it
11 that we want them to do?

12 Sometimes, for the agency, that
13 means that we have to wait to say something
14 because we don't know yet what it is that we
15 want consumers to do. We could put something
16 out that is so opaque -- we recognize that we
17 can create our own chaos by over-
18 communicating.

19 This, I think, is in the policy
20 section of the plan. When should we speak?
21 What is some structure and some ideas for
22 helping us articulate when should we speak,

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1 and then how do we apply that? But it is
2 exactly that type of discussion.

3 And what are the right outcomes to
4 measure here? I can think of a wrong outcome
5 in enhancing partnering to improve two-way
6 communication. The wrong outcome would be,
7 how many partnerships do you have?

8 Because we can drive it two days
9 before it is going to be measured, but are
10 they the right partnerships and are we using
11 them? Because the partnering there can be
12 government agencies, healthcare professional
13 groups, consumer groups, technology partners,
14 others who are pushing messages.

15 So those are the types of things
16 that would be really helpful, particularly in
17 the capacity goal. When I was first
18 discussing, and they said, well, you get to
19 present the capacity goal, I hadn't yet read
20 the plan. I said, "Oh, that's great. How
21 many new staff are we going to get?" Because
22 I came in with that was capacity, and I'm

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1 thinking about who needs to be where and what
2 do we need to get things done. That wasn't
3 the right outcome.

4 The strategies here we think will
5 help us on this idea of having the right
6 expertise, being more efficient and, thus,
7 being more effective. But it's fair that I
8 don't see, and I don't think we have thought
9 enough about the outcomes that we would use to
10 say, how far have we gotten in that strategy?

11 MEMBER GREENBERG: Yes, these are
12 all theoretical discussions that we are
13 having. But we are in the midst of a
14 potential swine flu pandemic now. I know that
15 is not an FDA issue; it is a CDC issue.

16 But, as we are sitting here
17 discussing this, I am thinking about all the
18 news I have heard in the last 24 hours. This
19 morning I was watching the Today Show and saw,
20 I guess, the chief spokesman for the CDC talk
21 about the swine flu and say how concerned he
22 was that a child had died. He never once

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1 during the discussion gave any of the tips
2 about what consumers or patients ought to be
3 concerned about, nor was there a link to a
4 website. So there was no real information for
5 people.

6 Then Vice President Biden got on,
7 and they asked him, "Well, would you let a
8 family member of yours go to Mexico?" And he
9 said, "Well, I don't believe in being in any
10 confined spaces at all. So I wouldn't ride
11 the subways and I wouldn't fly in an
12 airplane."

13 Okay, so right there you've got
14 just sort of mass confusion and no
15 information.

16 Then, on the front page of The New
17 York Times -- if I sound like a news junkie, I
18 cop to that; I am.

19 (Laughter.)

20 MS. WINCKLER: I'm guess there's
21 some in the room.

22 MEMBER GREENBERG: The front page

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1 of The New York Times says they are not
2 closing off any borders because
3 epidemiologically that's the advice they have
4 gotten, that that is not going to help reduce
5 the exposure to the infection.

6 So in no place have I seen, the
7 talk shows -- and this is, I think, a good
8 lesson for the discussion that we are having
9 today. They are getting out to millions of
10 people every morning, and we've got all these
11 opinion-makers. We've got Members of
12 Congress. You know, the head of the Health
13 Subcommittees are going to be going on the
14 news talking about these issues.

15 Those are the folks who are getting
16 that information out to millions of people
17 very quickly. It seems to me that this
18 strategy has to involve briefing people who
19 are opinion-makers and providing the websites
20 and making sure that they provide, you know,
21 the five things that you need to do, which I
22 didn't hear on anything I watched today.

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1 So that is, I think, from the
2 theoretical to something that is going on
3 right at this very moment. I think that that
4 has to be factored in.

5 MS. WINCKLER: And it strikes me
6 that in connecting that, then, to -- perhaps
7 it is even a strategy that is missing in
8 capacity. I talked about our rapid response
9 team. So we come up with the foundational
10 message that we are comfortable with and then
11 we push it out.

12 What you are reminding me is that
13 there should be an assessment of how it is
14 used. How is it further conveyed? Then what
15 does that tell us about the message? What do
16 we need to do differently in who we have
17 talked to and what it is that we are saying?

18 Because we may have intended to
19 have people with a certain health condition to
20 stop using a specific drug, but how was that
21 conveyed in the trade press for pharmacists
22 and physicians? And how was that conveyed in

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1 the consumer press? If it happens to be
2 related to children, how was that conveyed in
3 the parents' magazine?

4 It would help our capacity if we
5 did that followup. That is just me reacting
6 to, I think, as you say, we can have our
7 theoretical discussions, but if the practical
8 result is not what we want, how do we use that
9 to drive and change our practices?

10 MEMBER PETERS: I wanted to sort of
11 bring together a couple of comments that have
12 been made.

13 AnnaMaria I thought had a very good
14 suggestion around using a whiteboard and
15 coming up with very different categories of
16 types of risks that really happen over and
17 over again within the agency, but in different
18 ways each time.

19 MS. WINCKLER: Right.

20 MEMBER PETERS: So they are very
21 similar, but they are very different at the
22 same time.

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1 The rapid response team is also
2 developed in terms of taking kind of a best
3 guess at what is the best risk communication
4 here.

5 Baruch made a suggestion that
6 perhaps could follow up on the whiteboard
7 suggestion, which is not only identify what
8 those categories are, and not only make the
9 best guess as to what the risk communications
10 should be in order to promote the best
11 actions, for example, but follow up with
12 standard protocols for OMB clearance for that
13 type of risk category.

14 So that, ultimately, you can test
15 those communications and improve them on the
16 fly perhaps even, and use that knowledge to,
17 of course, improve the next one.

18 So Sally's example is one type of
19 risk. It is an emerging, very potentially
20 serious risk. Could there be a protocol
21 developed for that kind of communication,
22 which will happen again, where you can test

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1 communications as they are occurring in real-
2 time and understand what those messages are
3 doing, what actions they are promoting, how
4 well they are understood? Then use that the
5 next time.

6 MS. WINCKLER: That is very helpful
7 as we look at this, that distillation.

8 Let me go to the specific questions
9 which we have already been tackling. I think
10 we want to focus on these.

11 This is the time where I would
12 probably go join Nancy and support the
13 discussion because I have explained to you a
14 bit of what the agency is doing as it relates
15 to these strategies. You have had really
16 great ideas. The advantage to me sitting at
17 the table is then I also have my pen and can
18 continue to discuss.

19 So, if it is all right with you, I
20 will join at the table to continue to learn
21 from this discussion, because this slide and
22 the next one are really about questions that I

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1 think would help us.

2 In the capacity goal specifically,
3 what do we need to revise and what do we need
4 to think about, even building from the four or
5 five elements that you have already captured?

6 Okay?

7 CHAIRMAN FISCHHOFF: Added
8 advantage of letting you sit.

9 (Laughter.)

10 Mona is next.

11 MEMBER KHANNA: Thank you very
12 much, Susan. I thought the questions you
13 raised that you are looking to us to help
14 answer are very spot-on.

15 I wanted to paint kind of a context
16 because we are not operating in a vacuum when
17 we talk about getting information out there.
18 I wanted to just share with you all, some of
19 which you probably know, what is happening in
20 the media world right there. It is a sea of
21 tremendous change, as it is with many
22 industries.

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1 You asked a couple of questions.
2 You said, when do we speak, and you talked
3 about the rapid response team and the reach.
4 AnnaMaria mentioned the continuum of risk.

5 In terms of media, we have 28,000
6 media-related jobs that have been lost since
7 September of '08, mostly in print and
8 broadcast newsrooms, traditional newsrooms.
9 They are contracting and the volume of
10 workforce is decreasing. The only area in
11 terms of media that is really either staying
12 the same or expanding is going to be your
13 online media, so your resources that support
14 those departments or divisions, whether it is
15 a TV station or a newspaper or a pure online
16 media outlet.

17 Yet, at the same time -- and I am
18 speaking specifically now of broadcasting
19 because I think the volume of newspapers is
20 shrinking -- broadcasting, because of
21 unreliable and pricey regular programming,
22 newscasts are actually expanding.

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1 So you have a shrunken team of
2 people to put the news together, but you have
3 more time to fill. So content is desperately
4 needed, and lots of big cities have local 24-
5 hour news now that are coming up, even
6 emerging, even though there's so much change
7 in the industry. So I would say that content
8 is desperately needed.

9 So, to answer some of your
10 questions like, how do we reach, when do we
11 speak, rapid response team, I would propose
12 that it might not be a bad idea to do some
13 kind of version that is equivalent to the
14 emails that we get. I am on those mailing
15 lists, too, and I get every single recall and
16 every single communication that comes out of
17 the FDA that's meant for people who sign up
18 for these lists. So it is a lot.

19 But I am wondering if there could
20 be something where you could provide a daily
21 media update. The frustration I have with the
22 way the FDA is viewed in terms of how it is

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1 differently viewed than the CDC -- I think the
2 FDA has been stigmatized and it has had some
3 not-successful experiences in the past. So I
4 think there's a lot of work to be done in PR
5 for the FDA.

6 So, if you did something like this
7 and you came out more proactively, I
8 understand you need a rapid response team to
9 respond to issues that are the equivalent of
10 what the CDC is dealing with now with swine
11 flu. I guess the most recent would be the
12 pistachios and then the peanut butter before
13 that.

14 But, if you had some ongoing
15 communications and some ongoing suggestions to
16 fill some of these big news holes that are now
17 rapidly developing, I would propose that
18 perhaps it would raise the profile -- well, it
19 certainly would raise the profile of the FDA,
20 but, hopefully, in a good way, if you had
21 these ongoing communications.

22 I give a lot of talks to physicians

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1 and hospitals about how to deal with the
2 media, since I've been a full-time journalist
3 for almost seven years now and part-time
4 before that. One of the things that I say is
5 don't wait for that crisis. You have to
6 develop the relationship with the media,
7 whether it is your local newspaper or your
8 local television station or your local online
9 equivalent, when there is no news.

10 You develop that relationship with
11 them. So that when there is news that they
12 need to cover, they will think of you and they
13 will call you, and you are the subject matter
14 expert. If you are not an expert in that
15 area, you are the one that they will look to
16 to help point them to the appropriate
17 resource.

18 So I would think that if the FDA
19 could use these kind of quiet times when they
20 are not worrying about peanut butter and
21 pistachios, and develop ongoing relationships
22 with the media, that that, in fact, would help

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1 a number of things that we are talking about,
2 if certainly, of course, you have the capacity
3 to do so.

4 But, knowing that that might be
5 part of the strategic plan, you could build
6 that into the capacity you develop.

7 CHAIRMAN FISCHHOFF: Thank you.

8 So would you be thinking of --
9 Mona, one of the things that I have felt is
10 that we don't have, that the public often
11 doesn't have the context for what FDA does and
12 expects it to do the impossible. So I can
13 imagine a series of short, probably really
14 interesting stories on how food alerts, how
15 you gather the information, what the
16 difficulties are.

17 The kind of reporting that could
18 fill that dead time would really be
19 interesting and kind of get the word out
20 there. They're not probably hard. Somebody
21 could tell those stories really well.

22 MEMBER KHANNA: And the problem is

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1 that I think when this stuff happens, peanut
2 butter/pistachios, the first comment I hear
3 is, "God, I thought the FDA was watching all
4 that stuff."

5 Well, they are watching a lot of
6 stuff and they are doing a lot of stuff, but
7 we don't know what you're doing because you're
8 not singing your success stories and you're
9 not singing the responsibilities.

10 And it only works now because there
11 is so much air time to fill. It probably
12 wouldn't have worked 10 years ago or 15 years
13 ago. But I'm saying there is an opportunity
14 now that perhaps there wasn't in the past.

15 MS. WINCKLER: And if I could, that
16 is very helpful and fits in. We have just
17 been doing more of opening the doors of FDA to
18 the media and bringing them to our labs.

19 The usual question we get, or the
20 observation rather is, "Oh, I didn't know you
21 had scientists who did research. Why would
22 you do research?" And it is a teachable

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1 moment, but also giving them good visuals,
2 something other than the front of an office
3 building that just portrays a faceless,
4 nameless agency or a faceless agency with
5 three really familiar letters.

6 We have kind of taken a baby step
7 into that. This is an idea, and it does help
8 with capacity, because when you have that
9 foundation of knowledge, then they understand
10 what it is that we are trying to say and can
11 help us get the right message out in the
12 followup.

13 MEMBER KHANNA: Perfect. And one
14 last thing is you mentioned opening the doors,
15 and transparency, obviously, is very, very
16 important. But it would be very cheap, and
17 the return on the investment would almost be
18 priceless, if you hired a production team or
19 if you used the resources of HHS and shot your
20 own story. As long as it is educational and
21 not complete, outright, blatant propaganda, I
22 can almost guarantee you that it would be

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1 carried in most media outlets, just because of
2 that huge news hole.

3 MEMBER GOLDSTEIN: I think
4 capacity, obviously, it is an important piece
5 of what FDA does, the dissemination of the
6 information in an effective way.

7 As I think about what the real
8 priorities are, it brings me back to what
9 AnnaMaria said about the different areas or
10 the different levels of urgency when it comes
11 to disseminating information.

12 It leads me to think that part of
13 the strategic plan needs to really incorporate
14 that continuum, because you probably need
15 different strategies and different approaches.

16 You do need different strategies and
17 approaches to meet those needs.

18 During those more quiet periods, it
19 gives you a chance to think about the ways in
20 which you can build those platforms of
21 systems, if you will -- I tend to think in
22 systems -- where you can maximize and leverage

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1 your influence with that of the other agencies
2 again.

3 I'm thinking particularly of ways
4 in which you can partner with organizations,
5 professional organizations, existing
6 healthcare delivery systems, and particularly
7 for those circumstances where you're trying to
8 reach a specific population of patients.

9 So you have patients with chronic
10 illnesses who may be part of registries of
11 healthcare systems. I work at the VA. We
12 could tell you, we know who our patients are
13 -- I work in mental health -- who have post-
14 traumatic stress disorder.

15 If we knew a medication that they
16 were currently taking was now identified to
17 have some risk, we can communicate more
18 rapidly with that population than any other
19 healthcare organization probably in the United
20 States.

21 So why not have, as part of the
22 strategic plan -- and I saw; I was in there.

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1 It was great to see, working out some
2 relationship with the VA to have a way of not
3 only delivering a message, but then testing,
4 as Ellen was saying earlier, having as part of
5 your effort testing the strategy that was used
6 in that one circumstance to reach that
7 population of not only patients, but
8 providers, to see what can be improved upon
9 the next time.

10 So thinking about the different
11 levels of urgency, thinking about ways you can
12 partner to identify the audiences that would
13 be affected by the different levels of
14 urgency, and then building in a platform of
15 communication, testing, targeting, and
16 feedback, so that you can improve upon the
17 process along the way.

18 Making the dissemination process,
19 the bottom line is making the dissemination
20 process an iterative one, and part of the
21 science of what you are trying to enhance and
22 improve, using evaluation and studies to

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1 improve upon that process.

2 We can dive down and get even more
3 specific at some point. Maybe it would be
4 nice to have a session that focused on a
5 particular topic and allowed us to examine
6 that as a case example. I think we would all
7 learn a lot from that. We have so many
8 experts here at so many different levels. It
9 would be a fantastic opportunity for us to
10 tackle an issue, whether it is an acute issue
11 like how do we communicate about the -- at
12 some point in this epidemic, there's going to
13 be questions about vaccines. So how do we
14 communicate about the vaccines in a way that
15 is going to be most effective for the
16 population that is going to use it versus
17 taking something that we know is a chronic
18 issue that may not have a short timeline and
19 looking at it as well together?

20 CHAIRMAN FISCHHOFF: Can I suggest
21 -- I mean I like the idea of digging down.
22 Lee is concerned that we have conflict-of-

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1 interest issues that she needs to vet. So, if
2 we started talking about vaccines or
3 antivirals, it might mention specific
4 products. So maybe we will put our heads
5 together over lunch and see whether we could
6 define one of these issues that would stay
7 within our constraints.

8 MEMBER GOLDSTEIN: Just to
9 clarify, I don't mean necessarily today --

10 CHAIRMAN FISCHHOFF: Oh, okay.

11 MEMBER GOLDSTEIN: -- or tomorrow.

12 CHAIRMAN FISCHHOFF: I think
13 there's a few of you who would probably like
14 to do it right now. So let's wait at least
15 until after lunch.

16 MEMBER GOLDSTEIN: Okay.

17 (Laughter.)

18 I'm thinking of it as a process.
19 As a process of improving the dissemination
20 plan, it is to bring together experts to work
21 on those elements that might be included in
22 the plan, using this Committee potentially to

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1 do that in the future, not necessarily today
2 or tomorrow.

3 MEMBER LAWSON: I'm really
4 interested in the strategy to enhance
5 partnerships. I do recall at some point
6 within the agency that you did have an office
7 that focused on consumer initiatives, consumer
8 programs. It was an office that focused on
9 the health professional groups. I know, of
10 course, you certainly had a very strong
11 program with outreach to the media.

12 I'm not sure exactly how that
13 functions now; I suppose within the different
14 centers.

15 But I would strongly recommend that
16 you really look at the linkages with the
17 organizations, the consumer, health
18 professional organizations. They are such a
19 strong resource for all that you do.

20 As I listen to all of the comments
21 that have been made this morning, those
22 linkages are a great resource, one, in helping

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1 you with the messages, with the delivery, and
2 even the multiplier effect, when it hits.

3 So I think that is so important.
4 So I just would like to urge that you take a
5 look at how you can re-establish or strengthen
6 the linkages with those organizations, the
7 consumer base and health professional and
8 other groups out there.

9 MS. WINCKLER: If I may, that is
10 part of what we have been trying to do a
11 better job with through our external relations
12 folks and our Office of Special Health Issues
13 at the Office of the Commissioner, and then
14 also throughout the centers.

15 But we also struggle with knowing
16 what it is that the associations and those
17 organizations, what is the best way to get
18 that information? What is the best way to
19 present it?

20 So I think the associations will be
21 very helpful to us in the two-way
22 communication, both in being helpful in

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1 getting the message out, but also helping us
2 craft the message when we are about to convey
3 something that won't be understood by the very
4 people who we mean to influence.

5 That type of interaction is part of
6 what we want to pursue in that strategy, not
7 only what communication mechanisms do they
8 have, but how do we use their expertise? Then
9 this idea of using the healthcare delivery
10 systems as a mechanism to eventually reach not
11 only prescribers, but prescribers of specific
12 patients, and the patients, obviously, all
13 within the HIPAA requirements for protecting
14 patient privacy.

15 But is FDA getting the right
16 information to the people who use that
17 information? Because we don't change the
18 results. It is the prescriber or the consumer
19 who is changing their behavior. So we do see
20 significant value in the associations, and the
21 consumer organizations are looking for
22 thoughts on how we can better interact with

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1 those groups.

2 CHAIRMAN FISCHHOFF: Let's see,
3 Christine and then Musa and then Sally.

4 MEMBER BRUHN: I want to address
5 the idea of when do you speak. I think a
6 guideline that might be followed is, if you
7 had someone that you cared about that was of
8 this condition, when would you speak to them?

9 Because that is the role the FDA plays for
10 the entire population.

11 Although you don't know each
12 individual, you are the holder of information
13 that is critical to them. So you need to
14 think of them as though they were your own.
15 This is your mother. This is your aunt. This
16 is your child. What would you tell them and
17 how would you respond to that?

18 Then the whole concept of, what do
19 you tell them to do to control this risk? I
20 really appreciated Sally's concrete example.
21 What do you do and why, and how do you control
22 then the comments that may come from

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1 uninformed sources that raise fears that you
2 know are not valid at all?

3 Thinking today of the current issue
4 on whether we call it swine flu, which
5 everyone seems to want to call it, or what
6 others prefer -- what is it, H1N1? -- you
7 explain to them what the risk is and why it is
8 there, and then how to control it.

9 So in this concrete example, you
10 have people being concerned about, should they
11 eat meat products? Really, if they realized
12 that the virus was carried on moisture
13 particles from breathing, it was a respiratory
14 illness, the concept of not eating meat that
15 some people seem to bring about would be shown
16 to be totally irrelevant.

17 So that is, then, the value of
18 telling them why the risk is here and what do
19 you do then to control your risks. Of course,
20 there are specific recommendations that the
21 CDC has posted really very nicely on their
22 website for both your own family and then as a

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1 caregiver. I appreciated the specificity in
2 those recommendations.

3 Then to build on Mona's comments
4 about the value of using the media, the visual
5 image is so extremely powerful. I could
6 envision some talented artist showing little
7 flu particles on moisture floating in the air.

8 A creative person could make a visual picture
9 we would all remember, and it would be of
10 assistance in the current crisis as well as
11 ongoing crisis, as it would give the people
12 the understanding of what is going on. It
13 would empower them, then, to protect
14 themselves more effectively.

15 Then, finally, a last comment here
16 at this stage: using your partners, and I
17 really valued Mike's comments about using the
18 VA system. You certainly have individuals
19 right there who can be your target audience.

20 But I'm also recalling in some of
21 my reading interesting differences as a
22 particular message was conveyed to several

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1 different subgroups. Military personnel was
2 one, people who worked in the facility where
3 the experimenter worked, and then people from
4 the mall.

5 They responded differently to
6 different aspects of the message. They saw
7 risks differently. They responded to benefits
8 differently.

9 And the military in this case was
10 people who were currently active. So these
11 were primarily young men. So it might be
12 related to that military; age thing might be
13 more important than just military.

14 But use partners such as in this
15 case the VAs, but don't think they necessarily
16 reflect the type of response that would be
17 appropriate for the general population because
18 they might have specific past experiences or
19 current demographics that make them see and
20 respond to risks and messages differently.

21 So anticipate how there might be
22 differences and test your messages or your

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1 responses in a variety of demographic groups.

2 CHAIRMAN FISCHHOFF: Thank you.

3 We have a half an hour to go.
4 Before we go to the next -- it will be Musa
5 and then Sally -- let me ask the members to
6 look. You have in your folder, we have charge
7 questions which are meant to stimulate the
8 discussion for here. We have addressed some
9 of these issues, but just make sure that
10 you've got everything you have to say. They
11 are not restrictive.

12 Secondly, you have the slides from
13 -- you have the discussion questions on hard
14 copy. So we are not restricted to those
15 questions, but let's be sure we have had what
16 we have to say on them.

17 Okay, Musa, and then Sally.

18 MEMBER MAYER: I know that
19 uppermost in our minds are the most recent and
20 emergent crises that we are dealing with.
21 But, over the years, at least in my advocacy
22 work, I have been concerned about repeated

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1 episodes with drug safety and questions,
2 though they are lesser in the media, about
3 efficacy of drugs.

4 One of the things that has occurred
5 to me over the years in my -- I feel like
6 because of my involvement with FDA and the
7 things that I have learned about what levels
8 of evidence FDA accepts in terms of approving
9 drugs, and what we really know about efficacy
10 and safety at the time that a drug is first
11 marketed, I've been sort of privy to
12 information that the patients and public that
13 I work with does not have, simply does not
14 have.

15 They are operating in a different,
16 whole different level of what I think are
17 really illusions about safety and efficacy,
18 that when the FDA gives its imprimatur or its
19 approval to a drug, that means it is both safe
20 and it works.

21 There is this repeated experience
22 of betrayal that happens when serious safety

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1 concerns emerge, when drugs show themselves
2 not to be as effective as it had been hoped
3 that they would be. Somehow FDA always gets
4 the blame.

5 Yet, at the same time, and I see
6 this as part of the same dynamic, there is
7 this constant pressure to get drugs approved
8 sooner and with less evidence, actually, of
9 their efficacy and safety, which even
10 exacerbates the problem of how much we know
11 and how safe drugs are.

12 So it has seemed to me, and someone
13 on the Committee spoke a little bit earlier
14 about the uncertainty issue and how
15 uncertainty was such a major sort of subtext
16 of what it is like to be a consumer, and we
17 are all consumers.

18 Somehow FDA has to find a way of
19 doing some basic education to the public about
20 levels of evidence and how it is really a
21 societal decision about how and when we allow
22 products to be marketed and how much we know.

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1 It was a real shock to me to find
2 out that, when a drug was approved, that was
3 just the beginning of learning if it was safe,
4 and, in fact, it had only been tested in some
5 cases with some drugs that I've been involved
6 with on maybe a few hundred patients or less,
7 if it was an accelerated approval.

8 To what Mona was saying, there is a
9 tremendous need for sort of basic education
10 that would help media and it would help the
11 public understand, put in context the
12 emergencies that then later emerge about drug
13 safety issues.

14 So I'm not sure where I am going
15 with this, but if we are going to at some
16 future point drill down and consider specific
17 examples, I would like us to look at examples
18 also of drug safety because this will come up
19 again and again -- it is bound to -- as well
20 as issues of food safety and others.

21 Thanks.

22 MEMBER GREENBERG: Yes, jumping on

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1 that point, food safety and product safety,
2 which was an area I worked a lot on in
3 following the Consumer Product Safety
4 Commission's activities. Of course, they have
5 many, many recalls during the course of a
6 year.

7 We would try very hard -- and so I
8 am going to ask a question and I really don't
9 know the answer to it for purposes of FDA, but
10 we tried very hard to push the CPSC to push
11 manufacturers and retailers to find out where
12 those products were, if they could trace them
13 back, if it was a car seat.

14 A lot of times there was
15 information out there that said that this
16 individual had bought this particular seat.
17 We instituted a process that was put into law
18 just last year of having registration cards
19 for consumers who had bought the car seat or
20 the highchair that was ultimately recalled,
21 and then you could reach out to them. A small
22 percentage of people sent in the cards, maybe

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1 25 percent.

2 So my question with regard to the
3 FDA is you're working with doctors and you're
4 obviously working with device manufacturers
5 in the case of devices. Drugs are harder
6 because they are more widely disseminated.

7 But how much information is there
8 out there about who is actually taking the
9 drug, who is using the medical device? I mean
10 I am sure manufacturers are under obligations,
11 if it is a device issue, to reach out to those
12 who have a device implanted.

13 But how about prescriptions that
14 have been given to millions of people? How
15 much information do we actually have? You
16 want it to be, obviously, as targeted as
17 possible. I just don't know.

18 MS. WINCKLER: FDA would generally
19 not have access to that information. So we
20 would know about the use and some statistics
21 about how it is being used, but wouldn't know
22 who certainly. We have some sense of -- we

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