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

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MEETING

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THURSDAY,
AUGUST 14, 2008

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

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.

FDA PARTICIPANTS:

LAURA ALVEY, Deputy Director
Office of Communications
Center for Veterinary Medicine

MARJORIE DAVIDSON, Ph.D.
Education Team Leader
Center for Food and Safety and Applied Nutrition

LORRIE MCNEILL, Director
Office of Communications, Training, and Manufacturers Assistance
Center for Biologics Evaluation and Research

NANCY M. OSTROVE, Ph.D.
Senior Advisor for Risk Communication
Office of Planning
Office of the Commissioner

LYNNE RICE, Director
Office of Communication, Education, and Radiation Programs, Center for Devices and Radiological Health (CDRH)

PAUL SELIGMAN, M.D., M.P.H.,
Associate Center Director for Safety Policy and Communication
Center for Drug Evaluation and Research

FRANK M. TORTI, M.D., M.P.H.
Principal Deputy Commissioner and Chief Scientist
Food and Drug Administration

T A B L E O F C O N T E N T S

T A B L E O F C O N T E N T S (Con't.)

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

(8:15 a.m.)

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

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

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

Today and tomorrow, the Risk

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Thank you.

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

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

DR. NEUHAUSER: Good morning. My

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

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

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

and food innovations. Thank you.

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

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

communicating information to the public, primarily consumer health issues.

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

Thank you.

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

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

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

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

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

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

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

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

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

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

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

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

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

And finally, it will depend on the

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Adversely, you don't want

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

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

And finally, you don't want the

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

So, you don't want to turn your communication into a BIO 101 thing. People are listening to me, now is the chance to tell them all of the things that they didn't pick up in high school or maybe elementary school. You don't want just messaging sessions or some group of self-appointed experts sit around and decide what the public needs to know and how they need to know it and then give it to the people who can give it the production values and push it out the door without relying on the communication science or doing evaluation.

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

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

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

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

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

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

be useful to some people.

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

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

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

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

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

And Nancy?

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

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

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

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

I don't want to take too much time, so we can focus on the meat of the discussion. But we will know that I am getting into trouble in terms of how to explain something when I take too much time on a particular slide. So, we will see how that goes.

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

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

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

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

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

regimes for the many things that it regulates. So, it is not really surprising, I think, that oftentimes people forget about that.

So, why have we become more active? Well, I think it is partly because we have come to appreciate the greater role that communication has to play in assuring that the safety, effectiveness, and security of regulated products which, after all, is remember one of our mission statements. I guess we have realized that conceptually that we might be able to do without effective communications. But in practice, safety especially can be very problematic without effective communication. And we have recognized the need to explain the context of the regulatory actions that we take. I think everybody, well everyone here, perhaps but perhaps not everybody, recognizes that approvals are relative.

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

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

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

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

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

Back in February in our first meeting, we talked about how FDA communicates. And we kind of broke it down in terms of slicing the pie, as well. We communicate indirectly through regulating labels and labeling and through regulation of at least some promotional activities for some products. And we communicate directly as well. We have our press activities. We have a variety of communication vehicles about specific products and product classes and we will hear more about that later.

We do stakeholder outreach, and we

make direct response to inquiries, and carry out public education campaigns. Well, another way to look at it, in terms of how we communicate, is distinguish between activities that focus on on-going versus new information. So, we have a lot of educational information that really focuses, that really tends to be ongoing in web and print and TV. We do it ourselves. We do it with partners.

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

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

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

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

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

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

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

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

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

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

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

that we have in a scientifically sound way.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In that first box there, you know, you have got what basically we are talking about is informational or non-persuasive communications that we use, labeling, labels, informed consent. In some cases your healthcare provider letters and in the early communications that CDER has been putting out. And then you get into what, at one point we had in boxes, and then I think two nights ago I decided I didn't like it in boxes because it just was too much of a box and when you put something in a box, people don't think about

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

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

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

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

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

benefits and the availability of alternatives. These are, you know, a little bit more complex and fuzzier, in terms of trying to communicate.

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

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

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

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

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

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

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

Committee.

Linda?

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

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

DR. OSTROVE: Oh, I'm sorry.

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

DR. OSTROVE: Okay.

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

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

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

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

(No response.)

DR. OSTROVE: Thank you for your attention.

CHAIR FISCHHOFF: Thank you, Nancy. I think, I suppose lack of coordination is bad but if we discover that we are on overlapping pages, that is probably good. And I really appreciate the feedback that you have

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

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

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

I wanted to give you an idea of the

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

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

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

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

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

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

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

Another thing that I think is slightly different than some of my sister colleagues here is that our products are redesigned quickly. Products get on the market a lot sooner, a lot less or not a lot less, but less testing than drugs go through. And the products are iterative. As soon as they are learning something that is not quite right, hearing from physicians and patients, they go and start making the next version. So we can have, sometimes, ten generations of a product out there. So when we are trying to communicate about a recall or about problems, the question then tends to be which one is it because so many are out there. So, that becomes challenging for us, which leads to the communications challenges.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

information.

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

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

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

I did indicate that we have some evaluative data. You know, we don't do a lot of this. As Nancy mentioned, we were getting some relief from the processes to go out and get advice. But going through our Office of Management Budge and getting the clearances can take a long time. With our patient and physician notification, we actually in the beginning did an evaluation of the letter with women before we ever even created the letter. So that, although it was ten years ago and I was thinking as I was putting this together, it is probably time to do that again.

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

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

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

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

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

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

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

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

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

So, implants is an area where we

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

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

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

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

CHAIR FISCHHOFF: Thanks very much. That was very helpful. There is so much you are doing, if we can help a little the public health multiplier will be large. So, thank you.

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

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

responsible for the foundation of the FDA had to do with communication and accurate labeling of products. This was actually three decades before we even worried about safety, six well, five or six decades before we were actually mandated to test products for their efficacy. So, communication and the evolution of labeling, which are the two posters to the right of 1906, I think remind us all that communication and accurate information to the consumer and the professional has always been a cornerstone and fundamental element of what we do here at the FDA. And as Nancy pointed out, the professional label still is designed to be the most accurate and complete information for the prescriber regarding how a product is used.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

medical therapy for a gastroesophageal reflux disease and compared surgery versus medical therapy. In a study that we initially received, there is an imbalance in cardiac death between those who were in the medical side of the study versus those who were assigned the surgical side. After four months of review of this article, it became very clear to us that there were some fundamental problems with the randomization, with the categorization of some of these cases, and we concluded that, indeed, based on a review of their study, we could not distinguish a risk between those who were medically versus surgically treated and at which point we issued a follow-up to that communication and made it clear that we thought that patients should be confident in using these particular products without fear of excess cardiac risk. Here is just an example of -- here is our FDA consumer health website.

We also use a variety of outlets

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

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

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

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

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

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

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

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

So, for us the real challenges are always, always striking the right balance and figuring out how to communicate complex information early and deciding when to inform and what data to use, particular when the data is early and involving. We try to anticipate. We try to think about ways we can manage unintended consequences. We can't always do that but again, I think if we had greater expertise and experience in-depth on our bench when it came to people who understood risk and decision analysis and behavioral scientists, I think we would be certainly stronger in that

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

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

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

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

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

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

MS. MCNEILL: CBER.

CHAIR FISCHHOFF: How do you pronounce it?

MS. MCNEILL: "Sea-burr."

CHAIR FISCHHOFF: CBER.

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

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

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

Like CDRH, the Center for Devices,

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

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

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

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

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

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

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

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

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

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

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

recommendations on vaccination.

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

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

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

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

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

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

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

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

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

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

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

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

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

MS. ALVEY: Good morning everyone. As my colleagues have already spoken, a lot of what I am going to present to you all mimics and echoes their sentiments as well.

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