

UNITED STATES OF AMERICA

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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FOOD AND DRUG ADMINISTRATION

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RISK COMMUNICATION ADVISORY COMMITTEE

+ + + + +

MEETING

+ + + + +

THURSDAY,
AUGUST 14, 2008

+ + + + +

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

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PRESENT:

RISK COMMUNICATION ADVISORY COMMITTEE MEMBERS:

BARUCH FISCHHOFF, Ph.D., Chair

LEE L. ZWANZIGER, Ph.D.,
Designated Federal Officer/Executive Secretary

CHRISTINE M. BRUHN, Ph.D., Member

JACOB DELAROSA, M.D., Member

ANNAMARIA DESALVA, Member

MICHAEL GOLDSTEIN, M.D., Member

PRERNA MONA KHANNA, M.D., M.P.H., Member

MADELINE Y. LAWSON, M.S., Member

MUSA MAYER, M.S., M.F.A., Member

LINDA NEUHAUSER, Dr.P.H., M.P.H., Member

JOHN E. PALING, Ph.D., Member

ELLEN M. PETERS, Ph.D., Member

BETSY LYNN SLEATH, Ph.D., Member

MARIELOS L. VEGA, B.S.N., R.N., Member

INDUSTRY REPRESENTATIVE:

DAVID SMITH, Ph.D.

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Principal Deputy Commissioner and Chief
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1 P-R-O-C-E-E-D-I-N-G-S

2 (8:15 a.m.)

3 CHAIR FISCHHOFF: Let me welcome
4 you all. I am Baruch Fischhoff, Chair of the
5 FDA Risk Communication Advisory Committee.
6 Let me thank you all for coming. Let me thank
7 all of the panel members for their continued
8 service and, I think before I say another
9 word, Dr. Lee Zwanziger will officially call
10 us to order.

11 DR. ZWANZIGER: Thank you, Dr.
12 Fischhoff, and thank all of you. Good morning
13 to the members of the Risk Communication
14 Advisory Committee, members of the public and
15 the FDA staff. Thanks for coming to this
16 meeting.

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

22 Today and tomorrow, the Risk

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1 Communication Advisory Committee will have
2 presentations and discussion on the scientific
3 basis for translating principals of risk
4 communication into practice in situations of
5 emerging and uncertain risk.

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

13 Should the discussion turn to an
14 area of possible financial conflict,
15 participants are aware of the need to identify
16 any conflicts pertaining to them and to
17 refrain from participating, and their
18 statement an exclusion would be noted for the
19 record.

20 We would like to note that Dr.
21 David Smith, Industry Representative on the
22 Food Advisory Committee of the Center for Food

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1 Safety and Applied Nutrition is participating
2 as a guest industry representative, in accord
3 with the Charter of the Risk Communication
4 Advisory Committee.

5 We have a period of open public
6 comment each day listed on the agenda. If
7 persons not already signed up to speak wish to
8 request time, please see one of my colleagues
9 at the sign-in table outside of this room.

10 The entire meeting is being
11 transcribed and the transcript will be posted
12 on the FDA website. It can only contain what
13 the transcriber can hear, so please turn on
14 and speak into your microphones when you are
15 recognized to speak and then turn them off
16 when you are finished.

17 I would also suggest that we all
18 turn our cell phones off and any other
19 communication devices into a silent mode.

20 Finally, may I note that one of our
21 members, Ms. Sally Greenberg, is not here.
22 That is just due to a schedule conflict. And

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1 we may be missing Dr. Moxley due to an
2 illness.

3 And other than that, welcome to all
4 of our participants and thank you very much.

5 CHAIR FISCHHOFF: Again, thank you
6 all for coming. And what we will do now is
7 have the members of the Committee introduce
8 themselves briefly so those in the audience,
9 some of you have joined us before, those who
10 have joined us before will get a brief
11 reminder and those who are new, welcome and we
12 will talk about ourselves.

13 I am Baruch Fischhoff. I am on the
14 faculty in the Department of Social and
15 Decision Sciences and Engineering and Public
16 Policy at Carnegie Mellon University and I
17 will be presenting a bit of my work late. So,
18 you will get a dose of it later. More detail
19 later.

20 DR. PALING: Good morning. My name
21 is John Paling. I run an organization in
22 Gainesville called the Risk Communication

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1 Institute. And yes, I am an American for the
2 last 30 years.

3 As well as being interested in
4 helping patients understand risks, I am also
5 an adjunct member of the Department of OB-GYN
6 at UF, the University of Florida. And since
7 this is a meeting all about clarity of
8 communication, I should just tell you that I
9 later learned that the word adjunct is Latin
10 for "no benefits."

11 MS. MAYER: Good morning. I am
12 Musa Mayer. I am a breast cancer advocate
13 from New York City. I work with many
14 different organizations.

15 And I am also a writer and a
16 journalist. I have published a number of
17 books on breast cancer. So, I have a
18 particular interest in communication.

19 DR. PETERS: Good morning. My name
20 is Ellen Peters. I am a senior research
21 scientist at Decision Research in Eugene,
22 Oregon. I am a decision psychologist, which

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1 means that I look at how people process
2 information and how that makes a difference to
3 judgments and decisions that they make.

4 Thank you.

5 DR. SLEATH: Good morning. My name
6 is Betsy Sleath. I am a Professor of
7 Pharmaceutical Outcomes and Policy at the
8 University of North Carolina, Chapel Hill.
9 And a lot of the research I do focuses on what
10 types of actual communication occurs between
11 physicians and patients during visits about
12 medications and how does that impact outcome.

13 MS. DESALVA: Good morning. I am
14 AnnaMaria DeSalva and I lead the global
15 healthcare practice at Hill and Knowlton,
16 which is a global public affairs firm. And we
17 work with healthcare organizations across the
18 healthcare ecosystem in different sectors, on
19 a number of different types of communications
20 challenges and very frequently, and even more
21 commonly now, major risk events.

22 DR. NEUHAUSER: Good morning. My

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1 name is Linda Neuhauser. I am on the faculty
2 of the School of Public Health at the
3 University of California, Berkeley. My main
4 interests are in translating research to
5 large-scale action and especially by working
6 in a participatory way with the intended
7 beneficiaries.

8 MS. LAWSON: Good morning. I am
9 Madeline Lawson and I am the President and CEO
10 of the Institute for the Advancement of Multi-
11 Cultural and Minority Medicine. And our
12 primary focus is on addressing disparities in
13 health and healthcare and we do that in
14 collaboration with national health and
15 consumer organizations.

16 DR. BRUHN: Good morning. I'm
17 Christine Bruhn with the University of
18 California at Davis. I am in the Department
19 of Food Science and Technology and I am the
20 Director of the Center for Consumer Research.
21 And my interest is in consumer attitudes and
22 behavior in regards to food, and food safety,

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1 and food innovations. Thank you.

2 MS. VEGA: Good morning. My name
3 is Marielos Vega and I am a staff nurse with
4 the Department of Family Medicine at the New
5 Jersey Medical School. I am primarily
6 interested in disease prevention and health
7 promotion in minority populations. I work in
8 a city which is primarily Hispanic and
9 African-American. And I will always often say
10 that my office is a community. Thank you.

11 DR. KHANNA: Good morning. My name
12 is Mona Khanna. And my sincere apologies for
13 having my back to you. I am a physician by
14 training. My specialties are internal
15 medicine, public health and preventive
16 medicine, as well as occupational medicine.
17 But for the last six years full-time and prior
18 to that, part-time, I have worked in
19 journalism, in journalism organizations, as a
20 medical correspondent for CBS Television and
21 now as the Medical Director for an online
22 social media site for health called icyou.com

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1 communicating information to the public,
2 primarily consumer health issues.

3 DR. GOLDSTEIN: Hello everybody.
4 I, too, apologize for having my back to you.
5 And I have a new job since the last meeting.
6 I am now the Chief of Mental Health and
7 Behavioral Sciences Service at the Providence
8 VA Medical Center in Providence, Rhode Island
9 and now full-time again, as a full-time
10 faculty member, Professor of Psychiatry and
11 Human Behavior at Brown University Medical
12 School. And my interest is in clinician-
13 patient communication and also how we can
14 disseminate communication strategies within
15 the larger arena of health care. And helping
16 to bridge the gap between also what we know
17 patients need and helping clinicians to
18 respond to those patient needs.

19 Thank you.

20 DR. DELAROSA: Good morning. I am
21 Jacob DeLaRosa. I am a heart surgeon in
22 Pocatello, Idaho. And I came in late last

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1 night. So, I am glad my back is to you all so
2 if I fall asleep, you won't notice.

3 Like I said, I am a heart surgeon
4 in Idaho and I am an advocate for the
5 physician-patient relationship.

6 DR. SMITH: Good morning. I am
7 David Smith. I am the person on loan from the
8 other advisory committee. I am happy to be
9 here. I am the Vice President of Research and
10 Development and Quality for Pepperidge Farm.
11 I spent my career in the food industry in
12 research and development and obviously have a
13 critical interest in communicating to
14 consumers.

15 DR. OSTROVE: Good morning. I am
16 Nancy Ostrove. Like Lee Zwanziger, I am an
17 employee of the Food and Drug Administration.
18 I am the Senior Risk Communication Advisor in
19 the Office of Planning in the Office of the
20 Commissioner.

21 CHAIR FISCHHOFF: At the end of 16
22 digits, the difference between the two talks

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1 is an A and a B. Thanks for setting up. And
2 again, let me thank all of you for coming. I
3 am going to give a short introduction to what
4 we are trying to do here in this the third
5 meeting of this committee and then turn it
6 over to the FDA staff, who we are trying to
7 serve.

8 So, although the committee is known
9 as officially the Committee on Risk and --
10 the Risk Communication Advisory Committee, I
11 believe that the members of the Committee and
12 I think the FDA staff conceptualize our task
13 as communicating about risks and benefits. I
14 mean, all you need -- if there were no
15 benefits, all you need to know is that there
16 was a little risk and your decision has been
17 made.

18 So, we have had an opportunity to
19 try to help. As we are sort of learning the
20 FDA's business our first two meetings, we had
21 an opportunity to respond to a number of
22 topics that were brought to us and now we have

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1 thought well, we would hear more about some of
2 your challenges and then talk a little bit
3 about, and then spend some time with some of
4 the resources that we might be able to bring
5 to bear and then have the benefit of your
6 thoughts on where we could be most useful.

7 So, the context is that, under the
8 FDA Amendments Act, this Committee, and for
9 those who weren't here before was an FDA
10 initiative that began in 2005, 2006. And
11 before we had met, we went from a trial basis
12 to a permanent basis under the FDA Amendments
13 Act of last year. So, it can't really claim
14 any -- it wasn't proof of our efficacy because
15 were made permanent before we had ever met.

16 As a permanent committee, we are
17 here to, we have some specific charges under
18 the FDA Amendments Act. And we have
19 addressed, in our previous meeting one of how
20 to help FDA do recalls and then how to do
21 certain aspects of direct-to-consumer
22 advertising -- regulate direct-to-consumer

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1 advertisements but we are also here as a
2 general consultative resource. We make
3 recommendations but they have only the force
4 of persuasion. And as a result, our
5 effectiveness will depend on how useful we are
6 to the FDA staff, how strong the science of
7 communication is that we can bring to the
8 science of food, drugs, cosmetics, and so on
9 that FDA has its traditional strengths in.
10 Although, FDA is perhaps among the leaders in
11 having in-house expertise in communications
12 and the social sciences among the -- I serve
13 on advisory committees for the department -- I
14 am on the Department of Homeland Securities
15 Science and Technology Advisory Committee and
16 I am on EPA's Scientific Advisory Board and
17 chair its Homeland Security Advisory
18 Committee. And FDA is way ahead of either of
19 those departments, although when you think
20 about it, each of them has very important
21 communication responsibilities.

22 And finally, it will depend on the

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1 resources that FDA will choose to invest in
2 this kind of science, complimenting its other
3 sciences.

4 So, people want to know about, it
5 won't surprise any of you, people intensely
6 want to know about the risks in their lives.
7 Here is a question that we had on a national
8 survey late in 2001, and late in 2002, it
9 referred to terrorism but you would find this
10 was just about anything, very strong support
11 for provide Americans with honest, accurate
12 information about the situation, even if the
13 information worries people. So, people want
14 to know.

15 Here is an endorsement of a
16 similar, of telling people from a document
17 coming out of your Department of Health and
18 Human Services, where there is, I think, kind
19 of a remarkable statement of philosophy, which
20 I think one might not have heard ten years
21 ago. Keep the public fully informed. Tell
22 what we know. Tell what we don't know. Tell

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1 it often. Maintain credibility and public
2 trust by providing accurate science-based
3 information.

4 So, strong commitment and we don't
5 always deliver. One of my students brought
6 this to my attention. I did a project course
7 last fall on evaluating ready.gov, one of my
8 students found this, it was still up
9 yesterday.

10 So, we all understand the
11 bureaucratic processes by which one hand
12 attempts to tell people what they should do in
13 the case of an emergency and how to prepare
14 and another hand says, but our fingers have
15 been crossed while we are talking all of this,
16 saying this, so none of it may be true.

17 So communication requires
18 leadership. It requires, on the one hand,
19 strategic processes that integrate
20 communication with analysis and regulation so
21 that there is a coherent, well-founded message
22 that serves the audience as needed. And then

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1 there is strategic staffing so that an
2 organization has the people needed to get the
3 job done and uses those people in a
4 coordinated way.

5 Here is one model that I like of
6 how to integrate communication and risk
7 management and risk analysis. It is from the
8 Canadian standards association. It has been
9 around for about ten years. It is gradually
10 working its way through the Canadian
11 government and some of their suppliers.
12 Actually, I think Health Canada is probably in
13 the lead there. They have a very aggressive
14 program. Well actually, I grew up in Detroit
15 and we thought of Canada as our great neighbor
16 to the south, if you look at the micro-
17 geography of the U.S. and Canada.

18 And without going into great
19 detail, I would be happy to send you -- the
20 slides, I guess, will be posted, or a copy of
21 this document if anybody writes. But the
22 Canadians, their conception is you have sort

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1 of a traditional, in the middle, a traditional
2 risk management process. You conceptualize a
3 project, you gradually develop it. An
4 interesting part of their concept is that you
5 have, you probably can't see that but, there
6 are four-way arrows between each of the stages
7 sort of to check, have you gotten the job done
8 and if not, you have to go back. So they
9 acknowledge the possibility you may never be
10 able to get to the bottom, which is contrary
11 to may bureaucratic and organizational
12 processes, where you plow through, even if it
13 is not working.

14 And then they have, on the left-
15 hand side, they have risk communication as
16 integral to the process from the beginning to
17 the end, with two-way arrows. So they say, if
18 you read the text, it says, if you are
19 beginning to manage some kind of risk or
20 reviewing your existing management schemes,
21 tell people what you are doing, the individual
22 stakeholders, whoever's attention you get, so

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1 they are not blind-sided by the result. And
2 then listen to them, so you are analyzing the
3 problem that they are concerned about and that
4 they view this, the communication, as
5 essential to risk management from the
6 beginning to the end.

7 You know, as we all know, all too
8 often somebody creates a solution or creates a
9 problem and dumps it on our desk and say tell
10 the people, tell the people about it. But you
11 don't get this without boardroom leadership
12 that communication is that essential.

13 And then so, let's say you have got
14 the commitment or the commitment that DHHS and
15 that H5N1 document, then you need the people
16 who can get the job done. One way to think
17 about those people would be to say you need
18 four kinds of expertise. You need domain
19 specialists who represent the science of the
20 risks and the benefits. You are speaking
21 authoritatively about the phenomenon. You
22 need risk and decision analysts who will

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1 identify the information that is critical to
2 people's choices.

3 Well, you know, under many
4 situations, you have a narrow window of
5 opportunity to communicate with people. If
6 you tell them stuff that they already know or
7 they don't see any reason to know, or is
8 incomprehensible, that window may close on you
9 entirely. So, you have an obligation to, what
10 economists might call, create a supply curve
11 of information. Tell people the things that
12 they most need to know as early as possible.
13 If you do that, you may get the credibility
14 that may warrant the credibility that will be
15 needed to get further down the supply curve
16 and tell them more.

17 And if people only have a little
18 bit of time, then you have fulfilled your
19 obligation. And that doesn't come, this is
20 not something that one does intuitively,
21 unless you study your audience, you don't know
22 unless you analyze the problem. The things

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1 that are most important to us as scientists,
2 whether it is the classroom or any other
3 place, are not necessarily the ones that are
4 the most important to our audience.

5 Third, you need behavioral
6 scientists who will take advantage of the
7 research we have in order to design the best,
8 give it the best shot at communicating what we
9 think is the most relevant information. And
10 then, evaluate the messages so that we see how
11 well we are doing. You wouldn't give somebody
12 a drug without field testing it. With many
13 drugs the communications are a part of the
14 drug. If it is not taken right, it is not the
15 same drug as the one that was tested in the
16 clinical trial and yet we often communicate
17 about lots of things without any testing
18 whatsoever. So, we set ourselves up for
19 failure. We set our audience up for failure
20 and so the behavioral scientist, they know how
21 to do the kind of collaborative activity that
22 is needed, the reiterated design that is

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1 needed to create something that has a chance,
2 the best chance of working and draw on the
3 basic research. And then finally, to see how
4 well you are doing. And then, as the
5 Canadians would say, go back to work if it is
6 not good enough.

7 And then finally you need, I'm not
8 sure quite what the right word here is, but
9 systems specialists, people who can make the
10 whole thing work, who can get the
11 communications out the door, get them the
12 right production values, assemble the people
13 that need to be on the team, take feedback
14 from the field.

15 And you need to have all the, you
16 need the leadership that will have all of
17 these people working on their own tasks. So,
18 you don't want psychologists inventing
19 medicine, what we think is somebody ought to
20 be doing in a particular situation. Somebody
21 who knows the medicine has to check our work.

22 Adversely, you don't want

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1 physicians or pharmacologists pushing their
2 pet theories of citizen's competence based on
3 their own individual experience, which may or
4 may not be correctly interpreted. It may or
5 may not be generalizable. You don't want your
6 public affairs staff, part of whose job is, I
7 guess I've used the picture in a negative turn
8 here of spin, but every organization needs a
9 public affairs staff that will put the
10 organization's case out. You will get eaten
11 alive without it.

12 On the other hand, the kind of
13 communications that we are talking about here
14 are not public affairs but really public
15 health communications. We are trying to serve
16 the interests of the audience. So that can be
17 a different mind set than somebody who is just
18 thinking about the organization in the narrow
19 run. In the long-run, I think the public
20 affairs are served by serving public health
21 needs.

22 And finally, you don't want the

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1 people doing your technical analyses imputing
2 their own values in the way that they work the
3 numbers. And some of you will be familiar, we
4 could certainly talk about it, there are lots
5 of ways in which you can interject your
6 personal values, perhaps unwittingly, into how
7 to do the analyses.

8 So, you don't want to turn your
9 communication into a BIO 101 thing. People
10 are listening to me, now is the chance to tell
11 them all of the things that they didn't pick
12 up in high school or maybe elementary school.

13 You don't want just messaging sessions or
14 some group of self-appointed experts sit
15 around and decide what the public needs to
16 know and how they need to know it and then
17 give it to the people who can give it the
18 production values and push it out the door
19 without relying on the communication science
20 or doing evaluation.

21 You don't want to give guidance
22 without supporting evidence, so that people

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1 have a feeling of control. There are a lot of
2 that in Homeland Security. You don't want
3 universal guidance saying everybody should do
4 this, in situations where people have different
5 values. And you don't want to rely on
6 charisma, per se.

7 We have these very visible cases
8 where somebody spoke to people's heart in a
9 way that looks as though it was effective and
10 think that that is all that we need. Often,
11 the people who speak effectively to people's
12 hearts don't speak effectively to people's
13 minds because they don't create the staff
14 needed to develop the message appropriately.
15 Look at some of the work that has been done on
16 climate change, to take us out of this domain.

17 So, here is our agenda for the
18 meeting. We are still on a learning curve of
19 understanding FDA's needs and opportunities,
20 and even all of the things that is already
21 doing along here. So, we will hear from FDA
22 staff beginning with Dr. Nancy Ostrove.

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1 And then we have divided the
2 communication science and practice from the
3 committee into three groups. So, first three
4 sort of panels and then I think we have plenty
5 of time for discussion.

6 In some sense, but you can't still
7 evaluate the quality of our own
8 communications, which is, one we are going to
9 talk about what we are calling non-persuasive
10 communication. That is, how do you get a
11 message out when it is really up to the
12 audience to decide what they want to do? A
13 drug has been approved. It is good for some
14 people, not good for others. Then either the
15 people who receive it or you would like the
16 people who have the drug to be able to make
17 independent choices, balancing the risks and
18 benefits, or be within one or two degrees of
19 separation of somebody who can interpret
20 evidence for them. And in some sense, it is
21 none of your business that they do, as long as
22 it has been approved as something that could

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1 be useful to some people.

2 So, we are calling that non-
3 persuasive communication. Not unpersuasive,
4 not where you have tried and failed, but non-
5 persuasive in the sense that you are not
6 trying to persuade.

7 Secondly, there is persuasive
8 communication, basically where you don't want
9 people to use something, anybody to use it,
10 perhaps a particular class of people would
11 have a reaction to it, and how do you get
12 people to do that.

13 And then finally, what about
14 emergency communication. What are the
15 situations? However well you plan, problems
16 come up. Unexpected information comes from
17 the field, make an extra effort to find out
18 what is going on and you find that here are
19 new things that you want to communicate. So,
20 how do you prepare so that you more or less
21 know what you are going to say, more or less
22 have tested messages for those situations.

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1 But then, how do you manage the overall
2 situation? Adapt what you thought you were
3 going to say into the specifics of particular
4 situations.

5 And I think we have been fortunate,
6 we are very fortunate in this committee to
7 have people who are really experts in each of
8 these. So, thank you for coming. I look
9 forward to your input.

10 And Nancy?

11 DR. OSTROVE: Good morning and
12 thank you, Baruch, for that because I think I
13 can skip some of this stuff now.

14 I wanted to accomplish -- wow, big
15 group. See, when you have your back to the
16 group, you don't necessarily see it.

17 I wanted to accomplish a few things
18 with my remarks this morning. First, to
19 welcome everyone here from FDA, which I think
20 we have done already. To give some general
21 background toward the end of setting up kind
22 of a context for today and tomorrow's meeting,

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1 where we have been, where we are heading, and
2 to provide some feedback to the Committee as
3 well, because we have met two times already,
4 and we want to make sure that everyone
5 understands kind of where FDA is, with regard
6 to how we have been hearing what you have been
7 telling us.

8 I don't want to take too much time,
9 so we can focus on the meat of the discussion.

10 But we will know that I am getting into
11 trouble in terms of how to explain something
12 when I take too much time on a particular
13 slide. So, we will see how that goes.

14 As you all know, FDA's mission is
15 protect and advance the public health. And we
16 do that by assuring the safety, effectiveness,
17 the security of regulated products, we speed
18 innovations around the products we regulate,
19 and help the public to get accurate science-
20 based information that they need, in order to
21 use the products that we regulate in order to
22 improve their health.

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1 Now, historically, when it comes to
2 communicating with public about products, we
3 have tended to take kind of a passive role.
4 We focused on the past on generating and
5 analyzing information and we have kind of
6 focused on regulating the communication that
7 sponsors or producers make about the products
8 that they make available to the market. And
9 that is kind of historically how we looked at
10 much of our communication. It tended to be
11 focused, in the past, focused on labeling. At
12 least, certainly, for medical products. So,
13 in some ways, it has kind of been a passive
14 stance, you can call it taking a passive
15 stance.

16 Over the past several years, and I
17 guess I would bring it out to decades, we have
18 tried to take a more active stance, and we
19 have moved, attempting to kind of seek out
20 relevant information and proactively share
21 that information in order to help our
22 constituents make more informed decisions.

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1 So, this is kind of what we have
2 done in the past and I don't want to at all
3 minimize the fact that here has been a lot of
4 consumer education, especially surrounding
5 foods. And as many of you who have followed
6 FDA will know, especially if you follow FDA
7 kind of in general, is that we have this kind
8 of strange dichotomy. Although we are often
9 known as the Federal Drug Administration by
10 many, it is really a misnomer, since it is the
11 Food and Drug Administration. But there is
12 this kind of dichotomy between foods and
13 medical products because you get into that
14 dichotomy between products that we approve for
15 use and products that we simply, not simply by
16 any means, and products that are already on
17 the market without pre-approval.

18 So you get that pre-approval versus
19 completely post-approval regulatory regime.
20 And that has been, I think, problematic for
21 some people to see. And it is difficult when
22 one organization has very different regulatory

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1 regimes for the many things that it regulates.

2 So, it is not really surprising, I think,
3 that oftentimes people forget about that.

4 So, why have we become more active?

5 Well, I think it is partly because we have
6 come to appreciate the greater role that
7 communication has to play in assuring that the
8 safety, effectiveness, and security of
9 regulated products which, after all, is
10 remember one of our mission statements. I
11 guess we have realized that conceptually that
12 we might be able to do without effective
13 communications. But in practice, safety
14 especially can be very problematic without
15 effective communication. And we have
16 recognized the need to explain the context of
17 the regulatory actions that we take. I think
18 everybody, well everyone here, perhaps but
19 perhaps not everybody, recognizes that
20 approvals are relative.

21 As Baruch pointed out before, if
22 you don't have benefits, then risks don't mean

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1 anything. Well, similarly, when we approve a
2 product, it is really by weighing the benefits
3 and the risks in determining that at least
4 when used in a certain way, the benefits of
5 the product outweigh its risks.

6 Now, that can become especially
7 problematic for medical products where people
8 can legitimately, healthcare providers can
9 legitimately use them in ways that were not
10 envisioned by the approval. So, you know,
11 talking about kind of off-label or extra label
12 use. And people, and I am not sure that the
13 public necessarily understands that you really
14 do need to assess benefit in the context of
15 the risks.

16 Similarly, getting back, to our
17 mission statement, we try to speed
18 innovations. Well, innovations, just because
19 they are new, will generally create their own
20 challenges because people often do not have a
21 framework in which they can kind of put the
22 information that they get about those

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1 innovations. And they may have much higher
2 expectations for them than they objectively
3 should, in some ways, you know, given what we
4 know about the innovations. And similarly,
5 when something comes off the market, that is
6 not an absolute issue. It is very relative or
7 say if we restrict distribution, it is very
8 relative. And again, you have to look at the
9 balance of benefits and risks.

10 Back in February in our first
11 meeting, we talked about how FDA communicates.

12 And we kind of broke it down in terms of
13 slicing the pie, as well. We communicate
14 indirectly through regulating labels and
15 labeling and through regulation of at least
16 some promotional activities for some products.

17 And we communicate directly as well. We have
18 our press activities. We have a variety of
19 communication vehicles about specific products
20 and product classes and we will hear more
21 about that later.

22 We do stakeholder outreach, and we

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1 make direct response to inquiries, and carry
2 out public education campaigns. Well, another
3 way to look at it, in terms of how we
4 communicate, is distinguish between activities
5 that focus on on-going versus new information.

6 So, we have a lot of educational information
7 that really focuses, that really tends to be
8 ongoing in web and print and TV. We do it
9 ourselves. We do it with partners.

10 We have tried, especially recently,
11 to better facilitate access to product
12 labeling, which kind of contains the state of
13 the art, well, at least, kind of we think that
14 way, state of the art at a certain point,
15 about regulated products that are approved for
16 use. And we do a lot of stakeholder outreach
17 through web-based and phone-based methods.

18 When it comes to new information,
19 which tends to be typically safety or risk-
20 related, depending on who you want to frame
21 that, we have a number of differently titled
22 vehicles that we use that focus on risks that

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1 are new or emerging or, what is another word,
2 uncertain as well. And those include labeling
3 changes. Once we know more about it, they may
4 even include recalls. And again, we do this
5 through a variety of communication channels.

6 Well, the question has been raised
7 of how effectively we communicate. That has
8 been raised both internally and externally.
9 And in addition to hearing from our advisory
10 committee here, we have requested public
11 feedback in a number of instances. So, I have
12 kind of just listed a couple of those.

13 We had a December 2005 meeting. It
14 was a public hearing concerning the
15 effectiveness of our, of how we are doing,
16 kind of, on our drug risk communication
17 strategies. We just put out a notice, I think
18 it was just a couple of weeks ago about a
19 meeting that will be happening next month on
20 the use effectiveness and consumer perceptions
21 about allergen advisory labels that are
22 included on foods.

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1 And we asked to IOM, the Institute
2 of Medicine to report on the future of drug
3 safety, during which time they gave us some
4 information about our communication. And one
5 of the recommendations specifically that came
6 out of that request to assess the system of
7 drug safety in the United States, actually it
8 was a recommendation to Congress, to establish
9 an advisory committee that would focus on
10 communication with patients and consumers.
11 So, the IOM recognized that we could improve
12 the way that we have been doing that.

13 Baruch has talked a little bit more
14 about kind of how the committee has come
15 about. So, I am not going to spend a lot of
16 time with that. So, basically, in February,
17 we had our initial meeting that just kind of
18 set the stage for continuing discussion that
19 we plan to have about risk and, you notice,
20 and benefit information -- by the way, we did
21 not coordinate our slides. I think that is
22 well worth mentioning -- over time.

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1 And that first meeting took place
2 in February, well on February 28th and 29th.
3 But on the 28th, we focused on giving an
4 overview of the laws and regulations that
5 affect our communications and current
6 communication vehicles and activities. The
7 purpose there was to basically provide the
8 committee and the public, to some extent as
9 well, with kind of an initial and regulatory
10 context for the early discussions that we were
11 going to be having. To understand what the
12 boundaries were around how we communicate
13 because there are legal and regulatory
14 boundaries and to understand the boundaries
15 around research that we can do that is
16 specifically relevant to communications.

17 We had a similar panel that talked
18 very, very briefly about specific direct
19 communication vehicles activities not focusing
20 on emerging risks and kind of flushed out some
21 of those -- well, let's pass on that. That is
22 not really important.

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1 What was important was what we
2 heard from the committee in response to those
3 presentations and to the questions that we
4 raised. And what we heard, basically, is that
5 we should be designing communications at the
6 start, and Baruch has talked about this again
7 this morning. We should be tracking responses
8 to communication products. Again, you saw
9 that in the model that was put up. We should
10 be empirically testing messages before
11 release. I don't want to sound like a broken
12 record. We should increase efforts to reach
13 vulnerable populations, including those who
14 have less scientific backgrounds, speak
15 languages other than English, or have
16 difficulty accessing information
17 electronically.

18 We should communicate about
19 benefits, not just risks. And when we are
20 putting out early communications about
21 possible new risks, we should explicitly
22 address the uncertainties surrounding the data

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1 that we have in a scientifically sound way.

2 Now, this seems to be a good place
3 for me to take a breath and for us to take a
4 detour, a little bit of a detour. Consider
5 it kind of one of those times when you pull
6 off the highway. You know, you need to make
7 an important phone call or refuel in one way
8 or another, and this detour is to kind of
9 accomplish a couple of things. Actually, both
10 of those thing an important call and hopefully
11 psychological fuel-up for our committee
12 members.

13 We think it is important that the
14 committee and that everyone understand how
15 much we appreciate the feedback and the
16 recommendations, I am speaking directly to you
17 all, that we get from you and what we are
18 doing with the valuable advice that you have
19 offered us in the two meetings that we have
20 had in the past.

21 Note, by the way, that we haven't
22 just heard from the committee as a whole, we

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1 have heard from individuals as well on the
2 committee, who have clearly thought very long
3 and hard about how they individually, as well,
4 can contribute to improving our risk and
5 benefit communications. And I wanted to tell
6 you that our belief that risk communication is
7 an important priority is shown by our
8 including risk communication in the request we
9 sent forward for how and how much to spend of
10 our 2009 budget, which begins in October.
11 Because the actual number of dollars and the
12 FTEs, you know, full-time equivalents, that
13 are going to be assigned are still being fine
14 tuned. I can't, I am just not at liberty to
15 discuss the specifics today but I would say,
16 you know, stay tuned for more information
17 about that.

18 What are some of the things that we
19 have done? Well, we have established an
20 internal communications counsel that has
21 representation from across the agency. It is
22 designed to facilitate more coordinated

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1 activities to leverage our existing resources
2 and to determine where we should be putting
3 our efforts to improve our practices. That
4 is one thing.

5 Well, another thing, we have taken
6 initial steps to increase the extent to which
7 we can test messages and communication
8 vehicles prior to using them. In fact, we
9 have a person coming in at the end of the
10 month who is going to be focusing on setting
11 up an internal FDA network. It is basically
12 for internally testing communications that
13 need to have very expeditious reviews that
14 wouldn't allow kind of the time constraints
15 that are involved in getting OMB approval for
16 more rigorous testing.

17 In addition, we have recently
18 received clearance from the Office of
19 Management and Budget, that is OMB, to get a
20 relatively short turn around review of
21 customer satisfaction web-based surveys, so we
22 can get feedback on our website, using items

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1 that can be tailored to the specific sites,
2 rather than only using general items.

3 In fact, our advisory committee
4 site was recently redesigned and it included
5 kind of the General items that the Department
6 has already gotten kind of this generic
7 clearance from OMB for doing, for collecting
8 that information. And that has those general
9 items on it. That site is actually currently
10 highlighted on our home page and some of you
11 are on that picture. If you haven't looked,
12 you know, and you like that kind of thing, you
13 are there. You are up there.

14 Even more significantly, though, I
15 think, we recently have received clearance
16 from OMB, within a very short time for a web
17 feedback survey for a new site we are going to
18 be launching very soon that some of us are
19 fairly excited about. That site is designed
20 to educate the public about how we regulate
21 the promotion of medical products and
22 specifically about direct-to-consumer

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1 advertising of prescription drugs. We hope to
2 be using this mechanism for gaining feedback
3 on our sites more and more in the future.

4 About the website in general and
5 its accessibility and its navigation, our web
6 staff is working hard to educate our content
7 providers, the people within the Agency who
8 provide the content on how to write for the
9 web, and on ensuring that usability testing is
10 regularly used. And I would remind you that
11 we are going to be coming to you regularly for
12 your review of FDA's website as is mandated in
13 Section 915 of the FDA Amendments Act.

14 In addition, finally, your comments
15 on the draft press release for product recalls
16 led to a revised version that we are currently
17 preparing for more testing. So, just to let
18 you know about that because we believe that it
19 is important to have that feedback loop in
20 place.

21 On the road again, what is the
22 focus of today's discussion? Basically, we

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1 want to have you further explore FDA's direct
2 communications, those that are focused on new
3 emerging risk information. And we are going
4 to talk about, and we will have more specific
5 questions but it kind of comes around to what
6 do we do, what should we do, how do we, how
7 should we decide when, with whom, and how to
8 communicate. How shall we evaluate the
9 effectiveness of those communications?

10 And we kind of tried to put what we
11 do in a framework and we thought about how.
12 You know, earlier I talked about different
13 ways to slice the pie of how we communicate,
14 well in planning for today's meeting, we
15 looked at the reasons why we communicate and
16 who we communicate with and also to ask well,
17 who is the actual decision-maker within the
18 context of communication. And Baruch has
19 already actually talked about this, to some
20 extent.

21 So, we can look at the purpose and
22 Baruch talked about you will recall,

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1 persuasive communications, non-persuasive
2 communications, and emergency communications.

3 And again, remember, we did not -- we talked
4 about the meeting in general but we did not
5 coordinate our slides. And sometimes, in some
6 ways, I wish we had because when we talk
7 about, you know, kind of informing people,
8 that is kind of giving them non-persuasive
9 information.

10 So, it is very parallel with what
11 we have already heard this morning. And here
12 you have it, in fact. Non-persuasive
13 communication, persuasive communication and
14 what we have called explanatory information
15 where we are trying to explain an action that
16 FDA has taken, where the decision to some
17 extent is not -- is outside the power, so to
18 speak, of the public.

19 So, you can have a decision where
20 it is clearly up to the individual. You can
21 have a decision where it is kind of a
22 combination, where FDA may be making a

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1 recommendation and the individual makes the
2 decision but we hope to persuade the
3 individual that a particular way to go is the
4 right way to go. And then you can have
5 situations like with seizures, okay, and
6 certain types of withdrawals, excuse me,
7 recalls, not all of them, with prosecutions,
8 with injunctions, where the public really has
9 very little input on that. And what we are
10 trying to do is to kind of explain what it is
11 that we have done, and in some cases, to get
12 the public to take some actions that are
13 related because, as I mentioned, recalls, and
14 I think this kind of brings us to here,
15 recalls, even class one recalls are cases
16 where the producer may take a product off the
17 market but the patient or the consumer may
18 still have it sitting on their shelves. So,
19 they need to understand why this has happened
20 and what they should do in this particular
21 circumstance because it is important enough
22 from a public health perspective that they

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1 take this action. So, it goes even beyond
2 persuasiveness in some ways.

3 So, try to put together kind of a
4 framework which, by the way, I will say is by
5 no means perfect. But we tried to kind of put
6 -- and by we I am using the royal we because I
7 don't want anyone to take blame for this
8 except for me, I mean people in FDA have seen
9 it but I pretty much take responsibility for
10 the weirdness of it.

11 In that first box there, you know,
12 you have got what basically we are talking
13 about is informational or non-persuasive
14 communications that we use, labeling, labels,
15 informed consent. In some cases your
16 healthcare provider letters and in the early
17 communications that CDER has been putting out.

18 And then you get into what, at one point we
19 had in boxes, and then I think two nights ago
20 I decided I didn't like it in boxes because it
21 just was too much of a box and when you put
22 something in a box, people don't think about

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1 the boxes as being kind of, the boundaries as
2 being fungible, as being able to be a little
3 bit fuzzy. And I couldn't figure out a
4 graphic way of making fuzzy boxes, box
5 borders. PowerPoint has its limitations.
6 What can I say?

7 So, this kind of set it up as a
8 continuum of persuasive communications where
9 you have, in fact, pieces of labeling, for
10 instance box warnings, and early
11 communications, preliminary public health
12 notifications, in the case of CDRH and what
13 CBER uses, kind of toward that early end of
14 persuasive. And then getting into the
15 seizures, the injunctions, and the
16 prosecutions, and class one recalls and market
17 withdrawals toward the other end. So again,
18 not perfect. I fully expect complete
19 criticism of it. That is fine.

20 Well, what is the kind of
21 information that should be included in a
22 communication? So the next two slides

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1 basically show some information that is often
2 but not always, and not necessarily
3 consistently, included in our risk
4 communication vehicles. Well, should each of
5 these types of information be included in
6 every type of vehicle? Should it be a
7 function of purpose? Should it be a function
8 of audience or of the locus of the decision of
9 some other factor? I mean, we can even
10 envision kind of an N-dimensional matrix
11 indicating what information should be included
12 in what circumstances, and I couldn't do a
13 three-dimensional box. I certainly couldn't
14 do a four or five dimensional box on a
15 PowerPoint slide. Once again, I blame
16 PowerPoint for my limitations.

17 Now, these are somewhat more
18 straight-forward information but then you get
19 into the issue of the quality of the data that
20 is associated with the risks and benefits that
21 we are talking about and the quantity of the
22 data that is associated with the risk and

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1 benefits and the availability of alternatives.

2 These are, you know, a little bit more
3 complex and fuzzier, in terms of trying to
4 communicate.

5 So, with that as kind of a
6 framework, the next slides are basically the
7 topics for discussion for the next two days.
8 The first one, I kind of would like to do what
9 Baruch did, just kind of give you time to read
10 it so you don't have to listen to my voice.
11 This is the first topic for discussion. I
12 read fast but I think that was enough time.

13 This is the second, not that we are
14 necessarily doing them in any particular
15 order. They are really just meant to kind of
16 provide the general context of what we are
17 asking for.

18 Here is the third. Of course, I
19 guess this isn't great for the transcript.
20 But on the other hand, the slides are included
21 in all of the materials and I think the
22 transcriber could probably be very happy not

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1 hearing my voice constantly. And here we have
2 the fourth.

3 Okay, moving on. This is kind of
4 the order of the proceedings for today. We
5 are going to be hearing from the
6 representatives of our regulated product
7 centers about the vehicles and activities
8 that they use surrounding the communication of
9 emerging risk. We are hoping to have a
10 presentation from Dr. Frank Torti, who is
11 FDA's Principal Deputy Commissioner and FDA's
12 Chief Scientist. And he will be addressing
13 the committee probably around 10:30, I
14 believe.

15 And we are going to be having
16 discussion. And I guess our hope is is that
17 there will be a back and forth, a dialogue
18 between our FDA representatives and the
19 Committee to better get at the questions that
20 we would like to have your expert advice on.

21 So, thank you in advance for our
22 FDA speakers, for the speakers from the

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1 Committee.

2 Linda?

3 DR. BRUHN: Nancy, I'm sorry. I
4 have a question. I apologize for not knowing
5 the answer.

6 In one of your diagrams, you
7 referred to some acronyms and I don't know
8 what they are.

9 DR. OSTROVE: Oh, I'm sorry.

10 DR. BRUHN: What is CDER, C-D-E-R?

11 DR. OSTROVE: Okay.

12 DR. BRUHN: And what is C-D-R-H?

13 DR. OSTROVE: Let me tell you what
14 those are. Those are acronyms -- thank you so
15 much for pointing that out because it really
16 is an oversight on my part. Those are
17 acronyms we use to describe the different
18 regulated product -- the different centers
19 that regulate different products. So that you
20 are probably, this is Dr. Bruhn talking, who
21 was speaking, are most familiar with CFSAN,
22 which is the Center for Food, Safety and

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1 Applied Nutrition. The CDER is the Center for
2 Drug Evaluation and Research. CBER, C-B-E-R,
3 is the Center for Biologics Evaluation and
4 Research. C-V-M is the Center for Veterinary
5 Medicine. And C-D-R-H is the Center for
6 Devices and Radiological Health. Because as
7 you know, we regulate medical devices and we
8 also regulate radiation admitting things,
9 machines and whatnot, including the cell
10 phones I'm sure all of you have in your
11 various pockets or purses.

12 So, thank you very much for
13 pointing that out. Any other clarifying
14 questions before we move on?

15 (No response.)

16 DR. OSTROVE: Thank you for your
17 attention.

18 CHAIR FISCHHOFF: Thank you, Nancy.

19 I think, I suppose lack of coordination is
20 bad but if we discover that we are on
21 overlapping pages, that is probably good. And
22 I really appreciate the feedback that you have

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1 gotten and the work that you are reporting
2 from it. I think it is important for us to
3 get feedback, whether we are relevant or
4 whether we are irrelevant, so that it can
5 improve our performance and the fact that we
6 seem to be irrelevant on some scores is, I
7 think, is gratifying. So, thank you and the
8 others doing the work.

9 So our first speaker, well, I guess
10 our next speaker from FDA is Lynne Rice, who
11 is the Director of the Office of
12 Communication, Education, and Radiation
13 Programs.

14 MS. RICE: Good morning. I am
15 happy to be here and to be the start-off and
16 the C-D-R-H in the list of acronyms of all of
17 the product regulated centers. This morning,
18 I am going to share with you some of the
19 challenges that we face with our industry, as
20 well as communicating with our various
21 stakeholders.

22 I wanted to give you an idea of the

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1 kinds of stakeholders that we do have. We
2 regulate a wide and a diverse range of
3 products. I know I mentioned this back in
4 February but just sort of to bring you back up
5 to speed, things from bandages to various
6 diagnostic lab tests to all kinds of implants
7 and, as we mentioned, x-ray products, cell
8 phones, microwaves and a gambit of products.

9 I also wanted to let you know that
10 there are about 10,000 types of these out
11 there on the market. And just a hint, over
12 seven million Americans receive an implant
13 each year. So, there are many many people out
14 there that use medical devices and have
15 radiological products and lots of versions of
16 these things out there. So, the concerns, the
17 risks, the problems that we run into vary
18 across the board.

19 Another point that I wanted to make
20 is our industry is quite large. There are
21 over 25,000 manufacturers that we regulate,
22 again, with the number of products. So,

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1 dealing with our different industries can be
2 interesting. They have different
3 perspectives, depending on where they come
4 from and what products they market.

5 The other interesting fact is how
6 small our device industry is. The Small
7 Business Administration calls a small business
8 any company with 500 employees or fewer. And
9 if you take note, we have 90 percent of our
10 industry with less than 59 employees. So, we
11 have a lot of companies we are dealing with
12 that do not have a lot of expertise in various
13 areas, such as usability, and social testing,
14 and risk communication. So, we try and do a
15 lot of back and forth with them to help them
16 understand this.

17 Another issue we run into is a lot
18 of our companies, a lot of the products
19 sometimes are made by one or two companies.
20 There is not a lot of product on the market.
21 And so one of the concerns that we have to
22 take into consideration is a shortage of

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1 products when something happens with a
2 particular product made by one company. If we
3 were to pull that from the market, you know,
4 how would that affect the use and the need of
5 the industry of patients?

6 Another thing that I think is
7 slightly different than some of my sister
8 colleagues here is that our products are
9 redesigned quickly. Products get on the
10 market a lot sooner, a lot less or not a lot
11 less, but less testing than drugs go through.

12 And the products are iterative. As soon as
13 they are learning something that is not quite
14 right, hearing from physicians and patients,
15 they go and start making the next version. So
16 we can have, sometimes, ten generations of a
17 product out there. So when we are trying to
18 communicate about a recall or about problems,
19 the question then tends to be which one is it
20 because so many are out there. So, that
21 becomes challenging for us, which leads to the
22 communications challenges.

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1 So, we have talked about complexity
2 of information because the products range
3 across the board. Timeliness, a lot of times
4 we are getting information out to the public
5 after, obviously, the company has already done
6 that. So, it sometimes is hard for us to get
7 ahead of the game and make our information as
8 useful as perhaps what someone else, whether
9 it be the press or physicians or the company
10 has already gone out with.

11 Another challenge for us are
12 implants, as we mentioned. When we talk about
13 recalls, that can be quite difficult in
14 concern with alarming patients and concern
15 about how to handle that because, obviously,
16 they can't return that product to the local
17 Wal-Mart.

18 We have issues around communicating
19 unclear risk. That shows up a lot in our
20 radiation program side of the house. When you
21 are talking about risk, that may not be seen
22 today or tomorrow but 20 years down the line.

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1 It is very hard to get people to take action
2 on something like that.

3 And I feel like a challenge for us
4 is that we are not always, FDA is not always
5 seen as the first person one might go to when
6 they have a problem. We are a regulatory
7 agency. They see us as approving, and
8 clearing, and inspecting, and helping with
9 recalls of products. So, sometimes people
10 want to know why we are telling them
11 something. They don't think we are
12 necessarily the ones to bring that to them.

13 So, those indicate to you some of
14 the challenges I feel like we struggle with.

15 I wanted to give you a little
16 refresher on some of our non-persuasive
17 communication. We have lots of non-persuasive
18 communication. We provide a lot of
19 information out there on our websites through
20 our various news letters and through journal
21 articles. And our websites do provide
22 information so I will talk about our LASIK

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1 website. You know, we do a lot of evaluative
2 information, we have done on the web, as Nancy
3 has mentioned, and so we can ask that it is
4 that consumers want and what industry wants
5 and what healthcare professionals want. And
6 we try to use that information and put it back
7 into the system.

8 So, our LASIK website has
9 information such as what is LASIK, to help
10 people understand that. You know, when is it
11 not for a particular individual? Again, some
12 suggestions and advice. Risks of LASIK. We
13 give a link where they can go and find all of
14 the approved lasers for that particular
15 purpose because we do hear all the time they
16 want to know what they should be using, so
17 they can ask their physicians. And we do have
18 frequently asked questions again, based on
19 inquiries that come in.

20 So, a question may be, you know,
21 when do we actually or how do we decide to do
22 non-persuasive communication. We do have an

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1 organization that takes calls from consumers
2 and healthcare professionals. And when
3 questions get to be the same question over and
4 over again, you go, okay, it is time to put
5 information out there. Obviously, when we
6 have new products, new things on the market, a
7 website I didn't put on here is our wrinkle
8 filler website. There are many people going
9 and having those types of procedures and we
10 realize there really are issues and risks that
11 we need to be sure they are aware of.

12 So, if it is new information, we
13 generally, or new products, new concerns that
14 we are hearing, we will put these items up.

15 We do have, for our non-persuasive
16 communication, we have processes. We have
17 committees. And our committees are made up of
18 the various types of subject matter experts in
19 our organization and we kind of look and go,
20 you know, is this the kind of information we
21 need to put out there and we want to make sure
22 we are getting all the right minds in the room

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1 at the same time when we create these types of
2 sites. And then there are approvals within
3 our organization. And if we are doing FDA-
4 wide, as you see, we have FDA newsletters, we
5 will get the approvals from the other centers
6 as well.

7 We have really four main types of
8 persuasive communication. Our center has kind
9 of, you know, we have smaller numbers of
10 things and we actually think very long and
11 hard about our persuasive communication. We
12 really have to know that there is a level of
13 risk out there before we are going to use one
14 of these various vehicles.

15 I did want to put up, in the gambit
16 of radiation programs, we do regulate
17 mammography facilities around the country.
18 And one of our tools for notifying women if we
19 believe there has been a problem reading
20 mammograms is our physician and patient
21 notification. The difference between that and
22 the other three listed are the fact that our

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1 laws and regulations actually say that this
2 has to happen. And we have developed the
3 templates and we do require and review and
4 approve when these letters go out. So, we
5 have a lot more control in our center over
6 that particular activity, than any of our
7 other types of communication where we are
8 discussing with the manufacturer and trying to
9 get them to do what we want. Here we have a
10 real ability to say this is what you will say,
11 and this is what you will do, and this is when
12 you will do it.

13 But our other three here are what
14 we use primarily for, you know, notifying
15 individuals that there is a risk that needs to
16 be mitigated. Our public health notifications
17 are widely used for healthcare professionals
18 and generally written at that level. Our
19 advice for patients is a new product, where we
20 sort of tack on when there is a need for a
21 public health notification, where we believe
22 that consumers have information they need to

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1 know. They are generally written at a
2 different level, knowing that the audiences
3 exist and so we do have different vehicles
4 that we are using for that. We have not done
5 that many advice for patients.

6 And our FDA "Patient Safety News" I
7 mentioned to you last time, is our broadcast
8 quality TV program that is done, again, in
9 conjunction with the other centers to provide
10 this information to healthcare professionals
11 around the country.

12 Some of the criteria that we use,
13 and this is the criteria we generally are
14 using across all of our tools, fits in line
15 with things that we have seen before in
16 previous presentations. How urgent the
17 situation is, how significant the risk, nature
18 and frequency of adverse events, population at
19 risk, quality of the information that we
20 actually have to provide, and whether we can
21 actually recommend some type of action. That
22 is generally when we are using this

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1 information.

2 We do have, as I mentioned before,
3 we have templates and SOPs. We have processes
4 that exist so that we are consistent when we
5 put these documents out. As I mentioned the
6 patient and physician notification is required
7 by law. We have formats, we have boilerplate
8 language, we have checklists. We have
9 developed teams and then we get these
10 approved. The interesting things about our
11 public health notification is the one
12 persuasive communication where we do go and
13 get external review of the message before it
14 goes out. So, depending on what the message
15 is, we are using professional associations to
16 look at the message because these are for
17 healthcare professionals and modify them so
18 they do get an approval through an extensive
19 process.

20 And our advice for patients if more
21 of our internal review. And then the "Patient
22 Safety News" is based on already cleared and

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1 written documents. That is a monthly show.
2 So, during the month, they are collecting the
3 highest priority public health concerns to
4 develop the program. So again, it is a little
5 behind the time but we do have an editorial
6 board who approves all of the information that
7 goes out on that.

8 I did indicate that we have some
9 evaluative data. You know, we don't do a lot
10 of this. As Nancy mentioned, we were getting
11 some relief from the processes to go out and
12 get advice. But going through our Office of
13 Management Budget and getting the clearances
14 can take a long time. With our patient and
15 physician notification, we actually in the
16 beginning did an evaluation of the letter with
17 women before we ever even created the letter.

18 So that, although it was ten years ago and I
19 was thinking as I was putting this together,
20 it is probably time to do that again.

21 Our websites we have done some
22 extensive surveys on and actually have

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1 modified a lot of our information based on
2 that. You know, the things that we hear from
3 healthcare professionals that they don't have
4 time to go searching our web. So, creating
5 list serves and having them sign up and the
6 information coming to them is something that
7 we have done.

8 We do hear from consumers that it
9 is difficult sometimes for them to find
10 information they believe pertains to them. A
11 lot of times it is the key words or the
12 headings. So we have been working hard at
13 that but we also get asked for things that
14 clearly we can't provide. Consumers do want
15 us to rate physicians, rate products, and that
16 clearly is not our area of expertise.

17 And the kinds of things we have
18 been asking have to do with can you find our
19 information. Is it easy to use? Is it
20 timely? And have you actually taken any
21 actions? And again, we have very limited data
22 but the people that we are talking to actually

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1 say they have made actions, and again, I am
2 talking more healthcare professionals because
3 we don't have the reach to consumers that we
4 would really like to. But the healthcare
5 professionals that we are talking to say that
6 they do make changes, decisions, share the
7 information with colleagues.

8 So, the questions I feel like we
9 have, and they are probably similar across the
10 board, are the struggles being a regulatory
11 agency that has very important information and
12 trying to get it out over the noise of
13 industry and benefits and advertisement and,
14 you know, and physicians guiding what they
15 want patients to know or not knowing our
16 information because their day is so busy. We
17 really want to know how to get information out
18 to our stakeholders and the vehicles that have
19 the best reach. As you know, we all have very
20 extensive websites and you can create list
21 serves and people can sign up. But you know,
22 how do we really push information out? So we

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1 are interested to know are there better
2 vehicles for reaching, again, consumers versus
3 healthcare professionals.

4 The question about creating
5 different documents for different audiences, I
6 mentioned that we actually do that. We write
7 at different levels to the different
8 organizations but we are not sure is that
9 optimal.

10 What are the risks and benefits of
11 early communication? And we are talking
12 emerging risks and our center has not been on
13 the forefront of providing emerging risk
14 information. You saw we have a preliminary
15 public health notification but those are
16 certainly not used as much as our public
17 health notification where the problem is
18 clearly defined because we are, when you go
19 back to our challenges, we are concerned about
20 providing information that could cause a
21 possible negative impact.

22 So, implants is an area where we

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1 talk about going out early and alarming our
2 public when perhaps we don't know yet that it
3 really is a problem. So we tend to, in our
4 center, stick to sort of a known problem but
5 then that leads to timeliness because for us
6 to get to understanding the problem can take
7 longer down the road.

8 Techniques about conveying emerging
9 or uncertain issues is something we are very
10 interested in. Providing updates. A lot of
11 times, again, if we do a preliminary public
12 health notification, how do we, how often and
13 how do you go out and get back to the people
14 that actually saw the first one so they know
15 there is updated information, and how often,
16 and how do you actually close an issue out
17 when it is complete. And I think the age-old
18 question which is what is the best way to
19 evaluate, reach an effectiveness of our
20 messages.

21 So, those are for the Center for
22 Devices and Radiological Health some concerns

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1 that we are really looking for guidance on.
2 So, I thank you for your time and look forward
3 to hearing some advice. Thanks.

4 CHAIR FISCHHOFF: Thanks very much.

5 That was very helpful. There is so much you
6 are doing, if we can help a little the public
7 health multiplier will be large. So, thank
8 you.

9 So our next speaker -- I think we
10 will hold all the questions until after the
11 session. Our next speaker is Paul Seligman
12 from the Center for Drug Evaluation and
13 Research.

14 DR. SELIGMAN: Good morning. This
15 is an oddly-configured room. But there is
16 actually one feature of the room that I really
17 like, which are the posters on the wall. And
18 if any of you haven't had a chance to look at
19 them, they remind you of a very important fact
20 regarding FDA's history, which is when it was
21 founded in 1906 and Theodore Roosevelt signed
22 us into law, one of the two pillars that were

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1 responsible for the foundation of the FDA had
2 to do with communication and accurate labeling
3 of products. This was actually three decades
4 before we even worried about safety, six well,
5 five or six decades before we were actually
6 mandated to test products for their efficacy.

7 So, communication and the evolution of
8 labeling, which are the two posters to the
9 right of 1906, I think remind us all that
10 communication and accurate information to the
11 consumer and the professional has always been
12 a cornerstone and fundamental element of what
13 we do here at the FDA. And as Nancy pointed
14 out, the professional label still is designed
15 to be the most accurate and complete
16 information for the prescriber regarding how a
17 product is used.

18 The second thing I want to mention
19 before I launch into my presentation is that I
20 really liked Dr. Fischhoff's sort of
21 description of the kinds of expertise that is
22 needed. Because we in CDER, and I imagine it

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1 is true -- that is the Center for Drug
2 Evaluation and Research, we are an
3 organization that I would say is very top
4 heavy in domain specialists, consistent with
5 our sort of regulatory mandates for reviewing
6 and approving products. I don't have a
7 specific number but I would say that the vast
8 majority of us are indeed such domain
9 specialists, we practice a lot of risk and
10 decision analysis that really goes into the,
11 is basis of the way we make decisions about
12 approving products and what we say about
13 products, I would say we have a relative
14 dearth of individuals who I would
15 characterize as being either behavioral
16 scientists or systems specialists, which gets
17 to the issues related to evaluation and
18 channels that we use to communicate.

19 So, I just want to mention that up
20 front because I think I speak for my Center,
21 and I am sure it is true for many other parts
22 of the FDA as well, but I think it is

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1 certainly something to think about as we move
2 forward into the future in thinking about how
3 we develop a robust communication program and
4 the ways in which, and the kinds of resources
5 and expertise we really need to make us at the
6 FDA a more effective organization in terms of
7 communication.

8 So, our challenges are very similar
9 to that of the devices world. Tens of
10 thousands of products. We have got lots of
11 over-the-counter products, we have got branded
12 products, products that go off pattern and
13 become generic. They are used for a whole
14 wide range of uses and conditions from those
15 that are life saving to preventative to
16 symptomatic. We get on the order of close to
17 a half a million reports a year of adverse
18 drug events that serve as the basis for
19 approximately 900 safety related labeling
20 changes a year, including changes to our
21 warnings, precautions and adverse events
22 sections.

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1 Everybody uses drugs, I don't have
2 to be telling you this, regardless of the
3 language they speak, regardless of their level
4 of health literacy. Use of these products is
5 so pervasive in the United States, our
6 customers are basically the American citizenry
7 and the health professionals who serve them.
8 And there is no dearth of information out
9 there.

10 I just listed four sort of primary
11 ways in which drug information is communicated
12 but there are many, many more beyond just the
13 professional label, the information that you
14 pick up in the pharmacy that should be stapled
15 to or contained inside the bag of your
16 prescription. Things that often come
17 prepackaged from the manufacturer of certain
18 kinds of products, as well as medication
19 guides which are part of the professional
20 label that we regulate.

21 So, I am not going to go into great
22 detail, just to simply point out that there

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1 are a variety of mandated, regulated
2 communication tools, the professional label,
3 of course, being the most recognized one but
4 there are certain products like oral
5 contraceptives and estrogen products that are
6 required to be distributed with information
7 that is specific to the consumer to help the
8 person use the product properly.

9 We now have medication guides that
10 are FDA reviewed, communications to consumers
11 for about 380 some-odd innovator and generic
12 products. And as of this year, we now have
13 the authority to require that sponsors produce
14 and develop risk evaluation and mitigation
15 strategies for certain products that also may
16 include educational programs.

17 The professional label has been
18 updated in the last few years through the
19 highlight section, an index and a
20 comprehensive section. And now all of the
21 professional labels are available, almost all,
22 by the end of this year, I think I could say

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1 almost all of them will be electronically
2 accessible through the National Library of
3 Medicine DailyMed, so that professionals, as
4 well as consumers, can get ready access to
5 that information through that website.

6 In March of 2007, we published a
7 guidance on how we communicate to the public
8 not only in our regulatory capacity but beyond
9 that. And Nancy pointed out that we have a
10 history that goes probably a decade or more
11 that talks about other ways in which we
12 communicate.

13 Here is what the guidance basically
14 says. It says that we communicate emerging
15 risk when we think in our judgment the risk
16 may affect prescribing or use of a product,
17 when we think there are specific actions that
18 can be taken to prevent harm. If an
19 unapproved use of a product and there is not
20 only much off-label use of the products that
21 we approve but there are also many unapproved
22 drugs still on the market, when we think that

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1 in any of those circumstances there is a
2 chance of harm or risk opposed by these
3 products, we will communicate it. We pay
4 special attention to vulnerable populations,
5 children, pregnant women, the elderly, when we
6 think about making a decision about
7 communicating an emerging risk. And we often
8 do this before regulatory action is taken.

9 For the general public, we use
10 public health advisories. We now use as well
11 early communications about an ongoing safety
12 review, where we talk about a review that we
13 are currently undertaking before we have
14 indeed arrived at any conclusions about what
15 we would recommend for consumers or
16 practitioners to do.

17 There is a new consumer information
18 website at the FDA. I think most of you are
19 familiar with the fact that we are currently
20 in the middle of a major overhaul of all of
21 our FDA websites to make them more readily
22 accessible, more easily viewable, more easily

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1 searchable, and they make more sense in terms
2 of how professionals, regulators, and
3 sponsors, as well as patients and consumers
4 find information. And then we use, as well,
5 podcasts.

6 Here is just an example of a public
7 health advisory from last year. This is
8 related to our recommendation that over-the-
9 counter cough and cold products not be used in
10 infants and children under two years of age.
11 I suspect that advisory was well publicized,
12 well I know it was well publicized and it
13 certainly resulted in changes in the labeling
14 by sponsors of the companies who produce these
15 over-the-counter products to indeed change
16 what was written on the side of the packaging
17 regarding the use of these products in
18 children under two.

19 We have also, as I mentioned,
20 started using early communications. Here is
21 one of the first ones we did last year. It
22 was a study that we received that looked at

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1 medical therapy for a gastroesophageal reflux
2 disease and compared surgery versus medical
3 therapy. In a study that we initially
4 received, there is an imbalance in cardiac
5 death between those who were in the medical
6 side of the study versus those who were
7 assigned the surgical side. After four months
8 of review of this article, it became very
9 clear to us that there were some fundamental
10 problems with the randomization, with the
11 categorization of some of these cases, and we
12 concluded that, indeed, based on a review of
13 their study, we could not distinguish a risk
14 between those who were medically versus
15 surgically treated and at which point we
16 issued a follow-up to that communication and
17 made it clear that we thought that patients
18 should be confident in using these particular
19 products without fear of excess cardiac risk.

20 Here is just an example of -- here is our FDA
21 consumer health website.

22 We also use a variety of outlets

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1 for the healthcare professional. We have a
2 Drug Safety Newsletter which had three
3 editions published since last fall which
4 presents detailed information about recent
5 post-market safety reviews that we have
6 completed that is focused on communicating to
7 the health professional. It provides case
8 studies as well.

9 We also use healthcare professional
10 information sheets. And as Lynn already
11 mentioned, many of our drug stories are
12 carried in the "Patient Safety News." There
13 is just a screen shot of a drug safety news
14 letter and some of the reviews that were
15 covered in that letter. Here is an example of
16 a healthcare professional sheet that we use
17 related to fentanyl transdermal systems.

18 And to simply to point out that all
19 of our communications, whether they are
20 related to drugs, biologics, vaccines or
21 devices, are all distributed via the MedWatch
22 program, which goes out now to more than 102

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1 list service subscribers and many partner
2 organizations. And there is just a screen
3 shot of the "Patient Safety News" website.

4 So, that is a summary basically of
5 the communication outlets that we use for
6 patients in the general public and for
7 healthcare professionals. And as I mentioned
8 earlier, we used these to talk about an
9 emerging concern. We also use them for a
10 variety of other reasons as well. We receive
11 citizens' petitions. We may summarize a new
12 risk management program, describe either a
13 risk or actions taken when we receive a
14 request for new safety labeling.

15 We sometimes have used these
16 actions to share our perspective on an issue
17 raised by another regulatory agency. We are
18 not always marching in harmony with the
19 Europeans or the Canadians regarding our
20 interpretation of data. Sometimes they take
21 actions either contrary to what we are taking
22 or different in some respect. And we use again

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1 our communications to explain why it is we are
2 doing what we are doing and why our approach
3 differs from other agencies, as well as a host
4 of situations yet to be defined.

5 Just to give you some sense of the
6 magnitude, in calendar 2007, we issued safety
7 postings for 85 different drugs. Public
8 health advisories, information sheets, as well
9 as early communications.

10 So, for us the real challenges are
11 always, always striking the right balance and
12 figuring out how to communicate complex
13 information early and deciding when to inform
14 and what data to use, particular when the data
15 is early and involving. We try to anticipate.

16 We try to think about ways we can manage
17 unintended consequences. We can't always do
18 that but again, I think if we had greater
19 expertise and experience in-depth on our bench
20 when it came to people who understood risk and
21 decision analysis and behavioral scientists, I
22 think we would be certainly stronger in that

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1 realm. And we are certainly giving a lot more
2 attention, particularly, because this is what
3 we hear back from those who use their
4 information, that we really need to be better
5 in how we balance both the emerging risks with
6 the known benefit of the product.

7 We know that, not based on any
8 evaluative surveys or any formal information,
9 but just based on informal feedback, the
10 interactions we have had with professional
11 organizations and associations, the frequency
12 with which our information is used in the
13 press and used well by the media, as well as
14 the degree to which we are cited in various
15 professional journals that folks do look at,
16 read, adapt, and accurately reflect what it is
17 that we are trying to say.

18 We know very little about how to
19 reach certain target audiences. We have not
20 really explored in great detail, although we
21 use Patient Safety News for hospital
22 audiences, we use podcasts, we haven't really

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1 got a good sense of how best to use these
2 other venues and how best to broaden our reach
3 and, finally, how to measure effectiveness.

4 So, with that a quick run through
5 from snow falling on CDER. Thank you.

6 CHAIR FISCHHOFF: Thank you very
7 much. Our next speaker is Lorrie McNeill from
8 Center for -- I was going to try to use the
9 acronym but I don't know who you pronounce it.

10 MS. MCNEILL: CBER.

11 CHAIR FISCHHOFF: How do you
12 pronounce it?

13 MS. MCNEILL: "Sea-burr."

14 CHAIR FISCHHOFF: CBER.

15 MS. MCNEILL: Yes. When I first
16 started with FDA and I heard CDER, I had no
17 idea what they were talking about either. I
18 thought it was a tree and then I landed in the
19 center. And as I am sure you will guess from
20 hearing from each of the center
21 representatives here today, we each think that
22 the work that we do is the most important work

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1 of FDA. And I certainly would say that from a
2 biologic standpoint.

3 To echo both what Paul and Lynn
4 have said about some of the challenges in the
5 range of products, CBER, the Center for
6 Biologics, also has quite a diverse range of
7 products that we regulate from traditional
8 biologics such as whole blood and blood
9 components for transfusion and blood
10 derivatives or plasma derivatives that are
11 manufactured into products such as immune
12 globulins or anti-hemophilic factors to
13 vaccines, allergenic extracts that are used
14 for both diagnosis and immunotherapy, somatic
15 cell therapies, which include stem cell
16 therapies, gene therapies, and devices that
17 are used in collection and processing of both
18 blood and stem cells, tissues for both
19 transplantation and reproductive use and
20 xenotransplantation or the use of animal
21 tissues and organs in humans.

22 Like CDRH, the Center for Devices,

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1 a lot of our products are manufactured by only
2 one or two companies. The range from blood
3 products for transfusion, there are probably
4 more than 3500 establishments in the U.S. that
5 collect blood that is used for transfusion
6 use. But of the plasma derivatives, there
7 might be one or two companies that make a
8 specific type of immune globulin. And the
9 same with vaccines, there are a number of
10 individual or sole source manufacturers of
11 vaccines.

12 You have heard some broad
13 challenges from the centers so far this
14 morning. I am going to talk about a more
15 specific or narrow focus to give you an idea
16 of what we deal with in the center for
17 biologics and I am going to focus on vaccines.

18 The populations that receive
19 vaccines are often very healthy individuals.
20 The use of vaccines in infants is one that is
21 very much so in the news. Parents believe
22 that the only acceptable risk for their child

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1 is zero risk. And of course, no product is
2 available for zero risk. Vaccines are victims
3 of their own successes. Many of the vaccine
4 preventable diseases are not seen in great
5 numbers in the U.S. today. So, because of
6 that decline, people are not familiar with
7 them and don't understand why we need to
8 continue to vaccinate against them.

9 Also, risks of adverse events
10 following immunization and what those
11 perceived risks are by individuals seems to be
12 played up a great deal in the media and on the
13 web. Parents are also concerned that there
14 are too many too soon, from the standpoint of
15 the number of vaccines that their children
16 receive at a very early age. And also, as I
17 mentioned, the amount of information that is
18 out there on websites and in the media about
19 vaccines is very much an uphill battle for us
20 to fight against.

21 A recent example that we have faced
22 is the safety of GARDASIL vaccine. GARDASIL

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1 was approved in June of 2006 to prevent
2 infection with the types of HPV that most
3 commonly cause cervical cancer. Cervical
4 cancer is obviously a very serious disease.
5 There are 12,000 new cases in the U.S.
6 annually, with 4,000 deaths and even
7 worldwide, it is the second leading cause of
8 cancer in women with about 233,000 deaths
9 annually. So, this vaccine has tremendous
10 potential to prevent cancer.

11 So, why is this a challenge for us
12 and for the Centers for Disease control
13 because we are in this fight together? A lot
14 of the focus in the media has been that this
15 is a vaccine to prevent a sexually transmitted
16 disease and not cancer. And so a lot of
17 parents are concerned, and some of the more
18 conservative groups out there are concerned
19 that we may be promoting promiscuity rather
20 than preventing cancer with this vaccine.

21 There have also been over the past
22 few months, several high-profile reports of

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1 potential adverse events. When I say
2 potential, these are temporally associated
3 events and not necessarily causative events in
4 the media of serious problems following
5 immunization with GARDASIL. And of course, we
6 do have routine recommended screening for
7 cervical cancer and so, why do we need a
8 vaccine for it?

9 So, with the recent case that we
10 have been dealing with or cases that we have
11 been dealing with, there have been some
12 challenges for us that I think are a little
13 bit unique to the Center for Biologics versus
14 some of our colleagues across the Agency. The
15 responsibilities for vaccine safety are really
16 divided between FDA and the Centers for
17 Disease Control and Prevention. We have the
18 responsibility for ensuring the safety of a
19 product throughout its lifecycle both prior to
20 approval and post-market. CDC is responsible
21 for making recommendations on who should
22 receive vaccines. We do not make

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1 recommendations on vaccination.

2 In addition, the states are
3 responsible for determining what vaccines are
4 required for school entry. And again, FDA has
5 no role in that. So, there you get to the
6 persuasive message from CDC of here are the
7 vaccines and this is when you should take
8 them. They set the vaccine schedule for
9 infants and for adults versus FDA's non-
10 persuasive messages about the safety and
11 effectiveness of vaccines.

12 We also have, as with MedWatch and
13 a lot of this is not any different for
14 vaccines than with MedWatch, but there is a
15 separate reporting system called the Vaccine
16 Adverse Event Reporting System and as a
17 passive reporting system, there are some
18 limitations. The quality of the data that we
19 receive, I could get flu vaccine and walk
20 across the street and be hit by a bus and you
21 could submit a report to VAERS and VAERS would
22 accept that report because of the temporals.

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1 It doesn't assign causation or anything but
2 there is a temporal association that I got hit
3 by the bus across the street.

4 So, the quality of the data that we
5 receive in VAERS, we cannot prove a negative.

6 You cannot say that an event is not caused by
7 a vaccine. In the case of some of the reports
8 in the media, the very serious events, we have
9 not seen any patterns of events that would
10 cause us to be concerned but we can't prove
11 that the vaccine did not cause those events
12 and so it is a very difficult message to try
13 to craft for parents and with GARDASIL
14 potential recipients. So, that is a bit of a
15 challenge, too, and how do we evaluate that
16 data and try to make it useful.

17 What we did with the recent
18 GARDASIL example was work to develop an
19 information sheet that we posted on our
20 website. And part of the challenge with that
21 was we felt that it was important to have a
22 unified message with CDC on the vaccine's

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1 safety. But that also brought with it some
2 real issues of trying to get a cleared single
3 statement from two agencies that was done in a
4 timely manner. When the events occurred and
5 were in the media and we started to get lots
6 of questions, we thought that we could, very
7 quickly get something developed, reviewed,
8 cleared, and posted on the web. And I can't
9 tell you the exact length of time that elapsed
10 but it was almost three weeks. And to me,
11 that wasn't timely. We kind of missed the bus
12 on when the information was out in the press
13 and when we were getting all of the questions
14 to when we had a statement.

15 The statement, I thought, was very
16 good. It covered a lot of ground. It had the
17 persuasive message at the top from CDC about
18 the vaccine's effectiveness and how it should
19 be used. Also FDA's statement on the safety
20 of the vaccine and how it was evaluated in
21 clinical study and then a complete overview
22 of, well I won't say complete, but a very

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1 broad overview of the vaccine's safety to date
2 and that we have not seen any patterns or
3 concerns in the adverse events that have been
4 reported.

5 But again, because it took us a
6 while to get the information out there, I, in
7 my opinion, I don't think that our message was
8 necessarily as widely distributed, you know,
9 within the media, because it was not out there
10 at the same time that they were reporting
11 their stories.

12 So, that is a very specific
13 challenge in communication. And again, I
14 could echo everything that Lynn and Paul said
15 about what the challenges are that we face. I
16 agree completely with the questions that they
17 posed and having the advantage of seeing them
18 in advance, I didn't repeat them here but I
19 think that they are definitely things that we,
20 too, are seeking your input and guidance on.
21 Because of the variety of things that we all
22 do, I don't know that there is a "one size

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1 fits all" but I think any advice that you all
2 have for us, we can all use in our own way to
3 make the information products that we provide
4 more useful to the audiences and better
5 received by our audiences.

6 So, with that, I think you very
7 much for the opportunity to speak.

8 CHAIR FISCHHOFF: Thank you. Our
9 next speaker will be Laura Alvey from the
10 Center for Veterinary Medicine.

11 MS. ALVEY: Good morning everyone.

12 As my colleagues have already spoken, a lot
13 of what I am going to present to you all
14 mimics and echoes their sentiments as well.

15 I represent the Center for Veterinary
16 Medicine and some of the challenges that are
17 specific to our center are we are the smallest of
18 FDA centers, so with that we have

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