Centers working with Rutgers University. I mean, there is a lot of organizations at the state levels that would be wonderful partners for FDA.

But my question before, is it because of lack of funding or because of the logistic processing you are having difficulty?

MS. RICE: Well, for the Center for Devices, I can tell you it is there are both. All of what you said is a struggle. The money that we get to do these kinds of things and to get outreach, you know, again, things get prioritized and a lot of times, whether you end up with that money in a particular fiscal year or you don't. And decisions based on other things going on in our center. And then process itself is a long and drawn out process. And we tend to want the information today, the answers to the questions we keep putting out here. And for us to do it, could take years to get those answers. So, what happens is other things take over.

DR. SELIGMAN: I think -- well hold on a second. The other thing I think is a challenge for us is that we, FDA is embedded in a larger healthcare system. There are other federal agencies, like the Agency for Healthcare Research and Quality. The Centers for Disease Control that really have a broader mandate when it comes to looking at the way healthcare is practiced, the way information is delivered, the effectiveness of various public health approaches, when it comes to changing behavior, influencing the way information is taken and translated into appropriate practice. So, I think that part of it may be just, I think from our sense, that historically FDA's role and mission has been somewhat narrower. And we have, in many ways, seeded the, not necessarily seeded but I think recognize that there are other agencies, associations, both in the public as well as private sector, as well as in academia who have both the responsibility, expertise, and

resources to do this kind of work, where we basically haven't.

DR. DAVIDSON: We actually do a lot of research that we haven't been able, you know, in the limits of these short presentations been able to share with you. And many of you at the table actually are very familiar with a lot of the research that is done at our center. I will say that the time constraints are enormously frustrating. The process that you have to go through to get your research done to give you information when the next issue arises is tedious, very tedious.

CHAIR FISCHHOFF: Mona, and then David and then --

DR. KHANNA: Then John. Right?

All right. I have a comment and-- actually two comments. Two different subjects.

I wanted to respond to Marielos, what you said about screening for breast cancer and I don't think that that is an FDA

issue. It is more of an issue of medical associations and competing medical specialties offering different recommendations. And breast cancer has turned out not to be that simple either because you probably have all heard recently of the guideline that came out that women should not do self breast exams. And there is the clinical breast exams, there is a mammogram, there is an ultrasound. So all of this is, as you know, is dependent on family history and personal history.

Just as confusing is the screening for colorectal cancer with your fecal occult blood testing, colonoscopy, sigmoidoscopy, digital rectal exam, and we could go on and on.

So unfortunately, that is a medical issue more than an FDA issue.

The comment that I was originally going to make refers to a little bit of what Dr. Goldstein was saying where we have to understand the needs of the population and

then taking off on Dr. Peter's presentation where less is more. I have found that making the transition from practicing medicine to practicing medical journalism was most difficult in one sense that is directly related to this and that was you have to select the information that you present, not compress it. In medicine and in most of what we do, we try to do our due diligence with research, get all the different viewpoints, get all of the different professionals, expertise, etcetera, and then make our decision based on all of that. Perhaps what we need to do is select different pieces of information that we deem are most important instead of cramming everything into the message. And I think Dr. Peters, that is what you were trying to say. That is the technique that is also effective for journalism, is selection not compression.

DR. SMITH: You know, the common theme throughout all of your issues was risk-

benefit. And I think sort of following up on what Mona just said, you know, it really hit home on the communication issue that Ellen talked about and how we tend to use our perspective on what we communicate versus what the audience needs to hear.

And there have been so many cases in the food industry where what happens is an alarmist view of communication of gee, we have evidence that something is a concern and there is a risk. And you know, a recent one is trans fat, which we have known about for years but it has been more recent that the communications come out and the public tends to get very alarmist and we, as the food industry react to that and so we take trans fat out. And a lot of people put other fats in, saturated fat, and you know, a good example is well, gee, margarine is bad for me because it has trans fat so I will eat butter. And you know, we don't have that balanced communication of the good fat, bad fat, and

moderation is really one message that I think we, as a food industry, all across and including the FDA as part of the food industry, has really missed that moderation issue that it is not just taking today's science that says trans is bad and that is the news. But the news really has to be what the consumer really needs to hear versus what we, as scientists know should go out there. So, I think it really hit home and probably affecting all of your communications here in that whole moderation issue.

CHAIR FISCHHOFF: Musa and then Mike, and then Dr. Seligman.

MS. MAYER: Sorry. One can't see it. That is why we are struggling with it.

So, Dr. Peters listed first, actually, among the potential barriers to effective communication insufficient, uncertain, and changing information. What I have been thinking about and dealing with most over the last years is the safety of various

drugs and, specifically, drugs used for the treatment of cancer.

And one of the things that has hampered FDA most, I think, has simply been the inadequacies of the passive adverse event reporting system they have had, which are about to be remedied, we hope, anyway, in some important ways. And so during the break, I asked Dr. Seligman if he would talk a little bit about the Sentinel Program and share that because it is an issue that gives me a lot of hope that we may be, that we may actually have better information to communicate and that that may really help the whole process a great deal.

DR. SELIGMAN: Yes, I would actually be happy to talk about it but since we are nigh on lunch, is this something you would like me to do now or later? I can spend five or ten minutes talking about the Sentinel Initiative and what it consists of and what our hopes are for it.

But the two second synopsis is basically to work with healthcare organizations that have databases that we could use in a sort of distributed fashion to really get at data that we currently don't have access to, which is how frequently products are being used, for what indications, how often adverse events are being observed, abnormal laboratory values, etcetera. And really get at the kinds of population-based information in a rapid fashion that would really improve the evidentiary basis for our recommendation. So that is it in, sort of, two sentences.

The Sentinel Initiative has a webpage on a website that describes it in great detail. But I couldn't agree more and I think that was a point that Ellen made in her presentation, which is, you have got to have, I think it was the first point you made, actually, which was you have got to have good information and good evidence. And we have

always been hampered, particularly in a post-market environment, with information that was very difficult to interpret and weigh against information that was collected in the course of clinical trials.

CHAIR FISCHHOFF: Let me say since we will be, we would like to start the public hearing punctually at 1:00. So let me sort of call the conversation now. Let me encourage people in the audience who would like to speak to come and to see Lee during the break. And then perhaps we will pick this up right after lunch, both about the data opportunity and then, in some sense, the communication obligation that will go with the data opportunity provided by the Sentinel.

Somebody found a pair of glasses in the men's room, bifocals, very attractive. And there is a place for lunch across the street.

(Whereupon, at 12:03 p.m. a lunch recess was taken.)

A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

(1:02 p.m.)

CHAIR FISCHHOFF: Okay. Let me welcome everybody back. And we are now at the public hearing part of our meeting. There is some language that needs to be read into the record. So, both the Food and Drug Administration, FDA, and the public believe in the transparent process for information gathering and decision-making. To ensure such transparency at the open public hearing session of the advisory committee, meeting, FDA believes that it is important to understand the context of an individual's presentation. For this reason, FDA encourages you, the open public hearing speaker, at the beginning of your written or oral statement, to advise the committee of any financial relationship that you may have with any company or group that may be affected by the topic of this meeting. For example, financial information may include a company's or group's

payment of your travel, lodging or other expenses in connection with your attendance at the meeting.

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

We are fortunate now to have three members of the public speaking to us. I would like each person to come to the microphone, to state his or her name, and to speak directly into the microphone over there. And we would like to keep your comments to no more than ten minutes, at a maximum. Okay, thank you.

The first person is Dr. William Maisel, Director of the Medical Device Safety Institute also the Director of the Pacemaker and ICD service at Beth Israel Deaconess Medical Center in Massachusetts. Please.

DR. MAISEL: Good afternoon. Thank you very much for having me here today. My name is Dr. William Maisel. I direct the Medical Device Safety Institute at Beth Israel Deaconess Medical Center and I am privileged to be here today on behalf of the Heart Rhythm Society. My travel and lodging has been paid by the Heart Rhythm Society to be at this meeting, although I am not being paid for my time today. Could I have the next slide, please?

What I hope to do in the brief time allotted to me is to give you a little bit of background of what the Heart Rhythm Society is, what type of patients we take care of, and why we think we are relevant to the discussion that is going on today. I would like to describe the Heart Rhythm Society experience with product notifications that have affected some of the devices we use every day in our practice. And probably one of the most important messages I hope to deliver and

convince you of is that medical devices are different and I would like to explain why and why the communication to patients with medical devices may not be the same as communication for other devices.

We will talk about the terminology for medical device issues and, obviously, communication. And then I, of course, want to address what the panel is here to address today, which are emerging issues. Next slide, please.

The Hearth Rhythm Society is the international leader in science, education, in advocacy for cardiac arrhythmia professionals and patients and the primary information resource for these people on heart rhythm disorders. We represent approximately 5,000 hearth rhythm specialists and cardiac pacing in electrophysiology, which is the management of heart rhythm disorders. And arrhythmias are the leading cause of heart disease related death with sudden cardiac arrest,

claiming hundreds of thousands of American lives each year.

We also have millions of additional patients that have implanted cardiac rhythm management devices like pacemakers and implanted defibrillators. There are literally millions of patients in this country alone that have heart rhythm disorders and there are likely several people in this room who have heart rhythm disorders. Next slide.

So these are the type of tools that we use in our daily practice. There are implanted pacemakers and defibrillators which are "permanent implants." They treat very slow or dangerously fast heart rhythms. They are really amazing devices that have amazing technology and have been proven to save lives.

We do cardiac ablation procedures, where we pass catheters up into the heart to treat or cauterize the heart muscle to prevent or get rid of abnormal heart rhythms.

AEDs are automatic defibrillators

which have saved enumerable lives in airports and hopefully there is one somewhere in this buildings.

And we also, obviously, use medication. So we are not just about devices. We have many patients who take medications both for other heart-related issues and their co-morbidities. Next slide, please.

So, I think it is probably self-evident that devices are different than medications or food or what have you but there are certain characteristics that are particularly important to consider. Number one is that they may be a permanent implant. A device might be implanted in a patient and that patient is going to have that device forever. And sometimes removing the device is dangerous. Sometimes it has potential complications, including the potential to die from attempted removal of a device. And so the words we use to describe product issues with medical devices needs to be carefully

considered.

I mentioned that they have sophisticated technology which benefits many of the patients. And because these are permanent implants, they inevitably will experience what we consider "normal wear and tear." They wear out over time. For example, a pacemaker that is connected to the heart via lead or a wire will undergo five hundred million heartbeats over about a 13 year period back and forth, back and forth. So these devices will, inevitably, have performance issues and that is part of their normal life experience. And so we need to be very careful when we start talking about performance issues for medical devices. Next slide.

So, I chose the word recall to highlight one of the examples here but it is really pretty amazing that we use a single word to describe the "recall" of products from the market for the FDA ranging from pet food to tomatoes to heparin, all of which can

easily be taken off a shelf without any harm to anyone. And we use the exact same word to remove that device in the bottom right, which is an implantable defibrillator that is connected to the heart via a wire that has approximately a one percent mortality to remove the device. And so we need to be very careful with the terminology that we use. Next slide, please.

The other problem is that the words we use mean different things to different people. And so to the FDA, the word "recall" and this is from their regulations, is "the firm's removal or correction." So it doesn't require that the device be removed. There may be a way to mitigate the problem without removing the device. And to the FDA, that is what they mean. And if you read any of the FDA recalls that have affected heart rhythm devices, they are always very careful to say it does not necessarily mean your device needs to be removed.

But patients don't hear that. What they hear is my device is recalled. Next slide. And what they tell their family and their doctor and what they understand is that I need my device removed. And so just using that word recall affects the clinical interaction between a patient and a physician. And I have sat in the office with literally hundreds of patients who have had devices recalled. And they all come into the office thinking they need surgery to remove their device. They don't get it.

And it is a communication issue. And if you just go on the internet, I chose dictionary.com, it is no wonder they don't understand what recall means because recall does mean return of goods or a product. It doesn't mean to the general population removal or correction. And so we need to be careful about the terminology. Next slide.

So, we are talking about emerging and uncertain risks today. And it is a

challenging issue because there often is not a line in the sand. It is often very difficult to decide when we are business as usual, when we are seeing a normal amount of product performance issues, and when there is an emerging or uncertain risk. And we could draw another line for recall or product advisory above emerging risk. And those lines are blurry. And that is probably the most challenging issue here. Next slide.

And so, as has already been well outlined by some of the speakers this morning, it is a balance. You need to decide when it is worth notifying and when you shouldn't notify. And these are some of the factors that we think are important to consider.

Certainly, on the side of notification is informed consent. Many patients want to know about what is going on with their devices and the performance, although we would argue and we have advocated as a society, that physicians should be doing

this before the device goes into the patient. We routinely recommend that our implanting physicians tell patients this is a complicated device. The device is designed to work at a certain success rate and there may be product performance issues that develop over time. It is still beneficial for you to have the device. And so that can mitigate the need to notify over some of these low risk emerging issues, if patients are already understanding that that could occur.

Obviously, if you notify and that will facilitate additional reports or data collection, or accelerate getting an answer about a problem, that would be worthwhile and it may improve patient care. But it definitely increases patient anxiety when you notify. It may not turn out to be a true performance issue, so that is unnecessary patient anxiety. It can have an adverse impact on industry. And by that, I don't just mean their bottom line financially but in an

industry where there may not be many suppliers, it can make it difficult to get a product implanted into a patient who really needs a product. It can mitigate how quickly they are willing to bring new products to the market. And so, we need to be very careful and not unnecessarily notify.

And then it may adversely affect patient care when notification results in patients coming into physician offices demanding to have their device come out, even when you try to reason with them. And it happens because patients get anxious. Next slide.

The Hearth Rhythm Society has dealt with this issue over several years. And in 2005 and 2006, we had an ongoing discussions with the FDA, with industry, with physicians and patients to address many of the issues that the panel is discussing today. And the culmination of that was this report in October 2006 in the medical journal Heart Rhythm. It

was recommendations from the Heart Rhythm Society Task Force on Device Performance Policies and Guidelines. And obviously, I don't have time to go through the entire document, which is on the Heart Rhythm Society website. But there were a couple of important messages that are relevant today.

One is, it was recommended that the term recall be eliminated in public communications concerning implanted devices because of the reasons I have already spoken about. We talked about standardizing physician and patient communication. And in fact, we have a template for the type of information, the type of data that physicians and patients want from the FDA and from manufacturers. How many devices have been implanted? How many have failed? What type of failures were observed? What is the rate? What is the anticipated rate? A lot of very basic simple, data-driven information that we want when we are dealing with these issues.

And we also recommended direct patient notification for important issues.

Now, we have the advantage of having implanted registered devices. And although there are hundreds of thousands, if not millions of devices, we do have contact information. And in fact, this was instituted last year for the first time in bulk, where 170,000 patients were directly notified by a manufacturer about a product performance issue. You can give the message to the person who needs to get the message. You can give them the information that they need and you can deliver the message directly to them without necessarily alarming people.

One of the things that happens is if you see in the news pacemaker recalled, we have millions of pacemaker patients. They may not get that it is a certain brand and a certain model and doesn't affect all of them. And so you create this huge wave of anxiety among a number of patients unnecessarily.

Next slide please.

This is a brief portion of the clinical recommendation and perspective that we included on our one-page form. So, the form includes specific issues about data. But it is very important not to stop with just data or to say contact your physician. Patients don't like just being told to contact their physician. It can be weeks, sometimes before they can get an appointment or get on the telephone. And if we have thousands or hundred of patients calling, it is very difficult, even if we want to do the right thing, to get back to them.

And so we think that it is very important to give some recommendations, even if the recommendation is that there are no recommendations, but to explicitly say what you want done. For us, it is things like verify normal device function at the next normal follow-up or as soon as possible, etcetera. Next slide, please.

So, to conclude, timely accurate communication is critical. We think that efforts to standardize and develop terminology by product type, and we think medical devices or certainly permanent implanted medical devices are an important subgroup, to better communicate the intended message should be undertaken. And hopefully, you don't leave here with the idea that medical devices are different and you work on everything else and decide that medical devices are too tough to tackle. I think we would argue that they are one of the most important areas to tackle first.

It should be data driven. Survey specific audience, such as patients whose lives literally depend on their device, to determine which terms best convey the intended message. And there is an important role here for medical societies, and certainly the Heart Rhythm Society has and will continue to be available, but whenever possible, include the

professional society in delivering your message, particularly if it is not an hour-by-hour thing, but you have a 24 hour or 48 hour window, when you are going to issue a press release. We have had much more success, and we have done this with the FDA where the Heart Rhythm Society either simultaneously issues a statement or it has sometimes even been in concert with the FDA to provide a clinical perspective. Here is the information and the Heart Rhythm Society recommends A, B and C to give physicians and patients some reassurance that some knowledgeable people are working on the problem.

So, I very much appreciate your time and would be happy to answer questions now or later. Thank you.

CHAIR FISCHHOFF: Thank you. We have time for one or two questions. Mona?

DR. KHANNA: What term would you prefer instead of the term recall?

DR. MAISEL: We have recommended

terms such as safety alert, which doesn't have the implication of product recall, of removing a device. So that would probably be our preferable term.

DR. PETERS: I have always got to check to see if it is on. You talked about direct patient notification, after first notifying physicians. Did you evaluate how well that message worked, evaluate comprehension of it, reactions to it?

DR. MAISEL: That is an excellent -- we spent a lot of time thinking about how to deal with this issue. And it is a very complicated issue that I am sure you will wrestle with as well.

Here are some of the factors that go into that. Number one, major companies have an obligation, financial obligation to not withhold information. So we have asked, requested the opportunity as a physician to have a little window to go to our patients and contact them quickly about the information,

without them getting it on the front page of some newspaper. That can't happen because the companies are obligated to publicly report that information that could affect their financial bottom line as soon as it is available. They can't withhold that information.

So, we have advocated that, when possible, physicians receive a letter and have a window of about seven days to contact their patients to call them into the office to tell them what is going on before the patient gets the letter. And that is what we did this last time around.

In talking to the company that orchestrated that and in my own experience, it was highly successful, at least with regard to reducing patient anxiety. These are complicated issues. The patients don't walk away with perfect understanding of the issue but they really appreciate being thought of. They very much appreciate being in the loop,

rather than talked at. They feel like they are invested and someone is thinking about them. And so I don't mean to imply that that is the perfect and only method of communication because the message will be lost, but it was definitely beneficial.

CHAIR FISCHHOFF: Do you have a follow-up?

DR. PETERS: It is not quite what I asked. I was wondering whether you actually evaluated how well consumers comprehended the message that you sent, how much they trusted the source of the information, versus perhaps some other source, the extent to which you actually tested the message and its affects.

DR. MAISEL: We have not formally conducted testing on the message delivery.

CHAIR FISCHHOFF: Marielos?

MS. VEGA: As a physician, has your experience been different with different populations, like the elderly, Hispanics, etcetera?

DR. MAISEL: It is definitely different. It varies by those things. Certainly age is probably the biggest predictor of response. Elderly patients often have trouble getting the details of the message and will often rely on their physician for management of their problem or they will have family members come in. Young patients are researching on the internet and come in with printouts of news articles and information they have downloaded from the FDA and industry. And so there is a very different process that goes on, based on the age of the patient.

DR. GOLDSTEIN: Yes, thank you for your presentation. I was just wondering, because you mentioned there were some examples where there was a good partnership, where the message was crafted together. And I wonder if you could, if not tell us about those specific examples subsequently, share those examples of a better process so that that might serve as a

template for the future. That is the first question. And then I have another question if there is time to allow him to respond.

DR. MAISEL: So I would rather not get into device-specific or company-specific responses at this meeting right now. I would be happy to talk to you offline about that. But I would more describe it as we had a meeting of the minds with FDA and industry that was published in 2006. And since then, there has been a nice progress in how that process has worked. But I will give you specific examples offline.

DR. GOLDSTEIN: And the second part of the question was about the partnership it sounds like your organization has with the patients that are receiving these medical devices. So, if you could say more about how that works and what you have done as a society to make sure you are getting as much patient involvement in this process as possible.

DR. MAISEL: One of the benefits we

have of implanting permanent devices of the FDA's thoughtful decision to require registration of these devices is that when a device is implanted, before the patient leaves the operating room, the device is registered with the manufacturer, as required by the FDA. There are other permanent implants to which this applies. And so that supplies patient information, addresses, those sorts of things. The patient is certainly notified that this is happening. The patient can certainly have the opportunity to opt out of that process. I have never had a patient opt out. And that allows this contact. Now patients move, physicians move, so it is not perfect but it certainly allows the opportunity. We also have our devices and many other implanted devices are developing automated technology to communicate without the patient needing to do anything. So, bedside monitors that allow wireless transmission and updates over the telephone, those sorts of things that allow

the ability to keep track of patients and devices. And as I said, there are permanent implants that have that ability as well, not just our devices.

DR. GOLDSTEIN: Okay, actually --

CHAIR FISCHHOFF: No, no. I want to make certain there is time for other speakers.

DR. GOLDSTEIN: Okay.

CHAIR FISCHHOFF: We were sort of getting -- oh, please. Dr. Maisel, wait, one more question. And I think we were getting off the communication topic.

DR. PALING: I would like to say that everything, and I want to say everything in your presentation I heartily endorse. This is the sort, in my mind, of self-evident issue that we sometimes can be too academic to understand the implications of. I say this with no discourtesy intended whatsoever to my dear colleagues at the FDA. Every single one I have met, I greatly admire.

But hearing Ellen's excellent point, have you done -- I would ask this question more importantly, isn't it self-evident that if the FDA uses words in its communications with general public that do not mean what the general public overall means, then that is tantamount to a discourtesy, unless there is some legal reason why that should not be the case.

So, I would just want to put on record my hearty endorsement of the simple reality, the basic communication to the general public should use words in the manner that the general public expects those words to be used. And to that degree, I would, of course, encourage you to keep doing what you are doing.

DR. MAISEL: Thank you.

CHAIR FISCHHOFF: Thank you very much. Our next speaker is Jennifer Wilmes from the National Fisheries Institute.

MS. WILMES: Hello to the

Committee. Thank you very much for the opportunity to speak with you again. You may remember me. I am a registered dietician with the National Fisheries Institute and I spoke in February.

Today I am here to discuss an additional challenge, in addition to the challenges that have been brought forth by the different Centers within FDA. I wanted to add the challenge, which is also an opportunity of consistency across agencies. The success of FDA communication is contingent upon the either the amplification or muddling of messages from other agencies. In the case of seafood, the intertwinement of communication is particularly unavoidable, as the advisory is co-authored by FDA and EPA.

As a case study of mixed messages, I want to bring your attention to a website released August 1 of this year, just earlier this month, by the environmental protection agency, called Fish Kids. According to EPA's

Assistant Manager for Water, Benjamin Grumbles, the new website is a fun way for kids and parents to learn about the importance of fish in a healthy diet and how to choose the healthiest fish to eat.

While this seems, at face value, consistent with FDA's communication about fish, the content within Fish Kids strays dramatically from a science-based imbalanced benefit-risk approach promoted by FDA. Nowhere on the site can kids find any information on why they should eat fish or what the tangible benefits of eating fish would be. The site focuses on warnings throughout, accentuating the negative without ever highlighting the benefits.

The site's audience of eight to twelve-year-old children is exposed to phrases such as "mercury can damage growing brains in kids so they don't develop normally" and "we have to be careful when we eat these fish because some of them contain the chemical

mercury that damages growing brains in children and others have chemicals like PCBs that cause cancer."

There is no body of research showing brain damage in children from consumption of commercial fish. And likewise, this claim is not scientifically cited on the Fish Kids website. The use of these unsupported claims can frighten young children about mercury in fish and unnecessarily warn them away from a low total fat high protein food rich in omega-3 fatty acids at a time when the harmful effects of childhood obesity are all too clear.

Most importantly for this panel, communication initiatives like Fish Kids deteriorate the ability for any well done, well tested communications from FDA to do their job. I challenge the committee to consider not only the persuasive potential of FDA communications but that of sister agencies messaging in the same space and to examine the

possible need for greater interagency coordination.

And I am happy to take questions.

CHAIR FISCHHOFF: Okay. Thank you very much. So we have time for a couple of questions.

I will ask a question.

MS. WILMES: Okay.

CHAIR FISCHHOFF: Do you have evidence that kids have these negative reactions?

MS. WILMES: We are not aware of Fish Kids being tested. We are not aware of any testing that happened with Fish Kids. We are currently in the process, it is a brand new website, of reaching out to EPA. We think it is imperative that the website was tested and should not be exposed to children, if it hasn't been. And I think there is also a question of is this even an appropriate audience, eight to twelve-year-olds, to be messaging a somewhat sophisticated benefit-

risk concept to. So, I think that that needs testing at that level in the first place and then the actual website, itself.

CHAIR FISCHHOFF: Okay, thank you.

MS. WILMES: You're welcome.

CHAIR FISCHHOFF: Oh, wait, one more. I keep calling people back to the microphone. Thank you.

DR. PETERS: Thank you for your presentation and I just wanted to comment that there is some scientific evidence about the ability of children to understand benefits and risks. Now, it is at a pretty early stage but it would be valuable to think about that. And then, of course, the presentations of benefits and risks has to be done well.

MS. WILMES: Exactly.

DR. PETERS: But there shouldn't be a worry that children of say eight to twelve-years-old would not be able to understand well-designed communication.

MS. WILMES: Right. And I think

the emphasis is on well-designed. It is the actual word choice that, you know, had it not been tested, could be concerning.

CHAIR FISCHHOFF: Wait.

DR. PETERS: Not quite, almost. I would also just add to that there is some data around adolescents' ability to understand this.

And I would also add that I agree with you completely about the need to empirically evaluate these messages. That really is critical because you want to know, not just what people read but what they understand and how they are using that information. But it is also the case that, I think, eight to twelve-year-olds are, in some ways, ideal audiences. In some ways, they are the people who, as they become educated, they bring that education and knowledge, if it is done well, into older age groups and they can educate their own children. So, in some ways it is almost the perfect audience, I think.

MS. WILMES: Yes, my issue isn't so much with audience. I mean, I think that the audience needs to be explored. The take away from my comments are consistencies in the words that we are using and the ways that we communicate about these things across agencies. And that would need to be adapted if, you know, if FDA is communicating to pregnant women and that is their goal while EPA's goal is young children. But we don't want kids to be coming how saying different things than their parents are hearing.

So, I think that the need for consistency is really an opportunity to increase the persuasive potential of the communications.

CHAIR FISCHHOFF: Thank you.

MS. WILMES: Okay.

CHAIR FISCHHOFF: And our third speaker is Ronald Barrett? I'm sorry. From NIH.

DR. BARNETT: My name is Ron

Barnett. I am a science policy analyst at the National Institutes of Health. I want to thank the committee and the FDA for opening my mind this morning to the complexity of risk communications. I did quite a bit of reading when I was in grad school about risk communications, even cited Dr. Fischhoff on my dissertation. So, but obviously things are much more complex than they were 20 years ago.

But I am really here not as a policy analyst so much as a cognitive psychologist. And my question has to do with the role or potential role of visual communications in the risk communication process. We know from multi-media learning that, in many cases when verbal knowledge and verbal communications, written communications are complimented by pictures that are related to the semantic base of the textual information, that people learn information better, in general. That the information is more memorable. It is more retrievable.

We also know that we live in a culture that is somewhat biased against using pictures to communicate as if somehow it is more primitive. It is not as sophisticated as verbal language. All we need to do is look at the typical PowerPoint presentation, with the possible exception of a couple this morning, one being there were some good examples from the one we just saw from the Heart Rhythm Society of using pictures to compliment textual information.

So my question is, does the committee have any knowledge base in this area that could inform the FDA on the role of using pictures along with text to communicate risk communications? And if not, would you might speculate on its potential value? Thank you.

CHAIR FISCHHOFF: I guessed we would have a response or two. Linda.

DR. NEUHAUSER: I am glad you brought that up. And it makes me nervous about my upcoming presentation with just not

enough pictures of it. But there is a fair amount of literature. Let's say there is an increasing amount of literature, you know, a growing body of literature, not substantial, that looks at issues of graphic literacy and cognition and so forth. And it is completely in line with what you are saying. So the mix of text or pictures or in particular photos, realistic photos, there is a lot to be said for that.

My own experience of working with diverse audiences to co-develop communication, almost the first thing that they ask for is a lot of pictures, a lot of photos, in particular, to be linked with the text and illustrate that with small stories that go with them. So, the combination of text and narrative or stories and pictures seems to be quite a powerful combination.

Obviously in the private sector, advertising agencies and the like, they have a great deal of expertise in mixing graphics and

texts. They have to. So, thank you for bringing that up.

DR. PALING: I too, thank you and for a different reason. I have a difficulty speaking about it, as you can tell from my voice. My background, among other things, is that I was a television producer. So, I tend to be quite strong in my feelings about the efficacy of visual communications. And I, along with several other people, have given a substantial amount of time to improving healthcare communication by using visual aids.

I have been asked at this meeting, not to bring my own materials into the discussions. And so I would say to the simple answer to your question, is there, at least I feel that I am very well informed upon this field, and I hope FDA will strive to find from the many available resources, good visual communications to try and overcome some of the ongoing difficulties in effective communication.

I couldn't be any more bland than that.

(Laughter.)

DR. SLEATH: I just wanted to call your attention to the pictogram literature that was used, I have not looked at the literature in a long time, but used to help convey messages about prescription medications to patients. And part of the problem that was run into is that people interpret them differently and so they have to be very carefully tested. Especially culturally, things can be interpreted differently. And so, just, and I believe the United States Pharmacopeia right across the street was involved quite a bit with some of its testing. So that is another body of literature that is available.

MS. MAYER: Well, John Paling can't speak about his work but I can speak about his work because I just, actually, recently used one of his tools in a training module for

healthcare advocates that has to do with being able to give patients, a physician being able to give a patient a visual representation of what a certain number in a thousand actually represents. It is in the context in this training module of a discussion on numeracy and the difficulty people have with processing figures that have to do with risk or benefit, for that matter.

And it is just such a powerful tool because two in a thousand means an entirely different thing when spoken and when presented on a page of a thousand little figures. It is such a powerful tool, it is difficult to -- I don't have an academic background, so I don't have the wherewithal to talk about why that processing is different. But it is profoundly different and I thank you for bringing this up.

DR. PETERS: In addition to some of the excellent work that John does in sort of the applied world, actually teaching people

how to do this, there is also some more academic work out of Peter Ubel's group at the University of Michigan, Peter Ubel, Angie Fagerlin, there is a series of people who are doing work, looking at things like tables versus pictographs, for example.

One of the things they find, which is sort of congruent with an issue I brought up earlier is that people, at least in this one study that they have, believe that tables are more effective at communicating information. But they actually do understand the gist of the information better if a pictograph or some other more visual form of communication is used.

So there are lots of issues. I would actually agree with what Linda said. There is science around this but it is actually fairly new and lots of work to be done. But potentially some things that we can use here, in terms of helping the FDA to figure out at least some of what is known and

how to apply it. So, thank you.

DR. BARNETT: And I would just add, there is also evidence in health-risk behavior chains that tailoring material based on, first of all, low literacy groups respond more to visual cues, obviously, than those that are high literacy when low literacy can't even use the written materials. And then even evidence that when you tailor based on ethnicity, it is helpful to show photographs or videos of people from the same background, that that actually has an impact on the reception of the message, as well as even on the subsequent health behavior. So, we can bring that literature and I can help some of that. I am sure others in this group have access to that literature, too.

DR. BRUHN: In a few minutes I get a chance to talk about some of my work. And again, as you have described here, pictures are very important. They lead people to read something. In our focus group research we

ask, what would make you to read this or look at it. And it is the pictures that lead them to do that.

I am going to be handing out a sample of one of the things that we have developed and there will be a picture of it on the slides. Regretfully, when we went from the brochure we developed for our audience to a web-based version of that brochure, the photographs were reduced or the line drawings were reduced because the Communication Services decided that there were too many pictures and that if things were going to be downloaded by the public, that the number of pictures would reduce the time of the download. And our pictures were in color and they felt that might also reduce the time. So, sometimes there are technological restraints that prevent the use of pictures or photographs as much as one would like.

But, so I don't have research that indicates comprehension is so much better if

you have pictures or no pictures. But I have heard repeatedly that the use of pictures increased the likelihood that someone would at least read the material and catch a message.

CHAIR FISCHHOFF: Would you like -- everybody just agreed with you. You didn't get a chance -- would you just like to add another comment?

DR. BARNETT: No. I just thank you very much.

One thing, if the committee is not aware of Hans Rosling and his work with pictorially depicting large numbers, Google Hans Rosling. He is a public health official from Scandinavia. He does marvelous things with representing numbers.

The other is a recent book called Made to Stick by Heath. And the question they try to address is why are some sayings like, "Where is the beef?", why are those kinds of sayings so memorable in a culture or in a society? What are the characteristics of

those kinds of statements? It is called Made to Stick. It has a big piece of tape on the front of it. So, you can't miss it. Thank you.

CHAIR FISCHHOFF: Thank you very much.

So let me make the -- so I think what we should do now, here is my proposal, since we are a little bit early, let's have the 2:00 session. I think the people who are going to be here at 2:00, let's guess that they are here by 20 to 2:00.

Let's have our 2:00 session and then let's ask our colleagues from FDA who were here earlier to join us again at the other table and then for us to have a general discussion. I think that probably would be best rather than to, probably the best way to do it. Okay?

And so our first speaker will be Christine Bruhn.

DR. BRUHN: Thank you. I am really

pleased to have an opportunity to talk with you about some of the communication activities that we have engaged in. And this title is persuasive communication. But I don't know if I, as a person from the University can really say persuasive is right. Our goal is to allow people to act in a manner consistent with their personal values. So, I may choose one thing, someone else may choose another and we need to respect their wish to do that.

Our goal as part of the university and I think a goal of FDA might be to make people aware of the science-based information about a particular issue, its risks and its benefits, so that a person can make as informed choice as is possible and then they choose to do or not do, based upon their personal value system.

So, it might sound inappropriate but I think the first step in communicating is to listen. One needs to listen to understand where the public is coming from, where that

target audience is coming from, what information they want to know, what concerns they have, where their knowledge base is.

As one of our earlier speakers, Dr. Peters pointed out, sometimes we misrepresent whether other people know. We take the base of knowledge, what our base of knowledge is, or even the knowledge of our friends and start from there. And what we really need to do is look at who our target audience is and begin the knowledge with where they are and then take them to the next step.

We need to determine their information sources. So that we know how to reach them and also others like them in this target audience. And it might not be the source one thinks it might be. Then we need, of course, to develop and then deliver the message and to evaluate its effectiveness.

I will strive to look at each of these aspects or will show you some examples of each of these aspects and indicate then

what challenges I see in the future for FDA and for communication in general.

My first two examples are fairly straight forward. I am going to be looking first of all, at safe handling of produce and secondly, at safe handling of foods in general. The first one on produce was a project I did with a colleague. Safe handling of foods in general for a high, at-risk audience was professional colleagues at other universities who I believe did one of the best jobs of communication that I have seen. When I give examples and I talk about the best of the best, I talk about this particular group's program.

And then last, I would like to finish with a more controversial topic, something that has great potential but is often misunderstood.

I provided for the panel there a copy of the brochure that we have prepared and I have extra copies over here from the sides.

There is plenty of brochure copies. There is just a few magnet copies.

So this first project is consumer handling of fresh fruits and vegetables. This was a project funded by FDA in the end of the 90s, I think. And it was generally about, it was in response to a safe handling consumers -- I don't know if it particularly said consumer. I think it just said a call for research proposals on food safety in general. And it was a program that a colleague of mine at the university who was a microbiologist and I did jointly. My aspect was to identify consumer handling practices. We wanted to start where the public was. So we are going to express some changes but we feel those changes are more likely to be adopted if they are just small changes from what people are already doing.

And then my microbiology colleague evaluated the effectiveness of washing produce. People use the whole range of

methods. We chose the ones that were most commonly used and seemed most intuitive to our public and she evaluated to see how well they worked.

And then together, we developed science-based recommendations on how people should be handling produce. And then we evaluated these guidelines by using focus groups again to go back and determine how this information was understood.

So again, focus groups were used at the beginning to assess current practice, knowledge, attitudes. Then this was all quantified by a mail survey nationwide that included questions on handling, questions on convenient sources of information, how they wanted to have the information presented to them, if they had a reminder piece and so forth. And then focus groups again at the end to refine the publication. I have in the packet for the committee the publication on refining the brochure.

This is the brochure that you have. And notice the pictures. Line drawings in this case but that was cheaper for us than photographs and maybe easier to come up with and maybe more visible, perhaps, on a black and white publication. Every variation in print size, print style, boldness, italics, pictures, including red in some spots, these all came from interactions with our target audience, our consumers about what was meaningful for them, what would make them look.

I don't have the front page for you but we wanted to start out with pointing out how nutritious fruits and vegetables are. We didn't want to scare people away from a safe product. But we also wanted to give them, to have the feel that there are bacteria in this world. And some bacteria is harmful, and some are neutral, and you don't want the harmful bacteria there. So the brochure's focus is to help the people protect themselves

from harmful bacteria, while still enjoying the benefits of fruits and vegetables.

Sometimes you find out things you never would have guessed as a health professional. For example, we were going through these focus groups really well. Man, we had it all down. And then someone says, should I even wash the produce from my own garden? Of course, was our response. But their response was, well I didn't put any pesticides on it. And I suppose our response as we talked about us was, well, do you have birds in your garden? Are their birds in the back yard? Are there maybe snails? Do you have a pet? How about a dog, or a cat, or even a duck? And all of these things can transfer microbes, including dust.

So that is why we added in red there, wash all fruits and vegetables, including organically grown, farmers market and homegrown produce. So, sometimes what is obvious to you is not obvious to them. They

wanted specific details. Should I wash it every time? Yes. Always wash fruits and vegetables. How long should I wash it or how should I wash it? And so forth. So, the details all came from interacting with the public.

They also wanted a reminder and that is why I have the magnets. And the magnets, by the way, were the most expensive thing. Those are 50 cents each. We used round because we wanted to be consistent with the Fight BAC! campaign. So we didn't use all of our magnetic paper but that is what we did.

So, how do you distribute this? What do you take from this? We distribute it online because we now have it available through our cooperative extension as part of a free educational resource. But, as I mentioned, fewer pictures. Master Gardener's, very, very popular in California, are available to anybody who wants to stop by the Master Gardener's displays, which they have

programs and they also sometimes set up booths at the farmers market and so forth.

People sometimes have education materials at programs. We have included that there, referenced it. In media communications and that is an important piece. Many of us get contacted by the media frequently. And so we are able to fax the brochure to whoever the person who is interviewing us for Red Book or Ladies Home Journal or whatever, so they have a copy, too and can either refer to the online or regurgitate the information in their own style and byline as appropriate.

We offered it to the Fight BAC! campaign although when this was developed, Fight BAC! was having difficulty with funding and they did not express any interest. They have subsequently developed their own piece, but we did offer it to Fight BAC!. It was updated and reprinted in 2008, with additional emphasis on buying pre-washed produce.

This is the best of the best. So

that is an example of a risk communication that had, I think, all of the components, tying it with science, addressing people's needs, validating that it was communicating to the people. I will talk to you more about evaluating in a few minutes.

This is an example of another piece. This is USDA funded, and this is my colleagues at Ohio State, Colorado State, and Washington State. It is food safety materials for persons living with HIV/AIDS. And this is, then, for the highest risk population.

And I pull this up for you for a couple of important pieces. First of all, it is comprehensive. You might be able to see here at the top, it is Take Control: A Hands-On Approach to Food Safety for Persons Living With AIDS. And then Eating Away From Home While Traveling, and then Protect Yourself: A Guide for Persons Living with AIDS. And then the last one, Food Safety for High-Risk Populations: A Continuing Educational Course

for the Healthcare Providers.

So, it indicated then different areas where people might have questions about food safety and it also addressed the support people that assisted those.

This one is specific for HIV/AIDS. Their grant also included developing funding for people with cancer or for people with heart disease. One of our questions that came up from the panel today is should we have specific information or should we have general information? At least for these audiences, the researchers found that if they made one brochure for all three groups, none of the groups paid much attention. It wasn't targeted to them. So, they actually came out with three publications. The same information is inside because it is the same way of being safe but it had their condition on the front. And because it had their condition, they looked and paid attention to it.

So, here is the cover Take Control.

And this is what the inside looks like and I apologize for my own inept photography. I know a professional could do better than this. There are pictures. Not as many as they would have liked but there are some pictures there. There are bold headlines, "Eating Away from Home." Here are a few valuable tips bulleted and then a checklist underneath. They say what to do and they say why to do it. The people wanted to know why. Why I had to change my behavior. Why can't I do it the way I had always done it before? So these pieces of information were very important to the target audience.

How was that distributed? Well, I know it is available to people in cooperative extension because I have seen it that way. I know it was referenced in USDA's Food Safety Educator. I don't know other ways that they are distributing it. I would like to see it being distributed through medical offices. I think that would be, if it was available for

the physicians, so every time they had one of these people with these conditions, they gave them this food safety guide, that would be quite appropriate.

So now my third example looks at a controversial topic. So we have talked about educating the people. But it is more than reaching the public with food safety information. Enhancing safety and quality of life is more than just consumer education. This indicates that safe handling of food must be addressed in all stages from production through consumption. And there are different activities to take place at each of these stages.

The one area that is being used in some commodities but not in others, is the area of the pathogen killing step. The one in yellow. You have milk in the market that is pasteurized. That is a pathogen killing step. There are some people right now who believe they should be having raw milk and there are a

number of health risks associated with raw milk. But there are some individuals who, for their personal philosophy, want to purchase raw milk. I would be happy to talk about raw milk in greater detail, and personal philosophy, and the difference between adults and children. I, of course, have strong views on this topic.

But I will go to another one that I have very strong views on and that is the one also in yellow. Irradiation. Irradiation is a process when food is exposed to very carefully measured levels of energy. And this energy, depending upon the amount delivered can destroy harmful bacteria. It can replace fumigants that are used to destroy insects. It can extend shelf life. It has a number of benefits, just like heating has a number of benefits. In fact, it is parallel in many ways.

The food is like fresh. It is considered safe by the scientific community.

It is approved by FDA because Congress established a number of years ago that any application of irradiation must be treated like a food additive and must go by petition for specific applications that FDA approves.

So meat, poultry, and some other foods are approved by FDA. There is a petition before FDA now for fresh cut produce, which includes leafy greens. I would like to indicate that irradiation right now is probably the only method that can enhance, to a very high degree of safety, the safety of safety leafy greens like spinach and lettuce because it destroys the microbes which could even be in side the produce but it is not approved yet for that application.

It is considered safe by the scientific community. However, it is controversial in that there are special interests groups that speak against irradiation. They say dangerous chemicals are formed. They say nutritional value is

destroyed. They say it is used to clean up filthy handling operations. And they say all people have to do is cook the food.

The allegations that they present here are not supported by the science and the recommendation that all people have to do is cook foods ignores the risk from cross-contamination which occurs quite readily. Even though one might fully cook meat or poultry, cross-contamination can make people very ill. And of course, it doesn't pertain to fresh leafy greens, does it? Because you can't have a cooked lettuce or -- well, you can have cooked spinach but many people like salad greens.

So why are you speaking about this, Christine? Whey is this important? Is this important because of the profound public health advantage this technology offers? A report by Robert Tauxe from the Centers for Disease Control and published in emerging infectious diseases indicated that if half of

the ground beef that is currently permitted, half of the poultry that is also currently permitted, and half of the processed meat products that is not permitted yet but there is petition before FDA and has been for almost ten years to permit processed meats, if half of these products were irradiated, then the number of foodborne illnesses related to E. coli, campylobacter, salmonella, listeria, toxoplasma, could be reduced significantly and could save 352 lives every year, based upon their estimates of foodborne illness. Wow, that is profound. Save also, of course, preventing major diseases and preventing hospitalizations. So the potential impact is immense.

How do people respond to this technology? So then why is risk communication needed? When people hear science-based information about irradiation, the majority will buy the product but most people don't hear this so the communication is lacking.

There is a need to have this communication. When people only hear what those opposed to the technology speak, then very few were interested in buying the technology. You say, why even ten to fifteen percent? Because some have heard and know that what the special interest groups present is not science based.

Parents of young children, and you might know that as one of the groups that is at increased risk, the young children, that is. But the parents of young children are least likely to select irradiated products because again, they are in that protective mode. And if they hear controversy, they go to let's do what we have always done, which is not select this product that is processed by a new technology.

When negative information is countered, and there are studies that illustrate this specifically, then interest in buying increases. So communication can be effective when it is delivered in the

appropriate main. So that is my overview of those three technologies.

Now, what about extending that message, whether it be irradiation or washing, appropriate washing or other ways in food safety, messages are extended through community meetings and trainings, through handouts, through web-based messages and through a variety of media sources which the consumers use quite heavily? How do we tell if we have been effective in what we have done? These are general ways that one could assess effectiveness, the interest in the educational materials. I tell you that brochure has had a great deal of interest. But we don't really know if it has changed behavior. We have not requested and received money to measure if it has changed behavior.

Reported behavior is something I will show you in a moment. A change in reported behavior. Reported behavior is easier to assess but it is not necessarily

accurate because people say things but they don't necessarily do what they say. And the newest area of focus in consumer research nowadays is actually videotaping the public. And so they may say, oh, yes, I wash my hands before I start dinner. And then you have go the videotape on and you just watch how few people wash their hands or wash their hands when they should. So, observed behavior is the latest way that this research is going.

Changes in foodborne illness data, of course, that is the bottom line. That would be great to observe and to record. It is more difficult because there are so many compounding variables like, for example, our population where we have an increased number of people who are at risk for a foodborne illness. Marketplace purchases can also be observed in some areas.

Now, if you educate people, will they change their behavior? This is from the HIV/AIDS individuals where they have had a

great educational opportunity. They have seen and read this brochure and then they were asked, what would you do? And would you wash your hands? Oh, I'm already washing my hands. That is what the green line shows. Oh, I definitely would wash my hands. There are some over here who even though they are at highest risk are still not going to wash their hands. Incredible.

Would you avoid rare ground beef? Some say I am already doing it. Even more saying I will do it. Avoid raw seafood and so forth. Let's look toward the bottom. Avoid unheated luncheon meats. The issue here is listeria, which would possibly be there. You get a little bit more than 60 percent who say they are currently or definitely would.

Use a thermometer. That is what the Meat Institute, meat groups, and what Fight BAC! is recommending. Use a thermometer to make sure that your food is thoroughly cooked. It is an appropriate recommendation

but people don't want to do it, even those who are at very high risk. You have about 18 percent who say they are currently doing it. And only half, if you add currently and definitely would, only half indicate that they would use this method.

So, why not? Obviously this message, even though it is the best of the best, is reaching some behaviors but not reaching others. Remember the feedback loop that we saw earlier. Some of those behaviors have to go back into the feedback loop. And here are some of the barriers that we have identified that have led people to still follow this behavior and not embrace it yet.

Messages are not heard by everybody. When you have to go to the web to download something from FDA, then that takes their effort, their initiation. And it is hard when people have to initiate. They might not realize they need to. Sometimes targeted programs, though targeted and very specific,

they are short-term. When the program is over, the education materials just lay in the bookcase. They don't get out.

People think they are already knowledgeable. And certainly on food safety, about 80 percent of the people say they already know a lot about it. There is a time delay between unsafe behavior and getting sick. That is why as we heard earlier from Marjorie Davidson that people say I already know how to do this and they don't realize, if they have been doing incorrect things, why haven't they gotten sick every time?

People don't follow the recommendations because they believe that it doesn't affect them or they are too busy, or it is not convenient, or it is not necessary, or they like the taste of rare meat, or they like the taste of runny yoked eggs and so forth.

So, in today's world, food safety education is better than it has ever been

before. There are specific recommendations. Fight BAC! has four. And if you look on the web and look at "Handling Fruits and Vegetables," it is up to six. The guidelines are very clear. They tell you what to wash and how to wash it. They tell you how to cook it. They tell you what temperature to use.

Sometimes some recommendations are specific by age or health conditions like pregnant women, and listeria, and avoiding specific foods. Messages are presented nationwide and certainly Fight BAC! does that. But consumers don't know all of the specifics of these messages. They are listed on the Board but they haven't looked them up because they think they already know. People don't follow all of the recommendations. Education is not sufficient and that is why I wanted to throw irradiation in there for you because people think they are cooking their meat adequately. It is brown on the inside and it is darn hard to put the thermometer inside, so

they are not going to check it.

And I have got a project going right now where we are having people cook their ground beef. It is brown. It is black on the edges. Flames are coming up. It is really skinny. I stick my thermometer inside, it is 142. The temperature is 160. That is the recommended temperature. I have never known that. I never used a thermometer. I don't own a thermometer. Here is a thermometer. Thank you. But will they still use it? It is hot, inconvenient, and they think vision is enough.

So what are our needs? Our needs, I think, for FDA, and for this agenda in total is sustained educational programs. It is not just for two years or three years or while we have got the grant. It has got to be continued. We need endorsement and encouragement by physicians, health providers and others who are trusted parties. At my HMO, my gynecologist, OB/GYN person says and

are you taking calcium supplements? I respond by saying I'm drinking milk. But wouldn't it be great if they also said and do you have a meat thermometer? And do you test the inside of your thermometer? And here is a brochure for you. And I'll bet you have always wondered the best way to wash fruits and vegetables. And here is a brochure for you. Trusted people sharing that food safety is important.

We need models of appropriate behavior. If you are into watching the Food Channel and if you are a food safety expert, you just about cringe because there are so many examples of what people shouldn't do. We need a program to encourage what people should do and honor chefs who use thermometers and who wash their hands and follow appropriate action.

We need timely regulatory approval of innovative technologies like irradiation. And we need regulatory oversight of false and

misleading claims. If the public hears it, if the public sees it, if the public reads it, they think it is true. And often they don't pay a great deal of attention about who said it. "They say that it causes cancer." Would the FDA approve something that causes cancer? I mean, let's be reasonable and use our head.

So, we need stronger interactions with the federal trade commission and others so that the messages that are under approval, regulatory approval can be tested and validated for accuracy.

So thanks for letting me get all of my enthusiasm and dedication, some of it at least, off my chest.

CHAIR FISCHHOFF: Our next speaker is Linda Neuhauser.

DR. NEUHAUSER: Good afternoon everyone. And I would invite anybody who wants to stand up for a moment and, you know, get the blood sugar rising, if you wish, because I know it is hard around 2:00 to keep

your attention focused. Great.

My name is Linda Neuhauser and I am really delighted to be here. And I wanted to start off by saying how much I appreciate the FDA's commitment to doing better with communication and how heartened and impressed I was this morning to hear about all of the efforts that are going on. So, bravo to the FDA.

I am going to talk about what we are calling right now is persuasive communication. But like Dr. Bruhn, I am not quite so sure if that is the right word for it. I do believe that our job is to empower people with science and the best we can do. And then they will make an informed decision which, if we are doing our job correctly, should go in the right direction.

What I am going to address today are three questions. First of all, I am going to be talking about whether communication, mass communication in this case to the public,

whether this actually is successful in changing people's behaviors in a positive way. Secondly, what are some of the barriers we have to doing better with communication that is intended to influence people to change behaviors? And third, how can the FDA improve communication?

For the last one, I am going to propose a different process of developing and delivering communication and also have three recommendations, one of which deals with building capacity within the FDA as Deputy Commissioner Torti talked about this morning.

So, just an overview. And the reason I am going back to the fundamentals is there is often a lot of debate in the health communication around mass communication, about whether it actually works or not. And we know that it at least works sometimes. But does it work enough to make it worth our while?

And so looking at about four years

of evidence about the impact of health communication, mass communication, what we see is there is modest but positive effects. We do see that those effects are less positive among vulnerable audiences who might face barriers related to literacy, language, culture, or disability. And it is less effective for complicated issues such as the ones we are discussing that relate to risk communication where it is a complex mix of risks and benefits and perhaps numeric information.

It is more effective when there are multiple channels that reinforce each other and a number of people have talked about that today, the need to not look at the FDA as the only place that might get this information out but one of the places with many other partners. And as we have all heard multiple times today, we as yet have very little information about the impact of FDA communication.

So, a question might be, how come, if we have been studying mass communication for all of these years and doing it, investing billions of dollars in it, how come it is not more effective? And I would argue that a key reason is that we have built it on a very weak theoretical foundation. And a traditional model of health communication might look something like this, in which experts would take scientific findings and develop factual generic one-way messages that are delivered to the public in the hopes that people will learn and will change ways in a positive direction. And so there are many theoretical models like that and the whole enterprise of mass health communication has really been built up with this kind of guidance.

Now, a new review is that this is a weak approach. That, actually, scientific information in and of itself has very little meaning and is not persuasive until it is actually socialized to fit within the context

of people's lives. I like to say we have messages to send to scientists and people have lives to live and we really don't link those two very well. So, our job is to do better with that, to socialize information.

One of my favorite books, by the way, is a book called The Social Life of Information published in 2000 by Brown and Duguid. And it is quite an eye-opener, if you are interested in why factual approaches just don't seem to be that effective.

I would suggest that a better underlying model for our mass communication of the type that FDA typically does would be something called a social ecological model. And you could see a lot of different levels here. And one of the reasons it might be useful to have, is because it not only acknowledges the diversity of individuals but it also acknowledges the influences of the multiple context in which they live.

So, if you just pause for a minute

and look at this graphic and think about the recent contaminated vegetable issues, salmonella in vegetables, and then just try to think about how many of those social levels were engaged, were not engaged at influencing individuals about what they should know and what they should do. So, I think we could do a lot better by having multiple layers of influence.

I am going to address, in terms of barriers, two issues. One is looking at the concept of health literacy. And the reason I selected that was because health literacy is an emerging concept that seems to bring together a lot of factors that make a very large group of people in the United States quite vulnerable to being able to access, to read, to understand or act on health information. The whole area of health literacy is about 15 years old, so there is quite a body of literature around this.

Health literacy and literacy in

general is measured by the national assessment of adult literacy. This is a national survey that takes place very ten years. The most recent one was in 2003. And the survey measures for components for literacy, so health literacy, people's understanding of health concepts and being able to deal with those, prose, being able to look at texts, documents, being able to deal with the document itself, and then quantitative or numeracy skills. And you can see here that for each of those four components, that the population is divided into four levels of skills.

So, there is below basic. There is basic, intermediate and proficient. These run across the bottom here. The two most important levels to think about are the lower two. The below basic and the basic. But I would suggest that even the intermediate level in which there are quite a few people, is still one in which people lack skills to deal

with a lot of the information that we are talking about here that relates to risks and benefits across a wide variety of products that the FDA has authority over.

So, the below basic and basic. We will start off there. Those might be groups that you could call lower literate. And so just to look at the numbers here, we have about 93 million Americans that would fall into either below basic or basic skill levels. And again, take a chunk of those in the intermediate. Because until you get to the highest level which is called proficient, you are not really sure that people can handle the kinds of complex information we are talking about here. Tables, graphs, maybe having to deal with ratios and complex information. That really comes up at the higher level there. So 93 million people may well be cut off from most of the information that we are delivering to them today.

To get a sense of what does this

mean in terms of skills, this list here talks about the skills that you might be able to expect from somebody scoring at any one of these levels. I would like to draw your attention to the intermediate level right now. And at that level, that is the third level, people should be expected to understand the timing of their medications.

Now, to put this in a context of the problem in the United States, only one-third of the population actually adheres to taking medications in the prescribed way. Only one-third. That is a very, very poor outcome. And it is not so surprising when you see that the bottom two levels would not even be able to be expected right now with the kind of information they are getting to be able to accomplish that task. And a certain chunk of those who are in the intermediate level. So, we have a very big challenge.

This is an exercise that I would like us all to take for a moment. Some of you

may have seen this. But if you haven't, I think it is very hard for highly literate people, and I would suggest that most people in this room are probably in the top three to five percent of literacy in this country. So, this will give you sense of what it is like to experience low literacy.

What I would like you to do is to read this. And a tip is that the words are written backwards. So, just take a moment and see if you can do it.

So, I will call on Dr. Ostrove. Now, you are sitting in the physicians' office. I have given you enough time. You are at the pharmacy. You have only 30 seconds to ask me a question. Did you understand that?

DR. OSTROVE: Uh --

DR. NEUHAUSER: Do you feel embarrassed having to talk to me about it?

DR. OSTROVE: Oh, yes.

DR. NEUHAUSER: Okay. So imagine

the shame, the frustration you feel, when you are handed something that is beyond your capabilities of understanding and you are expected to make something out of this. And it might be a life and death situation for you.

So, how big is the gap between people's abilities, in this case to read, and the kind of information they get? Well, it is huge. So, the average American reads between a seventh and eighth grade level. And it is important to know that the average American has a high school education. So one of the findings from the health literacy research is people read about three to four levels below their last completed grade and that literacy falls off with age. We heard something about that earlier. About two-thirds of older adults would be in the lower two levels, or the lower literacy level groups.

And an important 20 percent read at or below the fifth grade level but most of the

health information that is given out through governments is at the tenth to twelfth grade. I just had an experience of analyzing the USDA's food pyramid website and looking at the level of that information. It was intended to be around a seventh grade but it actually ended up that parts of it were even at grade 23. So, again, it is not enough to have the intention to do something at a lower literacy level, you actually have to have a good process and we will get to that in a minute.

I don't want to talk much about risk communication because we have heard about that and will hear more about that this afternoon and tomorrow. But I just wanted to comment that overlaid over the problems of people's challenges with literacy at the base are the added demands of risk communication because it is so hard to understand, it changes a lot, you need trust, it is laden with emotions and values, and requires quite a bit of numeracy and it may be quite variable,

according to your cultural background.

I did want to point this out because I think this is a useful maxim. This is Vincent Covello, one of the risk communicators. And he says in high concern situations, many of those the FDA deals with, people want to know that you care before they care what you know. So, when you look, this came up at an earlier meeting, I think in February, where there was a comment. We were looking at the press releases sent out by the FDA and seeing if there might be ways to improve them. And one comment was that in none of the press releases could there be found an emotional expression of caring, except the one dealing with melamine in pet food. And I can't remember, if anybody here can remember it, it was something like we know that Americans are very concerned about their animal's health. Was that it John? John found that. Thank you, John. And this is so important to have emotional connection.

Again, one of the reasons for having a trusted humanized spokesperson from the FDA that can do a lot to get across that caring.

And then one last comment about risk communication messages. Looking at the scientific literature, there has been a lot of debate about whether high threat or high fear messages really work. And if you look at sort of meta-analytical reviews about this, I find it interesting that it seemed, the conclusions right now seem to be that high threat messages are really successful, if they are connected with high efficacy information, like here is what you can do now, keeping in mind, as people have said earlier, just a few messages, feasible things that people can do and so on.

So, taking all of this information in, are there things that we can do to improve our communication? And right now, I am talking about mass communication, pretty much textual communication, either printed or on the internet. And these are some of the tips

here. We have talked about some of these, but the first one here underlined, of course, is to co-design with the target audiences. Now, this is my story. I have spent the last 20 years working to try to turn around the classic health communication way of doing things into something different that is user and audience focused so that the people who are the intended beneficiaries are actually the ones who come up with and co-design the information along with the scientists or educators. This is the only thing, in my view, that actually works to get through all of the complex issues that we have talked about because we have talked about many things.

We have talked about people's challenges to be able to read and comprehend. We have talked about their challenges with the way that issues make them feel with their underlying values. Culture, language, etcetera. There are so many issues that it is

hard to quantify those and put those into some kind of normative cookbook recipe for doing things. And what I have found is that the only way to deal with that complexity is to actually get those people with you, work with you, design and test together.

And the bulleted points here are just some of the things that have come out from the literature and from experience, all of which have already been mentioned today. Ron Barnett's pictures, and stories and so forth, the emotions, putting information into small chunks. Think of USA Today. It is very easy to read the front page of that paper compared to say The Wall Street Journal and so forth. Focusing on behavior rather than too many facts and the like.

So, here is a proposed process for doing developing communication in a different way. And this starts out a lot differently from having experts take scientific findings and saying okay, now we are going to develop a

message. We are going to send it out to you the public.

In this one, we would start out much as Dr. Bruhn said, to think about what are the actual communication objectives and audiences. And Dr. Ostrove brought that issue up this morning. You know, as the FDA, what should we even think about when we are considering some piece of scientific information that should be communicated to the public?

Then the next step would be to actually get the intended audience, once they are defined, to assess them, maybe to survey them. Focus groups, whatever, find out what they think about a particular issue and see where their knowledge is, where their attitudes are, where their behaviors are, just like Dr. Bruhn did with the hand washing and so forth. You know, where are we right now? Where do we think people should go in terms of changing their behavior?

The next step, which usually doesn't happen in most communication development, is to set up a participatory design process with those intended audiences. And I would say here, give a special attention to the lower literate groups. One of the things that really bothers me when I look at the literature is that we have a lot of scientific evidence about communication. But if you look closely at it, you will find that almost never have people taken the lower literate groups and involved them in testing messages and so forth.

In one of the government websites that I examined, I saw that in the background information it had been tested and found to be very usable. When I looked deeper, it turned out that the group that actually examined it was college students. So, college students said a website was easy to use. Well, I would assume so. So, we need to pay particular attention to the more vulnerable groups here.

And then the process goes on to interactively develop. So, you have educators, scientists, various stakeholders, maybe policy makers, working with the intended audiences in the same room to develop messages, ideas, communication strategies. On the side, or combined with that, have the folks who will actually deliver the communication, those could be people from the media, they could be spokespeople from an agency, they could be professional groups, seafood industry, public information officers. There is all kinds of groups who could get the messages out that the FDA would think are valuable. Have them get together to figure out systematic ways to deliver this information.

Then the process continues iteratively until all of the groups are satisfied with the way it is. It is implemented, then it is evaluated and then there is always a sense it is going to be

revised again because if you evaluate it correctly, something will always be found that could be improved.

Finally, the whole process needs to be redone to adapt communication for other languages and cultures. I won't go into details about adaptation versus translation but it is an extremely important issue. I would just say that literal translations do not work. They are not respectful. They often lead to miscommunication and can be dangerous. So, an adaptation with people of the particular language group understanding, of course, that for example in Spanish, there are many linguistic variations and you have to bring folks like that together from Puerto Rico or Mexico, wherever, to make sure you have a sort of neutral Spanish.