U.S. 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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FRIDAY, AUGUST 15, 2008

The meeting came to order at 8:00 a.m. in room 1066 of 5630 Fishers Lane, Rockville, Maryland. Dr. Baruch Fischhoff, Chairman, presiding.

PRESENT:

BARUCH FISCHHOFF, PHDCHAIRMAN
LEE L. ZWANZIGER, PHDDFO/EXECUTIVE SECRETARY
CHRISTINE BRUHN, PHDMEMBER
ANNAMARIA DESALVAMEMBER
MICHAEL GOLDSTEIN, MDMEMBER
PRERNA MONA KHANNA, MD, MPH MEMBER
MADELINE Y. LAWSON, MSMEMBER
MUSA MAYER, MS, MFAMEMBER
LINDA NEUHAUSER, DrPH, MPH MEMBER
JOHN E. PALING, PHDMEMBER
ELLEN M. PETERS, PHDMEMBER
BETSY LYNN SLEATH, PHDMEMBER
MARIELOS L. VEGA, BSN, RNMEMBER

OTHERS PRESENT:

DAVID SMITH, PHDINDUSTRY REPRESENTATIVE
HEIDI REBELLODEPUTY ASSISTANT COMMISSIONER
FOR PUBLIC AFFAIRS
NANCY OSTROVE FDA STAFF

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

8:11 a.m.

CHAIRMAN FISCHHOFF: Okay. Let's -- I think we have a quorum. I think we have a quorum and let's start now. Let me think members of the committee for coming and continuing to contribute their service and members of the audience for listening to us, and as -- just in case there is anybody new, who wasn't here yesterday, we'll introduce ourselves now and then begin the program.

There is time at 10:30 for -- at 10:30 there will be time for an open public hearing. If there is anyone who hasn't signed up and would like to sign up, let me invite you to talk to Lee during the break and we can put you on. We value -- we've had actually excellent input from our -- from the audience in each of our meetings. So, our designated federal officer will do what she has to do.

MS. ZWANZIGER: Thank you, Dr. Fischhoff. Good morning and welcome

everybody. And thank you for being here. As was read in full yesterday, let me just briefly reconfirm that based on the submitted agenda for this meeting and all financial interests reported by the committee participants, it's been determined that no interest in the firms regulated by the Food and Drug Administration present potential for conflict or appearance of a conflict of interest 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 and exclusion will be noted for the record.

Thank you.

CHAIRMAN FISCHHOFF: Well, now to brief introductions and then get to our program. I'm Baruch Fischhoff. I'm the chair, and I'm in the Departments of Engineering and Public Policy and Social and

Decision Sciences at Carnegie Mellon University.

MR. PALING: Good morning. I'm John Paling. I am an American. I live in Gainesville, Florida, and I will take public -- a minute or two just to introduce myself, since I'm speaking this morning and I tend to be the exception to my colleagues around the room here.

My background was that I was a professor of biology at an English university. While I was there, a gang of us started to make wildlife films. Made the very first Nova film eons ago. Spent 25 years making wildlife films, learning how to intuitively as my colleague Mona across the way does, think what the public need in order to understand the scientific message that we tried to put over.

Since that time, I have spoken at many conferences, many of them medical. And I've always introduced myself jocularly as the least academically qualified of my colleagues

here. And that is true. I don't say it in a flattering way. Because I think the most dangerous thing is someone with marginal charisma to admit their ignorance and expect you to believe or respond to what they say.

However, because my experience is of speaking to hospitals, health care organizations, particularly doctors, also working with universities in helping patients understand risks, I think I see things from a slightly different perspective. And it's that that I will be offering.

But I do defer to the wisdom and greater scientific accuracy and the values of maintaining the scientific values as the predominate way the FDA works. So, I'm delighted to be with you and thank you for your attention.

MS. MAYER: I'm Musa Mayer. I'm a breast cancer advocate. I also have written several book and work as a journalist. So, it's really my expertise is a communicator

with patient communities that brings me here.

MS. PETERS My name is Ellen Peters. I'm a Decision Psychologist from Decision Research in Eugene, Oregon. We're a not for profit research institution. I study how people process information and how that makes a difference to judgments and decisions that they might make. And look towards using some of those descriptive models in order to help, try to help figure out how to help patients and others make better decisions. Thank you.

MS. SLEATH: Good morning. I`m Betsy Sleath. I'm a professor of Pharmaceutical Outcomes and Policy at the University of North Carolina, Chapel Hill. My research focuses on how providers and patients talk about medications during actual visits and how that impact patient outcomes.

MS. DESALVA: Good morning. I'm Annamaria DeSalva. And I lead the Global Healthcare Practice at Hill and Knowlton. And

Hill and Knowlton is a global public affairs and public relations firm. And we work with organizations throughout healthcare, solving different kinds of communications problems. And this morning, I'm going to be talking about how the industry in particular, tries to solve for important communications challenges when there's an urgent or crisis, or bordering crisis risks situation.

MS. NEUHAUSER: Good morning. I'm Linda Neuhauser. I'm a professor of Community Health and Human Development at the School of Public Health, University of California, Berkeley. My main interests are in translating research into practical programs and participatory design with diverse audiences for large scale communication.

MS. LAWSON: Good morning. I'm Madeline Lawson, and I'm the President, CEO of the Institute for the Advancement of Multi-cultural and Minority Medicine based here in Washington, D.C. And our primary focus is on

addressing health disparities.

MS. BRUHN: Good morning. I'm Christine Bruhn with the University of California at Davis. I'm in the Department of Food Science and Technology and Director of the Center for Consumer Research. And my work focuses on consumer attitudes, practices, behavior and education regarding foods, food safety, food technologies, so forth. Thank you.

MS. VEGA: Buenos dias. My name is Marielos Vega. And I am a staff nurse for the Department of Family Medicine at the New Jersey Medical School. What I also have to bring to table like this is the voice of minority populations. Thank you.

MS. KHANNA: Good morning. My name is Prerna Mona Khanna. I'm a journalist and physician, with specialities of internal medicine, public health and occupational medicine. My practice of medicine is limited to charity care and volunteer work. I'm a

Texas Medical Ranger. And my full-time non-charitable work, is as a medical journalist. I'm a former print reporter, medical correspondent for CBS Television, and currently serve as the Medical Editor for ICyou.com, a social networking site for health.

MR. GOLDSTEIN: Good morning everybody. I'm Michael Goldstein. I'm the Chief of the Mental Health and Behavioral Sciences Service at the Providence VA Medical Center, which is a new job for me. And I'm also an adjunct professor of psychiatry and human behavior at the Warren Alpert Medical School of Brown University. And my interest and expertise is in behavioral interventions to enhance health behavior change within health care settings, particularly in primary care settings. And I'm interested in, have done research in clinician-patient communication on many different levels.

MR. SMITH: Hi. I'm David Smith.

I am vice president of research and development and quality for Pepperidge Farm. And obviously, consumer communication is key to all of us in the food industry.

DR. OSTROVE: Good morning. I'm Nancy Ostrove with the Food and Drug Administration. Senior Risk Communication Advisor in the Office of the Commissioner.

CHAIRMAN FISCHHOFF: Let me thank you all. There are three members of the committee who are not here right now. Sally Greenberg was a liaison from, Sally Greenberg, rather.

DR. OSTROVE: She's actually member.

CHAIRMAN FISCHHOFF: Sally Greenberg, who had a scheduling conflict. David Moxley who's sick, and Jacob DeLaRosa who was here yesterday, but had some sick patients and went back last night.

It's also it's my sad duty to say goodbye to two, actually, two members of our

committee here, and one in absentia. That when FDA set up this committee, they assigned us terms of one, two, three and four years. So, that once the committee as a whole came up to speed, we wouldn't lose all of our institutional memory at once.

And Marielos Vega and Linda Neuhauser and David Moxley got the one-year terms, I think sight unseen, and I'm really very sorry to be losing your expertise. I understand that there's still the opportunity to keep you on as special government employees if you'll fill out a little bit of paperwork, well, maybe a lot of paperwork. I don't want to soft sell the burden.

And I hope that we've managed to -- well, I assume -- I know that we've managed to incorporate some of your perspective, but that's not the same thing as having you at the table and interpreting them for everything. So, let me thank you for your service, and hope that we haven't seen the last of one

another. So, thank you.

DR. OSTROVE: And I'd also like to add my thanks and extreme appreciation, Marielos. And both of you just having Linda and Marielos here and David, and we're -- I hope he's feeling better -- has just been fantastic for us. I mean, this is like the -- I mean, it's our third meeting, but the group is really jelling. And it's just -- yesterday was fantastic. I have to say.

And you two have just been such wonderful participants in these discussions and we've learned so much from you already. My expectation is, is that we do, you know, want to continue to have access to your expertise, and hope that you'll be willing to continue to fill out the paperwork so that we can do that.

And there are opportunities to be guest members of the -- at the meetings as well as to work with you individually. I'm really bad at this kind of thing. But I

really echo Baruch's sentiments and want to thank you very much for your participation and your willingness to do what needs to be done to be a member of one of these committees. I don't think the public realizes how much is involved.

So, once again, thank you very much.

MS. NEUHAUSER: We appreciated being on the committee and all the important work. I know it will go on extremely well.

MS. VEGA: And I also want to thank you, and thank everybody for being so wonderfully friendly. I mean, I think all of us have become good friends, co-workers. So, I definitely plan to continue to the degree that it is allowed, be part of this important mission. Because we need to put ourselves to work. And I'm not the type of person who will sit in an office and let things go by without doing anything. So, my services will always be available, if needed, thank you.

CHAIRMAN FISCHHOFF: There is, I guess, it's nice to have the paperwork amortized over two, three and four years, rather than just one. On the other hand, I imagine that you know, when the history of this committee is written, the people who were in at the beginning, will have had disproportionate impact on how we, on how the work was shaped. So, I really -- we really appreciate that.

What we're going to do today is to talk about -- I mean, one of the many wonderful things about this committee, is that although almost everybody here has scientific training, there only

-- it's a minority of the committee that are actually practicing scientists in the area of communication. And I think that that's -- you know, as one of those people, I think it's been an enriching experience for me to see what are the -- to find new ways of being useful, and find out that we're less useful

than we thought, and have some additional work to do.

And today, we're going to be hearing from three people who will be talking about the, sort of how the work expresses itself in the context of preparing for and dealing with emergency situations. And so we'll be, you know, learning from their experience and extracting the messages that are relevant to FDA's practice. We'll be -- either they'll be telling us, or we'll be inferring for ourselves where the science has been useful, and where the science has additional challenges.

The first two speakers will be AnnaMaria DeSalva and John Paling from the committee, and then we'll hear from Heidi Rebello from FDA staff. So, AnnaMaria, take it.

MS. DESALVA: Here we go. I got it. Okay, thanks Lee.

Good morning. And I really want to

thank you for inviting me to participate as a presenter in this part of the discussion. For me, it's been just a great pleasure to have been a part of this committee. I'm sorry to see Linda and Marielos move on. But look forward to working with you hopefully in the future.

I think the great value that I've extracted from this experience, certainly has been taking these discussions and thinking about how they apply in my daily practice as a communicator, supporting different kinds of organizations, but certainly the industry many times when there are special events and special risk situations.

So, what I'd like to invite you to do is to think about what's presented here, which is really essentially a case study. And to begin to consider how some of the themes that we've been discussing over the last day or so, some of the principles, some of the processes apply.

It's a little ironic, because as we were going through all the presentations and discussions yesterday, I was struck by how it all kind of builds to this one particular example that I've put together, which is focused on medical technology. So, I'll be curious to understand if you see some of the same similarities.

Of course, the industry is involved constantly in risk communication. And it really ranges according to the level of risk, obviously in terms of the level of intensity of the risk communication effort. This is not meant to really be a formal categorization of risk. But I just really meant to kind of chunk out the way that we think about the different types of risk that need to be managed and need to be communicated effectively.

It might start with the adverse events that are associated with the fundamental risk profile of the product. And

that would be characterized by the product's labeling and the clinical experience that was developed in order to bring the product to market.

It certainly could be emerging risks that are newly defined by the post-marketing experience of the product. And we had some related discussion about that yesterday. Sometimes, as a follow on to emerging risk, we experience established risk, or there are risks that are clearly identified that present a material threat to patient safety, and around which there must be some form of intervention or some form of control.

And then of course, the worst case scenario is, is that there is a life-threatening risk of a significant and intolerable nature where there's you know, some sort of a radical change, or certainly withdrawal of the product that may be required.

And there's a range of both general

and special controls that the industry employs to manage this type of risk, whether you're talking about a drug or a device. And I'm having a few formatting issues here. Sorry about that.

But they may range from special labeling changes, to you know, enhanced post-marketing surveillance in terms of post-market studies and registries, medication guides, the risk evaluation and mitigation strategies, the REMS programs now that are being adopted in the drug's phase.

You know, moving all the way to temporary suspensions of marketing when there are important safety questions that must be addressed. And then recalls, which at least in the device world, may include some sort of a correction, but also of course, involve full-on withdrawals of products.

And in each of these cases, or in many of these cases, there's some combination of both persuasive communication and non-

persuasive or explanatory communication. I've decided today to share with you basically a composite case study, drawing on some experiences I've had, and colleagues of mine in the industry have had.

And I've decided to focus on the device space. Because devices can be so difficult to communicate around for many of the reasons that we were discussing yesterday. And oftentimes, when you have a high-risk situation, you are employing both persuasive and also non-persuasive or explanatory communication.

So for the purposes of our discussion today, we're going to look at emerging risk that's newly defined by a post-market experience. And that becomes established and around which there must be an intervention, around which you know, industry works closely with the agency to determine what's the appropriate control and to implement that control.

So, as we go through this, it's really a story and I'd also like to say, that it's not often that industry people, frankly, get to tap the expertise of such an accomplished group. And so, I would really love if as we go through this, if you would consider ways in which the methods and the processes that are outlined here can be improved, or in which you would have some direct, substantive input. It would be great in the discussion period to go through that.

The goal in communication, I think on the industry side, when there is a major risk event, is certainly first and foremost to minimize and manage the risk for the affected patient population. So, we're sort of all on the same page. It's really all about patient safety. It's all about making sure that a risk is aggressively managed and mitigated.

And so the, it's incumbent upon the industry to define the risk, and to support the appropriate interpretation of that risk.

And that is of course, a tremendous communication challenge. And then also to create a clear pathway for risk mitigation, both by patients and by healthcare providers.

There are other objectives. It's from a commercial standpoint, obviously, many responsibilities and many different types of concerns. You know, hand in glove with minimizing and managing risk is of course preventing any undue fear, confusion, anxiety and skepticism. So, we all know that sometimes the fear factor can be worse than the risk itself. And so the appropriateness of the communication and the effectiveness of the communication really counts in that respect.

And everyone's skeptical of industry. You know, it's a very negative thing to say. And I don't mean to be unnecessarily negative. But when you think about one of the principles of risk communication, which is how credible is your

source, you know, unfortunately dynamics are such in the environment today, that it can be very challenging for industry to be very credible on the issue of risk, and risk management.

So we work very, very hard to make sure that the motives are clear, the processes and the data are clear and there is great collaboration with stakeholders beyond industry, and certainly, with the agency.

And that goes a long way to demonstrating credibility, commitment and trustworthiness, which of course is so important in effective risk communication. But also, the industry is looking to preserve its ability to address a medical need. So, sometimes with major risks, that need to be controlled, you run the risk of you know, throwing the baby out with the bath water.

Sometimes there is a product that has a role to play, and there's some ambiguity around the level of risk, or how that risk can

or should be managed. And you know, industry is going to want to preserve its assets appropriately, and it's going to want to make sure that its products can be used in an appropriate manner and effectively manage risk.

And that -- all of this helps to pre-empt undue reputation damage. So, every time there's a major event, a major quality or patient safety issue, there is a tremendous risk to corporate reputation. And corporate reputation, of course, is a company's main currency really. And so the stakes really couldn't be higher in terms of managing these situations effectively.

So, what are the critical success factors? And I can certainly see that my computer and Lee's is probably not directly compatible. So, I'll talk you through what these -- what the rest of these bullets say.

It's really about early integration with risk evaluation processes. And you know,

effective communication strategy has to start very far up stream in the process. This don't always happen. In the best case scenarios, it does. And you know, oftentimes companies -- I think healthcare companies are very committed to communication. It's been my experience in all my years in the industry, that companies are investing more and more and more in communication.

And a lot of them are building up I think very sophisticated corporate communications departments with senior people who get pulled in, you know, at the level of the executive committee, to work on emerging risk as it occurs. But that's not always true. And it can be very challenging when it's not true.

Within the company, you have to work in a very inter-disciplinary way, prospective planning against major scenarios. So, you know, major principle of crisis communication is preparedness. And you do

have an opportunity to anticipate the trajectory of an issue and how you can plan actively against it.

There needs to be, you know, rigor, appropriate speed and transparency and lots of stakeholder engagement to develop the correct strategy. So, everything that Linda was saying yesterday about, you know, participatory strategy development was really resonating with me. And it's something that we employ in the industry for sure, to make sure that we get both strategy and message correct.

Intelligent participation in the media coverage cycle, it's so important. And it's difficult. It's a difficult dynamic because the media are keenly interested in healthcare, obviously, keenly interested in risk and safety events. You know, rapidly consume any information that comes out from FDA on these subjects.

And you know, really oftentimes

strive for accurate and responsible reporting, but that can also, often be also a casualty of speed. And so, the industry really needs to be on its front foot and understand what the needs of the media will be and understand how to serve up the information in an appropriate way, but one that's also useful in terms of driving accurate coverage.

In terms of the application of crisis and risk, crisis and risk communication principles, you know, I think the crisis communication principles are well known and well-established in many places throughout the industry. And increasingly, risk communication principles and theory also is. And the industry has different ways of applying it.

I think you'll see from this example, that it can be extremely challenging to slow down, you know, and to apply those principles in a very thoughtful way when you're in an urgent situation. And

oftentimes, the opportunity to do your most thoughtful work in that respect happens probably immediately after an urgent or crisis event.

So, let me tell you a story then, about a company. And imagine that this is a medical device company that has a product that's used to treat a chronic condition, which may be causing material injury and disability in a subset of patients.

There have been individual events reported across the country, but the trending analyses over a 12 month period, really don't suggest a fundamental product safety issue. And as many of you may know, the industry, in medical device industry, has very sophisticated surveillance and quality systems management processes.

And so, typically there is on-going vigilance. And when there's critical mass of an adverse event, an investigation will be tripped. And there are, you know, constantly

on-going trending analyses.

So, in this case, trending analyses aren't indicating a fundamental issue. But at month 14 a prospective analysis indicates that within a year, events may reach statistical significance. So, they're not there yet. But there may be a problem, and it's not known of course, at this stage, what the root cause may be. It could be due to either patient demographics, or surgical implantation technique. It's really looking like the two most likely possibilities.

Based on the availability of some acceptable treatments for the same condition, and really out of an abundance of caution, the manufacturer decides to recall the device, removing it from the U.S. market. There's a comprehensive and also very visible announcement that ensues. And the root cause analysis will determine if the device should again be made available with a different design, or with improved surgical technique

training.

So, there is a very clear communication, public announcement, coordination with the agency. This is a device recall of some significance given the level of risk that is associated with the adverse event. And it's unusual because this isn't like -- it isn't happening frequently. Again, the level of events has not reached statistical significance.

So, in some respects, the level of intensity and awareness of this recall is disproportionate to the risk. And that's just part and parcel of the company having to make the decision to kind of do the right thing in their view for patient safety.

So, how this plays out ultimately is the root cause analysis determines that a subset of patients who can be clearly identified, are contra-indicated for this device based on certain physiological characteristics. So you know, we're able to

basically identify the population that's at highest risk and make sure that the -- if the device becomes available again, that it is used appropriately only in those patients for whom there is acceptable risk.

With effective communication and education, the manufacturer does hope to reintroduce the device because it does address an important unmet medical need. And the manufacturer endeavors to advance both knowledge and practice in risk management and communication and approve clinical outcomes in this affected patient population.

So, you've all heard the expression inevitably with every challenge or crisis, there's also an opportunity. And I think the really smart, thoughtful companies recognize that whenever there's adversity, whenever there's a very complex, challenging situation like this, it is an opportunity to kind of dig deep. And not just do the right thing, but use it as a learning experience for the

industry and really create strategies and programs that do advance knowledge and practice.

So the other considerations that will affect the strategy include these. This company is a market leader and well-respected, but it has experienced recently several product quality issues and also some visible corporate issues. So, you know, well-known, well-regarded, but some of the recent history creates a more complex communications environment.

The media environment is intense and reflects a keen interest in the subject of post-market medical device performance. Surgeons really like this device. They don't see a problem with it. They trust it. They count on it. A lot of them are going to be frustrated by a conservative course of action. And they will also be inconvenienced because they will be burdened by having to explain to their patients why this recall is happening.

And it's going to you know, just be a drag basically.

The nature of the adverse event is understandable frightening to the few patients who have it. It's you know, it's scary. And there are actually far greater risks associated with ex-plantation of this device than maintaining the status quo, which is something we discussed at some length yesterday.

And then also, your key assumption should be that this company is right-minded and is concerned principally with patient safety.

So, the continuum of planning that a company in this situation has to follow, really flows from the emerging risk, to the established risk phase through to the intervention of the field action and then as it resolves, we're in an evaluation and in this case, a relaunch phase.

And the needs really span from

obviously understanding what stakeholder needs are as the trend is being identified. Making sure that patients are supported during the phase of emerging risk, and preparing for potential intervention.

As the risk is established, we want to determine and validate a risk-mitigation strategy. So this happens sometimes extremely rapidly, where you trip an investigation where there's an emerging risk, and then you may reach the conclusion of your investigation and then right away, you have to determine what is the risk mitigation strategy going to be.

And you know, to what extent are you going to reach outside the company to validate that strategy. You know, moving kind of beyond a discussion with the agency, but including maybe some expert, external advisors.

So, all that happens very rapidly. You finalize what your plan's going to be, and you begin to align your internal and to

some extent, external stakeholders around a major intervention and communication's plan.

At the time of the intervention, or the field action, you are communicating very broadly and rapidly to a wide range of stakeholders. You're working very hard to minimize disruption and to prevent undue confusion and negativity.

You are, in the evaluation phase, trying to define what the impact has been of your mitigation strategy, and what remaining on unneeds are there for communication. So, you're looking hopefully both at process, how was your process effective, or not. And also, what has actually been the actual impact, and where do you need to course correct, or focus in the post-event phase.

And then in terms of relaunching, you know, in a situation like this, you may or may not successfully relaunch. If it looks like you can, then you have to precondition for the return to market, cultivate acceptance

and confidence that the risk can be managed, and certainly work very hard to drive appropriate use at launch.

So, you can see what the full spectrum of needs are at a very basic level. And again, you know, the urgency, the speed and the scope of what happens in that sort of middle point in that continuum, really makes it difficult. It creates some very significant challenges to the effectiveness of risk communication.

I think a lot of companies do it very well, you know, despite that challenge. But the opportunity to do some of the most thoughtful work and to really support stakeholders, can often ensue in the stages that follow.

So, in this particular story, in this particular case, FDA is advised of the investigation once it starts. A letter to surgeons is disseminated to advise of the adverse events, the onset of the

investigation, as well as patient monitoring and management considerations that they may have now that they know that there may be an emerging -- that there is an emerging and uncertain risk.

And the medical affairs and the communications teams at this company begin to map the potential trajectory of this issue. And they begin to look at what all the potential scenarios are, you know, sort of planning for the worst, and hoping for the best. And they start to initiate strategy and message formation.

And what they're doing in this stage, is that they're mining their existing knowledge and insights about the needs of target audiences. So what you're really hoping is that there's a lot of knowledge throughout that whole organization about their customers, about the patients they serve, about their special needs and different contexts.

So, you're starting from a strong place. Sometimes you're able to take advantage of the opportunity to gain additional insights through stakeholder consultation either informally and anecdotally, or actually through some qualitative market research.

In the established risk phase, the investigation concludes. The results point to several potential solutions. So it's not black and white. There's some ambiguity in terms of what the right thing to do is. And frankly, the company could do a couple of things that would be well-received or would be wholly appropriate in this context.

But so what they want to do is, they want to take their findings and all the -- and the potential risk mitigation strategies, and put it in front of an expert external panel. And as soon as they do that, they reach a decision to implement a recall and a withdrawal, which may be a permanent

withdrawal of this product.

But they want to basically eliminate the risk. The communications plan is then finalized. It's been in development to some extent up to this point. Now, it gets very intense to finalize that plan. And almost simultaneously systems are initiated.

So, the actual processes of implementing communication starts with the development of materials. The activation of global communications networks internally, preparation of spokes-people, preparation of call centers and very select external stakeholder engagement, depending on the materiality and the sensitivity of the subject.

And then finally, the overall plan, the comprehensive plan is reviewed with FDA, so that together the agency and the company can coordinate its communication.

At the time of the field action, the company announces with a great deal of

coordination with FDA. FDA mobilizes its own risk communications vehicles as part of a very coordinated effort. And you know, the day one flow looks something like a surgeon letter goes out the night before via Federal Express with patient -- with news, a proper announcement of the recall with the rationale. Specific steps that surgeons need to take to withdraw the product.

And also with patient communication guidelines. So the company recognizes that they're burdening surgeons frankly, with this recall and they want to help them have the right kind of balanced conversation with patients. And so some effort's been made to provide a related tool.

A press release goes out after the stock market closes the night before. And this gives the company the opportunity, because this is a material event from a financial disclosure standpoint, this gives the company an opportunity to begin to

communicate with some of its external stakeholders before the news hits the next day.

And many of you will know, or understand or appreciate that in these types of situations, it's so difficult for physicians. Because, you know, their patients are hearing about things from the media. And they're scared. And they don't always know how to interpret the information. And the physicians haven't had the opportunity to do any of the up front contexting.

So, sometimes what can happen here, is there is an appropriate outreach to opinion leading surgeons. Those discussions start to take place, so that people know that they're getting this information and news the next day.

There's a call in the morning with investors because this is a material event. And the reason why that's important is because the analyst community, the investor community

and the media community are very closely aligned. The company has, in terms of the way they consume and report out on information, the company has prepared for a media briefing.

They don't know if they need a media briefing. They don't think they need a media briefing, because this is really not big risk. And so, why should there be, you know, such a grand communication or media effort. And the truth is, is because of the heightened interest, they know that they have to be prepared to move with the media briefing if there is enough inflow from media and other sources.

And based on the level of calls they're getting, they decide that it's smart to go ahead and have their media briefing at about ten or eleven in the morning. Letters and email alerts go out to key third parties. They launch their consumer hotline. They extend their individual briefings.

There is some further targeted

media outreach, some meetings and discussion with key national media who may want to do some more thoughtful reporting. And of course, there's outreach through the field force and the customer-facing surveillance systems really expand and there's a lot of intelligence gathering in terms of how this news is being disseminated and understood in the field.

After the event, there are networks of clinical sales and marketing teams reach out to touch just about every single customer. And this is typical in the device space where there is, you know, very close working relationship with customers and where, you know, there are standard mechanisms for collecting this type of information and that those would be ramped up.

The external expert advisory teams are expanded and convened with greater frequency. There's some market research that's fielded to evaluate the company's

systems and process for communication, the impact of that communication and also what remaining unmet needs there are that must be addressed through the go-forward plan and a gap analysis is done to help improve knowledge and also what the company's currently doing and what it might do in the future.

And then finally, in the relaunch phase, from a communication standpoint, you have to think about how you communicate the root cause analysis to regulators, customers and patients so that's understood.

There's more data that's analyzed to define the relative risk-benefit in the new target population. It's not a given that the product's going to relaunch. The company has to really explore the rationale for bringing the product back to market, and what level of support there will be for its reintroduction.

And they know that they need to demonstrate the need for this product to come back to the market, and also a tolerance for

the risk it represents among the affected patient population.

Once the company decides to bring the product back to market, it develops and launches a new surveillance and risk management program. It intensifies its monitoring. It establishes a patient registry. It creates a risk communication demonstration project to really explore how risk communication can be improved in this group. And it provides through that program support to physicians and patients in terms of treatment decision making.

So, just a couple of thoughts about this case and then I want to wrap. Because I think it would be much more interesting to talk about it. And that is, that -- I've touched on some of these points already. You know, effective communication strategy really does begin very far up stream as emerging risks are identified.

And I've been in both situations

where I've been involved, you know, from day one, and I when I was involved basically two days before the announcement, which can sort of feel like an Olympic event in terms of you know, communications preparation. So, I think as communicators, we all understand how important that is.

It's important to build the knowledge, systems and networks of expertise before you need them in an urgent situation. So, you know, what's wonderful is, if a company not only has great repositories of knowledge inside the company, but also has very smart people outside the company, they can reach for, for really quick advice.

And I do that all the time. I call people like you when I'm in a tough spot, and will informally ask your opinion. And that quick exchange can really redirect and be incredibly helpful in the implementation phase.

The work that follows the risk

event is often where you get to do your most thoughtful work. So, even in the best-case scenarios, chaos can ensue, you know, from some of these announcements. And so, you know, hopefully it doesn't. And many times it doesn't. But you always want to be working after the fact to make sure that you're minimizing disruption.

And if a product's going to remain available or come back to market, you know, really just seize the opportunity to be very thoughtful in the way that you communicate at that stage. The participatory process is key throughout this. And without it, this case certainly wouldn't have been a successful one.

And then finally, you know, when all strategy flows from a primary concern for the patient, decisions and implementation really take very rapid shape. And I've had you know, the pleasure and the honor of working with some companies who are just very principled and you know, right on up to the

top, the chief executive officer who says, I don't care what types of problems we're going to have to solve, or how much litigation there may be. We're going to do the right thing for the patient. And that just creates so much clarity in terms of what needs to happen next.

And it takes a lot of the pain out of this process. So I think that that's also very much, you know, a best practice from a communications standpoint.

So, Dr. FISCHHOFF, I'll leave it to you how you want to -- you want to go on to John's presentation, or?

CHAIRMAN FISCHHOFF: Yes. I think actually if we did all three presentations.

MS. DESALVA: Okay.

CHAIRMAN FISCHHOFF: And then we have the general discussion.

MS. DESALVA: Okay good.

CHAIRMAN FISCHHOFF: Thank you very much.

MS. DESALVA: Yes, you're welcome.

MR. PALING: My friends, many decades ago when I was an angelic choirboy in the Church of England, I learned supposedly that the institution of marriage was ordained to procreate children for their nurture.

However, since being married to an American, well, actually, she's a Texan. But after 30 years of this experience, I have learned that in practice, for me, the institution of marriage has been a learning experience. Mainly that what I thought I knew and could say with assurance, is certainly not likely to be true.

And whereas before, I used to be indecisive, very frequently now, at the end of a conversation, now I'm just not so sure. And that not so sure, is very much how I feel genuinely about addressing you all today.

First of all, everything I say, I know is either known well by Nancy, or certainly if not she particularly, by her colleagues. And that what I will be bringing

is in fact different perspectives. I have thought long and hard about what my responsibility can be, given the fact that I tend to have a more general public view about both risk communication and my personal expectations about what the FDA should do to be effectively communicating the risks and benefits of those products that it regulates.

First thing I'd like you to know, I truly think FDA, from my limited knowledge, does an amazingly good job in all of its regulatory methods. But I do think, as we all know, the world is changing and in one particular way, the responsibilities of the FDA are irrevocably changing in the direction of having a second prime responsibility of being an effective risk communicator to the American public.

Not overtly so, until you begin to look at the details of where both regulatory frameworks and also expectations of the public are moving. If you think -- ask for yourself

the question, where out of all of the various agency in the U.S., should the public expect to get their reliable, objective information about the risks of healthcare? And it falls back on the FDA.

If you look at the questions that Congress sometimes beings up, challenging whether they could take over from the FDA and make some decision about policy, it is well-known, that the FDA quite rightly stands up and says, no, no. Only -- there's a legal phrase for this which escapes me -- only we at the FDA have the knowledge to be the risk assessors, and thereby the risk communicators.

So, my first message is, I think this is a journey, and that what I plan to do, is to direct my observations to how I think this second growing responsibility of being a risk commination agency, who that might take place.

Just to take one of the most recent documents, you can see, to increase the

transparency March 2007, of the agency's decision-making process. Now my italics, the increased openness will enable patients and their healthcare professionals to make better informed decisions on individual treatment options.

In other words, I want you to see that as I see it, as saying, it's not just a matter of saying we do risk communication, but it's now directed towards helping patients make better informed decisions.

Better informed decisions to me means that I think even at the most basis level, FDA's risk communication process should be challenged and potentially improved. From the 2005 meeting about risk communication that CDER has, I'm constantly repeating this quote. And in my mind, nothing is more important than the FDA -- this was what it was said in that recommendation, "Leads an effort to develop good risk communication practices for the agency and industry."

And by the way, I know, because people have said it in all directions, industry would love to collaborate with their time, with their priorities for the FDA, in order to try and put some suggested strategies together. So, things are moving. But I don't think things are as good as they might be.

Since I bring biological background, I thought I might suggest that we can all learn from the world of nature. If you wanted a benchmark for how to succeed with change, nature's been doing it for a few thousand years. And if you want great communication let me tell you the secret of the honey bee.

Bees when they go back to the hive, land and do a little communication dance. They wiggle their bodies, go round a little circle, wiggle their bodies again. That's saying, how far to go, the direction in relation to vertical is saying where to go in relation to where the sun is.

And many, many, many, many, successful animals in their communication have a cycle of giving a message, and not changing the message until they get a signal that that message has been received. And if you think about it, since the FDA has to work as a team in its agency, bees can provide a remarkably good example of how perfect teamwork should be.

I'm sure you're well aware of their reputation in this field.

Bees are perfect in every dimension. Well, how about if we look at them with a new perspective. What about if we slow them down 30 times and watch the perception is, that bees are perfect in every way, is suddenly seen to be a fallacy.

The reality is, that when returning to their hives, they are terrible navigators. The reality is, loaded down by pollen and nectar, and with all of the heat causing wing disturbances in the air, they look more like

professional wrestlers.

The power of the visual image will leave this memory and this message in your mind, as does the power of visual images in drug communications on televison. Probably better than any words can do. It's the music. It's true, but it illustrates for me one important point, there is a vast difference between reality and perception. And until someone challenges your and my routine view of what is truth, we will all by default stay with the world of perception.

And it is easier for someone from outside your world to point out potentially new perspectives. I'm going to dedicate this to Nancy in the front here for a reason you'll see in a minute.

This is a sequence from a National Geographic film on Okefenokee Swamp. Okefenokee Swamp to me is the emblem of change. And it reveals the universal biological principle that what survives in

nature and in institutions and in your life and mine, has to match the realities of the world in which we live.

You see, this swamp changes its position. What used to be peat at the bottom of the swamp, raises through the decomposing gases and changes to produce blank floating islands, nothing on them. But then small plants grow. They change it, bigger plants can grow. They change the environment again, so the only things that survive can be the ever taller plants finally leading to trees.

And I'm going to suggest that in this process of change, there's an analog, there's a metaphor for how the FDA is, and will continue to change rapidly towards improving effective risk communication as a major subset of its job. Here I am eons ago, showing why the American Indians used the word, Okefenokee for the swamp. It really means, when translated, land of the trembling earth. And if you watch, I think you'll see

why.

That was the bit for Nancy. You're never afraid of alligators. We spent three years making this movie for National Geographic. Because again, despite perception, it's for adults, not young children, or dogs or cats, alligators really on every statistical basis have a minimal level of risk for adult human beings.

But what the lesson for this is, that everything in the world depends upon a firm foundation of reality, including the strategies that my colleagues will advise for the FDA. And you can't build a house on a wobbly foundation.

Look at these plants. Swamp is so acid, pH3, that very few plants can survive there. And those that do, cannot get access to nitrogen. And they have learned to trick, to eat insects, to get the nitrate, the nitrogen that the acid water denies them.

This is a pitcher plant, no moving

parts, a hood, under which the insects go to get the nectar. This too is a metaphor. Once the insect is fed, it tries to escape. The hood conceals the way in which it went in. But look at the back. Trick, false perceptions of windows. The little insect weaken themselves and then drop down that horn of death, to be eaten by a plant.

I don't parade my relative lack of academic expertise as anything of value, other than to ask you to accept that I'm about to make suggestions most of which, inevitably be unrealistic because I do not know the practical, the political, the economic, the prioritizing issues that determine what the FDA does.

But my first thing, and this has been reflected in so many people's conversations is, that I can't get my mind around the fact that we can still accept unqualified words like, safe and effective. And it's been used so often. But to me, that

becomes a pommeling horse. That politicians, perhaps, who wish to point out in letters and in public, that what you're doing is not providing safety for the public.

And to me, this is such a big issue that I would recommend, which is why I'm putting certain things in little yellow boxes here. That one should constantly strive to recognize that the image, of the FDA is not universally that that I know it should have. And many times, people are skeptical.

For example, Dr. Bruhn indicating her frustration yesterday that there are these food risks. And even though the public know about it, seemingly, they will do nothing about it. Well, I have a suggestion that many people view the fact that the FDA and pharmaceutical companies have to list risks is simply a CYA procedure. They got to do it because the lawyers make them.

And I think it may be not a large number people, but there's a significant

number of people who just think you're envitably going to be crying wolf, and therefore, your credibility to accept what is clearly said, may not be something that previously you've considered to the level that it might merit.

My recommendation is that the FDA must now begin in both healthcare professionals and communications to the general public, to communicate the numbers. Our venerable chairman wrote a paper in 1995, that was circulated where he said, 20 years before that time, when risk communicators try and talk risk, number one, find the numbers. Number two, tell them the numbers.

You go through the list. None of them say, don't communicate the numbers. And the reason for me in my own upbringing comes from work with the EPA about ten years ago. Let me tell you what I learned from them working with Bill Riley and other people in the top of the hierarchy there.

Unlike the FDA, who from what I've been able to learn have been using safe and effective since 1962, sliding in through the back door, the EPA very much want people to know that there are risks. And when I worked for them, I used to explain to the general public just how inevitably people can become confused by the appearance of safety.

I told people that, everyone's aware how sophisticated computers are now. How sensitive are the detection equipment that we use to measure infinitely small quantities of stuff. And I told people that the level of sensitivity for a whole lots of things is as small as one part in a quadrillionth.

Notice what I'm going to do. You see a number of itself means nothing unless it's given a context. You're not communicating information. You're communicating data. And so, what I used to say is, well, one part in a quadrillionth, is very hard to realize that here, I'm putting on

the table a nine inch tall book. And just to give you some perspective, one part in a quadrillionth is the equivalent of a pile of these books going from here, all the way up to the moon and back, 300,000 times, like one second in 32,000 years.

My point there is two-fold. One is, that data for good communication requires perspective, context. But the other thing is to draw the lesson, frankly, at that level of sensitivity, you could probably find a cancer-causing toxic compound in anything you ever measure. Therefore, the key lesson for communicators to share with the public, with my EPA hat on, is it may not matter if something contains these. What really matters is, how risky -- quantity, probability -- is it for real people in real life situations. Which is of course, what our professional risk assessors in FDA and around this table are all about.

So, I am attuned to think that we

should be telling people that there are risks, but draw their attention to the probability being the most important thing of all. I say to you, I bring you quote, because Nancy and Lee know I read this stuff up voraciously.

The signs are already out there that you the FDA are going to have to be using, probabilities. There's no generality in Section 801, sector will publish a table of adverse events with number and frequency. So, I keep saying that not only for the EPA but for anyone, I don't think it helps people to give them a list of events without some level of probability.

So I looked at the patient information sheets from A to Z. Aleve. I'm not going to show you them all. But if you just look what the patients are being told at present, may increase the risk, can cause stomach, can do this, can cause kidney -- this to me, is deficient in the minimal level that I as someone who is voracious, to try to help

my stereotypical image, is my mother, or members of the public to understand risk, I don't view this as adequate.

And we heard yesterday, that things are beginning to change, and I'm sure they are. But I just need to say, right now, this to me, in my perspectives is a hugely important thing if one professes to talk about risk communication in an effective way.

There's a paper, and I've given a list of references that I know Lee will make available in health affairs recently, where a scientist spent considerable time asking the public what they think they should want. And what they wanted is for the top three or four or five risks to be put down along with a percentage. So, you could see if it's death, it's not one in a trillion, even though it might show on such a list.

So I view this, this is my perspective. It may be irrelevant, it may be impractical. Go from Z, FDA's analysis,

patients receiving this anti-epileptic drug, have approximately twice the risk of suicidal behavior, and then two, very helpful and very important numbers put in by the side of it.

Good risk communication practice, as I learn from reading the literature, and being a participant in peer reviewed pressures, is that you should avoid like the plague, the idea of talking relative risks. Relative to what? If you're trying to talk to the general public, or help doctors talk to the general public, it's crucial to talk in terms other than this is from the H.R., Hormone Replacement Therapy things. Twenty-six percent increased risk of breast cancer, 41 percent increase risk of stroke. And then all the things that you were speaking of so elegantly just a few minutes ago, come into play.

You're dealing with fear that is beyond the level of what the numbers or the numbers in perspective, should merit. And

I'll just give you an example. When I got into this, it turned out that the average risk of breast cancer of a woman over the age period where they'd be taking these treatments was three people dying out of 1,000.

If you did take hormone therapy, the risk was 3.8 people. So, .8 out of 3, gives you the figure. I'm trying to suggest to you, that when you look at how your public gets the information, predominately from the media, and you see this stuff slashed around all the while. And I think it's important that the FDA and the industry too, who were perhaps some of the worst of it, avoid using relative risk. My advice, maybe impractical, but there's my reason.

A small point here. Gentlemen doing research out of California, found that 40 percent of patients are so innumerate, that they will misjudge which is the greater of two risks. 1 in 667, they viewed as greater than 1 in 378. Being a bigger number. Now that,

is something that unless you know it, unless you care to be sure where the patients have the problems, I'm going to suggest you'll never be able to be effective in your communication.

How simple it is? How undergrading? How universally an improvement is it to express all proportions with a simple common denominator? It doesn't insult the scientists and now, in simplistic terms, the way I tend to speak, this has improved the likelihood of people being able to understand the significance of the numbers in a context.

Positive and negative framing. Well known if I told you or your patients that there would be a three percent chance of dying, people will typically not take that treatment. Ninety-seven percent chance of surviving, yes, they will. And so for a simple procedure, I consider that another of the remits of my dear friends of the FDA is to get around and to report within a year how

you're going to talk about risks and benefits so the public can move towards better informed decisions.

Well, it's really difficult. But I will tell you that unless you in some way address the reality, that if you're only presenting the negative framing and not the positive, then the public are going to be misconstruing the perception of risk, taking those figures and moving it up, the figure I gave you before was for a one-year risk of breast cancer, a typical period people will take it is for five years.

You could say, four out of a thousand will get it, but it's just as important to know that 996 out of 1,000 can take the treatment and probably from a statistical basis, will not get it. So, this to me is an important thing.

I was thinking as I lay awake this morning, deciding how I can try and be most helpful. I'm not sure I'm right, but I know

these are important ideas. And the principle has to be, how can I help in any perspective I bring, the FDA do a better job. How can they help both patients and healthcare professionals?

And unless you're frenetically concerned to find out what problems the public and healthcare professionals have communicating risks, then I suggest you cannot get to move towards finding improved methods of communication. My recommendation, try and use absolute numbers. Let's get away from this relative risks. Try and use a common denominator. Make sure you give a positive framing.

Oh, back to this early example of patient information sheets. Wouldn't that have been easier to say, the evidence showed that on average, two extra people out of a thousand, showed suicidal behavior. Isn't that a small number? Well, that's not for me to say. It's telling the public a number that

anyone, anyone can understand. And then also, should you wish, you could put the perspective there to show 998 out of 1,000 did not get that.

So, getting to the topic here of this issue of risks and benefits and what perspectives might I bring to do this. Somehow, the FDA will need to talk probabilities at a very early stage in its improvement process, in my humble opinion.

We've already gone through the process of different ways of communicating the numbers, which I think most of us support. I just need to say, that when we use words like rare and low, everyone knows that this is only in the perspective of the person or the organization making the statement. I happen to think this is not the most crucial thing as was said here by Dr. Seligman yesterday.

But I would tell you, that when the FDA says that patients rarely get this issue, I'm not being critical. I'm asking that

people accept the responsibility that like it or not, your communicating a probability. I'm not saying, let's get a big stick, let's get a regulation. But if that, rarely, means something totally different from what the public actually means by it, then if you have the time and the resources, I suggest there's a responsibility with the increasingly developing responsibility to be an effective risk communication organization.

Sit down among yourselves and try to find some limited frameworks. Low risk to the general public means between 1 in 5 to 1 in 10,000. When you look at IRB Requests for Information, in order to tell patients what the risks are of clinical trials, you get words like this, rare side affect, really turns out to be 1 in 25. Well, it might be in heart transplants, you see.

So I'm trying to say, I think that somewhere down the line, whether this EEC and different of us have got around to try to find

words, I'm just saying, I think it would be a good second level recommendation that you need to accept that your descriptive words are conveying meaning. And if you could find some informal way of trying to unify them, it would be responsible.

And then again, from one of our chairman's papers, you know you might say, well, shall we build it, and then they're just as confused as ever, or what if different disciplines want to do it different ways? Well, there is an example from the nutrition facts panel. Where the fact that people sat down and defined a format and consistently used it, helped the effective communication of the data that people were endeavoring to do in nutrition. This relates my own special field.

Everyone of these by the way, started in healthcare. Isn't that interesting? Well, not really. The first one, Descartes reputably was described as lying in his bed sick watching a fly

meandering on a wall and wondered in his scientific mind, how to plot the movements of the fly and decided that a simple graph would be the way to do it.

I've always forgotten the second gentleman's name. I think it's -- I could look the reference up. This one on the right was by an English physician, what we now call a bar chart, for the most bizarre of reasons, that could only be British. It was observed in the days of George III, who protested his madness, it became fashionable for the English gentry to also declare their madness. And this gentleman try to co-relate those two sets of figures, because there weren't that many of them, he put them into clusters which are groups of five years. And that was the very first bar chart. And there is a picture of them.

The bottom of the ones is particularly important to me, because Florence Nightingale was born only 50 miles away from I

was born and was brought up. The nurse is best known to mathematicians as the person who invented the pie chart using the area of the visual to represent the magnitude of the proportion.

In the Crimean War, she was anxious to get her message out: to communicate. Even though she was the first woman in the Royal Statistical Society of London, nevertheless, her concern was to make the numbers that she was an expert in the knowledge of, communicate to people. And so she showed, that the very small proportion of the deaths were due to war injuries, most of them were due to diseases through the lack of hygiene.

And this was one of the things that she wrote in her diaries, that even if people won't read the words, and she was particularly hoping the Queen could be influenced, I nevertheless hope that they will look at the pictures and understand the meaning, oh, that she said, on to see them into perspective.

For that's why I bring this in.

Yesterday, Musa kindly mentioned the possibility of having say a thousand little items of people on a page, and showing, since we've seen this thing, two of them, in different colors to indicate that two out of 1,000 might be suicidal, taking that previous figure.

I want you to see that it's equally possible to reverse that and to use the selfsame graphic to draw the public's attention, that 998 out of 1,000, the benefits framing, using the absolute numbers, 998 out of a thousand, will not be affected.

I believe that visual aids, a) absolute numbers, b) remove confusion, and, as the gentleman so eloquently said in the presentation yesterday, give the greater number of the people an ability to understand the numbers in context. So, consider using simple visual aids.

My wife, under whose thumb I live,

drew my attention to this. She has what's called, "duh science." When there's a great research project, the result comes out, she goes, "duh." And well, what did you expect.

I'm going to tell you what I have learned most from talking to doctors in most hospitals and finding out what they want from good risk communication. And this letter from my wife relates to a daughter, whose away at college, and the letter is addressed to her mother. And it has great medical sadness.

"Dear Mum and Dad: I have a lot of things to tell you. Last week the dormitory burned down, but we managed to get out alive. After a few days in hospital, I got out. But it took a little longer before they took the bandages off my eyes. Now, I'm okay. But because we have no where to stay, I moved in with Nigel, my boyfriend.

"You'd like him. He's a nice boy who comes from a good family. I've got some good news for you. You remember how you both

always liked children?"

(Laughter.)

MR. PALING: "Well, I'm going to have a baby in the Spring. Don't worry, none of this is true. I'm fine and I'm not pregnant. But I did get a D in Math, an F in French, and I thought you'd view it differently if I put it into perspective."

(Laughter.)

MR. PALING: Most people to whom I speak, want intuitively to do what journalist want to do, which is to put a new unknown risk into a context that makes sense for them. In other words, there is a desperate wish, to be able to show the world of risks of an everyday nature, with which we're at home, joking. Many of them, if you pick an individual one, can be criticized as being an inappropriate anchor.

But if you put a whole lot of them together and see what range of likelihood these fatal risks fall at, that is the thing

that doctors long to do. Many of them have devised their own from, you know, you have more risk driving to the surgery than you are, et cetera.

But I'm trying to suggest to you, that there is a value for risk communication, less so for the FDA, but for the individual physicians to be able to use some quotation of where the everyday risk zone falls.

And now something that I view as crucial. I'm so concerned to try and get the patients to understand the best we can give them of their numbers. The most useful thing of visual aids is not often the number. Not the clarity of the number. It is a bonding tool for physicians to use when they sit down with their patient, sit down side-by-side and say, "Mr. Jones, let me show you what this is like."

It is a tool which in my world of biology, we call a social lubricant. And I think down the line, that some appropriate

visual aids might be beneficial in helping the FDA's mission of showing the risks and the benefits.

Here's a final set of perspectives. A man called Peter Sandman, who's known to virtually every risk communicator and many members of the public, made his reputation on a series of risk equals hazard plus outrage statements. I have a similar one that is not as worthy, but I think is insightful.

When I talk to doctors, doctors only think about the probabilities, the odds. It's like looking for your keys on a dark night, only under where the lamp light illuminates. The truth as we know, is that to some degree, not as a multiplier, the real level of risk is some combination of a measurement of the consequences and a measurement of the odds.

But I also think what's not often understood, is what I call the Bill Gates' Lamborghini phenomenon. That the impact of a

risk in truth is only determined when an individual or an organization knows its resilience, or resiliency. By that I mean, let's take Bill Gates' Lamborghini. Say, Bill Gates had a Lamborghini. He left it by the roadside and didn't lock the door. It would not be impossible that that would disappear.

Yes, it would be a big probability. Yes, for me, it would be a huge cost consequence. But, if I was as rich as Bill Gates, then that resilience, or resiliency would mean it was effectively a minimal consequence in terms of how it would affect that person's life.

I think my suggestion is, that in the process of risk communication, the FDA could follow another of its small threads of responsibility and talk about wellness as the resilience to all of life's downfalls, including healthcare outcomes. And I will give you an example of this.

One week today, the English

Government revealed that it had had what's called a public risk register. And everyone whose known on the journalist list of BBC reporters was being phoned up to discuss this. What they had done for the general public, from National Enquirer level of tabloid to the most worth journal, was to show visual aids in England, pointing out that it wasn't terrorism or floods or, but what it really in their mind was the busiest risk, biggest risk, was pandemic flu.

But they made it even better by reporting that they had enough vaccinations, resilience, for one-third of the population. Now, was this brilliant communication, simply supported by visual aids? I think it is. It shows me, it may not be persuasive to you, there is both a place for visual aids. There's a universality of instruction, that won't be understood by everyone, but makes a considerable improvement for where we are before, just listing side effects.

This to me is a pole apart. I'm quoting several English things not because they're in any way better, but you're just not likely to know them. I work between the two countries extensively. This most talked about paper is a simple paper from scientists at Cambridge. Here's the title, which basically, I'll just pick out thing, showed that if people had four basic healthy behaviors, then it added effectively 14 years to their chronological age.

The four were, not being inactive, being a nonsmoker, very moderate alcohol intake and a plasma vitamin C level showing fruit and vegetable intake. Why do I tell you this? Not because, I mean, there's a huge lot of numbers. It's very well talked about there. I'm saying, perhaps new suggestion, when the FDA talks about risks, it might also find an opportunity to talk about promoting health at the same time. Bringing holistic approach to its status and to the importance

of its messages.

Now, I'm sad to say, I tend to disagree with several people who I respect deeply on my panel. And I think, Mr. Chairman, this is the next suggestion, something at odds with what you said should not be done yesterday. So, it doesn't hurt to have dissenting diverse views and you're better aware than I am.

I believe the FDA's responsibility now requires that you produce an overarching document before people, particularly the public, get to look at the specifics on your website or elsewhere. In other words, I think you're responsibility may be to produce a basic 101 of Risk Communication. And here is some of the things within a one-page document, Dr. Neuhauser is so superb at thoughtfully presenting information in simple and clearly understood ways, would do far better at this next than me.

But here are nine points that it

might cover. The reinforcement. FDA's giving its best efforts to be effectively safe. And when used as directed, most FDA drugs offer far more benefits than risk for most people. Three, yet all drugs have downsides. And when I had discussions with my friends at the FDA in my preparation for this talk, I asked me, show me where on the website this is. That this is so clearly said?

If you have a day and a half to pursue it, it's just that, it's not there yet. And I know it's going to happen. It's very easy for some bright person to come in and make suggestions that are already being handled. All I can do is say what I think matters. Yes.

Different people have different responses to different treatments. So, patients need to be alert. Estimates of risks apply to a population, not to the individual. FDA's going to change its decisions, talk to your doctor for the risks and benefits. These

are all good messages. Learn about your treatment and condition by getting information from the FDA on the new and improved website. And remember, you can increase your chances of a good outcome by keeping yourself as healthy as possible.

And risks, I would conclude, are not as simple as patients think. But I think they can be made simpler than sometimes we fear. I thank you for your time. I'm sorry to the next speaker to take so long.

CHAIRMAN FISCHHOFF: Let me immediately introduce Heidi Rebello who's a deputy assistant commissioner for public affairs.

MS. REBELLO: Good morning. It is a pleasure to be here. Can everyone hear me? Fine. Okay.

Today's discussion, I'll go over an organization overview of the Office of Public Affairs, the agency's overarching goals for communicating agency actions, the priority

issues facing the agency, the criteria for when we go about issuing press paper like news releases, the communication challenges we face and finally, some new approaches that we're excited about.

The Office of Public Affairs, just some general statistics. Office of Public Affairs is actually located, we report to the Office of the Chief of Staff, and that's in the office of the Commissioner. And within the Office of the Chief of Staff, there are a number of other offices like, the Office of Legislation and the Office of External Affairs, that all report to the Office of the Chief of Staff.

So, who we are, we have ten press officers and employ one senior writer and editor. FDA's in the news every day. And the office fields anywhere from 50 to 100 media inquiries from journalists each day. On average, we issue up to 25 press releases a month. Last year, we came close to 225 news

releases. This year, we're a little behind, we're just over 100.

We also hold media briefings over the phone as well as live press conferences. Just to give you a little perspective, if we're having an outbreak like we did with spinach or with salmonella, it's not uncommon to have 300 to 400 media outlets joining us for our media briefings.

Our press officers also staff all public meetings, including advisory committees like this one, and Congressional hearings.

We operate under two main goals when communicating agency actions and efforts. One, to provide consumers with timely, understandable, useful and actionable information. Secondly, to foster public trust and confidence. That every action the agency takes is an interest in public health. And we do this by trying to be more transparent and really trying to explain the science behind our decision-making.

The key issues facing FDA include, product safety and surveillance, whether it be food safety or medical product safety, that's devices, that's drugs, that's vaccines. This is where the focus has really been of late. In particular, there's been a lot of interest in import safety, since many of the products are made beyond our borders.

Regulatory actions, for example, we have new responsibilities and authorities under the Food and Drug Administration Amendments Act of 2007. And it's our responsibility to explain when we're implementing those new authorities and regulations and what they mean to patients. And then agency initiatives, like our Critical Path Initiative, where FDA is working across many science and regulatory areas to improve medical product development.

Here are the pieces we go through when considering what to issue press on. Has the agency taken an action? Do we have enough

data or information? Do we understand the issue well enough to explain it? And, do we have a clear message to the public and can we assure the public that we are finding solutions? So, it really boils down to the majority of the science and the clarity of the consumer message.

Some of the communication challenges we face. We communicate to a variety of audiences that all have different expectations, including patients, consumers, health care community, and researchers. Our issues are scientific and regulatory, and oftentimes very complex with lots of nuances.

We have legal limits to disclosure. We have to protect commercial and confidential information. We also have to say in an open investigation, balance the need for the public to understand the agency actions, without compromising the integrity of the open investigation.

Our data's not easily accessible.

What I mean by that is, that the information FDA houses in its databases, is not easily extractible in a form that oftentimes reporters request or seek. And our issues may be valuated or emotional. Like cloning, or vaccines such as Gardisil that Lorrie McNeill talked about yesterday.

More challenges. The public's understanding and acceptance of scientific uncertainties. We need to communicate the science behind our regulatory decisions, where the science is not always -- may not always be complete or clear, such as in early indications for emerging drug safety issues. We must always explain the benefit and risks of product in a way that people can understand, so that they can be better informed consumers. That's not always easy.

And there are limitations with adverse event reporting. I think you've heard that before in this meeting. And it's oftentimes very difficult to explain the

context around those numbers or reports.

Some additional challenges. We need to develop better standards or at least a consistent threshold for when we communicate. Crisis communications. When an outbreak, like spinach, or the recent salmonella outbreak hits, our office is relatively small, and we definitely adapt. But it is a strain on our resources. We need to do a better job at communicating at other audiences in reaching out to those other audiences. For example, we do translate some of our press paper into Spanish, but we need to do a better job at that.

Lastly, we recognize that measuring the reach of our press releases and our messages, is necessary to evaluate the effectiveness of any communication program. But we haven't found a way to do that effectively and consistently.

Some new approaches that we think we're making headway on. We just revamped our

website. And we launched a new home page last year. And we're continuing to make improvements. This advisory committee, we're excited about tapping into your expertise to learn how we can better communicate.

Our subject matter experts and technical experts are doing more interviews. Our commissioners have been meeting with editorial boards from major media outlets. We just did a tour of our FDA science lab at our Center for Devices and Radiological Health, which they're doing really cool cutting-edge science. And we brought a group of reporters around, and they were really, really impressed.

I think yesterday, someone asked, a panelist asked, whether or not we provide media for training. We actually don't provide training for the media, but we do try to develop good, working relationships with reporters that we routinely -- that routinely cover FDA. And the Commissioner actually

holds roundtable discussions once a month with groups of reporters, it's a roundabout issues, and we invite other senior leaders. And so, that's an opportunity for dialog.

We also invite reporters in and to the Office of Public Affairs, we meet with them to especially if they're new to the FDA beat, and so we discuss each other's needs.

Providing context. This is so important. I think we've made some strides here. Take an example from the recent salmonella St. Paul outbreak. During that outbreak, we happen to post to our website a news release that was about a food product. It wasn't tomatoes. It wasn't Serrano Peppers, it wasn't jalapeno peppers. But it was a food product that had -- that was being recalled with the potential to have salmonella associated with it.

Well, we posted it to our website, and of course, everyone immediately thought that it was connected to the current

salmonella St. Paul outbreak, when it wasn't. So, we quickly went back to -- it was a company's news release that we posted, because we routinely post those, and we added some language at the top of the news release to say, this isn't -- this is not connected to the current salmonella St. Paul outbreak.

And so that lesson reminded us the importance of context. And we made sure to add that language in other announcements during that same time period.

Finally, Dr. Torti yesterday mentioned that we are reaching out to science writers, to try to engage them in FDA science activities and we'll be holding a symposia in the fall. So, in summary, communications is the responsibility and top priority for FDA. And there's high level support within the agency.

There's also real will and desire to keep the public informed. And we absolutely welcome your advice and your

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

CHAIRMAN FISCHHOFF: Thank you very much. And I thank the other two speakers as well. We have the rest of the day for conversation. I understand that you have to leave fairly soon, so let's --

MS. REBELLO: I have some time.

CHAIRMAN FISCHHOFF: Okay. But let's be sure, want to be sure that we get a chance to talk to Heidi and Heidi get a chance to talk to us, and then we have a number of you know, challenging topics that came up from Janet -- John and AnnaMaria's presentation. So who would like to speak?

MS. LAWSON: Good morning. And I want to thank all of the panelists for their presentations. They've all been very informative. But I just have a question first for Heidi.

When the agency is preparing to issue a press statement, whether it's in a

crisis situation or otherwise, is -- what is the internal communication mechanism for your center communication offices? I mean, internally, is everyone prepared or informed so that once the press statement is issued, they can kind of reinforce it through their networks of organizations that they work with on an on-going basis?

I just -- I'm just interested in how that's done.

MS. REBELLO: Sure. Can you hear me?

MS. LAWSON: Yes.

MS. REBELLO: It's -- we have a central point of contact when we have -- or coordination for communications efforts when there is emergency issue going on, or an emerging issue. And so from the Office of Public Affairs, we coordinate closely with the people who reach out to stakeholders, through our Office of Legislation, to our technical experts in the Center.

When we go about issuing press, there's you know, a clearance process for anything that goes out to the agency. But it's really more of a coordination process. So that all levels of the agency are aware and are vested in what we're saying.

CHAIRMAN FISCHHOFF: Linda, and then Christine.

MS. BRUHN: I also wanted to thank each of our presenters. I enjoyed hearing their perspective. My question is for Heidi. At our first meeting, I believe it was the first one, we heard from a reporter who indicated that they were quite frustrated in trying to reach people at FDA and I don't know how long you've been here, Heidi, but this reporter, I guess has been on the news beat in D.C. for a number of years and described significant change in the last five to ten years as far as accessibility of some of the scientists at FDA.

Can you address how -- what is the

procedure when a reporter wants to go, not to the press office, but to the scientists? And how are you able to respond to that inquiry?

MS. REBELLO: Sure. I've been here two years. But I've been in the Federal Government in other Public Affairs Offices for about, going on 18 years.

We ask that reporters go through the Office of Public Affairs if they have a media inquiry for the most part. And we really act as a facilitator to make sure that they get to the right expert, and we coordinate you know the logistics of that interview. We also help to you know, a lot of our technical experts or scientists aren't used to talking to reporters.

And so we really have to help them get prepared so that they do a better job,