

1 Now what this ad did was to use
2 relative risk for the benefits and absolute
3 risk for the adverse events. We were able to
4 get FDA to take action on that drug, although
5 I was sort of surprised that -- at that time,
6 I thought there must be somebody at FDA who is
7 overseeing every drug ad and would
8 automatically pull that, but that wasn't
9 evidently how it worked. I was shocked to
10 learn how small the personnel in that
11 department was and how little they had to work
12 with in terms of overseeing that process.

13 So I am wondering if there aren't
14 some principles, some sort of best practices,
15 advertising principles, that could be
16 developed and laid out, such as the consistent
17 and responsible use of benefit and risk
18 information in advertising, as a part of that
19 particular initiative.

20 MEMBER GOLDSTEIN: Yes, I thought
21 there were other people.

22 I would just add to what Musa is

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1 saying about internal standards, because that
2 is something you probably have the most
3 control over. That is making sure -- and this
4 may be obvious, but I will say it anyway --
5 that the literacy level of the materials,
6 particularly those that are targeting
7 patients, are at a literacy level that is
8 appropriate for the population that you are
9 targeting; that there be translation of
10 materials.

11 That is a big task to do that
12 across all populations, but certainly coming
13 up with your own standards about how many and
14 how and who to involve as partners in that is
15 important.

16 I want to point out there are
17 already standards for health literacy -- and
18 we have heard about these before -- that have
19 been developed by a consortium of
20 organizations -- many of them are professional
21 organizations -- in association with agencies
22 like AHRQ. The Clear Communications Program

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1 that is part of the National Patient Safety
2 Foundation right now that was contributed to
3 by a number of organizations developed
4 standards for that.

5 As has been mentioned earlier, we
6 do want to think about -- this is another
7 strategy. I forgot which one right now. But
8 it is the one you mentioned about making sure
9 that the patient audiences and population
10 audiences on some level are addressed when
11 creating products and tools, and not just --
12 the whole idea that you have to have one
13 insert that is supposed to be applicable to
14 both clinicians and patients really just
15 doesn't make sense. We have heard a lot of
16 evidence about that over and over and over
17 again.

18 So that is a policy level,
19 obviously, issue that has to be addressed.
20 FDA can't do that alone. It has to come, I
21 guess, from Congress, but you can let them
22 know that it is not working. And we can let

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1 them know that it is not working.

2 I mentioned earlier the
3 opportunities as a policy to identify and work
4 with partners whenever possible to disseminate
5 the information that you have. I don't know
6 if you want to make that an internal policy or
7 look for a higher level to make that policy
8 for you, but I think that we need to make sure
9 that that is a part of the process that you go
10 through, identifying at all the different
11 levels that you mentioned, pre-, during, and
12 post-marketing, having those partners
13 participate in helping with the messages.

14 I know there are some regulatory
15 issues that get in the way of that because of
16 the requirements to keep some of that
17 information confidential. But, in terms of
18 principles, you can still develop ways of
19 working together with other organizations and
20 stakeholders, and think about it at all the
21 stages that you mentioned.

22 CHAIRMAN FISCHHOFF: Thank you.

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1 Maybe to pick up on AnnaMaria's
2 point, which several other people echoed, just
3 the sense of how important the outcome
4 measures are. In some sense, that is an
5 expression of your policy. What are the
6 outcomes that you want to affect and what are
7 your goals there?

8 Probably they are quite different
9 for what we called at an earlier meeting
10 persuasive and non-persuasive communication.
11 And maybe talk separately about each of them.

12 In the persuasive situations,
13 though, there's problems with a product and
14 you want people to act. It would be natural
15 to say, well, we want everybody to stop eating
16 this or to check with their doctor. But, as
17 you were saying, it is not realistic. The
18 realistic policy is one that could often look
19 pathetic.

20 You know, we're talking about hand
21 washing with H1N1. Well, I think the swine is
22 out of the bag, and I don't think we're going

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1 to get --

2 (Laughter.)

3 But, anyway, I'll try to model, so
4 we talk about H1N1. So you know there have
5 been studies in healthcare situations. Well,
6 you can't get more than 60 percent of
7 professionals looking at the disease, looking
8 at the risk, to wash their hands to a
9 standard.

10 I guess the epidemiologists tell us
11 there are situations in which, if you can get
12 -- you know, you have to reach everybody. And
13 there are situations in which if you can get a
14 certain percentage of a population vaccinated
15 for something, that will significantly damp a
16 disease, or a situation where you can get some
17 people to do it, to hear your communication,
18 to do it, and they will tell their kids or
19 their relatives, and so on.

20 So it seems like, as a policy
21 question, how do we come up with those
22 realistic, which are not so light that we're

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1 not demanding a lot of ourselves, but are also
2 realistic, because that realism sends a signal
3 to whoever else is responsible to say, "So
4 what we are going to do, we are going to get
5 people to wash their hands." Then they can
6 say, "Well, great. We don't need to staff up
7 our ERs because we're not going to have this
8 food-borne illness. You know, they have taken
9 care of this in the kitchen."

10 So the system depends on our having
11 a realistic signal. How do these numbers, how
12 do these goals get developed?

13 So I don't know if you have an
14 answer for that now, but it seems to me that
15 that would be part of the process.

16 And on the other hand, for the non-
17 persuasive, which in ways is intellectually
18 harder, where you want people to make the
19 decisions that are in their own best interest.

20 Let's assume we just stay on-label for the
21 people that you're actually talking to.

22 In effect, for me to make the right

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1 decision, I need to understand the risks and
2 benefits to the degree of precision that's
3 necessary for making the choice that maximizes
4 my goals. My goals, my risk tolerances may be
5 different than Mike's. And there may be
6 situations where I really just need a ball-
7 park estimate of risks and benefits, and it is
8 good enough. So it may make, actually, the
9 communication task much easier.

10 But how to set those policies in
11 terms of the goals, I think they're really
12 interesting questions, but really serious
13 ones, to be able to do the gap analysis, to
14 see who we're reaching and who we're not
15 reaching.

16 DR. SHUREN: Along those lines,
17 too, things we have been thinking about, and
18 would welcome input, suggestions, now or at
19 another time, is who we reach out to to help
20 us get that message across. I mean how we are
21 identifying the real communicators and the
22 change agents who, if we can reach them, they

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1 will carry that message through the right
2 streams, and we will get greater bang for the
3 buck. But that is a different kind of model
4 for the agency, but one that we are very
5 interested in pursuing.

6 CHAIRMAN FISCHHOFF: So you could
7 imagine, so one might imagine -- I don't want
8 to put you on the spot, but one could imagine
9 that actually for medical decisions your
10 audience is actually physicians, and that you
11 would like to see that you've got a
12 comprehensible product that most physicians
13 understand the risks and benefits well enough
14 that they can translate to the people they are
15 writing prescriptions or counseling before
16 implantation of a device. That would be an
17 interesting policy choice, who the target is.

18 DR. SHUREN: Well, and even taking
19 it to a further level, that there may be
20 particular then subgroups; there may be
21 particular healthcare systems; there may be
22 people in those systems who are really --

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1 they're the ones who people listen to. If we
2 have interactions with them, and they say,
3 "Yes, got it, and I'm going to put the word
4 out," we may be more effective within their
5 circle of influence.

6 CHAIRMAN FISCHHOFF: Or perhaps
7 people responsible for a formulary. If they
8 can understand it -- they've got their own
9 other sets of incentives, you know, that
10 they're exogenous to this system, but if they
11 understand the risks and benefits of competing
12 things, maybe that could be the goal as a
13 policy question.

14 Jacob and then Michael.

15 MEMBER DeLaROSA: In the industry,
16 we are known as KOLs, the key opinion leaders.

17 That is really what industry tries to find in
18 physicians, is the KOL. They get you when
19 you're younger, and as you're older, and then
20 there's older younger, et cetera, KOLs. Those
21 are the key opinion leaders. Then there's
22 some in different states and in different

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1 areas, and they are the ones that they focus
2 on them to spread the word on what should
3 happen.

4 MEMBER PETERS: Could I just ask a
5 follow-up question? How do you identify a
6 KOL?

7 MEMBER DeLaROSA: You smile.

8 (Laughter.)

9 No. The KOLs are identified, and
10 it goes back to Christine. You can go on
11 Google and you will get a thousand names. But
12 then there's the people that are actually
13 doing the writing and doing the presentations.
14 You identify those people by them giving a
15 speech, giving a talk, by data that they have
16 done, et cetera.

17 So they look at that, No. 1. No.
18 2, then, can he speak or can she speak? Can
19 they present? Are they open to hearing from
20 other people?

21 There's many people that, no matter
22 what, they always have their opinion, and

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1 their opinion is always right. These people
2 are open to hear from other people, to
3 understand. That's kind of what makes a KOL,
4 is all that encompassing, and then they
5 influence.

6 MEMBER GOLDSTEIN: I would agree
7 that that's an important strategy, to try to
8 identify influential people.

9 Another place to look is,
10 obviously, in academia. That is where
11 industry has looked before.

12 It gets back to the idea of having
13 a curricular process that includes the kinds
14 of topics that we are talking about.

15 In my organization, again, we are
16 an integrated health system where we have a
17 population that we serve. We have a Pharmacy
18 Benefits Management Group. Every time an
19 alert comes from FDA, they look at it first,
20 and then we get a VA-based alert that drills
21 down and tells us, me as a psychiatrist, what
22 implication that has for our patients.

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1 In some cases, they take it off the
2 formulary. In some cases, they send out
3 letters to all of their patients and tell me
4 that you can expect calls from those patients
5 within the next day, two, three days.

6 So, if we had that kind of a system
7 across the country, more than just the VA --
8 and we do; there are other systems that are
9 like that -- then those are the important
10 people, the ones not just on the Committee,
11 but in the process of helping to get the
12 messages out to patients. There are such
13 people.

14 It's called the Pharmacy Benefit
15 Management Group, and every VA has a
16 representative who is the key person. Then
17 every region of the country in the VA has a
18 manager that brings all those pharmacy
19 benefits people together.

20 Then, at a higher level, I'm
21 sure -- I'm not familiar with what's going on
22 up at the highest levels -- there's folks

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1 making those decisions probably every time
2 some new information becomes available. They
3 have their own process for making decisions
4 about how to influence the formulary and the
5 prescribing practices within that system.

6 DR. SHUREN: And I would say, along
7 those lines, we have been looking at, we
8 actually have a pilot underway with the VA
9 under an MOU we signed with them in which we
10 are giving our alerts, our health information
11 alerts, to them in advance at a point where we
12 think we are set on what we are going to say,
13 but maybe not every little word is exactly
14 right, and sharing with them so that they can
15 get a jump-start on preparing the pharmacy
16 bulletin, and have that ready to go when we go
17 out.

18 So that they can actually get that
19 message to their healthcare professionals.
20 Healthcare professionals are better positioned
21 to communicate with patients, and they can
22 make decisions regarding the formulary more

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1 quickly.

2 We are able to do that because it
3 is another government organization. So we can
4 share that information in advance and won't
5 otherwise have to release it.

6 The question is, what we are trying
7 to explore is, can we ever get to a place
8 where we could do that with other healthcare
9 systems also for sharing in advance? The same
10 idea.

11 MEMBER KHANNA: I'm glad you
12 mentioned that because I noticed in your
13 strategic plan that it was out there, not only
14 the VA, but it looks like you are doing it
15 with the DoD, too, obviously another
16 government organization.

17 But it also says that you are
18 working with AMA to develop the specialty
19 network. I believe it is probably for the
20 same reason, to develop that specialty
21 network. So if, say, there's device issues,
22 then you can trigger the network, that maybe

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1 if it is heart devices, Dr. DeLaRosa is in.

2 Again, I think a lot of this also
3 goes by word of mouth because I'm sure he's in
4 touch with colleagues who do the same kind of
5 work he does, and like Michael mentioned,
6 academic institutions.

7 I also think it would be nice to
8 develop kind of a hierarchy, like is this
9 information you want everybody to know, the
10 public, like tomatoes, peanut butter, spinach,
11 pistachios? We could go on. Or is this
12 information that you want maybe just the
13 providers to know first, perhaps with devices,
14 and then hope that they will be able to go
15 through their database and find the patients
16 who have the devices in them and inform them.

17 I know that I'm on the receiving
18 end of information lots of different ways, not
19 your generous email alerts that come out of
20 the FDA and other government organizations,
21 but also, obviously, when manufacturers do
22 voluntary recalls -- sorry to use that word

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1 again -- physicians get letters from that.

2 I also wanted to mention that just
3 the power of the internet -- and I know
4 government organizations I think are way ahead
5 in terms of using it, the AHRQ, at the FDA,
6 CDC, et cetera. But I belong to many
7 professional organizations, but the one that I
8 want to specifically mention today is the
9 Association of Health Care Journalists.

10 For example, going back to the key
11 opinion leader question, if there's a
12 journalist who is doing a story on a
13 particular health topic and wants an expert,
14 the first thing they will do is they will put
15 out a feeler to their colleagues who have done
16 probably similar stories and say, "You know,
17 hey, I'm doing a story on this particular type
18 of gastrointestinal device. Does anybody know
19 who an expert is?"

20 I have just been amazed that, when
21 the word goes out to all of these fellow
22 journalists, that the responses are quick and

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1 they are dead-on. Ironically, they are mostly
2 from academic institutions, not necessarily
3 the community-based physicians. I am sure
4 they are doing work, too, but I think more of
5 the cutting-edge, more of the key opinion
6 leaders, the thought leaders, are probably at
7 the academic institutions.

8 So I wouldn't discount the
9 professional associations as well. If you
10 want to get some word out to medical
11 journalists to have them vet it and get it out
12 to the public, there's a lot of medical
13 reporting associations.

14 MEMBER GOLDSTEIN: I was just
15 thinking about some other key ways to get the
16 message out to professionals. There are
17 intermediary organizations like the Medicare-
18 based organizations that do quality
19 improvement. I'm blocking on the acronym for
20 that.

21 DR. SHUREN: Quality Improvement
22 Organizations, QIOs.

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1 MEMBER GOLDSTEIN: Yes, QIOs.

2 Thank you.

3 As you know, they are funded by
4 Medicare. Their mandate is to help
5 particularly hospitals, nursing homes, home
6 health agencies, even practicing physicians,
7 adopt evidence-based guidelines, use
8 information technology.

9 They are funded primarily by
10 Medicare, but by other sources as well. They
11 go out to clinicians' offices just like
12 detailers do in industry, and they could carry
13 the message of drug safety and some of the
14 tools and resources that are developed as a
15 result of these efforts, and help clinicians
16 to use them. That is their mandate.

17 If Congress said part of their
18 mandate is also to carry the FDA message along
19 with the CMS message, then that might be a way
20 of partnering with an already-effective
21 organization that is designed to diffuse
22 innovation.

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1 CHAIRMAN FISCHHOFF: Let me just
2 ask the members of the Committee -- first of
3 all, some of you still have your lights on on
4 your speakers.

5 Second, take a peek at the
6 questions from FDA. Make certain we get all
7 the policy-related questions covered.

8 John.

9 MEMBER PALING: Since the FDA is
10 strategizing from a big picture, and, as it
11 were, starting again and taking a deep breath
12 and trying to put all the things into the
13 melting pot that might go in, I would just
14 like to add one thing that of itself is small,
15 but is an important mindset.

16 I've always been sad that there is
17 no better way of giving positive reinforcement
18 for good risk communication by the various
19 constituents who you administer. I would have
20 felt in a conceptual way it would have been
21 wonderful if the FDA could, but they can't,
22 provide some sort of annual forum for the most

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1 useful either clinician-focused or separately
2 patient-focused communications pieces that
3 incur risks and benefits.

4 That does many things. One, it
5 gives prominence and good public relations.
6 Let's just take a drug company as a case in
7 point.

8 For those that go out of their way
9 to try to show what they view as excellence in
10 that skill, it also encourages all the rest of
11 us to see what innovators can do, if they are
12 trying to do it.

13 And the other thing is, as Stephen
14 Covey, the author of The Seven Habits said, it
15 actually makes you as an individual better, me
16 as an individual better, if I say that I'm
17 looking to do this. It is just like a
18 psychological not trick, but it has benefits
19 all around.

20 So, although this may not be
21 possible right now, some organizations
22 possibly such as Sally's or some patient

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1 organization or some Web MD, or whatever it
2 would be, if you could facilitate possible
3 reinforcements for good risk communication, I
4 think that would be another strategy I would
5 at least like you to consider.

6 MEMBER MAYER: Perhaps this is
7 being done across the board in CDER. But one
8 example I know of that I think is particularly
9 effective is the head of oncology drug
10 products has been in the last two years the
11 major professional meeting, which is the
12 American Society of Clinical Oncology,
13 attended by 35,000-odd doctors, industry
14 people, advocates, and others.

15 They have been having advisory
16 committee meetings at the same place at the
17 same time, which is really useful. It
18 introduces physicians and others to the
19 advisory committee process. So the Oncologic
20 Drug Advisory Committee actually does its
21 business in front of a large audience of
22 interested people.

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1 And they also ensure that in the
2 curriculum of the conference itself there are
3 FDA-related issues. They are sort of hot
4 topics, things that many in the community will
5 be interested in.

6 It is a wonderful way, I think, to
7 get awareness out into the medical community.

8 If this isn't being done in other areas of
9 medicine, I think it really ought to be.

10 CHAIRMAN FISCHHOFF: AnnaMaria?

11 MEMBER DeSALVA: I'm glad that
12 Baruch asked us to revisit the list of
13 discussion questions because I almost
14 overlooked something important.

15 That is the questions that you have
16 posed with respect to emerging risk
17 information. You are asking us to identify
18 and discuss any principles or recommendations
19 derived from existing research for when it is
20 most appropriate to communicate with different
21 audiences about still uncertain or emerging
22 risks. I'm not sure we have really had that

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1 conversation or if you feel like you've had
2 any input yet on that matter.

3 DR. SHUREN: No, and, actually, I
4 would say those questions on emerging risk,
5 they are sort of a template of thinking about
6 even similar questions for the other topics as
7 well.

8 MEMBER DeSALVA: Okay. This is
9 such an area of critical interest. It is an
10 enormous area of personal interest for me. I
11 think it is fascinating and also just
12 incredibly topical. It is so critical that we
13 all get this right.

14 I wish I had the technical
15 knowledge to be able to say to you, "Here's
16 the research as I understand it and here's the
17 evidence and here's what I think it means." I
18 don't have that technical knowledge. I would
19 love to hear from others who perhaps do.

20 I think that FDA, though, is again
21 in an interesting position because you see
22 certain patterns. You know, you have the

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1 opportunity to kind of step back and say:
2 okay, what's the experience then? What are we
3 learning just anecdotally in terms of emerging
4 risk information? What are our stakeholders
5 saying to us?

6 I wonder if, as a next stage in
7 strategic planning, if you need to formulate
8 certain hypotheses that then can be validated
9 or looked at, and poked and prodded, in like
10 demonstration projects. Are there small
11 projects or pilots that can be done to test
12 certain hypotheses about the best way to
13 communicate emerging risks? And share that
14 with various stakeholders and allow that to
15 become a point of discussion, so that some
16 best practice begins to emerge.

17 There are probably other parts of
18 the community where there are points of view
19 developing about what best practice is or
20 could be. But it would be a wonderful step
21 forward to begin to formulate some really
22 intelligent hypotheses and test them.

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1 MEMBER PETERS: Just to follow up
2 on that, and I'm going to follow up in a
3 slightly different way, but then probably get
4 back to what AnnaMaria is saying.

5 When people have an emotional
6 reaction about something, which often happens
7 in emerging risks, one of the first early
8 building blocks of an emotional reaction is
9 surprise and a violation of an expectation.
10 The emotional reactions don't generally emerge
11 unless there is surprise.

12 You think about when a joke is
13 really funny. It is really funny in part
14 because it surprised you. They said something
15 sort of off-base somehow, and it violated an
16 expectation.

17 So one piece of perhaps
18 communicating about new emerging risks comes
19 much before the risk emerges. It is about
20 setting up expectations, setting up
21 expectations about how drug approval processes
22 actually work, and the idea that there will be

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1 emerging risks, at least for some drugs as
2 they come out into the marketplace. It is the
3 direct result of how the approval process
4 works. That is one thing, the sort of setting
5 up of more appropriate expectations, so that
6 people aren't surprised as much.

7 Then the second thing -- and this
8 is not an area where I know the research well,
9 but I wonder if someone here does. Has
10 anybody done longitudinal studies comparing
11 different ways of communicating, different
12 temporal patterns of communicating emerging
13 risks? I mean this is such a critical
14 question. I can't imagine it hasn't been
15 done, but it might not have been.

16 MEMBER DeSALVA: You know, I
17 thought we asked that question last year. My
18 sense, at least from the discussion that we
19 had at the time, my sense was it was such
20 early days that that work hadn't been done.
21 That was my impression.

22 CHAIRMAN FISCHHOFF: There are case

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1 studies in communicating about different
2 risks, but you're really talking about
3 tracking studies that will --

4 MEMBER PETERS: I'm talking about
5 real studies, not single anecdotes.

6 MEMBER GOLDSTEIN: The only work
7 I'm aware of that links that is talking to
8 individual patients about, when they have a
9 serious illness, about their own personal risk
10 and different ways of framing their risk. So
11 it is emerging for them because it is
12 uncertain and it is early on in their course,
13 and they are trying to make decisions about
14 different kinds of treatment.

15 Where they have looked at different
16 ways of providing that information, managing
17 their emotions, waiting rather than trying to
18 make the decision right away, it is pretty
19 clear you can't, for instance, develop a plan
20 with somebody when you've told them what their
21 diagnosis is because they stop listening to
22 you almost immediately, and they are not in a

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1 position to make a decision. It takes some
2 time for them to process the information.

3 So there's that kind of
4 information, but it is a different question
5 than an emerging new risk about a treatment,
6 but we can maybe learn from that other
7 research, too.

8 CHAIRMAN FISCHHOFF: I was thinking
9 about, well, what is science-based policy-
10 setting really? A lot of what we have given
11 you is a kind of a real politik of where are
12 the opportunities.

13 I would just add to that, among the
14 various people that you deal with, if there is
15 somebody who is really hurting, some industry
16 that is really hurting that would be ready to
17 deal and would like to run one of these
18 experiments, then I think a well-worked
19 example would probably desensitize some of the
20 other industries that are afraid of
21 communication. It probably works better than
22 people think.

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1 So I was thinking, well, what does
2 science-based communication mean? So this was
3 my take when I was thinking about this coming
4 in.

5 So one is, wearing my decision
6 science hat, I think the terms ought to be
7 well-characterized ones. So when I thought
8 about sort of the policymaking scheme that
9 AnnaMaria had, as I was trying to absorb, you
10 are basically talking about risks, but I felt
11 the benefits were folded in there. Because if
12 you have a really dangerous product, it
13 doesn't exist unless it is in stage three
14 because it already has a lot of benefit, but
15 things can go wrong there. You may still want
16 to do something about it.

17 So I would say, using decision
18 analytic terms, we have been trying to refine
19 those for three centuries. We more or less
20 have a vocabulary. If somebody thinks that
21 they've got their own way to analyze decisions
22 and it can't be translated into

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1 decisionmaking, then it is probably not
2 science-based.

3 A second thing I would look for is
4 whether, if we are talking probabilities,
5 utilities, you know, in that space there, do
6 we have a reasonable procedure for evaluating
7 them, figuring out what are the risks and what
8 are the benefits, what are the utilities that
9 people have?

10 If we are listening to our
11 audience, are we characterizing their desires,
12 their perceptions, in a scientifically-sound
13 way? First, it is kind of a theoretical,
14 methodological criterion.

15 The third is, can we, using this
16 model, predict its effectiveness? That is, is
17 it well enough specified that we can look in
18 the world and see what the outcomes are going
19 to be?

20 One could imagine that, both in
21 terms of the existing world -- you know,
22 imagine this is how we are regulating things,

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1 how many people, this is how we are going to
2 communicate. How many people are we going to
3 reach? Per dollar invested in communication,
4 what's the welfare and, you know, what's the
5 return in patient welfare or in agency
6 reputation?

7 Then we would also like to know,
8 what are the incentives that are created by
9 this scheme? So, I think other things being
10 equal, we would like incentives that lead the
11 people who provide these products to produce
12 products that have less risk and greater
13 benefit.

14 So a communication scheme that
15 showed disadvantaged products that are less
16 beneficial and riskier would be something that
17 we would want. We have science for
18 anticipating how different kinds of disclosure
19 will do it.

20 And secondly, internally, what kind
21 of incentives are we making for the creation
22 of information? So any regulatory agency or

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1 company has a staff that has built up
2 strengths in a particular market or regulatory
3 environment. They may be misstaffed for the
4 particular kind of challenges that you have.

5 So, unlike FDA, you find other
6 federal agencies that have no behavioral
7 capability at all, despite having large -- so
8 they don't measure the effectiveness of the
9 communication. They don't even know that you
10 could measure the effectiveness of their
11 communication. Or they look at one kind of
12 toxic end-point, but they don't look at
13 another because they have had a lab for 30
14 years that studies "X", and "Y" is an emerging
15 phenomenon and they don't have it.

16 So it is much more pleasant to look
17 at the incentives for the "X". In a sense, it
18 is much more pleasant to have the fight with
19 your external people, you know, the people you
20 are trying to regulate, and trying to force
21 them to do a better job. But, also, a
22 scientifically-sound approach would lead you

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1 to think whether the agency has the incentive
2 to grow with the times and produce analyses to
3 the level of precision that it can.

4 And I realize that that can't be
5 done -- from a decision theory perspective, I
6 want as much information as I need. I need to
7 look at the sensitivity of my decision. Once
8 I know what I want to know, I don't really
9 need any more information.

10 Now it may be that for regulatory
11 purposes you need that six significant figure
12 in order to close the case in court or shut
13 off some sort of political move. So it
14 wouldn't be a proper thing.

15 But I would like that the policy
16 ought to be one that would clarify what the
17 resource allocations would be, both internally
18 as well as looking at the incentives
19 externally.

20 Then one could think about, when
21 one is refining or developing the policies,
22 whether the people who have those skills are

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1 at the table.

2 And you could get way too much
3 precision in your risk analysis than you need.

4 I suspect that the ultimate decision analysis
5 is probably a whole lot closer to AnnaMaria's
6 scheme, which is get the basic categories up
7 there, think about your target audience, and
8 so on, then it is to an OMB-acceptable
9 cost/benefit analysis, which often has way too
10 much precision on a subset than you need for a
11 subset of the topics.

12 I've talked long enough either to
13 put other people to sleep or to give them a
14 chance to think about something else.

15 MEMBER MAYER: I was wondering if
16 it's completely outside the purview of FDA to
17 communicate other interventions that are
18 really not regulated by them, but that may be
19 of benefit to patients. There are any number
20 of products you regulate where the health
21 condition under question can also be
22 ameliorated by lifestyle changes, by changes

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1 in diet, exercise, all sorts of other
2 interventions.

3 If we are really talking about
4 clear communication to patients in a public
5 health sort of way, and we know that there
6 aren't really any other major sources of
7 public health information today, ought FDA to
8 also be communicating other strategies along
9 with the product risks and benefits?

10 What stimulated this was something
11 under Policy Strategy One, "when to include
12 the risks and benefits of not using particular
13 products associated with emerging risks."

14 I think it is obvious, but probably
15 should be said, that the risks of using, say,
16 drugs, the potential side effects for patients
17 are not present if there are other more
18 natural approaches. I don't mean products in
19 alternative, but, you know, losing weight,
20 exercising.

21 I guess I've made my point, but it
22 seems like there ought to be a place for that

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1 in policy, yes.

2 DR. SHUREN: The comments, I will
3 say, that folks are putting on the table raise
4 something that the agency finds challenging,
5 which is a culture of the agency. You have
6 highlighted one of them, which is that our
7 communications often are very product-focused.

8 As a public health agency, do we actually
9 think about our communications being more
10 public health-focused?

11 In that respect, it would be we are
12 dealing with people; if they have a particular
13 disease, how do we help them? How is this
14 communication helpful within the context of
15 that particular illness or wellness, if it be?

16 I did hear, too, I will point out
17 in terms of our ability to go out and sort of
18 use opportunities to put hypotheses on the
19 table and to test them. Certainly, in
20 clinical medicine you have raised off-label
21 use. Well, practice of medicine is to use a
22 product on-label and off-label. And in fact,

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1 clinicians don't just practice medicine; they
2 engage in experimentation all the time.

3 One of the challenges we hear today
4 is, how do you turn clinical practice from
5 experimentation into investigation? Capture
6 that information, so we learn from it. That
7 is sort of something I am hearing on the table
8 for the agency to consider.

9 We go out and we say a lot of
10 things, do a lot of things, but should we do
11 it in a more rigorous way, test it, and learn
12 from it, and having that learning feedback
13 model?

14 The other thing I heard here was
15 how we tap into what other people are doing by
16 way of innovation, moving away from a model of
17 very FDA-focused about what we should do and
18 sort of going out and saying: we don't have
19 all the expertise here. Let other people do
20 it. It doesn't matter. But let's be able to
21 sort of tap into that and then reward it when
22 we see it, so we encourage it.

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1 So that's terrific feedback.

2 MEMBER WOLF: I mean I think we
3 could spend probably the rest of the day
4 talking about pulling in what we know right
5 now about how to best communicate information
6 or what information is most valuable to
7 patients and families, and the like. A lot of
8 great points have been brought forward.

9 I think that one of the best things
10 that I've heard through a lot of the work on
11 the literacy agency has been this idea of
12 limiting and layering the content, so triaging
13 the message.

14 So I think it is great to keep on
15 talking and thinking about, "Oh, and give them
16 this, and how about that?" But, ultimately,
17 we have to come up with a clear, succinct
18 message.

19 Probably what is most important,
20 and I don't think I've heard this enough yet
21 today, is that, whatever you do, you need to
22 be very, very consistent. I think a lot of

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1 the problems that we have been starting to
2 identify is that there's such variability in
3 sources, even within -- so if FDA has a
4 template approach, that the type of content,
5 the amount of content, where you go,
6 everything becomes a routine. So any future
7 events can be expected, I guess, as far as
8 where to get the information, what information
9 I might get, where do I go to dig deeper for
10 more information as I need it.

11 I really think that the most basic
12 principle going forward is keeping the most
13 simple front-door or user interface at the
14 very beginning, and letting people kind of
15 gradually dig deeper, you know, get that New
16 England Journal article, that's great. You
17 know, if you want that level of evidence
18 that's equivalent to a physician package
19 insert and understanding chemical structures
20 of the drug and efficacy trials, by all means,
21 make that available to them. But that is
22 going to be at the end-point, not at the

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1 beginning.

2 So I get a little bit concerned.
3 I'm very disappointed in myself that I wasn't
4 able to make the earlier meeting in February.

5 But I get very concerned when we start
6 talking about putting a fairly sophisticated
7 amount of information and some quantitative
8 data at the very, very beginning with a lot of
9 individuals, which may not be the most
10 important or at least the most easily-
11 comprehensible information for people to get
12 into. It can be distracting.

13 We have learned a lot over the past
14 two decades from cognitive factors research,
15 not health literacy research necessarily at
16 the moment, on the negative impact of
17 distracting, less clear, or maybe not the most
18 directly relevant content to the main message
19 that you want to convey.

20 So the ordering of information and
21 making sure it can be consistent, I think is
22 what I would just leave my comment to.

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1 CHAIRMAN FISCHHOFF: Oh, Christine?

2 MEMBER BRUHN: One of the issues in
3 your policy here, the bottom one is "Assess
4 and approve FDA communications in policy areas
5 that have a major impact on public health."

6 Slipping through here, I couldn't
7 find the spot, but I know somewhere in the
8 plan there's a concern that, how do you get
9 people to return to choosing a product after a
10 recall is over? Of course, this is a food-
11 related incident.

12 I would like to point out that
13 consumers' failure to immediately buy a
14 product when the recall is over -- that is,
15 you look at spinach; it has taken a while for
16 people to come back to prior consumption --
17 should not be viewed as a failure, but rather
18 as an action by the public that is risk-
19 adverse.

20 In fact, if you consider that a
21 product line may have undergone repeated
22 recalls over recent years, and I am afraid

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1 that can be said for fresh produce and leafy
2 greens, it could actually and should be viewed
3 as a wise move by a cautious consumer.

4 So step back from considering it a
5 failure and use it as impetus for the industry
6 to address a wider range of activities in a
7 more effective manner to improve their
8 product, so it doesn't get in the headlines.

9 CHAIRMAN FISCHHOFF: I'm ready to
10 pick up on Michael's question of consistency
11 and link it to your question of organizational
12 culture. I don't know if this is a policy or
13 a strategy question, but one can imagine two
14 kinds of tensions. One is that often in some
15 organizations -- I think sometimes of there
16 being two communication skills. One is public
17 affairs, and one is public health. The public
18 affairs is about me, and the public health is
19 about you, the audience. You find that
20 tension in various organizations.

21 In an organization that deals with
22 something that could affect people's welfare,

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1 you really need both. You need sort of the
2 honest communication about the problem and the
3 risks and the benefits, and you need the
4 organization to put its best foot forward and
5 worry that it is presenting a consistent image
6 and it has defended itself in the court of
7 public opinion.

8 I see some of what AnnaMaria was --
9 I think some of your craft is actually
10 convincing people who are interested in public
11 affairs that they really need to do the public
12 health.

13 But it leads to very different data
14 collection. I mean, if it is just about me,
15 then I don't really need to do the risk
16 analysis; I don't need to pull those people
17 into the process to tell them my problem. I
18 just need to be able to spin it.

19 And I don't sense that that's a
20 problem at FDA. But it strikes me that that
21 is something that it is important to address
22 in the strategy, so that if the things get out

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1 of balance, if it is entirely driven by the
2 health people, and they forgot the agency's
3 brand, then you could get out of whack the
4 other way.

5 And the second thing is that --
6 maybe to pick up a point that I was making
7 before -- FDA has very strong -- FDA's
8 intended, you know, the ultimate goal is to
9 serve the public. FDA does have this very
10 strong scientific base, and it is a scientific
11 base that is in a way more focused, in many
12 ways more focused on risk than it is on
13 benefits.

14 Then it would certainly be nice to
15 have the production of information and its
16 summary that was driven by the consumers'
17 need, and not necessarily by the -- I mean, in
18 some sense, the technical staff, they know
19 where the action is; they know what they need
20 to get through.

21 But it would certainly be nice if
22 the framework that the technical people were

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1 providing information to was then upwardly
2 compatible with what goes out the door. So
3 the technical people will not be directly, you
4 know, unless they have a clinical practice,
5 they will not be directly communicating with
6 the public, but seeing these are the boxes
7 that we want to fill out. These are the
8 things that we need to tell people. It will
9 communicate to them what the mission is, just
10 as getting an orderly representation of
11 comparative risks and benefits will
12 communicate to the public what FDA is about.
13 So that strikes me as also part of the -- you
14 know, getting the agency on one page there is
15 part of the strategy.

16 DR. SHUREN: Yes, I have actually
17 often thought that we would do a better job in
18 our communication if we got rid of the
19 lawyers, we got rid of the scientists, and we
20 just hired a bunch of five-year-olds because
21 they will -- sorry, Nancy.

22 (Laughter.)

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1 MEMBER KHANNA: You just wrote
2 yourself out of a job.

3 DR. SHUREN: I know. I've been out
4 of a job for a long time.

5 (Laughter.)

6 CHAIRMAN FISCHHOFF: So let me
7 thank you for coming to us.

8 Let me thank everybody for their
9 comments.

10 Let's take a break. Let's take our
11 15-minute break since Nancy is here and
12 starting the next session. Let's pick it up
13 at 3:25.

14 Thanks, everyone.

15 (Whereupon, the above-entitled
16 matter went off the record at 3:13 p.m. and
17 resumed at 3:28 p.m.)

18 CHAIRMAN FISCHHOFF: Our next
19 session is on how to strengthen the science
20 supporting effective risk communication.

21 Tomorrow we will actually talk
22 about some specific research projects. Now we

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1 are talking more of the strategic
2 organizational goals.

3 We will have Nancy Ostrove, who is
4 Director for Risk Communication.

5 DR. OSTROVE: Hi, everyone.

6 MEMBER KHANNA: Could you stand up
7 please?

8 DR. OSTROVE: Pardon?

9 MEMBER KHANNA: I said, could you
10 stand up, please?

11 (Laughter.)

12 DR. OSTROVE: That is not funny. I
13 have lived with that all my life. That is
14 nothing new.

15 (Laughter.)

16 MEMBER GREENBERG: I feel your
17 pain, Nancy.

18 (Laughter.)

19 DR. OSTROVE: Thank you, Sally.

20 You know, I have a dog with a
21 Napoleon complex that is about this big, and
22 he has taken on like 60-pounders. And I call

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1 that stupidity, of course, but bad analogy.

2 MEMBER KHANNA: I only said that
3 because my term is almost over. So you have a
4 limited time period to get me back.

5 (Laughter.)

6 DR. OSTROVE: Well, I will have to
7 consider that and think about how to do that.

8 Actually, Mona, I don't get upset by that
9 anymore. And I think the major reason is
10 that, when I was in first grade and second
11 grade, there was always Elsie Sella -- I can't
12 remember her last name -- Essie Seller, I
13 think it was. She was smaller than me. So I
14 was not always the first one in line. So I
15 felt, okay, this is all right; I can cope with
16 this. And Essie, apparently, coped as well
17 with being the first one. So we did okay.

18 So, moving along, I am here to talk
19 about kind of the third goal. You may notice
20 that we didn't number the goals initially.
21 And in FDA's strategic plan, you can see that
22 we have Goal One, Goal Two, Goal Three, Goal

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1 Four.

2 I have to tell you, we went through
3 some real aggravation internally trying to
4 figure out how to order it. Because whenever
5 you have numbers, or even if you have letters,
6 there is an implicit ordering. What we wanted
7 to do was demonstrate, as we did with the
8 graphic, that these are really overlapping,
9 and it is very hard to separate out and to say
10 that one is more important than the other.

11 So I believe it was Lee's idea. We
12 decided to go without numbers, without
13 letters, and just say, okay, here's the
14 science goal; here's the capacity goal -- and
15 what was the third one? And here's the policy
16 goal.

17 Then, even when we got to the
18 strategies, we said Policy Strategy One, and
19 then you get kind of into an implicit ordering
20 and can't do anything about that. But we
21 figured at least at the higher level we would
22 try to avoid numbers and any kind of implicit

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1 ordering of the importance because they are
2 all important.

3 So this is the third one, which in
4 the actual plan is addressed first. But it
5 could be addressed at any particular time. It
6 is to strengthen the science that supports
7 effective risk communication.

8 It all comes back to the fact that
9 FDA perceives itself as a science-based and
10 science-led agency. Our belief that that
11 commitment to being science-based is not just
12 for product approvals, for instance, it is
13 also for our communication activities, to
14 point out that we support using the scientific
15 method to design and assess communications,
16 not just for other things as well.

17 So we had identified three specific
18 strategies that we believed would strengthen
19 the science of communication, risk
20 communication, at FDA. The first one that we
21 have here is to identify gaps in key areas of
22 risk communication knowledge and

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1 implementation and work toward filling those
2 gaps.

3 And in fact, one of the
4 deliverables from our perspective, and we will
5 be talking about this more tomorrow, is
6 putting together what is essentially a list of
7 research needs or a research agenda, and
8 prioritizing that research, both for our own
9 purposes in doing research, in conducting
10 research internally, and also for making
11 available to the private sector or to the
12 public in general, to encourage academics,
13 industry, anyone who is interested out there,
14 to consider FDA's needs in these areas when
15 they are planning their agendas for what they
16 intend to be doing in terms of research.

17 Now tomorrow we are going to be
18 raising this in more detail. For instance,
19 how much and what kinds of information do
20 medical professionals and consumers need in
21 order to make informed decisions, that is,
22 decisions that are basically to ensure their

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1 best outcomes?

2 We heard loud and clear about
3 providing quantitative information, but how
4 much and in what presentation format is ideal?

5 If, for instance, our regulations say that
6 information should be in fair balance or it
7 should be neutral, how should that be
8 operationalized? How do you most effectively
9 motivate consumers, especially when you are
10 talking about things like nutrition and
11 obesity, as obviously a huge issue both in
12 America and worldwide? How do you motivate
13 people to make the changes that they need to
14 make in terms of their diet and their activity
15 level in order to deal with that issue?

16 So those are all some of the
17 questions that are going to be raised that we
18 can discuss, we hope that you will discuss,
19 and you will give us feedback on tomorrow,
20 but, just in general, that is kind of a first
21 strategy.

22 A second strategy is to evaluate

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1 the effectiveness of FDA's risk communication
2 and related activities and monitor those of
3 other stakeholders. I think we talked about
4 this a little bit. Well, you talked about
5 this a little bit today already in the context
6 of capacity.

7 Again, this is one of the areas
8 where we really have a huge overlap between
9 the goals, where in order to really improve
10 your capacity, you need to know how effective
11 you are and how capacity relates to that. So
12 we need to have those evaluations.

13 Now we have, as I mentioned earlier
14 -- no, actually, I didn't mention this. The
15 Office of Women's Health, in addition to
16 providing information in different languages,
17 also consistently pretests its materials.
18 That is something that it does pretty much
19 without fail.

20 We are also in the process, just to
21 kind of tell you what we are doing at this
22 point, of looking at the impact of food

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1 recalls on the public's confidence in the food
2 supply and also its effects, that is, the
3 recall's effects, on home food safety and food
4 purchase behaviors. So we actually have work
5 that is being done now on that.

6 We also will be looking at how
7 retail establishments make decisions during
8 and after a recall, in terms of what they are
9 going to be doing with the recalled products.

10 Finally, and I think you have
11 already read about this to some degree in the
12 draft plan, the Office of Special Health
13 Issues has been working with medical
14 professionals, pharmacy professionals, a lot
15 of the professional groups, as well as
16 continuing its work with patient
17 representatives and those groups, to get
18 feedback and to figure how we can evaluate how
19 we are doing with regard to communicating with
20 those particular groups.

21 And to some extent, that office has
22 taken up one of the functions that we used to

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1 have that I believe Musa mentioned. We used
2 to have an Office of Health Affairs that was
3 really focused on dealing with health provider
4 organizations. That office kind of went away.

5 That function was taken up in the various
6 centers. But, recently, there has been a
7 recognition that there needs to be an agency-
8 based effort in that area as well. So we have
9 that kind of ongoing. But there's more that
10 needs to be done.

11 Finally, and I think this is
12 absolutely critical as well -- I mean I think
13 all of these are critical. You can get the
14 knowledge. You can do the science. But,
15 unless you take that information and you
16 package it in a way that it will be useful to
17 those who need to apply it in practice, you
18 might as well not have done it.

19 So that is something else that we
20 are also looking at, is how we most
21 effectively take the information -- well,
22 first of all, how we find out what our people

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1 need in terms of the science, what they need
2 to find out, and then how we take the
3 information that we have gotten through doing
4 the research and make sure that it is packaged
5 in a way and it is disseminated in a way
6 internally for sure, and perhaps externally as
7 well, depending on what it is about, so that
8 people use it, so that they find it useful and
9 they can put it into practice.

10 So, with that as kind of a very
11 basic overview, we get to the general
12 discussion topics that we have been kind of
13 addressing all day long. What strategies
14 could be further clarified to support the
15 goal? What strategies might we consider
16 adding to the goal? What additional
17 scientific questions need to be addressed to
18 meet this goal?

19 And as a kind of way of focusing on
20 a particular piece and getting you thinking
21 about specifics, but not meant to restrict you
22 to this as well, we are asking for suggestions

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1 or examples of ways that we can encourage
2 outside FDA researchers to pursue some of
3 these proposed research ideas, either with or,
4 more likely, without FDA funding, since we
5 have limited amounts of that and not a real
6 good mechanism in place for providing it.

7 So that gets us back to you, and I
8 will go sit down. If you have any questions,
9 I think I can answer them from there.

10 Thanks.

11 CHAIRMAN FISCHHOFF: Let's take
12 some clarifying questions. Lee and Nancy had
13 asked me, since this is something that I do,
14 asked me if I would give a few minutes
15 describing some alternative organizational
16 models. So perhaps we could take some
17 clarifying questions, and then I've got about
18 maybe five or eight, maybe 10, minutes of talk
19 that I will give.

20 DR. OSTROVE: And again, I
21 apologize. When I get up there, I just go.

22 Really, we really appreciate your

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1 doing this. This is something that we asked
2 Baruch to do because we believe that this is
3 something that we need to consider, a
4 different kind of model.

5 CHAIRMAN FISCHHOFF: So let me just
6 jump up and do that, and then I don't
7 interrupt.

8 Well, thank you.

9 So I prepared a few remarks and
10 some thoughts on how FDA might organize
11 itself. I think we actually don't have an
12 organizational scientist on the Committee. So
13 this is from somebody with advanced amateur
14 standing.

15 It seems to me if one wants to view
16 communication as a strategic goal, then you
17 need processes that will integrate your
18 communication with your analysis and
19 regulation, so that you tie -- this becomes an
20 integral part of the organization, not
21 something that is just at the end of the
22 pipeline. Secondly, you need the people who

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1 can do the work and are properly coordinated.

2 There's a few slides here that I
3 showed at our meeting last August. Not
4 everybody was there. Those who were here
5 clearly didn't forget a word that was said.

6 (Laughter.)

7 So you can find variance of this
8 among various organizations that deal with
9 risk. In the U.S. about 10 years ago, there
10 was a Presidential and Congressional
11 Commission on Risk. There are various
12 documents from the Blair government that are
13 very much in this spirit, the OECD.

14 The one I like best is from the
15 Canadian Standards Organization, which has
16 gradually been working its way through
17 Canadian government agencies and the external
18 stakeholders who work with them.

19 So the Canadians have this model of
20 risk analysis. It is probably not that
21 visible. But in the center, it says, it is
22 sort of a standard process for risk

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1 management. You initiate a process. You do
2 some preliminary analysis. Then you estimate
3 your risks, you evaluate them. That is, you
4 see whether they are commensurate with the
5 benefits. You do control strategies to get a
6 better deal for yourself. Finally, you have
7 action and then you monitor how well the
8 system is going. So that would be a
9 thoughtful way of doing it.

10 One thing I like about this,
11 between each of the stages, those little four-
12 way arrows say, well, go back if you haven't
13 gotten it right. You can go ahead. You can
14 go backwards or you can end because you can't
15 actually figure out how to analyze these risks
16 or bring them into line.

17 If you can't see it, on the
18 righthand side, there's the terms "risk
19 analysis," "risk assessment," or "risk
20 management".

21 So, conceptually, this is a fairly
22 common scheme. What I like about this is

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1 that, in addition, on the lefthand side, you
2 have risk communication connected with two-way
3 arrows to every stage of the process.

4 So it says that, when you are
5 starting to analyze a product of any sort,
6 that you ought to tell whoever your
7 stakeholders are that you are doing this, get
8 credit for doing it, and you ought to listen
9 to them, so that you are taking account of
10 their knowledge.

11 So if they say that, you know,
12 great for physiological effects, but there's
13 these psychological effects that we want to
14 consider, you ought to know that there are
15 people who are in this population who eat
16 something who might interact with people who
17 don't read this language, or whatever it is,
18 so that you understand the phenomenon that you
19 are dealing. Then it treats your public as
20 partners all the way through.

21 The Canadians have done really a
22 nice job. Health Canada has been in the lead,

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1 although the Canadian equivalent of the FDA
2 was the first to do it.

3 So, in my mind, this is what one
4 needs to do. One needs to have this
5 coordinated activity all the way through it.

6 So who do you need to do it? This
7 is one way that you could break this down.
8 You need people who really understand the
9 drugs or the food and the risks and the
10 benefits.

11 You need risk decision analysts who
12 will extract the information from that, as I
13 say, the fire hose of information that the
14 technical people will give you. What are the
15 few things that really matter for people's
16 decisions? You can't do that without having
17 listened to people already to see what is
18 important to them.

19 You need behavioral scientists who
20 will design and evaluate your messages and
21 will also help with the back way.

22 Then, finally, you need the system

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1 analysts for creating and using communication
2 channels. They are the people who do the
3 technical delivery, but also the people who
4 are in the public affairs office who are the
5 watchdogs for the regulatory things you need
6 to get right for your stakeholder relations,
7 and so on.

8 I believe that you need all of
9 those in order to do the job right. So you
10 don't want your psychologists inventing
11 medicine. You don't want your -- well, you
12 can read this.

13 This is what happens if one of
14 these skills are missing. Here's sort of the
15 reductio ad absurdum of what would happen if
16 you turned any of us loose. Just technical
17 experts, you would just get a teachable moment
18 and that is all that you would do.

19 So what are the models by which you
20 can bring these kinds of sciences together?
21 So I thought that the various things that I
22 have seen, that you think of like five ways

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1 that you could bring the missing kinds of
2 expertise into the system and then coordinate
3 them.

4 So I have called this "program-
5 level" -- I forget, somebody, maybe it was
6 Betsy who suggested the question, do you want
7 people in the individual programs? That is
8 what I meant by program level. You bring in a
9 behavioral scientist or a risk person if you
10 don't have it. Or, conversely, bring a
11 medical person into the public affairs office.

12 Do you want a core that is
13 someplace where you have residence expertise
14 in the risk analysis/risk communication
15 broadly defined?

16 Do you want, assuming that you had
17 the money that Nancy said you don't have, but
18 maybe if you made the case for it, you could
19 get the money, do you want to have competitive
20 grants whereby you would try to get people at
21 universities, think tanks, research institutes
22 working on your problem?

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1 Would you want to create centers of
2 excellence, as AHRQ is under the CERTs, and
3 other ones where you would get people
4 together.

5 And finally, do you want to
6 contract out for various services, which is
7 something that FDA does for various things,
8 including things in this area?

9 So I thought, well, what are the
10 positive and negative things about putting
11 communication scientists -- and by that, I
12 mean kind of the behavioral scientists, the
13 decision scientists who are most often
14 missing.

15 So if you put people in the
16 program, well, they learn the program and the
17 subject matter. They become experts in
18 devices or a particular class of food, or
19 whatever.

20 They develop working relationships
21 with the people there. So you are educating
22 the people you are interacting with

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1 consistently, and you are, again, learning
2 more. They learn to trust you. They know,
3 because you have relationships, so they think
4 you're not peddling something to them.

5 You could be very agile because you
6 are right there. A problem comes up. You may
7 be able to give some quick advice or run a
8 quick study, assuming you have OMB clearance.

9 On the other hand, you are likely
10 to be below the critical size to attract and
11 retain staff. Do you want to be the one
12 behavioral scientist in a very large army?
13 Who is going to go there other than maybe
14 somebody who is having trouble in the job
15 market or has a two-body problem in their
16 family? So it would be hard to get them and
17 sustain them.

18 The one person who represents a
19 discipline may lack either status or the
20 independence. They may be asked to say, you
21 know, "We don't really like this stuff. Show
22 me that it doesn't work." Or, "We really want

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1 to get this out. Come up with -- make this"
2 -- you know, you are more easily bullied if
3 you are in a particular chain of command.

4 You would certainly reduce the
5 opportunities for coordination across FDA, and
6 you might be helpless in terms of dealing with
7 the OMB restrictions on risk. We were talking
8 earlier today about what FDA as an agency
9 might be able to accomplish. You're trying to
10 get your study out. You probably don't have
11 the staff to do the paperwork.

12 Another alternative would be a
13 corps of kind of NIH, for those who are
14 familiar with NIH grants, if you are working
15 on -- I don't know -- Parkinson's, you might
16 have a corps, a biostatistics corps, people
17 doing different kinds of lab work, and a corps
18 of people who provide services.

19 You could imagine a strong
20 behavioral science, behavioral decision, risk
21 communication office that was on call for the
22 rest of the agency. So they basically just

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1 change the signs here and, you know, edit a
2 few words.

3 So, if you are at headquarters, you
4 may not understand -- it will take you longer
5 to understand the different programs. It will
6 be harder to make the relationships. You may
7 be bogged down. You know, as organizations
8 get bigger, they have their own consultative
9 processes that can be useful, but also take a
10 lot of time and suck the blood out of you.

11 On the other hand, they may be big
12 enough they even have status and independence,
13 and so on. So you could think of these two
14 models.

15 Or you could say, well, until we
16 solve the OMB problem, you say, well, maybe it
17 is just crazy to try to meet the American
18 public's needs with our limited ability to do
19 research. And you don't have enough people to
20 do the basic research on your problems. Maybe
21 we want to have a dedicated funding stream
22 that will go to people who will work with us.

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1 So, in the mid-1990s, the
2 Environmental Protection Agency built up a
3 decision and behavioral science program that
4 they teamed with NSF, which taught them how to
5 do peer review. It is totally vanished now,
6 but it was a nice program while it lasted.
7 They brought everybody together once a year,
8 so that the agency people got to talk about
9 their problems. It was really a nice program.

10 For a long time, NSF has funded
11 disaster research. The Disaster Research
12 Center at the University of Colorado has had a
13 summer workshop. The late Kil White started
14 it, I think sometime in the late 1960s, where
15 they brought in people from the practitioner
16 community and from the research community.

17 It was a separate budget, but you,
18 as a first responder, found out what had been
19 found there, and you told them: these are the
20 emerging problems. We have populations that
21 are this or our dams are no longer being
22 inspected the way they used to be.

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1 So that was what I was thinking
2 about, an external program that had some sort
3 of a ready contact. So, if you have this kind
4 of ready contact, these are like the EPA
5 program or the disaster program -- you, the
6 external researchers, would have those -- oh,
7 you know, I think these are the same points
8 for something else.

9 Well, what I wanted to say was the
10 good thing about that is they would learn
11 about your program, and then you would be able
12 to recruit people to it.

13 And I don't know what I did. I
14 think I did something wrong in cutting and
15 pasting late yesterday.

16 Maybe those do work. I don't know.

17 Anyway, I'm getting tired.

18 So you can fill it in as a homework
19 exercise. Think about how that would work.

20 (Laughter.)

21 Once a term, the mind goes blank at
22 the blackboard. This is my one time this

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1 term, I hope.

2 So another possibility would be
3 centers of excellence. We have the CERTs
4 doing pharmacological research. The
5 Department of Homeland Security has its
6 Centers of Excellence.

7 So the good part about them is that
8 they have academic pressure for innovation.
9 So you have people who are out there looking
10 for new ideas, interested in the new
11 challenges that you can bring them.

12 You might use them to recruit
13 people, graduate students, post docs, to FDA
14 problems to get a cadre of people who
15 understand it. They are large enough to have
16 the interdisciplinary teams that somewhat
17 mimic the kind of interdisciplinary work that
18 you have here.

19 On the other hand, there are the
20 academic pressures for innovation, which are
21 much narrower often than what you want. It is
22 the publish in particular journals that holds

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1 people back from really serving your needs.

2 It is very hard, if anybody is
3 interested in how the Department of Homeland
4 Security Centers of Excellence are going, it
5 is very hard to pull people close enough into
6 operations that they really understand what
7 it's doing.

8 I don't think that DHS has been
9 successful in doing it. It could be that
10 somebody else is doing it. I understand the
11 CERTs may be more -- but it is a real
12 challenge.

13 Then any large organization has its
14 own internal dynamics, and those may be
15 consuming in a way that distracts them from
16 what you are doing.

17 I'm thinking big because, if you
18 had a big plan, then maybe you could get a top
19 off of the budget. NSF's strategy for
20 increasing its budget for the last 25 years
21 has been to keep the disciplinary programs at
22 relatively constant dollars, but to pitch

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1 initiatives to Congress. They sort of
2 circulate them around the different
3 directorates. They say, "Here's this great
4 opportunity, something that we could do." So,
5 you know, maybe this is possible for FDA as
6 well.

7 Then a third model would be that
8 you have people who are kind of pre-vetted for
9 dealing with particular kinds of problems. I
10 am thinking particularly of problems that
11 recur, so somebody who can evaluate a
12 particular kind of product. So people who are
13 contractors, they will learn your programs.
14 Indeed, they develop the relationships.

15 They often, if they are
16 contractors, they will work faster than
17 academics, who have their own other things
18 that go on in our lives. A consulting
19 organization that has a big contract could
20 have a robust staff that are not civil
21 servants, and they may have other clients that
22 they can keep a larger staff.

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1 They can also work to scale. So,
2 as academics, we don't repeat ourselves. Much
3 of what you need is, in fact, repetition. You
4 say we've kind of got a protocol for doing
5 recalls for this and we need to know how it is
6 going to work there. You need the work to be
7 done to a publication peer-reviewable
8 standard, but it may not have the kind of
9 theoretical interest that an academic would
10 need to go in. So this is a niche that they
11 might fill.

12 So they may lack the status to
13 ensure sound design. Maybe the agency wants a
14 particular result. Then you are a contractor,
15 and they may be somewhat pressured in a way
16 that academics might -- we pride ourselves
17 that we aren't.

18 Second, if you are contracting it
19 out, then the expertise is outside of FDA. So
20 you don't have people who have a particular
21 skill who are coming to the meetings, who are
22 saying, oh, here's how a psychologist or a

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1 sociologist or an anthropologist, a decision
2 scientist thinks, to get that discourse, that
3 way of thinking into the routine discourse of
4 the agency.

5 Then somebody within FDA needs to
6 be managing those projects. Sometimes it will
7 be a burden, and sometimes it will be a joy.
8 It could be a plus or a minus.

9 Then I thought, well, what do I
10 think? So here's my weak recommendation, that
11 one could imagine a hybrid where you had a
12 corps of people who are really dedicated to
13 this and have some sort of routine
14 relationship. You know, some people are more
15 committed to some parts, some programs, than
16 others. You bring up some kind of a working
17 relationship. I think it would be a really
18 exciting place to work.

19 You have some external cadre of
20 people who are working on FDA-related problems
21 and are training graduate students who would
22 be really happy to come, who create the

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1 workforce that you need.

2 If anybody read, there was an op-ed
3 in The New York Times -- I don't know -- I
4 think it was one day this week, about the
5 demise of the university system, saying we're
6 training people for academic jobs that don't
7 exist, that won't exist at the rate we're
8 training, even when my generation retires.

9 But we're seeing really qualified
10 people, and if we elevated the status of the
11 sort of practical work, the mission-oriented
12 work that you do, that you could get people to
13 train. If there's the demand, there could be
14 the supply, if we were good about it.

15 And finally, you need somebody who
16 will produce the work on demand at the pace
17 that you need it. So, if there were the
18 resources -- I don't think this is expensive.

19 I think you could do this for single-digit
20 million dollars in terms of an increment, to
21 bring all of these capabilities in.

22 So here's some thoughts about how

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1 it is that we get the capabilities, just sort
2 of my tentative partial answer to Nancy's
3 questions on how do we make it possible to do
4 this.

5 Okay, everybody has a copy, a hard
6 copy.

7 The floor is open.

8 Okay, Michael and then AnnaMaria.

9 MEMBER WOLF: This is a quick
10 comment on the last slide that you had. I
11 think that's great.

12 Do you think that the nature of the
13 work that FDA does -- I mean it is unlike NIH.

14 Particularly, you have a true public health
15 service, and especially the emerging threat
16 kind of issue, that the competitive grant
17 mechanism -- is that one of the issues that
18 has been kind of a struggle?

19 Or, if you have work that you want
20 to get tested, if you want like to learn more
21 about building the science of risk
22 communication, I guess you can do it going

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1 forward. But, if there is just-in-time
2 questions or inquiries, or that kind of work,
3 can that be done in the timely manner that you
4 would want it to be done with a competitive
5 grant submission process?

6 DR. OSTROVE: You know, that is one
7 of the reasons that we kind of asked what some
8 of the processes are. When you say
9 competitive grants, I'm not familiar, for
10 instance, with using competitive grants. Is
11 it likely to be timely? Given kind of the
12 requirements, given how our Contracts Office
13 works, no, I don't think so.

14 I mean, because they have to deal
15 with contracts from across the agency, and
16 they just have a lot of work on their plate.
17 Nothing seems to be able to come out in a
18 short period of time, unless you are starting
19 at the very, very beginning of a fiscal year.

20 If you have money at the beginning of a
21 fiscal year and you know what you want to do
22 with it, that might be the only time that you

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1 could actually do that.

2 So I guess that would be a
3 possibility, but otherwise, in terms of fast
4 turnaround, we have no fast turnaround for
5 getting contracts out or competitive grants.
6 We have no fast turnaround, even where we have
7 generic approvals for getting clearance.

8 One of the things we would have to
9 look into is, if, for instance, there were
10 centers for excellence, whether that kind of
11 thing would entitle us to not to have to get
12 OMB clearance. I don't know, to be perfectly
13 honest with you. It would be something we
14 would have to look into.

15 So doing anything quickly, that is
16 one of the reasons why we have been looking at
17 our internal people or why kind of the idea of
18 using SGEs is, at least initially, very
19 attractive, because you don't need OMB
20 clearance.

21 MEMBER WOLF: Yes.

22 DR. OSTROVE: And, boy, that, in

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1 and of itself, is really attractive.

2 MEMBER WOLF: No, I mean I think
3 when I was hearing Baruch talk, I definitely
4 like the idea of having some link and the
5 hybrid model is very intriguing. But, for
6 like a fast recovery, like you need some
7 existing infrastructure with links in it like
8 centers of excellence or like the CERTs are,
9 or like some model like that, if you wanted to
10 go that route.

11 So I mean I can understand why you
12 have the current model now, I think now, after
13 listening to the presentation.

14 MEMBER DeSALVA: Baruch, something
15 about your presentation made me think of
16 another capacity-related question, which is
17 about information infrastructure. So, in
18 thinking about organizational structure and
19 getting the right mix of people, and the right
20 organizational strategy, it triggered a
21 thought about the information infrastructure
22 to improve risk communication.

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1 I am just wondering, I don't think
2 I saw that reflected in the plan as much, and
3 whether or not that is something that needs to
4 be considered in the next draft, or if you
5 feel like that has already been adequately
6 addressed.

7 But especially as we move more
8 toward like paperless models and new types of
9 information technology systems, is there a
10 need or an opportunity for the agency to take
11 a next step there from an information
12 infrastructure standpoint?

13 DR. OSTROVE: Is that a question or
14 a comment?

15 MEMBER DeSALVA: It's a question.

16 DR. OSTROVE: Yes, I think Malcolm
17 may have talked about this a little bit
18 earlier today. We are in the midst of kind of
19 assessing our various information
20 infrastructures. I think we recognize that we
21 have to do that kind of ultimately with
22 communication in mind.

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1 We are moving toward a much more
2 electronic-based system, but right now we are
3 not there. I think it is a very good point
4 that we definitely need to think about. I'm
5 not sure -- and it probably does need to be
6 mentioned in the strategic plan, yes.

7 MEMBER SLEATH: One idea I had,
8 Nancy, is back home we are always getting
9 alerts about how much money AHRQ has for
10 comparative effectiveness research and how
11 fast they have to spend it.

12 So, to me, risk communication falls
13 under some of their main areas of interest. I
14 wonder if someone high level at the agency
15 should talk to someone at AHRQ about having a
16 call for proposals in this area.

17 Then AHRQ has a study section and
18 funds them, and whatever. I don't know
19 politically how all that is done.

20 But when you asked the question,
21 how do you stimulate researchers to study this
22 area, one way to do it is to write an RFA, a

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1 Request for Applications, in risk
2 communication. Then you don't have to worry
3 about OMB if AHRQ is giving them the money and
4 that kind of thing.

5 I mean they really have a lot of
6 money. Like overnight, they got an influx.

7 DR. OSTROVE: Yes, I think it may
8 be restricted to comparative effectiveness
9 research.

10 MEMBER SLEATH: I've heard it is
11 not just comparative effectiveness about
12 drugs. It is comparative effectiveness of
13 interventions. I mean you could clarify,
14 could it be comparative effectiveness of how
15 you deliver risk communication to people?
16 That is how I would package it. Because to
17 me, that would fit, because people have said
18 it is broader than just drugs.

19 DR. OSTROVE: And that sounds like
20 something we should definitely look into. We
21 do have interactions with AHRQ. I mean there
22 is no question that FDA -- I mean FDA is on

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1 the CERTs, has representation on the CERTs
2 Board.

3 So I'm not the person, but there
4 definitely is that interaction. So it is
5 something that is definitely worth looking
6 into.

7 MEMBER SLEATH: One other place
8 would be NCI because I know that you have
9 probably worked with them as well, but they
10 fund a lot of communication research and are
11 interested in risk communication. Their
12 cancer centers that are funded by them have
13 corps that are just focused on dissemination,
14 because you also mentioned dissemination in
15 here. The dissemination, what I have been
16 told, doesn't have to be explicitly about
17 cancer.

18 MEMBER GOLDSTEIN: And just to
19 follow up on Betsy's comment, I do think both
20 AHRQ and the Cancer Communications Branch --
21 there's a separate Cancer Communications
22 Branch within NCI, and I think it is Bob

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1 Croyle who, over decades now, they have
2 developed a whole series of not only RFAs, but
3 also Centers of Excellence.

4 So the center of excellence idea
5 that Baruch was talking about I think is a
6 fantastic idea. There's no reason why it
7 couldn't center on risk communication around
8 drugs and devices and food.

9 So there is a real opportunity
10 there, especially with the confluence of
11 forces to put money into that specific agenda
12 with that tailored objective of the research
13 program, and have centers, not just one center
14 necessarily, but centers that would be renewed
15 competitively over time that would address
16 risk communication. That would be wonderful.

17 That is a wonderful way of getting the
18 benefit of that collaboration.

19 CHAIRMAN FISCHHOFF: And there's
20 probably a strong case for communication being
21 a factor in cost containment for people taking
22 things that they don't really need and don't

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1 really understand.

2 That is to say, not that you are
3 trying to discourage people, but if people had
4 a better understanding of things, then, at the
5 very least, they wouldn't be taking
6 antibiotics when they don't need it. There
7 are probably other things that are of marginal
8 benefit or, as Musa was saying, if they
9 understood it, they would see it is not as
10 good a deal as it is doing.

11 So my prediction would be that
12 better communication would lead to less
13 expense without sacrificing health outcomes.

14 MEMBER PETERS: This is just
15 following up with what a couple of people
16 started to talk about. Within NCI, there's
17 also the Tobacco Control Branch, which should
18 the FDA get regulatory authority over tobacco,
19 could potentially be a good partner.

20 There are other NIH agencies as
21 well. I have had some contact with -- and I'm
22 going to totally muck up their name, but it is

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1 basically there is one of the NIH Institutes
2 that has to do with, in part, eating
3 behaviors. I think it is -- does anybody know
4 which one this is? I can never remember what
5 it stands for.

6 So like the Challenge Grants had
7 one Challenge Grant opportunity that was
8 targeted to the FDA. It could be that some of
9 these agencies who share some common interests
10 might be willing to target, if not an RFA that
11 has money that goes with it, might be willing
12 to target a PA or part of a PA toward FDA
13 interests.

14 MEMBER WOLF: This is going out on
15 a limb, but in the context of trying to find a
16 way that the FDA can build capacity for
17 internal funding, so you actually hang onto
18 something rather than having to partner, or
19 maybe even be perceived as a weaker partner to
20 other funding agencies. It is funny when you
21 think that you've got a partner -- no offense
22 to AHRQ; I do a little bit of AHRQ -- because

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1 AHRQ is now having money, and AHRQ has always
2 never been really a place to have money in
3 recent years.

4 But does the FDA have a foundation?

5 DR. OSTROVE: Yes, in the FDA
6 Amendments Act, the Reagan-Udall Foundation
7 was formed. It is not fully operating yet.

8 MEMBER WOLF: So is that being
9 perceived as an opportunity to at least bring
10 in money?

11 DR. OSTROVE: Potentially.

12 MEMBER WOLF: Good. Okay.

13 DR. OSTROVE: Yes.

14 MEMBER WOLF: Do I want to know how
15 much money?

16 DR. OSTROVE: Like I said, it's not
17 really operating fully yet.

18 MEMBER BRUHN: Okay, I have a
19 question. What's AHRQ? These people that
20 have all this money?

21 MEMBER WOLF: The Agency for
22 Healthcare Research and Quality.

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1 MEMBER BRUHN: What are they? The
2 Agency --

3 MEMBER WOLF: The Agency for
4 Healthcare Research and Quality.

5 We are all smirking because they
6 have money now, right?

7 MEMBER DeSALVA: Are we addressing
8 the questions now? All right, I just want to
9 be sure.

10 One thought I had in Nancy's
11 section about research needs, and this has
12 been said to some extent already, and even in
13 prior meetings, but I think warrants some
14 emphasis for the strategic plan, is, of
15 course, to make sure that evaluation
16 strategies really look at the unintended
17 effects of risk communication.

18 So this is sort of a new day.
19 There are going to be new strategies, new
20 communications methods, new attempts to
21 mitigate risk. I suppose it goes without
22 saying that some of them could have an adverse

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1 impact.

2 You know, I have been hearing some
3 interesting anecdotes that have surprised me.

4 Some of the controls that are put in place
5 for the drugs that have an intense
6 risk/benefit profile, and require medication
7 guides or REMS, because of the burden
8 associated with working with those risk
9 mitigation strategies, sometimes alternative
10 methods will be used to treat those diseases
11 or treat those patients. Sometimes those
12 alternative methods introduce new or more risk
13 than just working with the approved product or
14 the approved indication.

15 So that is just one example. I
16 know there are many others. But it will be
17 important, I think, to identify the lessons
18 early and define what they are as part of the
19 strategic plan.

20 CHAIRMAN FISCHHOFF: How would you
21 go about doing that? I mean, what kind of
22 structure would you put in place for that kind

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1 of learning?

2 MEMBER DeSALVA: Well, I mean, you
3 know, Baruch, I'm not the research expert here
4 at the table, but to me it is an evaluation
5 challenge, and I'm sure that there are
6 specific evaluation methods that would be
7 appropriate for the major strategies that FDA
8 uses to communicate risk, and then, also,
9 secondarily, the strategies that the industry
10 is asked to employ.

11 Then there may also be like some
12 real-time surveillance; there may be a way to
13 monitor and identify what's happening in the
14 real world and report that back in a more
15 qualitative way.

16 Maybe you all would be in a better
17 position to advise than I would on that.

18 CHAIRMAN FISCHHOFF: Yes, I was
19 thinking more of, where would you put that in
20 the process rather than what would be the
21 specific techniques?

22 MEMBER DeSALVA: Oh, I see. In

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1 the strategic planning process or --

2 CHAIRMAN FISCHHOFF: Yes. Yes.

3 MEMBER DeSALVA: Well, I see that
4 as belonging in this research section. In
5 other words, how do we make policy and
6 strategy evidence-based? Part of the evidence
7 that needs to be considered is, what are the
8 impacts, the effects, all the effects, of risk
9 communications? So, to me, that lives in the
10 research and evaluation portion of whatever it
11 is FDA finalizes as a plan, but it touches all
12 the other aspects as well.

13 MEMBER GOLDSTEIN: I'm thinking
14 now about systems-related research questions
15 that we were talking about earlier. I know we
16 will talk tomorrow more about the matrix
17 really of different levels of research. I
18 think it is really great that we have those
19 questions.

20 In terms of partners again, I'm
21 thinking about work that is going on not just
22 in the NIH or even in AHRQ, but in other areas

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1 to improve the quality of medical care. These
2 are projects, some are funded by the agencies
3 we have talked about, but some are funded by
4 other groups like the Robert Wood Johnson
5 Foundation comes to mind, where they are
6 trying to tackle the problem of obesity
7 particularly.

8 They have had a lot of experience
9 with tobacco control interventions and other
10 interventions to enhance chronic care. They
11 have supported large trials of interventions
12 that try to improve the quality of chronic
13 illness care.

14 So they have methodologies and
15 strategies for designing and developing and
16 evaluating those kinds of large-scale
17 campaigns to improve care. It is slightly
18 different than improving care, but it is
19 improving one aspect of the messaging and the
20 communication that consumers and patients are
21 receiving.

22 So, in terms of methodological

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1 assistance, partnership, even potentially
2 funding, some of the foundations might be
3 other sources to help you to answer and
4 address these questions.

5 CHAIRMAN FISCHHOFF: Nancy, does
6 FDA have a process for doing projections of
7 workforce development? Like the IOM
8 periodically has reports on what we need in
9 terms of physicians in various categories,
10 nurses we need in different categories. Is
11 there that kind of planning process at FDA
12 that would need to sort of recognize these new
13 categories and needs to be brought into it?

14 DR. OSTROVE: Well, I'm probably
15 not the best person to ask that, but Malcolm
16 would have been.

17 But there is workforce planning.
18 That is a very good point. I think that, in
19 putting together this kind of focused
20 strategic plan, that is one of the reasons
21 that we felt that we needed to coordinate with
22 the Strategic Planning Council and the other

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1 groups. Because, as Malcolm pointed out, the
2 kind of goal No. 1, that whole strengthening
3 FDA, that involves some of those issues and
4 some of those areas in terms of workforce.

5 But I have to say that, in a recent
6 surge, and I think we talked about this
7 probably the first year we met, I don't think
8 there was a recognition at that point of the
9 need for social and behavioral scientists, nor
10 has the Fellowship Program necessarily kind of
11 incorporated that.

12 But part of that may simply be a
13 function of kind of the small number of
14 individuals who would work as mentors, who
15 would be able to work as mentors in a
16 Fellowship Program, if you were looking for
17 people who had that kind of expertise.

18 So I think that it is something
19 that we need to make sure that it is
20 coordinated, essentially, with the larger
21 strategic planning activities that the agency
22 is undergoing.

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1 MEMBER GOLDSTEIN: Just one more
2 idea in terms of potential partners, OBSSR,
3 the Office of Behavioral and Social Science
4 Research, which is part of NIH, they're
5 developing their new research agenda with new
6 leadership. This is an opportunity to
7 influence that process.

8 So they actually cut across all of
9 the different NIH institutes and advise --

10 DR. OSTROVE: Yes, we have had some
11 interaction with them --

12 MEMBER GOLDSTEIN: Well, good.

13 DR. OSTROVE: -- under their
14 previous leadership.

15 MEMBER GOLDSTEIN: Yes.

16 DR. OSTROVE: I really appreciate
17 the feedback on kind of the second discussion
18 topic in terms of encouraging outside
19 researchers and collaborating with other
20 groups. This has all been extremely helpful.

21 I'm not sure if I'm in the position
22 to be asking this question.

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1 We had kind of the other discussion
2 topics as well concerning any strategies that
3 need to be further clarified or ones that we
4 might consider adding or additional scientific
5 questions.

6 I would just want to make sure that
7 you guys are all comfortable with that. I'm
8 not begging for critical feedback here. If
9 you are comfortable, that's great, but just to
10 remind you that those questions are on the
11 table as well.

12 CHAIRMAN FISCHHOFF: I think we've
13 all worked pretty hard, the audience as well
14 as the panelists.

15 I'll make this a last call for
16 comments.

17 Mike?

18 MEMBER GOLDSTEIN: I think you did
19 a really nice job with the specific strategies
20 and identifying the layers of science
21 strategies that are needed.

22 I just want to again emphasize the

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1 value of effectiveness research -- we have
2 talked about it -- and looking at the
3 practitioners, the end-users of the service.
4 In some cases, it is consumers, but in some
5 cases it is clinicians out there.

6 The science of effectiveness
7 research has evolved and the idea of working
8 with groups of practitioners, hoping not only
9 to conduct the research, but also to inform
10 the research. So it is the idea of practice
11 the research rather than research in practice.

12 So there's some folks -- this is
13 AHRQ again -- that developed the network, I
14 mentioned the Primary Care-Based Network.
15 They are using those to gather questions, not
16 just serve as sources to answer the questions,
17 but as networks to do the research.

18 You could go to those groups of
19 researchers and ask them what their needs are
20 and ask them what kind of questions they would
21 think are important in having these
22 discussions with patients. They are using

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1 both hats, their clinical hat and their
2 research hat, in those settings. That is one
3 idea.

4 And just one model that we haven't
5 talked about -- we talked about a lot of
6 different models. There's the model that has
7 been utilized to evaluate research at the
8 practice level, which is the REAIM model that
9 I could point you toward. It has pretty much
10 been adopted by NIH, and especially NCI, in
11 testing the effects of interventions that are
12 delivered at the practice level.

13 REAIM just stands for Reach, and
14 then Effectiveness, which is based on
15 controlled trials; then Adoption, to what
16 degree does the end-user, say physicians in
17 practice, utilize the innovation?
18 Implementation, to what degree is it
19 implemented as it was designed? And then
20 Maintenance, which is after you walk away from
21 your initial training, et cetera, to what
22 degree is the behavior maintained by the

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