UNITED STATES OF AMERICA

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

OFFICE OF THE COMMISSIONER

RISK COMMUNICATION ADVISORY COMMITTEE

Thursday, February 28, 2008

The meeting came to order at 8:00 a.m. in the Grand Ballroom of the Hilton Washington DC North, 620 Perry Parkway, Gaithersburg, MD, 20877, Baruch Fischoff, PhD, Chairman, presiding.

PRESENT:

BARUCH FISCHOFF, PHD, CHAIR
LEE L. ZWANZINGER, PHD, EXECUTIVE SECRETARY, DFO
CHRISTINE M. BRUHN, PHD, MEMBER
JACOB DELAROA, MD, MEMBER
ANNMARIA DESALVA, MEMBER
MICHAEL GOLDSTEIN, MD, MEMBER
DAVID MOXLEY, MSW, PHD, DPA, MEMBER
LINDA NEUHAUSER, DRPH, MPH,MEMBER
JOHN E. PALING, PHD, MEMBER
ELLEN M. PETERS, PHD, MEMBER
PRERNA MONA KHANNA, MD, MPH MEMBER
MUSA MAYER, MS, MFA, MEMBER
BETSY LYNN SLEATH, PHD, MEMBER
MARIELOS L. VEGA, BSN, RN, MEMBER
MARSHA YAROSS, PHD, INDUSTRY REPRESENTATIVE
GREGORY BAIRD, CONSULTANT
STEVEN GORELICK, PHD, CONSULTANT
DANIEL HANEY, CONSULTANT
MICHAEL WOGALTER, PHD, CONSULTANT

A G E N D A

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

(8:36 a.m.)

DR. FISCHOFF: I'm Baruch Fischoff, the Chair of the very first meeting of the Food and Drug Administration Risk Communication Advisory Committee, and I'd like to welcome you all here. I'd like to particularly welcome our panel, our consultants, and particularly, before we get started off, to thank the staff, which has worked extremely hard to get this Committee together, and to get us all paper-worked, and in this place together, so let me thank them. And then, I guess, Lee, do you have anything you need to say?

DR. ZWANZIGER: No, thank you.

DR. FISCHOFF: Okay. Fine. So what we're going to do now, everybody has the program, we're going to start by introducing ourselves, in part to one another, although we did have a bit of a chance to meet yesterday, partly to introduce ourselves to you. And let

me sort of kick off, and just say a few very general remarks.

I'm Baruch Fischoff. I'm a Professor at the Carnegie Mellon University. I'm in the Department of Social and Decision Sciences, and of Engineering and Public Policy, and I head the Decision Sciences Undergraduate Major. If any of you have high school seniors or juniors, please come and see me during the break.

My own background is I have an undergraduate degree in Math, and in Psych from Wayne State University, a Ph.D. in Psychology from the Hebrew University of Jerusalem, and I'm interested in risk and decision making, generally. And the way I think about the task that's ahead of is that there's really four sets of skills that one needs in order to do a proper job of communicating in two directions with people; you need people who really know the science about food, or drugs, or nuclear power,

whatever the risk is, you need risk and decision analysts who are capable of taking all of that wonderful information, and identifying the facts that people need to know in order to make good decisions balancing risk and benefits. You need to know behavioral science in order to find out what's really on people's minds so that the experts know about it, find out what the experts know, and render it comprehensible to people. And then you need people who create the human, electronic, and other links between the information, the technology, the drugs, the food, and the people whose lives and well-being depend on that. And those communication links can be as simple as electronic communications, which are complicated enough, or as complicated as creating community organizations or institutions that make it possible for people to feel that they have a right to know about the facts, and have the intermediaries who can help them to make sense of it, and take

advantage of the sorts of science and technology that we're capable of bringing to bear.

If we do this right, then people are able to get the best on this risk and benefits. Industry, and science, and universities, and elsewhere are able to do things that people find most useful to find the adoption process as predictable as process. So this is a complicated skill set. It's rare, in my experience, to find those people in one room, much less on one committee, and so I'm really very grateful to the members of this Committee, who have agreed to participate in this enterprise, and to the staff for having chosen them, and then done all the paperwork to get us here.

My own work is pretty broad. I've worked on everything from nuclear power, to teen sex, or helping young people avoid sexually transmitted infections, and I'm interested in the sort of intermediate range.

My colleague, Alan Badley, at the Applied Psychology unit of the Medical Research Council at Cambridge, England makes the distinction between what he calls applied basic research, and basic applied research, where applied basic research is taking the stuff that you've learned in the lab, and see whether it works in the world. And if it doesn't, then you don't understand the phenomenon fully. And basic applied research is looking at the phenomenon, identifying issues that you might not have realized that you stayed in the lab and looked at the endogenously generated problems that we're very good at keeping ourselves occupied with. So for my scientific career, I try to work at that interface.

I'm on a couple of other Federal Advisory Committees. I'm on the Department of Homeland Security Science and Technology Advisory Committee, and EPA's Scientific Advisory Board, and I Chair its Homeland

Security Advisory Committee. And I found those are committees that are varied in their own right, and I've learned a lot from them, and I hope we're somehow able to give back a little bit from the investment that the American people has made in the scientific enterprise.

So let me pass the baton off to Marielos Vega.

MS. VEGA: Good morning. My name is Marielos Vega, and I am a staff research nurse with the Department of Family Medicine at the New Jersey Medical School. I was born and raised in Costa Rica; therefore, Hispanic health issues are very important to me, and particularly in this Committee, health communications and risk communications, as it deals with the Latino/Hispanic community.

I am very, very grateful to be in this Committee, and be able to be a voice for Latinos and Hispanics. Thank you.

DR. MOXLEY: Good morning. My name

is David Moxley. I'm from the University of Oklahoma Norman, where I'm on the faculty of the School of Social Work, and chair of the program, the graduate program in community development, and community health development. Most of my work is with small communities that experience weak or inadequate healthcare coverage for poor people, and for addressing significant health disparities.

Prior to joining the University of Oklahoma last year, I was, for 20 years, at Wayne State University in Detroit, where I was also in the School of Social Work, and I chaired the program in community practice. I do maintain a research project on helping older African American women leave homelessness, and stay out of homelessness through community development strategies, and health enhancement approaches.

I'm very much concerned about healthcare inequalities, populations who are deprived of healthcare, and the interaction of

healthcare with employment, mental health care, housing, safety, transportation, and nutrition.

DR. SLEATH: Good morning. My name is Betsy Sleath, and I'm Professor of Pharmaceutical Outcomes and Policy at the University of North Carolina at Chapel Hill. I'm also a Research Fellow at the Cecil G. Sheps Center for Health Services Research, that's also based in Chapel Hill.

I'm a pharmacist and a sociologist who has studied communication now for 15 years between doctors and patients, pharmacists and patients, and so I'm thrilled that the FDA has formed this Committee, because I think, from the research that I've done, we can do a lot to improve communication, and to help consumers.

I'm especially interested in low-literacy patients, and getting communication across to them. And I also am interested in Latino health, because I was at the University

of New Mexico prior to coming to the University of North Carolina, so I've kind of been in a state with established Latino communities, and then in a state that's struggling with how to communicate and provide health and medicine information to Latinos.

DR. NEUHAUSER: Good morning, everyone. I'm so glad to see all of you in the audience. Thank you for joining us. My name is Linda Neuhauser. I'm a Clinical Professor at the School of Public Health at UC Berkeley in California. My main interest is in understanding what we know from the research about good communication, and how we can do better.

I also direct a center called Health Research for Action, and what we do there is take the lessons of research, and translate that into better communication that meets the needs of the public, especially that helps overcome barriers that relate to literacy, language, disability, or culture.

My work involves highly participatory processes, in which the members of the public are engaged in being co-designers of the work, and a lot of what I do is take government communication, and improve that by working with the public, whether it's print, internet, video, or audio in format.

DR. PALING: Good morning, ladies and gentlemen. My briefest introduction to you will be to tell you that my name is John Paling. I come from Gainesville, Florida, and despite this speech impediment, I am an American for the last 20 years.

Part of good communication, to my mind, is thinking, not what I want to say, but what you, the audience, would most want to hear. And in thinking what I might say in a few seconds by way of introduction, I would like to tell you some things that I think, if you give any attention to my slim contribution to this elegant Committee, you should know in order to filter off what I say.

The first thing is, indubitably, I am the least academically qualified of all the members in front of you. My background was that I was a Junior Professor at the University of Oxford eons ago. In my first days, I met with colleagues who were anxious to share their enthusiasm of nature with the general public, and we formed a wildlife film company. Our very first film, truly, was of the mating behavior of fleas, which I tell you of not just because of its oddity, but because it brings to mind one thing that I contribute to the Committee.

We found the biology of fleas mating that, on a social occasion, I would happily share with you, so fascinating that we were driven to try and tell the message, and making a film of it seemed the easiest idea to come to mind. To do it was different, so is the comparison with ease of ideas about risk communication, and the enormous difficulty which our colleagues at the FDA are already

grappling with in order to do a great job with what they're doing.

However, with enthusiasm combined with ignorance, we carried on improving methods of filming fleas on living rabbits without a microscope until we were able to do it. And my lesson for myself, giving me confidence to speak within this group, is that sometimes, if you don't know what can't be done, and you actually set out and determinedly try and do it, the world has changed since it was last attempted, and your efforts might be embraced.

Out of that, a whole gang of us, seven of us, left the university, made wildlife films across the world, including the very first Nova film, PBS Nova. Out of that, I have become, in part, a public speaker, speaking at conferences, and my own advocation, both in the environmental field, and also in healthcare, is speaking to people, hoping to try and teach them what I've learned

from colleagues like those on the table around me; namely, I am a communicator that tries to use my knowledge of visual aides, from my television career and production from television, to try and share what I find fascinating with people who would not normally be exposed to the highly technical, and very important work that these colleagues around me provide.

I have written books on this field, but my dream, and meeting these friends yesterday has resurrected this dream, is possibly to draft a script for another Nova or front line, and see if some of these ideas we could not get into the public arena, in addition to the work that's being done through forums, such as those of you in the media.

I'm thrilled to be here. I will come with different perspectives, but I'm grateful for the diversity of the membership of this Committee.

DR. PETERS: Good morning. It's a

pleasure to be here today. Dr. Paling is always a hard act to follow, but let me tell you a little bit about myself. My name is Ellen Peters. I'm a Senior Research Scientist at Decision Research in Eugene, Oregon. And yes, I am awake already this morning. As an undergraduate, I studied engineering and marketing. For my Ph.D. program, I studied psychology, and in particular, I focused on judgment and decision making.

I'm interested in risk perceptions and decision making, and, in particular, in describing how people process information as they form judgments, and as they make decisions, so that, ultimately, we can help them make better decisions, hopefully.

I look a lot at how what we think about influences how we feel about some risk, and also, how our feelings about risks influences what we think about them. I've looked a lot at number processing, for example, with Medicare patients, working quite

a bit with the elderly, looking at how adults across the life span process information in different ways. In particular, in emotional ways, as well as in number processing ways.

I also look a lot at individual differences in numeracy, or number ability, and look at how those individual differences make a difference, not only to people's ability to understand numbers, to know that nine plus three is twelve, but it actually makes a difference to how people use numbers in understanding risks, and in coming decisions that they make.

We've looked at cancer patients, Medicare decisions by the elderly, and a number of other decisions in similar domains. Thank you.

MR. HANEY: Hi, I'm Dan Haney. I'm a journalist. I worked my entire professional career for the Associated Press. I was there for 34 years, and during almost that entire time, I covered medicine. And I was the

medical editor of the AP for the last 10 or so years, so I worked every day talking to the medical profession, and communicating to the public the risks and benefits of medical therapies.

I retired from the AP three years ago, and am now a medical freelancer. And I look forward to being on this side of the table, having dealt with the FDA for all those years from the other side. This should be very interesting.

DR. GORELICK: Good morning. My name is Steve Gorelick. I'm a Professor of Media, Sociology at Hunter College in New York City. I'm also the Director of the Graduate Programs in Integrated Media Arts, which is a program that looks at all emerging technologies, one of which will have emerged today while we're sitting here, and revolutionize the world, and disorient us by tomorrow, and how to use those technologies as adjuncts to mainstream media to communicate

with the public about difficult issues.

I briefly wanted to say that most of my work has had to do with risk and crisis communications in a slightly different area than medicine, and illness, and such. I work with several federal agencies advising and helping communities that have been recently struck by a sudden act of, for the most part, catastrophic violence. So I actually am a trained criminologist in addition, my doctorate is also in Criminology, and we work both with communities in advance of the apprehension of a suspect, if there is a sort of an ongoing difficult situation in a community, where a community is terrorized. But very often in the aftermath of something sudden, and I don't have to recount which incidents we're talking about. So my kids and my colleagues call me the Bad News Guy, and it's --when something bad happens, my 10-year old knows, well, daddy is going down to his office and closing the door, and leave daddy

alone.

I just briefly want to say, sitting here, I realized this is the only topic of all the research things I've done over the years that I came to out of just genuine curiosity on my own. It's like, I wasn't trying to like work with any graduate advisor, or anything, or impress anybody. The questions that this group is considering are the questions that are the most organic to my interest. They just sort of -- I'm just infinitely curious about all the things that you all work on. And I know much of the work that many of you have done, and I'm thrilled to be here.

DR. DeLaROSA: Good morning. My name is Jacob DeLaRosa. I am a practicing heart surgeon in Pocatillo, Idaho, affiliated with Idaho State University. I'm a specialist in medical devices, and in open heart surgery, and with a special interest in communication between the doctor and the patient, the senior patient, the elderly, the geriatric, the new

term, the mid-lifer. I'm very excited to be here, and on this Committee. Thank you.

DR. YAROSS: Good morning. My name is Marsha Yaross. I'm Vice President for Clinical Quality Regulatory and Health Policy with Biosense Webster in Diamond Bar, California. I am a cell biologist by training, and have worked in the past 20 some years in the medical device industry. I'm also the industry representative to the Circulatory System Devices Panel, and I'm delighted to be here joining this panel this morning.

Risk-benefit decisions and risk communication decisions are some of the most critical decisions that those of us in industry face, and I'm really very pleased that we will be able to participate in this meeting this morning, and tomorrow. Thank you.

DR. GOLDSTEIN: Hello, everybody. My name is Michael Goldstein. I'm a

physician, a psychiatrist, and an internist, and I work at the Institute for Healthcare Communication, which is a non-profit foundation based in New Haven that develops educational programs to help clinicians communicate more effectively with patients. I'm also an adjunct professor at the Alpert School of Medicine at Brown University, and most of my work has been in developing, translating, disseminating educational programs that help clinicians to engage, empower, partner with patients to develop more effective clinical decisions together. And I'm really pleased to have an opportunity to be a member of this panel, and learn so much from the other perspectives that the other panel members are bringing in.

I hope that my interest, and background, and expertise in helping clinicians to communicate more effectively will help us develop the kinds of guidelines, materials, and resources that will help many

of you, as well as the FDA, communicate to the public more effectively, and help clinicians to communicate about risks and benefits of products, foods, and other procedural materials in ways that will be most effective, so I'm excited about the potential.

DR. KHANNA: Good morning, everybody, and thank you for being here. My name is Prerna Mona Khanna. I'm an Asian American, native of India, immigrated to the United States as an infant. I'm triple board certified in internal medicine, occupational and environmental medicine, and public health and preventive medicine. After completing these three residencies, I worked for four years as a medical director in Southern California, before finally transitioning and working full-time in medical broadcasting, where I was a reporter for CBS Television for four years. I'm now an adjunct associate clinical professor at the University of North Texas Health Sciences Center. I have a dual

appointment in the Schools of Medicine and Public Health, and I focus on health disparities.

I also serve as a medical expert to national shows, such as the Early Show, Good Morning America, and CNN. And I am the Medical Editor of the user-generated social networking website for health, ICU.com. I'm a Lieutenant Colonel with the Texas State Guard. As such, I'm a Texas Medical Ranger, and a Medical Officer with the Disaster Medical Assistance Team, where I have been volunteering for more than 10 years to such high profile events, disasters such as after the September 11th attacks, and Hurricane Katrina.

I left medical management and daily clinical practice because my bias in medicine is the most important part of a patient and physician visit, and interaction of the health education part. Unfortunately, that's the part where, I think, receives the least time

and attention.

I've been fortunate enough to use my newspaper, magazines, television, radio, and online media to empower patients across the world to have a higher quality of living through enhanced health status. And I hope to use my skills as a medical doctor and professional medical communicator to enhance the work of this panel. Thank you.

MS. DeSALVA: Good morning. I'm Anna Maria DeSalva, and I'm really delighted to be here, and honored to be here. I work at a large global public relations firm, named Hill and Knowlton, a lead global healthcare practice, and our portfolio of healthcare clients really represents the whole healthcare system, including providers, and payers, and manufacturers of healthcare products, devices, biotechnology, pharmaceuticals. And as I consider my career, which really has been spent entirely in the area of healthcare communication, it's evident to me that really,

consistently throughout all those years, I've been trying to work with organizations to problem-solve, to help people make better health decisions, so for that reason, it is really very important, and very rewarding to be able to be a part of this Committee.

Prior to joining Hill and Knowlton, I was on the corporate side of the business, and I led strategic planning for a large corporate foundation focused on healthcare, and was very involved in international health, and also in health promotion, with a particular focus on women, which I think brings some, or offers me some insight and prior experience that I expect will be relevant. But mostly, I look forward to working with this Committee, and I thank you for being here today.

MS. MAYER: Good morning. I'm Musa Mayer. I'm a writer, a breast cancer patient advocate, and research advocate. About six months after I published my first book, I was

diagnosed with breast cancer myself, and it changed my life. I became very involved, and this was now 19 years ago, in helping other women make meaningful choices during times of great personal crisis.

Most of my work today, and for the last dozen years or so, has been focused on helping women with metastatic breast cancer make the complex treatment decisions they face. I also ---- and I do most of that work on line, and sometimes in person. I'm also very concerned with promoting an understanding of evidence-based healthcare, evidence-based medicine, both in patients, but particularly in advocates who often do not understand the complexities of healthcare research.

Recently, I've completed a course, that is available on line, to train advocates in evidence-based healthcare, and the sort of fundamental principles of that. So I see myself as a communicator, both with patients, with healthcare advocates, and also with the

medical community. I've written many articles published in medical journals, as well.

I serve on an Institute of Medicine panel that deals with early drug development, and I've worked for a number of years as a patient representative and consultant with FDA. I'm really delighted to be here, because we are focusing on really the central issue of understanding, and how to help people understand about benefits and risks of interventions. Thank you.

DR. BRUHN: Good morning. I'm Christine Bruhn, with the University of California at Davis. My area of expertise is food science and nutrition. I take some of the principles of risk communication, and apply it to the food-related decisions that the public faces every day. In particular, I focus on areas that impact health, like safe food handling, look at new technologies that offer opportunities for health, as well as for environmental impact, because I believe the

first stages of effective communication is listening to your audience, and responding to their needs.

I spend a lot of my time with focus groups, and working with the public trying to understand their perception of their information needs, their current base of knowledge, and then what types of information, and how it can be most effectively presented to them. I am really thrilled to be on this Committee, and look forward to working with the others as we enhance our development and communication about risks.

MS. LAWSON: Good morning. I'm Madeline Lawson, and I'm the President and CEO for the Institute for the Advancement of Multicultural and Minority Medicine. We refer to it as IAMMM, and the Institute is focused primarily on addressing disparities in health and healthcare, and doing so in collaboration with national health organizations, and consumer organizations. We look at the

chronic diseases that affect people of color disproportionately, and how we can work in collaboration with organizations to, one, better inform and educate our patients, our consumers, and how we can bring about some improvement in the quality of care for all Americans.

I've had a longstanding career in the field of health, health education, and awareness. I've been a patient and consumer advocate most of my adult life, and it's a tremendous opportunity to serve on the Advisory Committee, and to work with the other members of the Committee in looking at ways that we can better inform, and better communicate with the consumers, and so I look forward to participating with all of you.

DR. WOGALTER: Hello. My name is Mike Wogalter. I'm a Professor of Psychology at North Carolina State University. My area is human factors, ergonomics, and I'm Director of the Cognitive Ergonomics Laboratory at NC

State. Most of my research across the last 20 years has dealt with warnings, and risk communication, and risk perception. And we've used a variety of methods ranging from surveys, questionnaires, to reaction time, to memory comprehension test, to actual behavioral compliance, a variety of methods, and we've looked at, also, different stages of processing, such as what grabs attention, what holds attention, what leads to understanding of the meaning, and it could deal with the types of wording, the complexity of the message, whether you use symbols. And also, how to motivate people to do whatever you're asking them to do. And I guess that's it.

DR. FISCHOFF: Thanks, Mike. Well, thank everybody, and let me introduce Dr. Lee Zwanziger, who is the Designated Federal Officer for this Committee, and brings quite a bit substantively to the table, as well.

DR. ZWANZIGER: Good morning. Thank you, Dr. Fischoff, you're too kind.

Yes, I'm the Executive Secretary, Designated Federal Official for the Committee. That means if you ----Designated Federal Officer for the Committee. If you have problems or concerns, please let me know. I will just be reading into the record here a Statement of Conflict of Interest required at all of our meetings.

First, let me just welcome the Committee and the consultants, and all of the members of the audience, FDA staff, and the press, and thank you for attending.

The following announcement addresses the issue of conflict of interest with respect to this meeting, and is made a part of the record to preclude even the appearance of such at this meeting. Today, the Risk Communication Advisory Committee will hear about and discuss the relation of FDA's Risk Communication programs, and the Agency's responsibilities. Tomorrow, the meeting will continue with presentations and discussion of

FDA's proposed template for press releases announcing product recalls, with a view to incorporating recommended practices of risk communication.

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

We would like to note for the record that Dr. Marsha Yaross, Industry Representative on Circulatory Systems Devices Panel for the Center of Devices for Radiological Health, is participating as a guest industry representative in accord with the charter of the Risk Communication Advisory Committee.

In general, participants are aware of the need to exclude themselves from involvement in discussions if their interests

would be affected, and their exclusion would then be noted for the record. With respect to all other participants, we ask in the interest of fairness that they should also address any current or previous financial involvement in any of the firms if they wish to comment on any specific product, but the meeting today should be primarily about general issues.

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

The entire meeting is being transcribed, and the transcript will be posted on FDA's website. However, it can only contain what the transcriber can hear, so I would just remind all participants when speaking please to turn on and speak into your microphones when you're recognized to speak, and then turn them off when you're not

speaking.

I would also suggest that all of us here should turn cell phones and other communication devices into a silent mode, and thank you very much.

DR. FISCHOFF: Thank you very much. I was thinking, when my kids were younger, that one of their favorite shows was a Canadian show called "You Can't Say That On Television." So Lee will be telling us if there's something, you can't say that on a FACA chartered, Federal Advisory Committee Act chartered committee. And one of the things we can't say is, we can't hear from the audience in this forum except in this designated period, but we do welcome you to talk to us. As several people have said, your need to know your clients, and you're our clients. We're trying to serve you as part of the American people, and the people that you all are trying to serve. So please, let's do as much of that as we can.

We have a little bit of extra time, and it occurs to me we could use this as a kind of dream time, in the sense that, maybe people on the Committee could talk about dreams that they have for this Committee. This may be our most effective dreaming because, after the break, we'll hear what FDA is legally allowed to do, and not to do. But let's sort of throw ourselves open to the possibility the things that they can't do now, if we make a good case for it, maybe somehow it will become possible for FDA to do it. So who would like to start with what you'd like to see us accomplish? Please.

MS. DeSALVA: I'd be happy to start. I've had a very pleasant experience in the last several weeks that I shared with Dr. Zwanziger, and that is that I've had a number of clients from industry approach me and say, can this Committee that you'll be serving on help us? We want to understand better how to manage risk. We want to understand better how

to communicate around risk. We need some guidance. And this is such a highly expert panel, we would love to be able to understand better how to tap its insights. So I have felt that those queries have been extremely sincere, and very concerned. And it would be good to know, and good to define how we may be able to extend that kind of insight and guidance even beyond what the current agenda and charter is.

DR. FISCHOFF: If I could ask, what do your clients think of as help?

MS. DeSALVA: Well, I think they're in a mode of reinvention, in many cases, you know, thinking about how to sort of press the refresh or restart button, and reinvent the way that they talk about products. And I think that it is imperative that some of the academic knowledge that this Committee has relative to how you help people make decisions, balance risk, and the kind of analytics that go into that process would be

really very helpful for members of industry to better understand. So I think that, as they develop programs to even have a sounding board, or to be able to tap in some way, shape, or form the individual expertise of people here would be of interest. I mean, I realize that that's outside the charter, and in many respects, not appropriate at this time, but I thought it was worth sharing with you that there is that level of interest.

DR. FISCHOFF: Perhaps just to share something that was brought -- that one of the options that, as I understand, occurs within FDA is for us either to succumb to people from other FDA Advisory Committees, or for members of this Committee to serve there, so that's sort of, I guess, an official channel of collaboration that we could be looking at over time. Linda?

DR. NEUHAUSER: One of the dreams I have is that we could take the notion of risk communication, and make it something that I

might call opportunity communication, to take the vast scientific knowledge we have, and actually make that more accessible to the general public, and to professionals; that we could take what we know, and make sure that it relates to the literacy levels, the languages, the cultures, and other needs and preferences of people for communication.

My dream would be that all the communication that we develop would be done in partnership with many different kinds of people in the public working hand-in-hand to do that together, and that we test all of this, and we build our knowledge base about whether the ways that we're communicating risk or benefit are actually working.

DR. GOLDSTEIN: Excuse me, to follow-up on what Linda said, it would be wonderful, a dream, to be able to help the FDA and other government panels to identify the best way to tailor our communication so that it isn't just one way, so that we learn about

the impact of communication vehicles on different populations, different groups of, not only patients and consumers, but also the clinicians that we hope will deliver some of these messages in more effective ways. So it would be to create, in a sense, not only a number of different kinds of interventions, but a laboratory, a way of testing, and refining, and enhancing the communication until we are satisfied that the communication, indeed, is meeting its purpose, that people are more informed, more engaged, more able, and actively participating in the kinds of decisions that they need to every day to manage chronic conditions, or avoid the risks and the consequences of some of the dangerous things that are out there from a point of view of health, so that would be my dream.

MS. MAYER: I would really love to see FDA find a way to help the public understand more in depth about the whole process of product approvals, and levels of

evidence required, and to help the public manage expectations about what is known, and what is still unknown, particularly in the area of drugs, particularly around safety issues and efficacy issues.

I feel like we're constantly in the position of having to explain, yet not being able to, the limited information we have when new drugs are approved, and that there is a real gap in public understanding of what that process really entails, what the process of clinical research is all about. And it would be truly a wonderful thing if FDA were able to communicate that clearly.

Other issues that are on my mind, and a constant source of -- a constant challenge for me as I talk with patients, in particular, and even healthcare advocates, have to do with the issues of complexity and ambiguity. It's very difficult, when you're in an emotionally stressed state, with a new healthcare problem or crisis, to process

information in a way that enables you to make really good healthcare decisions.

I'd like us to -- one of my dreams is to think about what the process of handling complex information is, and how people deal with partial knowledge in ambiguous situations, and how we can help communicate these situations, which are, after all, the most common healthcare choice situations, much more clearly.

DR. DeLaROSA: Hi. Jacob DeLaRosa. I have a dream. No. I would like to see a designated representative from the FDA, very similar to the model of the CDC, to communicate with media, consumers, all questions and concerns of the FDA. A single voice with a single message regarding the issues of the FDA.

DR. FISCHOFF: Could you say a little bit more, you know, particularly for people who are unfamiliar with the CDC?

DR. DeLaROSA: Well, what I think

is that, whenever there's a concern that's been brought up; for example, just recently in regards to vaccines for viruses and for flu, right away the CDC comes on board to the media and answers all questions. When there's a question in regards to, why is a certain virus not in -- or an anti-virus into the medication that we've all received for our flu vaccination, right away it's addressed, the concern is brought up and taken care of, so there's never a question.

What I see happening with a lot of concerns with devices and with drugs currently that are monitored by the FDA, or approved by the FDA, is that there's never truly a response right away, which leaves a big question, especially when there is a study that comes out from the Cleveland Clinic, the Mayo Clinic, and right away, everyone jumps on board without having a voice from the FDA, or the concerns from the FDA. So I think it's very important that, immediately, that the FDA

needs to respond, and give the risk assessment of what is actually going on right away.

DR. FISHOFF: Just as a follow-up to that, CDC's Emergency Communication Unit, which I think handles some of that, is having a -- I think they're calling it an Evaluation Summit at the end of April. And I think that they've -- from their perspective, they've made a lot of progress on the organization that would put you in a position to do that. And now they're saying, well, are we getting it across? Do we have the content right, and is the content understood where we are? But I think that's a really interesting idea.

DR. SLEATH: My dream would be to really empower patients more, to encourage them that the FDA could kind of -- we could work on empowering them, and having them demand that they have the right to kind of have the answers to their questions. A lot of times, I think questions just go unasked because they're either intimidated, or someone

already said, you know, getting medical information is often in highly emotional charged situations, where it's hard to comprehend what someone is telling you, so just encouraging consumers to ask questions, to design ways to help them do that, not only with physicians, but with pharmacists, nurses, et cetera. And then, on the other side, is kind of providers really encouraging them to ask questions, and to admit - I'm in pharmaceuticals - but to admit how they're really taking medications, because we have so many medications available now compared to the early 1900s, and to just level the playing field, and have open communication on both sides, because I think a lot of times, there's just fear on the part of patients or providers, assuming that people are taking things a certain way, when they really may not be, and the consumers may not have understood what the provider said on how to take something.

DR. BRUHN: I think we have a common theme here, and I'd like to enforce it even further. My hope is that we are able to identify and help FDA implement an approach that will help the public to understand the state of science, and our scientific knowledge about the benefits and risks of the factors that they're making decisions about. And we want to empower the public to make their own personal decision about what choices they will do, and that's a decision based on knowledge. They may choose to accept or reject, depending upon how their values are brought into that equation, but they know what science says about an issue.

I guess, in the long run, what I'm really hoping for is that we are going to be able to assist the FDA to have increased funding, actually, to permit the FDA to do their job of evaluating the science, and communicate this information to the public in a more effective, and more informed manner, so

that the public can make informed decisions.

I think the public needs -- I'm hoping the public will recognize, because it will be so blatantly true, that the FDA is able to prepare information for the public, and interpret the science the best way anybody can. And then they, as individuals, use that science to control their own lives.

DR. YAROSS: Marsha Yaross. My wish, as I listen in part to the discussion about developing the best practice, is that we think about a repertoire of practices, because the diversity of products we're talking about, the diversity of situations, the diversity of audiences, whether it's the clinician, the patient, et cetera, probably, and most likely, certainly, doesn't dictate a single size fits all. So I think that it's very important that, as we deliberate, and as we make recommendations, we retain the flexibility for adapting the recommendations to the specific situation.

DR. PETERS: My dream would be to understand how we can communicate this information about risks, as well as about benefits in these sometimes very complex decisions that are sometimes emotional, as Dr. Mayer pointed out, to patients, and physicians, and others who differ quite a bit in abilities, abilities as well as preferences, so that they can comprehend the information, but comprehension is just the first step, so that they can integrate that information, and they can actually use that information and act on it in ways that are consistent with their personal values, because people differ in those personal values.

And this should be both in the short term, when they're simply choosing or rejecting a treatment, for example, but also in the long term, when they're adhering to that treatment - excuse me - when they're adhering to what they chose, or also in ways that allow them to re-evaluate information

when it's needed, either when the information is changed - because information does change, Science changes as we go along - or when their personal values change.

DR. PALING: Since a dream need not be evidence-based, let me make a suggestion that's on my mind, and that is that one of the many difficulties in effective risk communication, which is in the charter of this Committee, is how to not just deal with the risks that the public, quite appropriately, is their major concern, but also to keep that balanced against the benefits.

I have seen several examples, over the last years, when all the focus is on risks, often spoken deceptively, albeit unintentionally, as a percentage increase in risk of 38 percent, which might be infinitesimal in small numbers. And, as a result, people become over-panicked. I don't say we should not speak of the risks, of course we should, but balance is not what most

of the public have accessible to them.

And now, Mr. Chairman, my real dream with no evidence-base at all. Those of us who love the intellectual subject of risk communication, which, here on the panel you have an over-abundance of, often wish that we could get more people to see its benefits. Some people, like Michael, spend a great deal of expertise and time trying to change doctors, so at least they present the best of our knowledge in a way that patients can understand. Usually, there's little interest, candidly, on the part of medical practitioners, like Jacob, and we were speaking about this yesterday, who are far more interested in the new papers on other different, important topics to do with the field.

Here's my odd dream. We know well, in risk communication, that you can bias, color, twist how people respond to a description of a risk by a phenomenon we call

"framing." If I tell you three out of a hundred are going to die in a certain scenario, few people would accept that. Reversing that, and telling them 97 percent might survive, than many, many more people would find that. There's a whole range of framing knowledge that is around this table.

I view that almost like a placebo. When we had the recent discussions about drugs in baseball, one of the wittier remarks I read in a Sunday editorial was how good it would be if we could pretend we were giving them a drug so that performance increased, but really we weren't. That, obviously, is flippant, but what concerns me in healthcare communication is that, whenever we talk about a evidence-based improvement in a drug treatment, we go through a highly complex procedure, double blind, controlled examinations, to make sure that what people think is going to be the outcome does not, in fact, alter the truth of what level of improvement comes from the

critical feature that we're investigating.

In a similar way, my dream would be, I'd love for someone down the line to recognize that we are actually, potentially, adversely affecting the medical outcomes of healthcare treatment if we only present the risk, and do not put it into perspective. That is literally a dream. We're far from it, and it might have no factual basis, if ever it were to be discussed.

DR. FISHOFF: Actually, there probably is a basis in psycho-somatic medicine, so I think there are people who could talk to that. Are there others? Well, we have time for a second round, amendments to your dreams, appendices, elaborations.

DR. PALING: Can we have yours?

DR. FISCHOFF: I'm in listening mode. Actually, years ago somebody said, if you want to change organizations, change the paperwork. So I would - I guess my dream involves - this is a very prosaic one, but

finding ways in which one could kind of institutionalize the sorts of processes that we're talking. So, for example, if it's dealing with an emergency, we have a regular procedure, and that's people's job to do these things. You don't have to do this in an ad hoc way. And if you change the paperwork, then you've got the subject matter experts producing the data that the communicators need to know. So often, risk communication is brought in as the tail-end of a process. We've done this, you explain it, or we've messed things up, you explain it, or we've got this great product, you explain it. Whereas, in any sort of systematic product design, you would start with the customer, you would figure out what the customer needs. Clearly, everybody does that to some extent, but actually, for products where the information is a major part of the component, the product design process ought to include, what's the information going to be? What is it going to

look like? Are we going to be able to explain this to people in a way that they're going to take advantage of it? Could we redesign the product in a way that there will be fewer compliance problems, and better usage? So I would like to see risk communication driving the risk analysis and risk management process. And, in a way, sort of a rule-bound organization like FDA has limits, but it also has opportunities for encouraging people to organize their work in a way that will just make this a routine process, rather than a kind of crisis part of it. And doing the routine work well will reduce the number of crises, and will have the information and the team kind of on tap when they need to be mobilized for a crisis.

We're very happy to introduce the Food and Drug Administration Commissioner, Dr. Von Eschenbach.

COMMISSIONER VON ESCHENBACH: Good morning. First of all, I apologize for being

a little late, and I also apologize for the fact that my visit here today with you will, unfortunately, necessarily have to be brief, because of, as you can imagine, many of the other things that are going on at FDA.

But having said that, I really want to emphasize how important it is to me to be here with you this morning, and to be able to do a few things. First and most importantly, perhaps, is to thank you, thank each and every one of you for your willingness to contribute, for your willingness to share your gifts, of your talent, and your expertise, and to serve the FDA. And in fact, serve the people of this nation and the world in what is an extremely important initiative and effort. And so, I really --it's very important to me to thank you, and thank you sincerely, not just on my behalf, as Commissioner, but on the behalf of the entire FDA. And to also thank the many people at FDA, like Nancy and others, who have really invested so much of their

effort and their talent into bringing this Committee and this day to fruition. Because they, too, recognize from the perspective of the FDA, and the importance of our work in protecting and promoting the health of every single American, how critically important this particular initiative is.

And so, that is the second reason why I'm here, is to not only just thank you for your effort and your commitment, but to really emphasize to you, to the FDA, and to those we serve, the public, how very important this effort is, and how committed we are to making certain that it plays a very central and core role in the FDA's effort to accomplish its mission.

It's a bit unusual, because many of our Advisory Committees, many opportunities that we access to help be informed as to what the right thing to do is, whether it's advice with regard to a particular drug, or labeling change, et cetera, it's about the issue of

what is the right thing to do.

This is an important Committee, because it really embarks on a slightly different perspective, it is not just, what is the right thing to do, but most importantly, to do it in the right way. And that, to me, as a clinician, especially as a surgeon, is as important in the outcome. It's one thing for me to make a diagnosis and know the right thing to do is a particular operation, but I absolutely must do it in the right way, if we're going to get the desired outcome. And from that clinical perspective, as it relates to the mission of FDA, one of the critical important things is that we put what we do in the context of this patient, the person that we're serving in the center of all of that effort.

What we do is only important as it ultimately impacts or affects that person. And we are in a moment of time where, as we think of that person being in the center, and

that person being the end for which all of us are working and contributing, then our relationship with that person, with that patient, with that public, is extremely important. That relationship must be built on trust, and that trust comes from communication, and from dialogue.

Without that communication, without that dialogue, without that understanding, that trust is extremely difficult, if not impossible to establish. And so, how we communicate what we do is as important as what it is that we're doing.

And frankly, just as we need to learn, and just as we need advice, and just as we need the input of expertise to help us know what to do, we need advice, direction, and expertise to help us determine how to best do it, how to best communicate and engage with those to whom we're here to serve.

Frankly, I think this comes at an extremely important time in the Agency's

history. It's a time in which, quite candidly, if one looks at external data, there has been an erosion of trust. And some of that is not necessarily because people believe we are doing the wrong thing, but basically because, perhaps, they need to better understand and appreciate what we're doing. And when that trust is at issue, and especially in the context in which we're dealing with issues in which people's confidence has been, perhaps, eroded, and we're dealing with subject matter that affects their very life and well-being, or the life of their children, or those they care about and their well-being, then clearly, communication becomes even more important.

And so, I cannot over-emphasize how important I believe your effort is, and how much we are going to look forward and depend upon you in our undertaking of the ability to communicate, to those we serve, the issue of risk. And the issue of risk is not only for

them to understand what is at stake with regard to the potential problems that might occur, adverse events, if you will, but also to be able to understand that in the context of the balance of the risk, as opposed and compared to the benefit, because there is no drug, no medical device, no product that the FDA regulates that doesn't carry with it some potential risk, as well as the promise for great benefit.

And helping to engage in that conversation, in the framework of establishing openness, transparency and trust, is a skill, and it's a skill that requires us to not only be thoughtful and mindful about what we say, and how we say it, but even more importantly, to be aware of how it is being heard and understood. It doesn't matter when I sit down with a patient in terms of what I tell them, it only matters in terms of what they heard, and understood. And that is a skill, and that is an area in which we will look forward to

making a considerable commitment, and a considerable effort.

You are our experts to help advise us, and to help us understand and learn how to do that well. Each of you have extraordinary and unique skills, and background, and experience that, in itself, is a valuable contribution. But when one sees you together, and then appreciates how much greater the whole is than the sum of its parts, then FDA is truly blessed and privileged to have you a part of this effort, and this commitment.

And so, I thank you for that. I wanted to emphasize to you how very important I, we, the Agency, view your effort. You are charting new waters, so to speak, in terms of the very nature of this particular kind of an Advisory Committee, and I believe, like most efforts, we must look at that as a learning experience, and a developmental experience. And I know that you will be thoughtful and mindful of that, and that we will continue

this dialogue in terms of conversation with regard to how we can serve you better, in terms of you being able to serve us better, but in the context of that, the recognition and the realization is, it's us serving the people who have entrusted their lives in our hands. And so, with that as the framework, I am deeply grateful to you. I thank you for your willingness to serve and commit. I look forward to a continuing dialogue with you, as you help us to more effectively dialogue with those we serve, and specifically, to be able to address the issues of risk in a way that it is understood, and it is heard and appreciated in a way that results in positive, rather than negative, outcomes. And that is both as it relates to individuals, as well as it relates to society, in general. It's a tall task, and not one that we take lightly or superficially. We recognize the enormity and the burden that we are asking you to bear, and to carry. There's much at stake, and yet, at the same

time, I think there's so much great opportunity for us to serve even better.

Communications will always be at the core of our responsibility in that service, and you're helping us to do that well is something that I think we all long appreciate.

I will take questions, if there are particular things that you would like to ask of me, as you begin this process. And again, I apologize for the fact that I won't be able to stay with you for the bulk of the meeting, but you're in good hands. I can assure you of that.

DR. FISCHOFF: We are in good hands. Well, thank you very much. If you weren't otherwise occupied, I think we could use you on our Committee. So in the spirit of your remarks, you know, give us feedback. And once we get through our spring training, don't be afraid to throw us a few high, hard ones. People who have comments or questions?

DR. PALING: I really appreciate your graciousness, the warmth of your welcome, and your remarks. One of the things, as an outsider, is that I've always hoped that, in the past, the FDA would have had more emphasis on trying to gauge, evaluate, if you like, the efficacy, how effective are the previous methods of communication. Would you like to share what your, or your Agency's thoughts have been on that, and whether you're reasonably comfortable the way things are at present?

COMMISSIONER VON ESCHENBACH: When I first arrived two years ago, just a little over two years ago, I set five strategic priorities that I thought were thematic for the organization in terms of areas where we really needed to make significant progress. Some of them were things like bioinformatics, and our information technology infrastructure, but one of them was communications. And communications was a very, very broad agenda

for me at that point, because I saw it as thematic, as transformational for how the Agency was, in fact, relating to those to whom we serve across a full continuum. And to really begin to put that on, if you would like, the same scientific basis upon which we should be doing everything else within the Agency, so that we were strategic about those things that we were choosing to do, but we were strategic in the context of being data-driven and analysis-driven over what was the outcome, and how could we even do it better, because it's a continuous process of improvement.

And we really had to change, not just some of the things we were doing in terms of process, but, quite candidly, even address some of the issues having to do with culture, to be more open and transparent, and to be fair. That's a very difficult ask of an organization where people have been conditioned that, every time they stand up,

somebody shoots at them. And yet, at the same time, that requires us to be open, and to be more vulnerable.

I met with a group in the field the day before yesterday in one of my all-hands meetings, and I indicated to them one of my current ideas, which is to welcome reporters to be embedded in the Agency in terms of field activity, so they actually get to see what it's like walking in their shoes. And when you walk in their shoes for one day, you have a dramatically different appreciation and opinion for what they are doing as public servants.

Well, the idea of an embedded reporter in the FDA was something that started people twitching, but it's those kinds of things that I think we have to be open to. But then, when we do things, we have to ask, what is the impact? And we're doing that across a variety of measures, so the answer to your question has been a little bit of long

one, but I tried to emphasize the fact that I see this as a part of a larger thematic agenda of openness and transparency in terms of, not just what we're doing, but how we're doing it, and people beginning to understand and appreciate that. And then do that in a variety of schema, everything from, I now have "Brown Bags," where I'll invite the press in to sit, and I get 20 minutes to tell them about something I want, they get 40 minutes to ask me any question that they want. And so your effort is really a keystone, because it really addresses, not talking to the media, but talking to those we serve using a variety of media to get the -- as I've indicated to folks, our goal is to not communicate to simply just inform, but is communicate to also transform, to move people to, not just knowing things, but to changing and altering how they are responding to that.

So as we communicate risk about a drug, for example, it's one thing to inform

them about it. A second, more important issue for me, to transform them so that they use that product appropriately, and, at the same time, put it into a context. And let me be very specific about that.

One of the things that we learned in the spinach E. coli outbreak was communicating problems with regard to the spinach resulted in us being able to mitigate and stop any further deleterious problems, or outbreak, but it also put the use of fresh produce into a decline, and we were really unable to reverse that over a long period of time, so the longer term effect of that communication was, in fact, a negative one. And if we were more strategic and thoughtful, perhaps we could get the desired outcome without the unexpected outcome, and deleterious one. And that carries through to a variety of ways in which we communicate.

The second most important thing, and we need to do the measures, and we need to

determine how well we're doing this, is, I feel strongly that it's important for us to communicate early, rather than late. But in communicating early, it's often, we're communicating with a much smaller degree of certainty based on the evidence, and we are trying to help people to understand that we haven't said that it's actually a problem, only that we're concerned that it may be a problem. But what kind of reaction does that get as we provide that kind of information is the issue, and that's something in which I think your work is going to be extremely important. So we've got a pretty ambitious agenda for you, but you can see the detail is why it's so important. Yes?

MS. VEGA: Good morning, Commissioner.

COMMISSIONER VON ESCHENBACH: Good morning.

MS. VEGA: It's a pleasure to have you here today. The demographics of this

country are changing day-by-day at a speed, I think it's faster than it has ever been anticipated. I'm particularly speaking, in my case, about the Latino population. How prepared is the FDA, in terms of the work it does, in terms of what we are going to be doing, in terms of communicating with the public, how prepared is FDA to deal with those changes in this country?

COMMISSIONER VON ESCHENBACH: There are two parts to that answer; one is, we are looking at this from the point of view of, what can we do at the macro level? Simple example, perhaps is, we are in the midst of total renovation of our website, because our website, frankly, needs to be modernized, but that's a kind of a mild way of putting it. When I'm more of my surgical personality, it's a little stronger. But in the process of doing that, and in the process of doing it in a way that meets what we've just discussed, we clearly have a way of people being able to go

to a Spanish version of the website, so how do we get it into a language, how do we get it into a format that's culturally sensitive, and ethically sensitive?

But I've also learned, from my experience, that the macro level is really not the effective one, it's the micro level, and how do you get to the communities, and let the communities take the material, and let them be able to disseminate it in the appropriate language fashion, and culturally sensitive way? So I think creating the link and the liaison with those who disseminate the information is as important as what we are doing.

Now that's, quite candidly, labor resource-intensive, and there is an issue of how much you can do, and when you can do it, given those constraints, so I, quite candidly, tell you that we're a little bit away from that, but that's not something that I don't think we should not be working towards. And I

think, until you really get into the micro level of the community itself -- and again, I think it's part of this issue of, it's not important what we say, it's only important what they hear, so you have to put yourself on that other side of the equation, but it's not simple.

DR. NEUHAUSER: Commissioner, thank you very much for your remarks and attention to these important issues. I have a related question to Dr. Vega, and that relates to your view of FDA's leadership. Many of us see this Agency as the pre-eminent one in the United States, as you said, to promote and protect the public in the areas it deals with, as well as in the world. And a couple of years ago, I was a participant in a workshop held by the U.S. Surgeon General that looked at health literacy, and the finding was that most of the information from federal agencies available to the public is maybe three to four grade levels above the average reading level of Americans

in the United States. And a question arose, which federal agency might take the leadership to turn this around? And I personally, given what we know about communication, think this is fairly low-hanging fruit. We know how to develop communication that is at the average reading level of the public, but it's curious to many of us that we haven't seen yet a federal agency say, we will be the one to take the leadership in the United States, and as a model for the world, because it's a worldwide problem, to make sure that, let's just say, the reading level of our information is simply accessible to the public. So I wonder what you think about that as a goal.

COMMISSIONER VON ESCHENBACH: Well, it goes back to --well, let me try to put it in this context. When I've looked at the issue of communication, it was an issue of how, do we relate to those who are telling our story? And I've already spoken about that. And then, how do we do a much more effective

and better job of telling our own story? And what tools do we have to do that with?

The single most important tool I believe right now, today, in the 21st century for us to tell our own story is the internet, the web. And so, first and foremost, we had to totally revamp our website. Now that's not to say that our print materials and everything else is unimportant. It's important, and we're going to continue to address those kinds of things that we disseminate and publicize, but the website, given there's only so many hours in a day, so many people in the FDA, and so many dollars in the bank, that's where the focus is.

And the first thing on the website that we chose to really modernize and go after was those parts of the website that were directed specifically to consumers, the public that we're serving. And how we go about that has to be based on the kind of leadership and sensitivity that you just alluded to, to get

it right with regard to how we are -- the language we're using, and the words that are being used to communicate the messages. So I would like to think that, ultimately, that will be viewed as leadership on the part of the FDA.

And there's a standard of excellence that we're going to hold ourselves to, that I hope will be recognized as something that will put us out in the forefront as a government agency. And then we're moving systematically through the other parts of the web that are directed more towards professionals. But through all of that will be part of this opportunity with regard to communications of risk, and risk and benefit. And I do think that, as a prelude to, hopefully, beginning to stimulate, over time in terms of our leadership role, I think it's one of the opportunities for FDA, not tomorrow, but perhaps sometime later, is to really catalyze a conversation around a

doctrine of risk, because I really believe, and that's something Secretary Leavitt is very interested in, as well, and he kind of has -- he's sort of genetically engineered that way because of his EPA experience when he was in Environmental Protection. But we both view that society needs to really have a broader conversation around risk, and our expectations, and our understanding of risk, because I think there's more to it.

So I'm giving you a very, you know, 50,000 foot aspiration on one hand, some very practical, specific things we're doing right now today, but all of which I hope will translate into FDA's mantra of, we are the leader. And as Senator Kennedy said in my confirmation hearing, we are the single-most important agency in healthcare in the United States, and I think we are always going to want to behave that way.

DR. MOXLEY: Good morning. This is probably not within the FDA charter, but I

walk a lot around communities, and urban areas. And you have to walk a long distance in certain communities to get to health communication. Libraries are decimated in a number of communities, children's museums are decimated in a number of communities, pharmacies are hard to get to, Green Groceries are hard to get to, and you have to wonder about how people receive communication about health, and communication about risk. And I just want to point out, and I think of this in terms of strategy, actually, how, outside of large health science centers, which often dominate the geography of the communities that are adjacent to the communities, but they're not part of the community, linking to information that actually is accessible, and at an appropriate level of health literacy is really very difficult. And there are crises in communities relative to digital access. And I'm wondering from your perspective is, who's looking at the whole picture relative to

health in communities?

COMMISSIONER VON ESCHENBACH: Well, at the risk of there being a revolution behind me, I am going to make it very clear that FDA cannot do all things, even though our portfolio is extraordinarily large and diverse. But we can help to contribute to make sure that all things get done. And so, this is really kind of the thematic of a strategy of collaboration and cooperation. We're really reaching out to create liaisons and partnerships. And not only among other agencies within the federal government who do own some of this real estate, but even beyond and outside of that. So, for example, engaging in conversations with WebMD, and a variety of other entities that are engaged in this dissemination of information.

And I think one of the challenges, and one of the areas that we're really working on, which is one of those other five strategic priorities that I alluded to, because these

things interdigitate, is the need to put everything on a modern information technology platform or infrastructure. And as we work towards that, and as we kind of do that in a collaborative, integrated way, one can begin to see opportunities emerge that we don't currently have, and aren't accessible, but could easily be.

So, for example, let me give you a case in point. It's one thing for us to revise our drug label, but how do you make that information really practical and useful to both the healthcare provider, as well as to the healthcare consumer? And once we get on a modern IT platform, and we not only understand how to message, but we can also create an IT infrastructure so that, at the point of sale, or the point of dispensing, namely, pharmacies, for example, electronically, we can communicate or transmit, in real time, accurate, up-to-date, precise information about that product. And the information

technologies, and the systems, the software systems are such, that you could have a menu of the formats in which you would want to disseminate that information, including language, and its content, that could be directed towards the microcosms of what's appropriate in this particular environment, for this particular patient, so that they get the information that they need, that's useful to them, in a format that it's understandable, and workable, and they're getting it immediately in real time, and it's accurate, and it's up-to-date, not something that's been in a PDR that's two years old. And how can we keep them informed as to what we know today about that drug, as it relates to its effectiveness, and its risk, and how it should be appropriately used.

So I'm not owning the whole territory, but I think we could work collaboratively with partners, whether it's the pharmacy industry, communicators like

WebMD, FDA, and information technologies that get to the point that you believe we need to get to, which is libraries and other institutions are not, necessarily, the answer to tomorrow's challenges. And so we need tomorrow's solutions for tomorrow's challenges to get us to that point. I think we can contribute to that, but I don't think we can be the sole provider of that.

DR. MOXLEY: Would that kind of capacity be in public places, or in households?

COMMISSIONER VON ESCHENBACH: Well, that takes us to another level. I mean, when -- I've had interactions with Intel, and a variety of others, and Microsoft, for example, who are actually working on technologies that will enable this to be, not just in your home, but on your Blackberry. And now, does everyone carry a Blackberry? Well, not in every community in this country, but more and more. So the point is, there are tools that

are available today that weren't available five and ten years ago, and there are going to be tools that are going to be available five years from now that we still haven't even imagined. And what I think our responsibility to do is to look at the need, look at the opportunities and the tools, and then we, the FDA, our responsibility, I believe, is for content. We've got to get the content right, and then work with others to disseminate that contact in a way that gets us the result we really want, which is that person who's providing that medication to their child, understands what they're doing, and gets it right. Does that help?

DR. FISCHOFF: I like your idea of the -- just before you came in, we were -- one of the panel members talked about how important it is for people to understand, in effect, the epistemology of the sort of knowledge, the content that FDA has to provide. And it strikes me that, when it's

just the battle over the endpoints, then you don't know where the data come from, how credible they are, what kind of new evidence and surprises are credible. It just strikes me that your notion of an embedded reporter, some enterprising journalist can find a way to describe that process as a way of giving people a picture of where the data come from, so they have realistic expectations of what happens, even when everybody is doing their best to --

COMMISSIONER VON ESCHENBACH: That would be very --

dR. FISCHOFF: Yes.

COMMISSIONER VON ESCHENBACH: And I do apologize that I have to leave, but I know we will continue this dialogue, because, again, one of the things I would like you to really appreciate is that your effort is not an effort in a vacuum. It's an effort that's going to be an integral part of a much larger agenda and context for the FDA.

For example, in a very short period of time, we will be announcing Sentinel, which is a major commitment and initiative on our part with regard to post-market surveillance. And there's much that we could talk about in that regard once Sentinel is announced, but it will put us in a position, as we go forward with modern information technologies, and access to large healthcare systems with electronic databases, to be engaged in our ability to detect early signals of adverse events, as well as early signals of unexpected efficacy. That gives us data and information for which we're going to have to make decisions with regard to communication.

Now that, in itself, is a whole scientific effort, because there is a body of science which needs to be applied to be able to do that analytical process right. But at the same time, once we have that information, then there are major challenges as to, what do we say, and when do we say it, and how do we

say it in a way that engages with those whom we're serving. So you're going to be helping us to address a fairly substantial level of transformation within the Agency, and I think, hopefully, that will prove to be extremely exciting, and stimulating for you, as well. So it's going to be, I think, for us, a great advantage to have you. For you, I hope it's going to be kind of exciting and fun to be engaged.

DR. FISCHOFF: Thank you. I think, from our perspective, if you'd like to push risk communication upstream into the science and technology of designing Sentinel, we're at your service.

COMMISSIONER VON ESCHENBACH: Thank you.

DR. FISCHOFF: Thank you for coming.

COMMISSIONER VON ESCHENBACH: I'm going to leave you with the people who really know what they're doing, and what's going on,

and Nancy's leadership. So, again, my thanks to all of you.

DR. FISCHOFF: Thank you.

(Applause.)

DR. FISCHOFF: Okay. Thank you, everyone. And our next is -- I'd like to introduce Nancy Ostrove, who will be -- who's a Senior Advisor for Risk Communication at FDA, will be talking about an overview of what FDA has been doing in this area.

DR. OSTROVE: Okay. I won't say we're going from the sublime to the ridiculous, but I C- well, you've heard from Dr. Von Eschenbach, and I think that's -- I can't -- you've already heard my welcome, as well, yesterday. And what I want to do is kind of give you some background. And I'm going to try and go through it fairly quickly, which most of you know means pretty fast, at this point, because I know that we're going to want to make up some time. But here is kind of our background, just to give you the kind

of context in which you're going to be working. That is going to be followed by some more background, and by the afternoon, you'll all be able to talk again. And, obviously, there'll be questions I'm sure you're going to want to ask.

Dr. Von Eschenbach didn't specifically talk about our mission, but essentially, our mission is protecting the public health, advancing the public health. And what do we mean by that? We mean speeding beneficial innovations to the public, we mean facilitating dissemination of useful information, specifically when we're talking about advancing the public health.

All right. Okay. Innovations and information about what? Well, specifically, about the many products that we regulate, which probably are worth about 25 cents on every dollar that consumers spend when they go out to spend money. And this is just kind of a list, and I'm sure it does not include

everything, but we're talking foods, drugs, biologics, and biologics in itself includes blood, tissues, non-therapeutic vaccines, drugs, of course, include therapeutic vaccines. We're talking medical devices, cosmetics, veterinary and animal products, and radiation-emitting electronic products. And the key word here is "complexity." The variety of these products reflects the complexity of our authorities, which can vary even within the broader product classes that I just showed. The authorities, for instance, within devices, can be extremely hard to understand if you try to get to kind of understand the differences between Class I, Class II, Class III devices, and then talk about PMAs versus 510Ks, believe me, you don't want to get into it, but there you go. You just have a huge complexity.

And FDA's organizational structure mirrors those categories, which is something that really, you know, is not necessarily

automatically accessible to people who are thinking FDA. They're not thinking of the Center for Drug Evaluation and Research, they're not thinking of the Center for Food Safety and Applied Nutrition. They're thinking FDA, and we've definitely heard that from our audiences.

Yet, at the same time, our audiences cut across these categories, and they have different needs, depending on what the product is that we're communicating about. So here's kind of your first set of complex interactions.

We have multiple audiences; they have lots of different names. And whichever the primary audience is, is going to differ by the product. So, for instance, foods and cosmetics, this is really the only broad category where our primary audience is, in fact, the general public. And it's important to understand that, for foods, as opposed to, for instance, drugs, biologics, well, most

drugs, not all drugs, biologics, and some medical devices -again, we're getting into the complexities here - we have limited pre-market approval authority, so that, in itself, has important implications for prescription drugs, for biologics, for certain medical devices, for food additives. That's kind of the one area in food where there's a certain degree of pre-market authority. These things have to be approved before they're actually out there. But, generally, foods, they're out there.

Now, there is also over-the-counter drugs, but there's also always a pharmacist available, or in general, unless people are getting them over the internet, there's a pharmacist available. And even if you're going to legitimate sites on the internet, you have access to pharmacy.

So my point was actually that, for foods and cosmetics, historically, the Agency has recognized that it's really important to effectively communicate to the public, so we,

in fact, have a group within the Center for Food Safety and Applied Nutrition, a consumer studies team, that does research on consumer understanding of food labeling and food labels on a regular basis. Consumer research was critical in terms of developing the Nutrition Facts Panel, which you see every time you go and you pick up some kind of prepared food. So there was that recognition, but again, foods and cosmetics, that's the area where our primary audience is clearly the general public.

For medical products, it's really been another situation. Historically, the communication between the Agency, well, between healthcare providers about the products that we regulate, has been, well, we've communicated with the healthcare providers.

I always go back to these slides that Commissioner Kessler used to like to use years ago, when we were talking about patient

labeling. In the 1500s, the Royal Academy of Physicians had a statute - I don't know if they called it a statute - but there was a rule out there, basically, fining physicians if they told patients even the name of medications, because it was thought that, well, that would be dangerous for the patients to know, so they were fined 40 shillings if they did that. And even as early as 1938, we had a Federal Register Notice that went out from FDA that said that drug labeling needed to be written only in such medical terms as are not likely to be understood by the ordinary individual. 1938, not that long ago.

Now there have, admittedly, been significant changes in recent years, but every time FDA has tried to, for instance, expand labeling, to mandate labeling to be focused toward patients, to have patient labeling, FDA has, basically, faced significant challenges, for good reasons.

We faced challenges from concerns

about this interfering with the practice of medicine, about it interfering with the practice of pharmacy, about it having effects on liability exposure that manufacturers have, and these are all concerns that the Agency needs to be cognizant of. But, as I said before, clearly, the environment in terms of communicating with the public has changed. There have been a number of things that kind of everybody knows about. First of all, consumer empowerment and patient advocacy.

Contributing to that, we have the concerns of an aging population. And I can tell you, you know, the fact that, when I wear my contact lenses, I can't quite see that as well as I'd like to, aging population, baby boomers, all the marketers out there will tell you that that has an incredible impact, certainly on marketing.

There's also a population that has, at least a segment of the population, that is increasingly sophisticated, and has certain

expectations about the kind of information that they're going to get. Now that is not the whole population. I think Dr. Moxley has clearly pointed out that you have more than one population that we're talking about.

New and expanded media. The Commissioner talked a little bit about that. Rapid development of new treatments. Many of the new treatments that are out there have very, very unique complexities that can be extremely difficult to communicate. And we've heard this discussed this morning, as well, the recognition that literacy has an impact, both literacy in its more general sense, and health literacy, as well.

So how does FDA communicate? Well, there's -- I look at it in that we communicate in two kind of general ways. One is an indirect way. We communicate indirectly with the public by our regulation of labels and labeling. And historically, regulating labels and labeling is how we've defined our major

communication responsibilities.

Again, for some products, foods, cosmetics, and over-the-counter drugs, that's focused on the general public. But generally, but for the larger - well, no, I can't say it's the larger segment, because foods are - it's just huge, but for medical products, our focus has been on healthcare providers, and that's what the labeling generally tends to focus, that's what it's directed toward.

We also regulate advertisements for some products, specifically for prescription drugs, and biologics, and for restricted medical devices, which is a very small category of devices. Otherwise, and not everybody realizes this, advertising is regulated by the Federal Trade Commission, so most advertising for devices, for instance, all the advertising for foods and cosmetics, is regulated by the Federal Trade Commission.

And further, there are limitations in the extent to which we can have an impact

on this indirect means of communication. For instance, some labeling is reviewed, some is not prior to the point that it appears in the public. So for instance, we make the distinction internally between approved labeling versus promotional labeling. Approved labeling is, for instance, what we also call the package insert for drugs and biologics. It's what you see, what a physician will see if they consult with the Physician's Desk Reference. And it's the little, you know, often accordion thing that you unfold if you get a prescription drug that's in a little box, and it's kind of stuffed in there. Generally, advertisements are not reviewed before they're used in the public, and there's lots of reasons for that, and you will get more information about that later on today.

Bill McConagha, in fact, is going to be discussing some of these issues later in detail, including issues related to First

Amendment protections of commercial speech. We can, in fact, take enforcement action only if a law is violated. Laws often do not address communication issues, so they're not going to say, well, this particular type of communication vehicle needs to be written at a fifth grade level, or an eighth grade level. So you can't necessarily take -- you can't take enforcement action unless the material, whatever it is, is violative in some other way where the law will permit such action. So we communicate indirectly, we also communicate directly. We put out press releases, we do public education campaigns, many of them in concert with other agencies, and sometimes private sector groups, as well.

We have a number of people who respond directly to inquiries from the public. We have a variety of tools regarding specific products and product classes, and we're going to have a panel later on this afternoon that are going to talk about some of those tools,

so I'm not going to go into detail about them. But limitations apply here, as well, in terms of what we can say. And again, Bill McConagha is going to be talking about some of that this afternoon, so I'm not going to go into any detail.

A question has been brought up, how effectively are we communicating? This is a major question that we've been faced with. There are some basic issues that arise just right off the top of your head. How much do you communicate? When is more actually less, because you're overloading people? When do you communicate? When is soon too soon? When does that have an unintended consequence? By what means should we communicate, what channels should we be using? How do we know how we're doing?

And as you all probably know from the pretty consistent coverage of our actions in the national press, I'm not sure if the Commissioner used this term, but you stand up,

and you kind of get pummeled, so this is fairly -- this is not quite an everyday occurrence, but it certainly happens often enough that it's very clear that everyone has their own perspective, and depending on what side they happen to be coming from, you're going to get entirely different criticisms. So how do you measure effectiveness, as well?

Now, here are some sources of feedback that we have gotten relatively recently; well, are ongoing in some cases, with regard to our communication efforts. We have been facing feedback concerning consumer-directed advertising of prescription drugs since back in the 1980s when Boots Pharmaceuticals first decided that it would be appropriate to let people know that Rufin was a low-cost alternative to Motrin.

We hear, pretty consistently, that it's important to be notifying the public about emerging risks of medical products. But again, those questions that I raised earlier

come up. How much, when, what are going to be the consequences of this?

We are always getting feedback concerning health claims on foods and dietary supplements. We have gotten feedback, in addition to this ongoing stuff that comes from the public, specifically from -- well, we've gotten feedback because we asked for feedback. In the case of the recent Institute of Medicine report on "The Future of Drug Safety," there was a chapter that specifically looked at FDA's communication of risk information about drugs. And we've gotten feedback relatively recently from the FDA Amendments Act, FDAAA, whatever you happen to like to call it.