

1 really wouldn't have much of that information.

2 So we try to leverage and get the
3 information through the intermediaries and the
4 healthcare professionals. I say
5 "intermediaries" with respect as the learned
6 intermediary.

7 But we don't have much of that what
8 in a food context we would call trace-forward
9 information about the ultimate consumer.

10 So it is trying to influence and
11 getting to the right audiences, and using the
12 organizations who may represent those patient
13 populations or using the health systems. It
14 is part of why we try to make sure that, when
15 we say, "Here's an action that we are taking,"
16 who are the targeted healthcare professional
17 involved, if there are healthcare
18 professionals involved, and the patient
19 populations that we would want to reach. Now,
20 with the reminder about the health systems are
21 the health systems and what information do
22 they have.

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1 I was reminded in the Salmonella
2 Tennessee outbreak in February of 2007, I had
3 a colleague who was working at an emergency
4 room in New York City. A couple of weeks
5 after the outbreak, she was just venting and
6 said, "You wouldn't believe how many people
7 had Salmonella poisoning on Valentine's Day.
8 And if had only known what peanut butter it
9 was that was contaminated, we could have
10 helped some people triage." She said, "So it
11 was too bad that we didn't know what peanut
12 butter caused the problem."

13 What I knew is that we did know on
14 February 14th exactly what brand was
15 associated with the contamination and had
16 disseminated that information, but hospital
17 emergency rooms weren't on our distribution
18 list. For a food recall, I think it just
19 wasn't part of a specific outreach and saying,
20 oh, it's right, because the intent was we're
21 warning consumers not to use this specific
22 product. We wanted to make sure healthcare

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1 professionals knew.

2 So it was a learning experience,
3 and we probably did get to the association for
4 hospitals and emergency rooms, and all of
5 that, but it was about eight o'clock at night
6 and it was one of those where we probably
7 should have had a mechanism to use that old
8 technology and just send a fax into the
9 emergency room. Maybe in the current
10 environment, the fax would get more attention
11 paid to it than the 1,384 emails that came
12 across.

13 But that, for me, it just struck me
14 as a lesson to learn, and then to incorporate
15 the learning from it.

16 CHAIRMAN FISCHHOFF: It strikes
17 me, on this last question, it strikes me that
18 maybe there's a kind of capacity that we might
19 need; actually, to do something on the science
20 of distribution. That is, I think there is an
21 evolving practice, and we see mistakes, and
22 then we learn it.

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1 But there are people who study
2 networks and could perhaps help FDA
3 rationalize its set of partners and also
4 identify those people who are outside of all
5 networks, or at least outside the conventional
6 networks, who might otherwise be left behind.

7 My guess is that industry knows
8 something about this, although the people who
9 get left behind may have less, too. They may
10 have fewer resources, so they may not be an
11 industry specialist.

12 But it seems like some kind of a
13 systems analysis of who gets what for
14 different categories of messages with what
15 speed, and how we need to patch that, it is
16 probably worthy of some permanent capacity to
17 study how well the current system works, who
18 gets left behind.

19 At our last meeting, we saw people
20 had put quite a bit of effort into figuring
21 out how many people get consumer medication
22 information with their pharmaceuticals. So

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1 this is a well-functioning system, and even
2 there I think it was 75 or 80 percent of
3 people get -- I forget the number, but not
4 everybody gets that piece of paper.

5 So you guess on these more chaotic,
6 informal networks of peanut butter lovers that
7 we probably have something to learn there.

8 MEMBER GOLDSTEIN: I just want to
9 second a point that Musa was making about some
10 more general educational efforts that FDA can
11 help support through, again, partnerships, not
12 do it by themselves.

13 But we could certainly educate
14 consumers generally about how to understand
15 efficacy and how to understand risk and
16 benefit.

17 We could also help healthcare
18 providers learn how to talk to their patients
19 more effectively about that. There is
20 evidence that they don't do a very good job
21 right now.

22 There's also evidence that there

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1 are gaps in the curriculum. I know most about
2 the medical school curriculums, but there
3 isn't enough in there about public health in
4 general, but, also more specifically, about
5 engaging in educating their patients about
6 risks and benefits and helping them to make
7 informed, shared decisions.

8 So, to the degree that FDA could
9 partner with other government agencies to help
10 support the development of curricula to train
11 healthcare professionals to address these
12 issues with their patients, that would be a
13 worthy long-term investment that would help
14 raise, I think, the receptivity of a whole
15 population of commissions who are out there to
16 respond when there is a need to get a message
17 across. They will know how to do it. They
18 won't be starting from scratch.

19 MEMBER DeSALVA: That actually
20 prompts me to think of something very
21 practical about the plan, and that is that,
22 typically, when strategy changes, as it does

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1 in a strategic plan, the story changes, too.
2 So there would be perhaps an opportunity in
3 the capacity section of the plan to look at a
4 refresh of FDA's core messaging around risk
5 management, risk communication, and also what
6 the role the FDA plays in communicating about
7 risk.

8 So I know that has been in play,
9 but to refresh it and to really make it even
10 better as part of this plan would be a good
11 idea.

12 MS. WINCKLER: And if I could put a
13 fine point on that, it strikes me, combining
14 those last two observations, that one of our
15 core messages is often: talk to your doctor,
16 pharmacist, or other healthcare professional.

17 But if we haven't helped explain to them what
18 it is that should be done, I'm not sure we
19 have helped anything.

20 CHAIRMAN FISCHHOFF: Sokoya, then
21 John, and then Betsy.

22 MEMBER FINCH: I want to speak upon

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1 partnerships. I enjoyed the story you told.
2 The only thing that I can think about in terms
3 of enhancing that to prevent the crisis on the
4 14th, where the information comes down and one
5 hand not knowing -- I was thinking that it may
6 be really wise to have a group of diverse
7 partnerships that are outside of the box that
8 we have, so to speak.

9 I was sitting here trying to think
10 of who could that be. But it needs to be
11 someone or organizations that have common
12 threads, a common mission like the FDA.

13 I think that once you pull those
14 individuals, those partnerships together, once
15 you sit around the table, then solutions will
16 come out that may not come out with this
17 group, so to speak, because you all are trying
18 to solve one problem.

19 Again, I can't think of any other
20 institutions, public or private, that would be
21 a part of that group, but it needs to be
22 outside of the box that would give you more of

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1 a positive outcome to the solutions you are
2 trying to reach at in terms of when to say it,
3 who to say it to, how to say it.

4 MEMBER PALING: I would just like
5 to add a further dimension to the suggestion
6 that you might get added benefits from
7 linkages with consumer organizations. I think
8 we all love the idea that you get more input
9 from more people, as best you are able to do,
10 in making your decisions in a practical
11 manner.

12 I ran an environmental group. One
13 of the things we learned there is that, in our
14 efforts to incentivize businesses, it matters
15 little how powerful the EPA's public relations
16 machine is or what Sierra Club does or what
17 Greenpeace hangs from their loft.

18 What matters more is if someone who
19 is like them, and thereby has an inherent
20 trust, if someone begins to take even minute,
21 small steps, conceding that there is an issue
22 and this is what they are doing about it.

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1 I relate that to you because in our
2 world we find it is far better to get small
3 businesses making small decisions, however
4 inadequate the perfectionist might see them to
5 be, because they, in practice, have more
6 influence.

7 So I bring that to you and
8 immediately see the relevance because, if you
9 do both get more people who are co-opted as
10 special government employees, if you also saw
11 it as an opportunity to influence the public
12 from those people who are most likely to
13 influence individuals, it might reinforce your
14 endeavors.

15 MEMBER SLEATH: I just wanted to
16 make a comment on increasing involvement in
17 behavioral science staff. I know you
18 sometimes have intern programs that are really
19 useful. So that is one idea I thought of.

20 Also, maybe post docs, you know,
21 people that have trained with experts in
22 communication, et cetera.

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1 Then another thing that I think
2 would be helpful from a prior meeting is
3 making sure there's statistical review, like
4 you have done for the new drugs. I found that
5 helpful. I was on a committee that was
6 deciding to approve or not approve a new drug,
7 and the fact that it had a rigorous
8 statistical review as well as a scientific
9 review, I think the same standards have to be
10 for this type of research as well.

11 I want to second what Michael said
12 about curriculum development because I don't
13 think there is good information out there in
14 this area or curriculums. The only thing I
15 can think of that is out there is Pfizer has
16 something on their website that somebody
17 pointed out to us before.

18 CHAIRMAN FISCHHOFF: Well, let me
19 set a good example then and give you opinions
20 on discussion topic to bullet two.

21 So it asks, for those who don't
22 have it, it says, "What types of questions can

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1 we reasonably answer using in-house surrogate
2 audiences or variations on consumer
3 satisfaction surveys or focus groups?"

4 So three thoughts: one is that FDA
5 has a very diverse workforce, not so much
6 geographically and professionally. So you
7 could characterize the workforce here and know
8 what you're missing. Somebody probably has
9 those numbers on top and can figure out a way
10 to routinely supplement it.

11 Second, I would personally
12 professionally be skeptical of consumer
13 satisfaction surveys. People really don't
14 know what they need to know. We, the experts,
15 know what they need to know. So you could
16 feel like you have been well-informed and
17 still missed it.

18 That was Musa's examples of people
19 who thought that they were fortunate to get
20 treatments and discovered later that important
21 information was missing. So I wouldn't put
22 very much there.

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1 I think consumer satisfaction
2 things are one of those things that it is
3 easier to rig than others. We can create
4 tests that people or things pass or that they
5 fail.

6 Third, within the social sciences,
7 focus groups, at least in the social sciences
8 that I'm familiar with, focus groups are not
9 used as a testing mechanism with any rigor.

10 If anybody is interested, there is
11 an article by Robert Merton, Public Opinion
12 Quarterly, 1988. Send me a note; I'll send
13 you a file.

14 Merton has been attributed as the
15 inventor of the focus group as part of the
16 American Soldier Project during World War II,
17 and was asked to give a talk at a meeting
18 celebrating the 40th year of focus groups. He
19 said he hadn't tracked it. He said that the
20 current use of focus groups as a source of
21 evidence, as opposed to as a source of
22 hypotheses, he thought was just totally

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1 inappropriate.

2 What he had originally invented was
3 the focused interview, which is "focussed"
4 with two "s's" for some Merton-esque reason,
5 which is something like the cognitive
6 interviews that people sometimes use as kind
7 of one-on-one, think-aloud, test-these-
8 materials, meant to simulate something like
9 the experience of an individual grappling with
10 a piece of paper or a type of message, and
11 that that was typically used as formative, but
12 you can get some kind of testing evaluation.

13 He said sometimes, when they were
14 rushed, they would do focused groups just to
15 get a lot of opinions quick. But he thought
16 in the focus group it was impossible to hear
17 anybody to the end. There are things that
18 people say in a focus group that they don't
19 say otherwise.

20 In the social sciences I know, you
21 could not publish a paper with focus groups as
22 evidence of what people believe. So they can

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1 be a way of generating ideas quickly. There
2 are some things that are processed in groups.

3 If you could get a group with a composition
4 within which things are processed, and get
5 that process moderating in a way that mimics
6 the way the group does, which is a very tall
7 order, you might be able to get some evidence
8 from a focus group.

9 She's got a PC. She's got to
10 reboot. It will take us until noon. I'm a
11 Mac person. I've seen the commercials.

12 (Laughter.)

13 Musa?

14 MEMBER MAYER: Well, while we are
15 waiting --

16 CHAIRMAN FISCHHOFF: I've seen the
17 rebuttal commercials, too.

18 (Laughter.)

19 MEMBER MAYER: I just wanted to
20 respond to Baruch and the focus groups. I
21 agree completely and don't really see the
22 advantage of a focus group as a means of

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1 getting the kind of information you are
2 talking about, about communication.

3 It seems to me that one could
4 accomplish a lot using scenarios, typical
5 scenarios. In other words, asking a large
6 number of people, be they staff, special
7 government employees, or if it is not a time-
8 sensitive situation, maybe even going outside
9 and doing some more formal research on this.

10 Doing some sort of model
11 communications for given scenarios and asking
12 people what they understand, if we say this,
13 what does it mean to you?

14 I mean there are others on the
15 Committee who are far more knowledgeable about
16 how to do this, but I think the critical issue
17 is selecting the people that you ask
18 appropriately, so that you are getting the
19 kind of cross-section of populations that you
20 really need to get. Can you get that from FDA
21 staff? I would sort of be surprised if you
22 could. To me, that is in a way the most

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1 important thing, is that you ask the right
2 people.

3 MEMBER DeLaROSA: And in regard to
4 asking the right people, I think the FDA has
5 many talented people, but I think it is
6 imperative that, when you ask a question, it
7 is important to ask the people who are
8 actually doing it in regard to giving the
9 medicines, putting in the devices.

10 You know, I get many calls from
11 many companies in regard to product, in regard
12 to opinion. I think when something does come
13 out in regard to the question of a recall for
14 a product that is implanted or a new valve, et
15 cetera, that besides talking amongst the
16 scientists within FDA, how do we present this
17 idea, I think it is important to go outside
18 and ask the people who are actually putting
19 them in what their opinion is on what is going
20 on, and who they are putting them in and who
21 they are prescribing.

22 MEMBER PETERS: I had two comments.

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1 One is I agree with what Baruch said in terms
2 of sort of what you can get from these
3 different kinds of panels. You guys know
4 that; you are scientists, too.

5 I would encourage something that we
6 brought up in a previous meeting, which is I
7 really believe you guys need to have some kind
8 of serious discussions at higher levels
9 probably than perhaps you guys about OMB
10 clearance and about how to get some more
11 general protocols passed through that would
12 allow you to do faster research with better
13 samples. I think that is critical for your
14 capacity issue in terms of understanding how
15 to best communicate to people and to improve
16 those communications over time. That is my
17 sort of first big comment.

18 My second comment is a question and
19 a followup. How big a sample can you guys get
20 in-house? How many people?

21 DR. OSTROVE: Well, we don't know.
22 I mean it will really depend on what the

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1 issue is and how many people we would think
2 are appropriate.

3 We have, for instance, a lot of
4 people who work in kind of administrative
5 positions. The agency is large. So,
6 conceivably, we could get a fairly large
7 sample. But that is also going to be
8 dependent on their supervisors and whether
9 they can take the time out. So there's
10 logistical concerns as well.

11 MEMBER PETERS: There's also one
12 other issue that I haven't heard anybody bring
13 up. Ideally, like Musa said, you would get a
14 wide variety of people who differ on a variety
15 of different dimensions, maybe including
16 testing them for numeracy and literacy.

17 Are there any potential issues for
18 an employee who gets identified in terms of
19 their numeracy and literacy levels or
20 something like that? It is something you want
21 to think about in terms of their careers
22 because you don't want to harm somebody.

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1 MEMBER GOLDSTEIN: Yes, a comment
2 on that same bullet about customer
3 satisfaction surveys. I would agree that
4 satisfaction alone is problematic, but you can
5 get very valuable information, particularly if
6 you are looking at, again, a specific
7 population, a targeted population, of patients
8 about their response to a given intervention,
9 dissemination, intervention.

10 Asking them concrete questions
11 like, "Well, did you read it? Did you get it?
12 Did you understand it? Did you act on it?"
13 or even more open-ended questions about, "What
14 did you do? Did this help you?" Those kinds
15 of things can be very valuable in evaluating
16 the impact of something that you have
17 delivered, an intervention. It may be less
18 effective in the planning process.

19 But, if you get very specific about
20 the questions and you're not just asking about
21 likability, but asking about what they did or
22 didn't do, that can be much more valuable.

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1 CHAIRMAN FISCHHOFF: Christine and
2 then Lee.

3 MEMBER BRUHN: In some cases, there
4 is evaluation already available on messages
5 that have been publicly presented for a long
6 period of time. I can think of one message
7 that on the surface looks excellent. It has
8 both benefits and risks of a particular
9 consumption. But, when the target audience --
10 this is for pregnant women -- when the target
11 audience was then interviewed as to, "What do
12 you take from this message?", and through
13 focus groups, and then through a large survey
14 by another group, "What have you done since
15 you've seen this message?", the risks were
16 huge in these people's minds. The benefits
17 were not seen well or at least not
18 internalized.

19 And a product that could offer
20 benefits was ignored because of the potential
21 of risk of overconsumption. So, instead of
22 eating a moderate amount of this health-

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1 promoting product, they stopped consuming it
2 entirely.

3 So that goes back to evaluation. I
4 know that is part of your plan as well, the
5 importance of evaluation. But you are
6 thinking of messages as you are framing them
7 now, but I would like to point out the value
8 of going out and seeing what is already being
9 distributed and how has that come, and then
10 consider reframing a message so that the
11 benefits are seen and acted upon in what might
12 be considered a more rational approach.

13 CHAIRMAN FISCHHOFF: Thank you.

14 Lee?

15 DR. ZWANZIGER: Thanks.

16 I just wanted to mention three
17 things quickly.

18 One, there is a set of keys that is
19 at the guard's desk. If anybody finds they're
20 missing one, you might want to check there.

21 Two, we don't have a cafeteria in
22 this building. Probably the closest place is,

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1 if you go upstairs and look just slightly to
2 your left as you go out of the building, there
3 is a place across the street. You will have
4 to show ID again as you get into the building.

5 The guards are doing their level best to help
6 us all quickly.

7 Third, as usual, I will just remind
8 Committee members that we need to stop
9 Committee discussion until we come back
10 online, so that it is all held in the public.

11 Thanks very much.

12 CHAIRMAN FISCHHOFF: And we'll
13 start again at one o'clock with our open
14 public hearing.

15 Thank you all.

16 (Whereupon, the foregoing matter
17 went off the record for lunch at 12:03 p.m.
18 and resumed at 1:06 p.m.)

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1 information may include a company's or group's
2 payment of your travel, lodging, or other
3 expenses in connection with your attendance at
4 the meeting.

5 Likewise, FDA encourages you at the
6 beginning of your statement to advise the
7 Committee if you do not have any such
8 financial relationships. If you choose not to
9 address this issue of financial relationships
10 at the beginning of your statement, it will
11 not preclude you from speaking.

12 So we are fortunate to have one
13 speaker today who is Jeffrey Secunda from
14 AdvaMed.

15 You can come to the floor mike over
16 here.

17 Welcome.

18 MR. SECUNDA: Good afternoon.

19 My name is Jeffrey Secunda. I am
20 Vice President for Technology and Regulatory
21 Affairs at AdvaMed, the Advanced Medical
22 Technology Association.

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1 AdvaMed is the leading trade
2 association representing the manufacturers of
3 medical devices, diagnostics, and health
4 information systems. Therefore, that is my
5 disclosure.

6 I appreciate this opportunity to
7 address the Risk Communication Advisory
8 Committee in regard to the Draft Strategic
9 Plan for Risk Communication.

10 AdvaMed applauds the Food and Drug
11 Administration for completing the Draft
12 Strategic Plan published on April 15th. The
13 draft sets forth a well-thought-out,
14 aggressive plan to improve FDA's risk
15 communication policy, capacity, and the
16 scientific basis of the agency's risk
17 messaging, which is critical to the public
18 health.

19 I would like to address two basic
20 policy issues outlined in the strategic plan
21 and part of this morning's discussion.

22 First, policy strategy No. 3 calls

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1 for FDA to, quote, "re-evaluate and optimize
2 policies for using partnerships and other
3 leveraging activities to facilitate effective
4 communication about regulated products."

5 Furthermore, this strategic point
6 acknowledges that critical communications
7 should be tested prior to use and that sharing
8 messages before issuance with stakeholders
9 could provide timely and useful feedback,
10 improving the accuracy, relevance, and
11 effectiveness of the message.

12 Capacity strategy No. 4 calls on
13 FDA to clarify roles and responsibility of
14 staff involved in drafting, reviewing,
15 testing, and clearing messages. Furthermore,
16 this strategy point states that, depending on
17 the product and issue, reviewers may include
18 physicians, pharmacists, biologists, chemists,
19 pharmacologists, nutritionists, engineers,
20 communication professionals, attorneys,
21 compliance officers, and policy analysts.

22 AdvaMed believes that manufacturers

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1 of products affected by FDA risk
2 communications should be routinely involved in
3 the development and evaluation of the risk
4 communication. This is analogous to the
5 development of risk information that
6 manufacturers develop and submit to FDA for
7 all pre-market applications.

8 AdvaMed requests that manufacturers
9 be added to the list of stakeholders and
10 knowledgeable parties that are consulted by
11 FDA in the development of risk communications.

12 FDA should have a clearly-defined
13 policy that acknowledges the usefulness of
14 engaging industry to facilitate effective
15 communication about regulated products.

16 Secondly, AdvaMed once again calls
17 on FDA to use accurate and understandable
18 language in all press releases and other risk
19 communication. Although the term "recall" may
20 have its place in the agency lexicon, it is
21 generally understood by the public to be
22 synonymous with removal. Recalls affecting

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1 foods and drugs which have a limited useful
2 lifetime generally do require removal when
3 safety problems are identified.

4 Devices, however, fall into several
5 categories of recommended actions that are
6 elucidated in the risk communication. Such
7 categories include: stop using a device, seek
8 medical attention immediately. Evaluate
9 performance of device at next scheduled visit
10 to physician. Change setting on the device at
11 next scheduled visit to physician. Confirm
12 the device settings, and possibly, in the case
13 of a diagnostic test, repeat the diagnostic
14 test.

15 Terms such as "notice,"
16 "correction," and "removal," coupled with
17 appropriate adjectives such as "urgent" or
18 "critical" are precise and widely understood.

19 The term "recall" should not be used in risk
20 communications when it will confuse the target
21 audience and obscure the intended message.

22 Thank you for your attention.

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1 CHAIRMAN FISCHHOFF: So let me
2 just say thank you for your comments.

3 We have a little extra time because
4 we only had one speaker from the public.

5 AnnaMaria DeSalva has offered to
6 walk us through the kind of strategic planning
7 that she would do with a client like us, and
8 we are waiting for some of her materials to
9 come.

10 So let's have a little open
11 discussion for the Committee until the
12 materials arrive. So we can talk about
13 anything within our charge questions.

14 Let me also throw out the
15 possibility that we have at our option to
16 provide non-binding recommendations to FDA.
17 We have done it at least at our last two
18 meetings, maybe our last three meetings.

19 I think we ought to have
20 recommendations at a fairly high level in a
21 way that will help provide the agency with
22 guidance in its work. Perhaps, as is the case

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1 of the meeting today, the FDA has been working
2 on the strategic -- many people at FDA have
3 been working on the strategic plan for quite a
4 while. I think that it helped them that we
5 recommended that they see it through, in
6 addition to all of the detailed comments that
7 we have made, some of which have found their
8 ways into their discussion.

9 So if people can have some ideas,
10 then maybe we will spend a little time talking
11 about that, kind of sort of a small number of
12 recommendations that we think would help FDA.

13 Maybe I will just kind of open the
14 floor to that.

15 Ellen?

16 MEMBER PETERS: I would just
17 reiterate something I said before about
18 looking at the higher levels of FDA perhaps
19 working together with higher levels at some of
20 the NIH organizations with OMB in terms of
21 clearance, to be able to actually test
22 communications.

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1 CHAIRMAN FISCHHOFF: I would say I
2 would second that.

3 Are there other suggestions for
4 recommendations? Or maybe we could have a
5 little -- please.

6 MEMBER GOLDSTEIN: Are we just
7 focusing on the capacity one right now?

8 CHAIRMAN FISCHHOFF: Well, we ought
9 to do the things that are on capacity.

10 MEMBER GOLDSTEIN: Sure.

11 CHAIRMAN FISCHHOFF: But if you
12 have been thinking ahead, and just say
13 something you would like people to be thinking
14 about for a later part of the discussion, it
15 would be nice.

16 If we get recommendations on the
17 table now, I can think about some drafting
18 overnight. There are a couple of things we
19 are only going to get to tomorrow. So I guess
20 I would welcome anything, you know, pacing it.

21 MEMBER GOLDSTEIN: So my
22 recommendation is just a more specific one

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1 than the strategy that is listed related to
2 collaborating with organizations. It would be
3 to collaborate with organizations who are
4 involved in dissemination research,
5 particularly dissemination within the context
6 of the healthcare system.

7 That would be AACPR, particularly
8 their efforts to promote patient safety, and
9 it would be organizations that are healthcare
10 organizations themselves like the VA, the
11 Bureau of Primary Health Care, other systems
12 of care that are government-supported where
13 there is already a relationship and an
14 opportunity to test strategies for
15 dissemination of innovations in either risk
16 communication messaging or training clinicians
17 to use decisionmaking tools or a whole number
18 of innovations and dissemination.

19 So that is the more specific
20 recommendation, based on strategy six, and it
21 relates to five also, capacity strategy five.

22 CHAIRMAN FISCHHOFF: Okay, maybe I

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1 will just throw it open while we are waiting.

2 It's coming. It's coming. Let me just throw
3 it open to a general discussion and any other
4 topics, things people didn't get in this
5 morning.

6 Betsy?

7 MEMBER SLEATH: Well, one thing
8 Susan asked this morning was our input on,
9 should they hire staff across the centers or
10 centrally? I just wondered if people had
11 opinions on that.

12 CHAIRMAN FISCHHOFF: Do you?

13 MEMBER SLEATH: Not really.

14 (Laughter.)

15 That's why I was asking. I don't
16 know.

17 MEMBER DeLaROSA: You know, there
18 are so many experts. Just like on this panel,
19 there's experts. I believe that the FDA,
20 again, needs to tap into that expertise across
21 the country.

22 I checked my email during lunch,

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1 and I had two inquiries in regard to two
2 different devices from two different
3 companies. Again, they want the opinion.

4 I think the FDA, it is imperative
5 that they, again, look at the experts that are
6 out in the world and ask them, not just in the
7 U.S. but around the country, when it comes to
8 questions when things come up. I think it is
9 very important. So I don't necessarily think
10 that they need to hire these people, but
11 contract with them and get them involved.

12 My other point that I want to bring
13 up is in regard to, again, back to our first
14 meeting. There really needs to be a point
15 person from the FDA and, again, a person who,
16 when there is something that comes out, a
17 recall or something big, just as we have right
18 now going on with this virus, and it is going
19 to be an issue right now with vaccine. We are
20 going to a level 5, and if it goes to a level
21 6, it will be an issue how that vaccine is
22 going to be distributed, and FDA will need to

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1 get involved.

2 I think it is important, again, to
3 have a point person to calm the fears and to
4 be able to discuss this thing, so the
5 community can identify with one single
6 speaker.

7 CHAIRMAN FISCHHOFF: Christine?

8 MEMBER BRUHN: I would like to
9 specifically suggest, when looking at
10 coordinating with other government agencies,
11 to stay in close contact with the CSREES
12 Research Grants that are awarded by USDA, the
13 program leader in food safety. Many of these
14 grants include food safety education for
15 different areas of the public. They all
16 involve an evaluative component.

17 Within these grants, then, some of
18 the questions that are asked in this document
19 where FDA needs more information can and have
20 been and will be addressed, such as: who do
21 the consumers believe? Where do they go for
22 information? What are the components of

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1 trust? How do they interpret different
2 messages?

3 CHAIRMAN FISCHHOFF: Let me ask you
4 a clarification question. I mean you made
5 this point just before the break as well, that
6 there are evaluations out there perhaps for
7 things that are close to what FDA might be
8 considering that have been done for whatever
9 reason.

10 How does one find them? I mean
11 maybe one needs to follow Jacob's strategy:
12 just know the experts and they will lead you
13 there.

14 And maybe it is so specialized that
15 it doesn't pay to try to create an archive of
16 them. But how would you suggest --

17 MEMBER BRUHN: You know, that is a
18 really good point because it is not part of
19 the keywords. The keyword search does not
20 tell you credibility.

21 But when you read the entire
22 document, by golly, there's two tables that

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1 are just directly related to this concept.

2 I happened to be reading something
3 that is in the current Food Safety Education,
4 which is an online journal from the Institute
5 of Food Technologists, and it is about
6 consumer response to new food technologies.
7 They did a thousand-person internet search,
8 and that's how they got their people. They
9 divided them by education and by age group,
10 and they indicate where they got their
11 sources.

12 So when this meeting is over, I
13 will send to you, Lee, a list of some of the
14 references that I have encountered through
15 looking in this particular area.

16 Food Marketing Institute is one of
17 your partners as part of the Partnership for
18 Food Safety Education. They have a yearly
19 journal called Trends. It might be Trends in
20 the Supermarket or Consumer Trends, or
21 something like that. They have a whole
22 section on recalls and how people responded to

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1 recalls and what people do when they hear a
2 recall, and a little bit about why they do it.

3 That's a thousand-person survey.

4 The Food Research Policy, Food
5 Policy Center perhaps is its official name, at
6 Rutgers University. Researcher William
7 Hallman, H-A-L-L-M-A-N, just announced maybe a
8 week ago, or perhaps it was two, a nationwide
9 survey he did on how people responded to the
10 tomato recall, where they got information,
11 what they did, why they did it.

12 So I will give a list of those as
13 well as others. So I guess it is just keeping
14 your ears open, because sometimes recall will
15 be there. I'm sure it is in the study just
16 released from Rutgers. But other times it is
17 within the context of the whole article, and
18 you need to know to look for it.

19 CHAIRMAN FISCHHOFF: Musa?

20 MEMBER MAYER: This is pertaining
21 to the capacity strategy six, "Improve the
22 effectiveness of FDA's website as a primary

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1 mechanism for communicating with different
2 stakeholders."

3 We heard this morning that
4 sometime, I think it was in the next five
5 weeks, a new version of the website was going
6 to be rolled out. I had a question about how
7 the effectiveness of communication of this
8 website is going to be evaluated, what plans
9 are in place to do that, and how this
10 Committee might help with that process.
11 Because it seems to me that this would be the
12 time to actually set in motion an evaluation
13 process when the new format is there.

14 DR. OSTROVE: Yes, I don't know
15 what the plans are in terms of evaluation. I
16 mean I do know that there has been research
17 that has gone into the formation and that much
18 of what we put up is user-tested. So there is
19 usability testing.

20 But I am sure that we will be
21 looking at statistics that we get, and I can
22 get more information about that from our web

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1 staff.

2 MEMBER MAYER: Can I just follow
3 that up? It just might be interesting as a
4 topic for this Committee to focus on, to
5 examine the website from the perspective of
6 the people on this Committee.

7 DR. OSTROVE: I think, and I would
8 have to go back to the FDA Amendments Act, but
9 I believe actually that there is something in
10 there that suggests that there be a regular
11 evaluation or a regular kind of look at the
12 website, potentially by this Committee, but
13 certainly by experts.

14 I'm so sorry, I just can't remember
15 the exact reference, but I'm pretty sure there
16 is something in there on that. Overnight I
17 will get that information, but I think that is
18 a very good point and it is something that we
19 need to definitely bring up.

20 I suspect it's not something that
21 we would want to do, obviously, before the new
22 web content management system went into place.

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1 So we really haven't thought about it up
2 until now, but I think that now is the point
3 that we do have to start thinking about that.

4 MEMBER GOLDSTEIN: This is, again,
5 just a specific recommendation coming out of
6 our earlier discussion about capacity strategy
7 seven. It is the curriculum development idea.

8 We want to make sure that the
9 clinicians not only get the information they
10 need, but are trained to utilize that
11 information within the context of their shared
12 decisionmaking with patients.

13 So it would be a curriculum that is
14 about risk communication more generally and
15 about helping them to have productive
16 communication interactions with patients to
17 enhance a patient's capacity to make decisions
18 and also help inform the process of having
19 those conversations themselves.

20 And that curriculum might be
21 developed in collaboration, again, with some
22 of the partners. AHRQ again comes to mind;

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1 CDC comes to mind as co-funders of that
2 effort.

3 It could be in collaboration with
4 the organizations that oversee the education
5 of students in various health professions.

6 CHAIRMAN FISCHHOFF: Please, yes.

7 MEMBER SLEATH: Nancy, I just want
8 to ask you about the website. The website is
9 primarily in English, and then are parts of it
10 in other languages, like info sheets or
11 anything like that?

12 DR. OSTROVE: Well, actually, if
13 you look at the site that is specific to the
14 Office of Women's Health within FDA, all of
15 the materials that the Office of Women's
16 Health puts out are translated at least into
17 Spanish and in many cases into other languages
18 as well.

19 But, across the agency, that is not
20 done consistently. There are materials that
21 are on CDER's website, some of which are in
22 Spanish as well as English. I'm not sure

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1 about others.

2 There are some. It is not
3 consistent. It is something that I think
4 everyone is aware of and aware of the need to
5 consider this and to push it through. If we
6 don't have something in the plan about it, I
7 expect that there should be.

8 MEMBER SLEATH: Well, you have a
9 little bit in there under capacity strategy
10 four, like that reviewers should consider the
11 needs of vulnerable populations, limited
12 English proficiency.

13 I guess I just want to make sure it
14 doesn't get lost because I think that is only
15 going to become more important over time, that
16 messages are getting to everyone.

17 DR. OSTROVE: That is not going to
18 get lost. There are so many people internally
19 who are aware of that and who are frustrated
20 because, again, it is a capacity issue.

21 But thank you very much for
22 bringing that and making sure that it is in

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1 the forefront.

2 CHAIRMAN FISCHHOFF: Sort of
3 perhaps a complementary thing: I was still
4 thinking about Christine's point. I mean a
5 capacity issue is having people internally who
6 not only sort of know where the experts are,
7 who know where the material is, but can also
8 do a critical reading of it.

9 So you could get the right stuff by
10 a keyword, but not know what are the strengths
11 or weaknesses of an online survey, who they
12 get and who they don't. Or somebody does a
13 study with the proverbial college sophomores,
14 and they are good for some things and not for
15 others. It may depend on which college they
16 are. It may depend on how people think, which
17 may be more general than what they think,
18 where the popular representation is.

19 So one could have an illusion of
20 knowing by getting -- even if you know the
21 keywords, you can have an illusion of knowing
22 how good the data are. There really is not a

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1 substitute for having people on staff.

2 DR. OSTROVE: Yes, we're well aware
3 of that.

4 CHAIRMAN FISCHHOFF: Okay.
5 AnnaMaria?

6 MEMBER DeSALVA: I have it.

7 CHAIRMAN FISCHHOFF: Let's go.

8 MEMBER DeSALVA: I would like to
9 explain what it is that we have put together
10 here. It is a sketch, essentially, of how to
11 think about the continuum of risk and then a
12 framework for planning around desired outcomes
13 and behaviors, looking at a gap analysis in
14 terms of where performance is currently with
15 agency-sponsored risk communication, and what
16 the implications would be for capacity
17 research and evaluation and policy.

18 So this is really just a framework
19 for us to talk through, and we are going to
20 talk through a particular example and see if
21 that helps us address some of the issues that
22 were coming up repeatedly earlier today.

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1 I thought it would be helpful
2 perhaps to show this slide first. If it looks
3 familiar, it is because I presented some
4 version of it last year when I spoke to you
5 all in August. I presented a fictional case
6 of how industry deals with urgent
7 communication, and when there is a real
8 crisis, what are all the communications
9 planning methods that the industry puts into
10 play. This was my first slide or a slightly
11 different version of it.

12 But I simply wanted to try to group
13 categories of risk as the way that we might
14 think about them, although I think we all know
15 that there is no agency-sponsored
16 categorization of risk and there is no
17 industry-sponsored categorization of risk that
18 is a common framework that everyone uses.

19 But, for planning purposes, I
20 wanted to put this back up here to see what
21 the Committee thinks. Are these useful
22 categories of risk?

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1 We talked earlier this morning
2 about patterns and how patterns are emerging
3 as FDA's mandate is changing to communicate in
4 real-time with greater transparency emerging
5 risks as they become known, and to manage
6 established risks even more assertively.

7 Are these the right categories?
8 The reason why that question is relevant is
9 because the way to begin to do the exercise
10 that we talked about this morning or earlier
11 today is to then think about each of those
12 circumstances, think about each of those
13 episodes along that continuum of risk, and
14 what stakeholders' needs are.

15 So the process could be taking a
16 template like this and doing it for each of
17 your major audiences, those that you feel are
18 really very important. If you look at this
19 vertical axis here, what are the desired
20 outcomes and behaviors for each category of
21 risk? What kind of a gap analysis would you
22 do in terms of how the agency is currently

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1 performing?

2 So, when you look at the current
3 risk communication methods and the total
4 experience of these audiences when risk
5 information is shared either by the agency or
6 by the industry, what's working; what's not
7 working? If there were a very candid analysis
8 about what the positives and what the
9 negatives are, that would be a part of this
10 process.

11 Then from that gap analysis and the
12 consideration of the desired outcomes and
13 behaviors would come some clarity around
14 priorities and imperatives. So what must
15 happen? What needs to change? What are the
16 goals moving forward to create the better
17 outcome?

18 Then how does that break down in
19 terms of capacity, in terms of research and
20 evaluation, and in terms of policy? So using
21 the framework of the existing plan.

22 And this, essentially, becomes a

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1 filter for thinking through where the
2 opportunities to improve are. I think it
3 would help us drill down in some new areas.
4 Probably some new strategies and tactics might
5 emerge.

6 But I've suggested here that, for
7 purposes of discussion, we could start the
8 process, probably not complete it, but look at
9 two priority audiences that interact with each
10 other in a very important way. That is, of
11 course, physicians and patients.

12 If you were to take a fictional
13 case, again, similar to the one that we talked
14 about last August, and you were to say, let's
15 pretend for the purposes of discussion that
16 there's either a drug or a device that is an
17 important treatment for a major chronic
18 condition, and it's moving along this
19 continuum of risk, it may have at any stage
20 just simply normal adverse events that are
21 associated with its basic risk/benefit
22 profile.

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1 Over time, there may be some
2 emerging risks that are newly-defined by post-
3 marketing surveillance. It is unclear what
4 that risk means.

5 Then, over time, that risk becomes
6 more established and defined, and it is clear
7 that it presents a material threat to some
8 patients. So there is a patient safety issue.

9 And then, finally, worst-case
10 scenario, there is a life-threatening risk of
11 a significant and intolerable nature.

12 In each of those instances, what's
13 the desired outcome in terms of physician
14 behavior, patient behavior, and their
15 interaction? Where do we stand? What's
16 happening right now in the real world? And
17 what does that tell us about where we need to
18 focus?

19 It probably gets more interesting
20 as you move along that continuum to the right.

21 I mean it may be that this group says, well,
22 okay, maybe this is a good exercise to go

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1 through, but we don't have to talk about the
2 first column; we can take that offline. So I
3 just put that forward as an option if you
4 think it is worthwhile.

5 Let me start just by asking, are
6 these categories the right categories?

7 Nancy and Lee, I don't know if FDA
8 has -- I suspect that you have discussed
9 previously the relative merits or dismerits of
10 actually formally categorizing risk and
11 helping people sort of interpret events within
12 specific terms.

13 I don't know if there is a reason
14 not to do that, but if we should do it for
15 this exercise, and if so, do these categories
16 look like reasonable categories?

17 DR. OSTROVE: Am I being put on the
18 spot here?

19 We also have people, you know, from
20 FDA in the audience as well.

21 To me, I mean you are basically
22 kind of defining -- it makes sense to me as a

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1 continuum, where you are talking about
2 basically your static or stable, you know,
3 what you expect things to be, which is your
4 first column there, which I would say, yes,
5 probably not that much worth at this
6 particular point in kind of discussing that.
7 That is kind of the steady-state situation.

8 Then, when you are getting in
9 emerging risk that you are really uncertain,
10 and that is one of our major, that has been
11 one of our major issues. What do you do when
12 you have enough information that you know,
13 well, maybe something might be happening, but
14 the data are so problematic, just the data
15 themselves are a problem, that you don't
16 really know whether there is an association
17 even between the product and the problem, or
18 whether the problem may be just a function of
19 the underlying disease or increased broader
20 use. I mean there are all kinds of factors
21 that go into that.

22 Again, I apologize because my

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1 vision is aging. That's a really long way
2 off.

3 The next is I believe where you
4 said that there is potentially an impact?

5 MEMBER DeSALVA: Yes, it's
6 established risk. This one is going to be
7 easier to see. Established risk presenting --

8 DR. OSTROVE: Oh, yes, threat to
9 patient's safety --

10 MEMBER DeSALVA: Right.

11 DR. OSTROVE: -- and then life-
12 threatening risk. Yes, it makes sense to me.

13 Baruch, can we get, among people in
14 the FDA in the audience, is it something where
15 we could get a hand --

16 CHAIRMAN FISCHHOFF: Lee and I were
17 just doing -- these are really questions to
18 FDA rather than questions to the panel.

19 DR. OSTROVE: Right, right.

20 CHAIRMAN FISCHHOFF: We would be
21 happy to see you tussle with this.

22 Are there two or three people you

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1 would like to invite to work through this?

2 DR. OSTROVE: Actually, I'm looking
3 to see whether people who I have seen earlier
4 in the day -- I am not sure if there are any
5 FDAers left in the audience. Okay. I see
6 one. I see a couple. Ah, there you go.

7 Would any of you like to kind of
8 sit in the discussion or provide any feedback
9 about the reasonableness of this as a
10 continuum? You know, not getting into a whole
11 lot of detail because then we lose the value
12 of these hearings. But does it seem
13 reasonable?

14 Greg, Anita.

15 CHAIRMAN FISCHHOFF: Let me invite
16 you to join us at the table for this informal
17 discussion. There will only be a videotape
18 and transcript of what you say.

19 (Laughter.)

20 I got a message from somebody who
21 is viewing us remotely in San Diego. So just
22 very informal.

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1 (Laughter.)

2 While they are fighting their way
3 to the front, Mona had a question.

4 MEMBER KHANNA: Well, I don't know
5 that it is a question. More it is a comment.

6 That is, this directly parallels
7 the pandemic scale or the scale that the WHO
8 is now saying that we are at level 5. So I
9 think it is very reasonable because,
10 essentially, as you go toward the right, you
11 are increasing the risk. I think it is very
12 common to have scales of this nature.

13 I like the different factors -- I
14 think it was the other slide -- that go into
15 each, that you have to evaluate for each
16 single of the four categories, the capacity,
17 the priorities. I think that is where the
18 struggle will be. What is our capacity to
19 handle a risk of, say, scale No. 3, the gap
20 analysis? I think that is where the thought
21 process and where the resources need to be
22 devoted toward, is the left column.

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1 But, as far ascending priority or
2 ascending incidence, prevalence, whatever you
3 want to call the risk, I think it is perfectly
4 reasonable.

5 CHAIRMAN FISCHHOFF: Thank you.

6 Would you like to introduce
7 yourself and then speak a little bit to this?

8 MS. RAYNER: Yes. Hello, everyone.

9 I'm Anita Rayner with the FDA's
10 Center for Devices and Radiological Health.

11 I think the one observation I have
12 right off the bat, nothing like being put on
13 the spot -- (laughter) -- is that I like the
14 progression of risk. One of the things that
15 gives me pause is that it tends to minimize --
16 and perhaps it's the choice of words and the
17 continuum -- is that it may minimize the risks
18 associated with products from the get-go, at
19 the point when they are actually put on the
20 market. Some of these products have very
21 significant risks associated with them, and we
22 know that, and yet the risk/benefit balance is

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1 taken into account. That compels us to the
2 decision that the product should be on the
3 market.

4 But I don't want us to lose track
5 of the fact that there are some very
6 beneficial, but yet very risky, products that
7 are out there. That needs to be taken into
8 account. That is kind of the background level
9 of what we are dealing with.

10 MR. BUSSE: Hi. Greg Busse, Center
11 for Drug Evaluation and Research.

12 My comment is similar to Anita's in
13 that it's difficult to apply a single system
14 to all the various products that we have under
15 our jurisdiction here at the FDA, even when
16 looking at drugs. While we can have a simple
17 classification system, I can think of an
18 example similar to Anita's where you can look
19 at the risk/benefit profile of an oncology
20 drug, which would be very much different than
21 a dermatology drug.

22 So it would be hard to equate where

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1 drugs from different classes with different
2 risks fall on this continuum in relation to
3 one another.

4 CHAIRMAN FISCHHOFF: If you're
5 willing to stay, I think it seems like these
6 are really more questions for you people, if
7 you can think about this some more. I think
8 it would probably be informative to the panel
9 for our work now and in the future just to see
10 how you all wrestle with it and how different
11 it looks like from different perspectives.

12 You can sit down, too. I mean join
13 us. We have an extra chair next to Christine,
14 if you would like to come up.

15 Christine and then Mona.

16 MEMBER BRUHN: Yes, I have a
17 question, too. Would it be helpful to
18 indicate how widespread the population at risk
19 is? For example, would the communication
20 strategy be different if this was a product
21 used by many people but only a very specific
22 subgroup had risk versus it was used by many

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1 people and everyone was at the same level of
2 risk? Is there another dimension? Is it
3 three- or four-dimensional instead of two, is
4 my question.

5 MEMBER DeSALVA: Well, I'm only a
6 communications expert, but that makes a lot of
7 sense to me. The central question here with
8 this discussion is, is this reasonable for
9 purposes of a planning exercise to help our
10 thinking? And part two of that question is,
11 are there any applications of a scale like
12 this in actuality? You know, somewhere in the
13 future, does it make sense to try to
14 categorize risk because that will help both
15 with strategy and with communication around
16 how you mitigate the risk?

17 So, if someday we were to say it
18 would make sense to create some sort of
19 categorization system similar to what WHO has
20 done for pandemic preparedness, then that
21 scale needs to be developed more and it needs
22 to be validated. It needs to be pushed and

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1 tortured and stretched, and obviously become
2 something that holds up scientifically and
3 otherwise.

4 I would think that it would have
5 more than one dimension because of the
6 relative meaning of risk, depending on the
7 setting.

8 Mona, were you going to say
9 something?

10 MEMBER KHANNA: Well, I was
11 actually going to comment on what our FDA
12 friends, the comment they made.

13 I would look at this as kind of an
14 absolute risk. I would not look at it as a
15 relative risk compared to other medications.
16 Perhaps classes of medications, you would look
17 at it as relative risk.

18 Let me give you an example. Here's
19 what comes to mind. When we had possible
20 poisoning, I guess, of anthrax, and we knew
21 that we could effectively treat that with
22 Cipro, well, we also knew it would require

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1 long-term treatment with Cipro to effectively
2 get at the bug. Yet, we also know that long-
3 term use of Cipro is associated or linked to
4 tendon rupture.

5 So you are going in knowing that
6 you are going to treat a patient for six to
7 twelve weeks with Cipro. For that duration of
8 time, there is a higher than regular
9 probability with the regular use of Cipro, say
10 for pneumonia, of tendon rupture.

11 So the first column, your
12 risk/benefit ratio profile, is already higher
13 than it would be for using Cipro to treat
14 pneumonia. So you know your risks are already
15 higher.

16 So I would look at this more as an
17 absolute risk table perhaps targeted toward
18 the indication it's being used for and the
19 medication that is being used or device.

20 CHAIRMAN FISCHHOFF: We have
21 another person from FDA. Please introduce
22 yourself, and welcome.

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1 MS. STIFANO: Hi. Toni Stifano,
2 also from the Center for Drug Evaluation and
3 Research.

4 You know, I was looking at this,
5 and actually you just spoke to some of my
6 concern. That is, it really isn't appropriate
7 for relative risk. It really does speak more
8 to absolute risk.

9 But that's always really hard to
10 know. I mean you can sit and know your little
11 pile of data, but you don't know. You don't
12 know what's going on on the outside. So it is
13 very difficult.

14 But also true, when we are weighing
15 the kind of communication, the type of
16 communication, in the audience that we are
17 hoping to target, we do in a sense do
18 something along this line in thinking through
19 what we are going to do and how we are going
20 to do it, when do we engage other parties
21 within the government to magnify the message.

22 So we do, in a sense, try to do

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1 this, but I don't know that it is necessarily
2 formalized. So this is an interesting way to
3 see it formalized.

4 CHAIRMAN FISCHHOFF: Thank you.
5 Ellen and then Musa.

6 MEMBER PETERS: I guess I have kind
7 of a question because I'm having a little bit
8 of trouble understanding how this would work.
9 Is the idea behind this that you would pick a
10 particular kind of pharmaceutical, for
11 example, and maybe even as specific as a
12 particular pharmaceutical in a particular use,
13 whether it is for anthrax versus, I think,
14 pneumonia -- I forgot what the other use was.

15 Or is this sort of a very generic thing, not
16 tied to a drug, that you would use to come up
17 with these sort of generic recommendations?
18 Because I would think about it very
19 differently depending upon what you see the
20 use of it as.

21 MEMBER DeSALVA: Yes. For
22 purposes of today, we were going to make it

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1 specific to a specific situation because we
2 thought it would help the brainstorm more if
3 we were all thinking about a specific
4 situation.

5 But the goal for strategic planning
6 would be to elevate the insights that come out
7 of that discussion to help shape both strategy
8 and tactics for the risk communication plan
9 for FDA.

10 So, for instance, let's say we are
11 talking about, as we did last year, an
12 implantable device, and it is being used to
13 treat a major chronic condition. The
14 situation is that there's no clear risk that
15 requires a radical intervention, but there are
16 some early signals that indicate that there
17 could be a problem down the line.

18 Out of an abundance of caution, the
19 manufacturer makes a decision to temporarily
20 suspend marketing. In technical terms, and I
21 realize this is sort of a sensitive subject,
22 it's a recall in the world of devices.

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1 But if you play that scenario out
2 and you think about, what's your desired
3 outcome in that situation in terms of how
4 physicians and patients are going to mitigate
5 risk, and you take that journey all the way
6 through, looking at the world as it currently
7 is and the world as it could be, and what does
8 that mean in terms of changes that could take
9 place, the idea being that if you do that a
10 few times for a few different types of
11 situations, you isolate some essential truths
12 that are useful for planning.

13 So it may seem a little tedious,
14 but one way of doing this would be to do it
15 for each category that FDA regulates. So go
16 through an exercise like this for food, for
17 devices, for drugs.

18 MEMBER PETERS: Is it possible that
19 you would actually end up with multiple of
20 these? Because different patterns emerge for
21 this type of drug versus this type of drug
22 versus devices.

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1 MEMBER DeSALVA: I think that
2 would make sense. I mean I think that, as an
3 exercise, it is never a totally perfect
4 process. So, if there are clear trends, if
5 you can look at an implantable device has a
6 certain set of needs that a device that isn't
7 implanted has, and a cancer drug with a very
8 intense risk/benefit profile has different
9 needs than a drug that is used in primary care
10 and has 15 years of use in millions of
11 patients, you're right.

12 So the key would be, I guess, to
13 pick out a couple that are representative that
14 would allow this process to be productive.
15 Because, really, what we are looking at is,
16 what are the specific strategies and tactics
17 that should be reflected by a new strategic
18 plan for risk communication that changes the
19 outcome and really creates a very meaningful
20 difference or result for the agency and for
21 patients?

22 CHAIRMAN FISCHHOFF: Musa?

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1 MEMBER MAYER: So, to me, I'm still
2 not 100 percent onboard with this as a way of
3 discussing this. That's because the third
4 dimension is missing here.

5 The third dimension really concerns
6 the severity of the condition, disease,
7 situation, whatever it is, the seriousness of
8 this. Because all of that is going to
9 mitigate the categories here.

10 Many cancer drugs, for example,
11 wouldn't even start in those first two
12 columns. You would start with established
13 risks presenting material threat to patient
14 safety. These are drugs that have been in use
15 for 15 years.

16 So it is the fact that we are
17 dealing with a life-threatening illness that
18 we -- I just don't see how it would work to
19 put on the same grid something when you aren't
20 somewhere representing the severity of the
21 condition.

22 MEMBER DeSALVA: And I think that

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1 is exactly what Ellen was saying in her
2 question.

3 MEMBER MAYER: Yes.

4 MEMBER DeSALVA: Which is why this
5 isn't a one-size-fits-all. It wouldn't be one
6 framework that answers all the needs and
7 questions for the plan. It would need to be
8 done several times for several different types
9 of products and situations.

10 So my point being is I realize that
11 is laborious. So the relative merit of that
12 in terms of what you get out of that exercise,
13 is there value in it? It is a discovery
14 process. So what do you discover? By going
15 through this exercise, what do you discover
16 that's new and different that will actually
17 change your strategic plan?

18 So, for instance, when you look at
19 the very end of the continuum, life-
20 threatening risk of a significant and
21 intolerable nature, those are very, very, very
22 frightening situations where an immediate

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1 intervention has to take place, and where
2 there may not be a clear enough protocol, for
3 instance, for how the agency communicates and
4 how the manufacturer communicates, or how they
5 collaborate.

6 It may be that there is a way to
7 improve that that would come out of this type
8 of exercise, where it becomes clear that, from
9 a policy standpoint, the agency has an
10 opportunity now to take a step forward to
11 establish some standards and policies, and how
12 these two sectors collaborate around an urgent
13 risk situation.

14 So that would just be one example,
15 but it is really just a framework. So I don't
16 want to take us down an unhelpful path.

17 MEMBER MAYER: Just one more
18 clarification. It occurs to me that maybe
19 you're really talking about emergent
20 situations, that is, situations where there is
21 some new signal of some kind that has never
22 been there before --

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1 MEMBER DeSALVA: Yes.

2 MEMBER MAYER: -- that constitutes
3 a potential emergency, which wouldn't apply to
4 most drugs. You wouldn't really talk about
5 most products in these terms -- only if a
6 product, for example, after being widely
7 adopted, there would suddenly emerge a very
8 serious safety issue.

9 MEMBER GOLDSTEIN: I think the
10 discussion we are having is a reflection of
11 the value of taking this kind of an approach
12 to thinking about strategic planning. If you
13 just think about what's going on, we have
14 asked a number of different stakeholders from
15 FDA about their perspectives of what is
16 important in terms of these categories and
17 priorities. We've gotten clarification about
18 the meaning of some of the terms and the
19 differences that might apply across different
20 situations, foods, drugs, devices, the
21 conditions, the populations that we might be
22 serving.

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1 So what it does is it is helping us
2 to sharpen our thinking about those categories
3 there. Even before we started -- we haven't
4 even started looking at any other particular
5 categories or using an example.

6 This process of trying to break
7 things down into what's important and to whom,
8 and for what reason, is a way of trying to get
9 our arms around what is really important as a
10 priority. Then the strategies and tactics
11 will evolve from that in, hopefully, an
12 organic way, rather than the other direction.

13 I know FDA has already done a lot
14 of this work, but this is sharpening, I think,
15 even more the process and bringing out some
16 perhaps factors or eventually strategies that
17 might help the FDA move forward.

18 MEMBER PALING: Michael said very
19 much what I wanted to say. So I support him
20 totally.

21 To me, this is, I would have
22 thought, a very helpful framework to use when

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1 you really don't quite know what to do with a
2 new problem. I mean I deeply respect you all
3 in the FDA. You are on the cutting edge; I'm
4 far on the outskirts looking in.

5 But I think all those categories
6 are important. I think the second category,
7 which is elaborated by Nancy, we don't really
8 know. It may be; it may not. It is a uniform
9 problem, the uncertainty is huge. So I think
10 it helps you to do that, too.

11 And we have all been saying from
12 the very first of our meetings that there are
13 risks and there are benefits. I would like to
14 put Michael's comments in this framework and
15 then ask AnnaMaria a question.

16 There is a risk that may not be
17 helpful. You may spend your time and get
18 nothing from it. But I see a real benefit.

19 Since you have been very
20 differential, and not pushing it forward as
21 your idea, but your whole career is doing this
22 professionally with industry, have you found

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1 in general that the use of this tool, the
2 benefits exceed the risks?

3 (Laughter.)

4 MEMBER DeSALVA: Well, I can tell
5 you absolutely that when you have a very
6 outcomes-focused communication planning
7 process, in other words, you're really trying
8 to drive a change of a highly material nature,
9 that almost without exception, even though you
10 are living downstream of strategy and process,
11 and you are doing the communication piece, you
12 inevitably start addressing issues and
13 problems upstream.

14 So the communications planning
15 actually inspires and elucidates things that
16 could change further upstream in terms of
17 business practices or policies. That is a
18 very helpful process.

19 I'm sure any of you who have tried
20 to write a speech or an article or some
21 communications tool or product, it inevitably
22 makes you think about things you haven't

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1 thought of before. It gives you the
2 opportunity to either share that insight or
3 revisit something that is much more
4 fundamental than the story.

5 So, yes, I think there is a big
6 reward in applying the same kind of discipline
7 and discovery process to communications
8 strategy as there is in other areas that are
9 substantial or scientific in nature.

10 I think what is difficult about
11 this setting is that we don't really have time
12 to do this in a way where I think you would
13 experience all the benefits of it. So I'm
14 happy to present it as a framework. I don't
15 know if it something that we should actually
16 take the time to kind of travel through or
17 not, but I will leave that up to Baruch and to
18 the rest of you.

19 CHAIRMAN FISCHHOFF: Let's have a
20 comment from Michael.

21 MEMBER WOLF: I'm grappling with
22 this because I think the value of having

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1 something intuitive that gives you a protocol
2 for addressing these and categorizing, that's
3 all helpful. I'm not sure if this is the
4 model that immediately, having not looked at
5 this before, helps me. So I am just going to
6 lay that out there.

7 But one message that keyed in, and
8 one of the reasons why I kind of noted to
9 Baruch that I wanted to speak, is one of the
10 elements that everybody keeps on talking
11 about, as I have been hearing throughout the
12 conversations this morning, is this idea of at
13 least beginning to pull from precedent; that
14 as we encounter new issues where risk
15 communication has to be pulled into play for
16 the FDA when a new threat comes up, dealing
17 with the virus right now, that we have
18 precedents to fall back on, that we have
19 existing messages to pull through.

20 At least having a template like
21 this, I can imagine is going to allow us to do
22 that much more effectively. It is just

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1 getting that down.

2 I spend a lot of my time at
3 Northwestern just dealing with trying to get
4 rid of jargon. I think a little bit of this
5 is getting this down to a very user-friendly
6 and much more simplified approach.

7 CHAIRMAN FISCHHOFF: Okay. Well,
8 let me thank -- oh, Jacob?

9 MEMBER DeLaROSA: This is just a
10 comment, and it's an interesting comment.

11 In medical school and in training,
12 and as you advance in medicine, in cardiac
13 surgery, this is sort of how you think. You
14 think in regard to, in cardiac surgery, you
15 rip someone's chest open, you fix their heart,
16 and then there is another problem. Then you
17 have to try to assess the risk. If I continue
18 forward or what I do, how to fix it.

19 This is really what defines, then,
20 a good surgeon from a great surgeon, is how
21 they communicate the risk then to the family
22 and be able to think about it.

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1 And then really in everything, so
2 not just in what you all do, but in what we
3 all do in life, this is sort of the same
4 thing. It's a continuum of risk.

5 CHAIRMAN FISCHHOFF: Let me thank
6 AnnaMaria for coming out and doing this really
7 very valuable exercise.

8 Let me thank our friends from FDA
9 for also coming off the bench to help us.

10 It is now two o'clock and we are
11 going to move on to our next session, which is
12 we are fortunate to have Jeffrey Shuren, who
13 is Associate Commissioner for Policy and
14 Planning, talk to us about the goal from the
15 strategic plan to optimize FDA's policies on
16 communicating product risks and benefits.

17 So let me draw the Committee
18 members' attention to -- we have copies of
19 these slides, but with Malcolm Bertoni's name
20 on them. Those are the slides, I think, that
21 we are going to be looking at, and then look
22 again, you know, sneak a peek at the

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1 questions. They are the second set of
2 questions that were given to us.

3 Welcome.

4 DR. SHUREN: Thank you.

5 Good afternoon. Good to see
6 everyone again.

7 I'm sorry we're going to keep you
8 in your chairs for a little bit over an hour
9 or so. I understand if you get restless.

10 For this part, we are going to talk
11 about the section in the Draft Strategic Plan
12 pertaining to policies. I think you will see
13 throughout the document that all of the
14 different sections, they really interplay with
15 one another.

16 We need to have the right policies
17 in place to facilitate our progress in the
18 other sections of the report, getting the
19 right capacity in the agency, strengthening
20 our understanding of the science.

21 A friend of mine used to be a
22 professional hockey coach. I am not much of a

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1 hockey player. Actually, I'm not a hockey
2 player at all. But with the Caps now going
3 into the second round for the playoffs, it has
4 come to mind. Everyone has heard this before.

5 In hockey, the coach would talk about, "This
6 is how I coach people for life," it's really
7 all about not skating to where the puck is,
8 but to where the puck is going to be.

9 Unfortunately for FDA, we don't
10 have that luxury. We have to skate to where
11 the puck is. There is always some emergency,
12 some fire we have to put out.

13 But, by the same token, if we do
14 not plan for where we need to be down the
15 road, we just have more fires to put out. So
16 we have to think to be far more preventative
17 in nature.

18 What we have done is we have come
19 up with four strategies related to policy.
20 The questions are at the end, but let me put
21 them upfront.

22 What we want to hear is, did we

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1 pick the right priority areas to focus on or
2 should we be looking at other areas?

3 Then, secondly, for these
4 particular policies, we need your help making
5 them come to life. So, if there are
6 scientific questions that need to be
7 addressed, we should put them on the table,
8 but we're very interested, from a practical
9 standpoint, how do we move forward to either
10 make changes or put policies in place today,
11 recognizing maybe we don't have all the
12 information, but we have to address the
13 challenges that are before us right now?

14 Maybe that means for some of these
15 it is going to be a more flexible approach,
16 one where we are thinking a pilot, creating
17 sort of a living laboratory as we figure
18 things out, rather than waiting until we have
19 all the information before we take a step
20 forward.

21 Strategy one is develop principles
22 to guide consistent and easily-understood FDA

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1 communications. So this goes to internal FDA
2 policies.

3 Is there certain information that
4 we should be applying consistently in our
5 communications or subset of communications?
6 For example, this Advisory Committee has
7 talked about the importance of putting risk
8 and benefit into context, particularly in the
9 settings of approvals of products and recalls.

10 What about using risk and benefit in the
11 context of when not to use a product?

12 The second area is to identify
13 consistent criteria for when and how to
14 communicate emerging risk information. I know
15 this has been discussed many times, but we
16 sort of see this as a buildoff, a key area for
17 us. Certainly, where we struggle for many of
18 our other communications, is some action tied
19 to it? We are explaining an action or we are
20 recommending an action. Here we are not
21 really sure what the action should be, but we
22 are putting the information out there.

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1 What happens as we kind of move to
2 the next one? How does this sort of change
3 our thinking on communicating emergent risk
4 when we are looking at re-evaluating and
5 optimizing policies for using partnerships and
6 other leveraging activities to facilitate
7 effective communication about regulated
8 products?

9 Here we are not talking about let's
10 just work more closely together. It is about
11 how do we build an effective, integrated,
12 interactive risk communication environment?
13 How do we have that back and forth on
14 developing the communications, on when the
15 communication is out there and clarifying it,
16 and then getting feedback on the
17 communication? How do we do it better next
18 time?

19 In that context, does that change
20 how we think about our communications on
21 emerging risks because we are not in a static
22 environment? We are now in a very interactive

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1 environment.

2 The next area is on assessing --
3 oh, let me back up. One other area is for our
4 medical professionals. I'll come to that.

5 Next is assess and improve FDA
6 communication policies in areas of high public
7 health impact. Here we picked four target
8 areas and again would like to get your
9 feedback if these are the right areas or not.

10 First is to modernize effective
11 communication in a recall.

12 I want you to know this actually
13 reminds me of being home on Sundays because
14 every time I try to relax my neighbor decides
15 to mow their lawn.

16 (Laughter.)

17 It goes without fail.

18 Recently, I think it was the Robert
19 Wood Johnson Foundation that had a survey out
20 looking at recalls, what were Americans
21 actually getting by way of information, what
22 were they doing about it? In fact, it looked

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1 like Americans, if there was a recall, they're
2 finding out, certainly about some of the big
3 ones.

4 But, interestingly enough, they
5 weren't doing much about it. They would tell
6 a friend. They would tell a neighbor. But
7 they wouldn't actually look on their shelves
8 to see if they had the food. And it just sort
9 of begs the question. Yes, we got a message
10 out there, but they didn't take the action we
11 were hoping they were going to take.

12 The second area is to ensure that
13 patients get useful written information about
14 their prescription drugs they use. The
15 framework that is currently in place is
16 creating a lot of confusion for patients. We
17 have the private sector that is providing
18 information. We have pharmacies providing
19 information. Then we have information that
20 industry develops and that FDA approves, like
21 medication guides and patient package labeling
22 and patient package inserts.

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1 So patients get bombarded with all
2 these different sources of information. They
3 may not know what to do.

4 On the private sector side, for
5 pharmacies, the National Association of Boards
6 of Pharmacy went ahead and have surveyed what
7 is actually going out there. While a lot of
8 pharmacies are providing information, at least
9 about a quarter of that information doesn't
10 appear to be adequately useful for patients.

11 So the question is, what should we
12 be doing to provide more useful and consistent
13 information for patients on the prescription
14 drugs they use?

15 The next area is to another set of
16 stakeholders, medical professionals, ensuring
17 that they get useful information about FDA-
18 regulated products, when and in what form they
19 need it.

20 Traditionally, for the agency, we
21 have focused so much on labeling. We try to
22 get the labeling right. I'm a physician, and

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1 I have to say I find labeling so profoundly
2 unhelpful.

3 I think that it has actually
4 improved with the changes we made and having a
5 highlight section on the labeling. But, for
6 me, having that out there doesn't help me when
7 I most need it, and that is at the time I need
8 to make a clinical decision. I need that
9 information there when I'm with the patient.

10 While that may not be the place
11 where FDA normally tracks and trods, be
12 thinking about, how do we work with others to
13 do a better job at getting the information
14 that medical professionals need when they need
15 it, at the time of clinical decisionmaking, in
16 the form that they need it?

17 And then lastly, to modernize the
18 regulation of prescription drug promotion.
19 Our regulatory framework is decades old, and
20 it was developed at a time when the means of
21 communication were far more limited and the
22 focus was on medical professionals.

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1 But, since then, we have so many
2 new forms of communications. The internet has
3 really sort of spun the head on what's
4 labeling and what's advertising. It doesn't
5 really understand regulatory balance.

6 And now we have consumers who are
7 getting information about products in direct-
8 to-consumer advertising. Yet, our regulatory
9 framework will say that, if we are dealing
10 with consumers, we may actually provide them
11 with different information if it is labeling
12 or advertising, but they don't know the
13 difference.

14 And in other cases, we say that you
15 have to provide the same information to go to
16 medical professionals and to consumers, even
17 though their level of understanding is
18 different. So consumers get bombarded with
19 fairly technical information.

20 So, with that, I will return to my
21 seat. I look forward to the discussion.

22 CHAIRMAN FISCHHOFF: Thank you.

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1 Comments?

2 Yes, Musa?

3 MEMBER MAYER: Thank you for that.

4 Regarding what you were just
5 talking about, ensuring medical professionals
6 get useful information when and in the form
7 they need it, I wonder if there has ever been
8 any initiative of tying that useful
9 information to existing guidelines that
10 patients consult, so that they could click
11 through. If they are looking at a guideline,
12 that they could directly click through to the
13 information you would like them to have about,
14 say, the drug that they were going to
15 prescribe or the procedure, or whatever it
16 was.

17 I know there is a lot online for
18 physicians now that takes them through sort of
19 tree-like decision matrices. I am wondering
20 if that could be used.

21 MEMBER DeLaROSA: I have a
22 question. We talk about, as a medical

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1 professional, about the labels, the labels on
2 our drugs, devices, et cetera. But there is
3 so much that we hear about off-label use.
4 What is the regulation, or is there really any
5 standard on off-label use?

6 I mean it seems like companies want
7 to get an FDA approval so they can get their
8 product to market. Once it gets to market in
9 the U.S., then what is the regulation of its
10 being used off-label? So I guess my question
11 is, what do you all do about that?

12 DR. SHUREN: Well, it depends upon
13 who is doing the talking, if you will. So, if
14 we are dealing with the manufacturer or
15 someone who is acting on behalf of the
16 manufacturer, there are certain limitations
17 put on what they, in fact, can say. Those
18 limitations really apply to off-label
19 promotion where there is very limited what, in
20 fact, you can say.

21 If you now move down the spectrum,
22 you are dealing with the healthcare

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1 professional untied or unlinked to the company
2 and not acting on their behalf. Then it is
3 otherwise practice of medicine. They can talk
4 about it and they can use it for off-label
5 use.

6 MEMBER DeLaROSA: So there is no
7 regulation by the FDA to use something off-
8 label? I mean, once you all have approved it
9 -- let's just take drug-eluting stents,
10 coronary stents. The coronary stent, you
11 know, it works in single vessel disease. But
12 then it is now being used around the country
13 and the world off-label to be used on multi-
14 vessel disease.

15 So you really have no more control
16 after you guys have blessed it?

17 DR. SHUREN: Well, you can think
18 about it for control on two levels. One is
19 the information. So, if you are dealing with
20 whatever the use is that you are trying to get
21 the product approved for, there are standards
22 in place for the level of evidence that you

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1 need to provide to demonstrate that that
2 product is relatively -- if you think about
3 the ratio of benefit to risk, for that
4 particular use.

5 So we have control then on the
6 evidence, and then in terms of what you say
7 about that particular use. Once we move to a
8 use that is not approved, the manufacturer is
9 very limited in what they can say. But you
10 have healthcare professionals who may use it,
11 and there isn't that control in terms of what
12 the evidentiary standard is for that use.
13 It's left as practice of medicine, and, of
14 course, what then may be said in other circles
15 regarding that particular use.

16 That is kind of the societal choice
17 that was made and the framework that was
18 established by Congress.

19 MEMBER KHANNA: Yes, just very
20 quickly, we have mentioned the Agency for
21 Healthcare Research and Quality a couple of
22 times at this meeting. Carolyn Clancy, the

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1 head of that agency, puts out columns once a
2 month. Actually, it is very timely; this
3 month's column is off-label use, what it is,
4 why we do it.

5 Her columns are directly
6 applicable, I think, to lay people. So it is
7 written in very simplistic language, but it
8 goes into this whole concept. I get that
9 email, too. That came across last week.

10 MEMBER BRUHN: I just have a couple
11 of suggestions about modernizing effective
12 communication in a recall. Certainly, that is
13 an appropriate goal.

14 I was impressed through some of my
15 colleagues in the food arena that, for
16 example, in the spinach recall, a major
17 national store that sells produce was able to
18 send an electronic message through their
19 computer, so that immediately no more -- when
20 people tried to buy this product, brought it
21 to the cash register to have it scanned, the
22 message came up that it was not to be sold

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1 because of a recall.

2 So this involves working with your
3 partners, and this is something that works
4 with a chain or a store that has computerized
5 entries. But it was very effective in
6 stopping the sale of that product.

7 So even stock persons didn't have
8 to go and check the shelves, although, of
9 course, we encouraged them to do so. But if
10 they missed something, when you bring it by
11 the scanner, blank, comes out the message.

12 Another national chain that is a
13 membership store sent messages to all their
14 customers who had purchased a recalled
15 product. They knew who those customers were
16 because you are a membership store, and they
17 know what you bought because it is on your
18 screen.

19 So that is another example. This
20 is another food example.

21 My mother got her prescriptions
22 from a national chain. I know she had cards.

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1 I would think this kind of an approach might
2 work in the drug arena as well.

3 So partnering with those people who
4 sell the product could be an effective way of
5 stopping them. It actually might be a way of
6 enforcing the importance of a recall, because,
7 you know, I've seen that again, as you have
8 described, people say, "Oh, yes, hey, don't
9 eat this product. It's being recalled," and
10 not checking their own refrigerator or their
11 own cupboard to see if they have the product,
12 and eating it and sometimes ending up sick.

13 But when you have multiple people
14 saying the same things, it enforces it and
15 might make the people think, hey, this could
16 happen to me; it's not just happening to
17 someone else, which is the normal type of
18 reaction that people have.

19 MEMBER PETERS: This is sort of in
20 response to ensuring that patients get useful
21 written information about the prescription
22 drugs they use. I have two different things.

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1 One we have talked about before, and our
2 public speaker earlier today mentioned it as
3 well.

4 It is the use of legal terms once
5 again, the use of legal terms when
6 communicating to consumers who are hearing
7 those legal terms, but have a different
8 meaning than what is intended by the FDA.

9 There's kind of two ways you can go
10 with that. You can go with using the legal
11 terms and educating consumers, and trying to
12 educate them that, well, when I say, "safe and
13 effective," I mean this thing, but to
14 everybody else in the world who you talk to
15 way more often than me, by the way, it means
16 something completely different. That is one
17 way of going about it, I suspect possibly not
18 very successful.

19 The other way of going about it --
20 and someone, and I apologize, I forget who,
21 but someone earlier today mentioned it -- and
22 this is probably somebody higher level in FDA

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1 that has to work on this, but having different
2 terms for different uses. If consumers aren't
3 going to understand the term and they are
4 going to use the term in a different way, why
5 use the term with them? That was one point.

6 The other point I wanted to make on
7 a different topic is the use of quantitative
8 information. One of the things we haven't
9 talked about very much, but has been there in
10 the testing of quantitative information, is
11 the need, when you provide quantitative
12 information, to have comparisons. Because if
13 I tell you that there is, oh, a 6 percent
14 chance of this risk, what people usually ask
15 is, well, compared to what? You know, they
16 need a comparison number.

17 So the drug facts box does that
18 explicitly. They provide a comparison number
19 there for the drug in some trial that was run,
20 as well as a placebo control that was run in
21 the same trial. So they have that explicitly
22 in the drug facts box.

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1 But I didn't want to lose the point
2 that that comparison is actually necessary for
3 people to be able to draw meaning from the
4 numbers.

5 CHAIRMAN FISCHHOFF: AnnaMaria and
6 then Musa.

7 MEMBER DeSALVA: There was just
8 one comment I wanted to make on the section of
9 the plan and policy that talks about ensuring
10 that medical professionals get useful
11 information about FDA-regulated products when
12 and in the form they need it.

13 I think we have discussed this
14 before, but as part of the discovery process,
15 and thinking about how do we get to the right
16 outcome, and how should risk communication
17 change, I think a key question remains about
18 whether or not or how risk communications
19 should be staged. Is there ever a time when
20 health professionals and physicians need to
21 hear information first? Or is it more
22 effective, ultimately, to communicate certain

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1 risks first through professional channels,
2 through physicians or through medical
3 societies?

4 Certainly, no one wants not to be
5 transparent with consumers, but we do want to
6 get to the right outcome and make sure that
7 physicians and patients are having the right
8 kind of discussion that truly mitigates risk.

9 MEMBER MAYER: This is to your
10 point about modernizing the regulation of
11 prescription drug promotion. I'm not entirely
12 sure what that means, but I do know that --
13 well, let me give you an example that
14 illustrates some of the problem that I have
15 seen.

16 A particularly egregious one of a
17 product I won't name basically said, if you
18 could reduce your risk of getting breast
19 cancer by 50 percent, if you could cut your
20 risk in half and run only a 1 to 2 percent
21 chance of serious adverse events, wouldn't you
22 take this drug? That was the communication.

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