less resources and less manpower but as we like to say internally, we are a small but mighty center. We regulate, just like my colleagues, a diverse and oftentimes controversial range of products. Items such as cloning, BSE, and genetically engineered animals. And what we hear time and again from both industry and the public is that they had no idea we even existed.

Some examples of how CVM communicates non-persuasive information are through our website. We have pages on topics such as cloning, pet food, NSAIDS for dogs, which the acronym stands for non-steroidal anti-inflammatory drugs for dogs and that includes a downloadable brochure. It is a public education campaign in place. We put out a newsletter six times a year entitled The FDA and the Veterinarian and we have over a thousands subscribers to that. We put out an annual report. Unlike some of the other centers' annual reports, ours not only

discusses our successes but also our failures and puts things into context.

We issue CVM updates, which are similar to press releases but are tailored more towards our stakeholders. We also put out consumer articles. We exhibit at over a dozen conferences a year. And we hold public meetings which not only keep our stakeholders and the public informed but it provides a forum for participation and comment.

Examples of persuasive communication, what we consider persuasive communication, where an action is required are recall notices, warning letters and untitled letters which are geared towards advertising and promotion.

And some of the criteria that we consider before issuing a persuasive communication are surveillance. We monitor approved drugs post-marketing. We look for tends and patterns in the reports. How confident are we in the information? And in

the absence of confidence, how do we balance the need to protect public health with the need to provide accurate information? And as my colleagues said previously, this is something we struggle with all the time and it is kind of a risk-benefit ratio we try to apply. And typically these types of communications are targeted towards industry.

So, how can we best serve our stakeholders in providing timely and important information? What vehicle provides the optimum exposure? Again, these are questions that we would like the committee to consider. Does the target audience determine the type of document we provide? And how can we utilize outside groups to participate in disseminating our message?

And finally questions that we continuously ask ourselves and again that we would like the committee to consider are how do we balance the need to communicate early while issues are still emerging, without

causing undue alarm in the public or damage to a business or industry? We have to consider that as well.

And what are the best techniques for conveying an emerging or uncertain issue? In the case of melamine in pet food, we were faced with no definitive cause for many weeks of what was causing the illness in animals. Yet, we had an audience that wanted and demanded information on an almost daily basis. We decided to hold press briefings, even when we had no new information to report. And that is kind of how we handled that issue until we did find the definitive cause. We said as much as we could at each press briefing.

And then finally, how do you practice follow-up as the issue unfolds? And how often do you communicate? And how do you come to closure? How do you announce to the public the investigation is over and, you know, no more new information will be emerging after this. And again, this echoes what my

colleagues have said in their previous presentations.

So, I thank you for the opportunity to present today. Thanks.

CHAIR FISCHHOFF: Thank you. And our next speaker will be Marjorie Davidson from the Center for Food Safety and Applied Nutrition.

DR. DAVIDSON: Good morning. I am Marjorie Davidson from the Center for Food Safety and Applied Nutrition and I didn't put our acronym down here but we are called CFSAN, just to keep a similar process as everyone else.

I wanted to go over a little bit about our different kinds of communication. Some of the risk communication challenges that we have. As well as I would like to highlight just a little bit of the evaluations that we have done in our various kinds of communication. It is a quick and dirty presentation, if you will but sometimes we are

successful and sometimes we are not. And I just wanted to give you a little sense of how we are doing.

Examples of our non-persuasive communication, our public meetings on regulatory proposals, issuance of plans, guidances. We have fact sheets on our different products, web pages on a variety of also issues and products concerning food, constituent updates about CFSAN activities, a toll free hotline, email inquires and EdNet list serves.

Other non-persuasive communication factors that we have at CFSAN are package labeling, where we provide information on regulated products such as weight statements on food products, ingredients lists, manufacturer contact information, nutrition facts panels. We also have safe handling labels on egg cartons, warning labels on unpasturized fruit juices.

Persuasive communication, an

example of that are consumer education campaigns. They are primarily used for preventing illness from unsafe food handling practices. Examples that I have presented earlier to the committee are Be Food Safe or Fight BAC! campaigns which focus on the four safe food handling practices, behaviors that scientists had determined were the most effective in preventing illness, if followed. Other examples are how to safely handle fish and seafood, safe handling of fruits and vegetables, just handling practices under many products.

The risk communication challenges that we have confronted in our consumer education is how do you persuade consumers who have life-long experiences with handling food to change their unsafe food handling behaviors. If there is a product that everyone in this room is familiar with, it is food because everyone has to deal with it.

To that end, we want to alarm

consumers about the risks in foods sufficiently to persuade them to change these practices but, at the same time, not to cause a lack of confidence in the safety of the food supply. Some of the evaluation we have had on that challenge is we have seen large improvements in food safety practices, in safe handling practices between 1993 and 1998 when we first started evaluating these trends. In our 2001 survey, the gains were maintained.

In our 2007 survey, we found that the youngest age group showed better practices than a similar age group did in 1993. So we are showing generational improvement.

As far as keeping the confidence in the safety of the food supply, this is the Food Marketing Institute trends show that in 2006 there was 82 percent confidence in the safety of the food supply. In 2007, it went down to 66 percent. That was taken right after spinach recall. Then in 2008, it came back up to an 81 percent confidence rate.

Persuasive communication. One of the methods of our persuasive communication is our consumer advisories where we advise consumers about emerging food safety risks. A couple of examples are about the risks from listeriosis in certain refrigerated food products. This was advice for pregnant women, older Americans, young children, and people with weakened immune systems. Other examples are advice to pregnant women, mothers of young children, nursing women, and women planning to become pregnant about the risks of methylmercury in fish to their young child's developing nervous system.

We find these advisories particularly challenging. For example, some of the questions we ask ourselves is what do you do in disparate scientific belief and risks. One of the examples in methylmercury risk. There is very sound and strong views on both sides of the scientists, how significant that risk is and how it contributes to

confounding the message delivery when we get our advisories out there.

Also, how do you mitigate the impact of your message to one segment of the population, such as many of our advisories are to those at-risk categories, pregnant women, older Americans, people with weakened immune systems, how do you prevent the spillover to the general population that doesn't need to be worried about the issue?

And also how do you effectively balance advice to avoid a food and eat the same food for the health benefits at the same time?

I just wanted to talk a little bit about some of the evaluation that we had done, for example, on the risk communication advisory on fish, which shows how these challenges show up in the evaluation as well. Most U.S. adult consumers have eaten seafood in the past year, which is good, and they are aware of the health benefits and health

concerns related to eating seafood. At the same time, most consumers have heard of methylmercury as a problem in some seafood but few of them know the specific details. So that is a continuing challenge we have in the complexity of the message about methylmercury in fish.

Nearly all pregnant women report that they limit or do not eat the fish as highest risk of methylmercury, which is what our goal is. And at the same time, some report limiting their eating of other fish as well.

Another persuasive or explanatory crisis communication is another type of communication we have, which is warnings and recalls. And these are issued for an immediate threat to the public health. Recent examples are spinach contaminated with E. coli, melamine in pet food, botulism poisoning in Castleberry brand can foods, and Salmonella Saintpaul, which we are undergoing right now

in tomatoes, jalapenos, and Serrano peppers.

Here again we have the challenges, how do you characterize the risk in an emergency, Others have talked about that one, when there is so much uncertainty. Sometimes we don't know what the product is. Sometimes we don't know where the product is coming from.

And then also how do you balance the scientific desire, as mentioned earlier today, to speak precisely about a risk with the development of a comprehensible consumer message? And then how do you manage rapidly changing consumer advice during an outbreak to effectively impact consumer behavior? As we go through the process of an outbreak, we will narrow to products, we will narrow it to geographic locations and then also, how do you effectively tell consumers when the emergency event is over?

And also how do you reconcile the characterization of a risk in a product such

as raw spinach during an outbreak and the continuing risk from the same product when it is in an outbreak? There is continuing issues with the safety of the food supply that are inherent in eating food, in some instances, and we need to concern ourselves with how we balance those messages.

People have spoken to the difficulty of getting research and evaluation through OMB, processes we also use evaluations as I have shown from other organizations. Rutgers University, for example, had told us after the spinach recall, these are just some of the highlights of their research, that most people, we were successful in most people had heard about the outbreak. However, large percentages of people thought the recall was still in effect and thought it was still ongoing or didn't know if it was still ongoing.

And as the process of our risk communication went on during the spinach

recall, the news coverage was more about the investigation and didn't re-emphasize the consumer advice about what to do.

So, that is my quick overview of CFSAN risk communication challenges. And I appreciate your time and I truly welcome your advice.

CHAIR FISCHHOFF: Thank you very much. We have seven minutes. I am sure the other panelists have been sitting on their hands waiting to ask some questions. So, let's ask questions until 10:15. And since we are expecting Dr. Torti at 10:30, we will take a break right then.

Okay, Mona.

DR. KHANNA: I have a question for Lorrie McNeill. My question is about your information that it took three weeks to get the information out for one particular example. What I would like to know from you is why. And you could probably explain that by telling us what the approval process is

like to get information out from the FDA.

MS. MCNEILL: That is a really good question. I think part of the issue here is I don't believe it would have taken that long had we just been dealing with one agency. We have our own internal process where we work with, my office works with the subject matter experts, in this case two different offices, the office of vaccines research and review that know the product and the office of biostatistics and epidemiology, which are the folks who review the adverse experience reports.

So, we work with those two offices in developing the message and we clear it within the Center and with our center director's office. And then we have to, in this case, is we decided that we would have a more powerful message if it were a joint message from both agencies, again, since we both had a role in vaccine safety, we worked with CDC. And within CDC, we were dealing

with several institutes and I don't know all of their acronyms very well but I believe the National Institute for Childhood and Respiratory Diseases, if I have got that one correct, the Immunization Safety Office, the STD people, and the cancer people. And so, they are not all in one place. And so they have their own process for getting something cleared and there was a lot of back and forth on how much we should include in the message, how detailed we should be about some of the information. We included an overview of the serious events that we have seen to date. We talked about Gilliam-Beret Syndrome. We have talked about fatalities that had been reported and the fact that we had not been able to associate any of those with the vaccine. But there was much debate on how much detail should we provide about those deaths. And so it was a lot of back and forth and negotiation. And honestly, I thought that within a few days, we had a really good

message within my center that we were ready to go with. And so I think that was the added challenge in this case. Normally, doing something like this doesn't take that long. So it was just a very unique situation.

MS. DESALVA: I first wanted to thank the panel for all of your comments. And it is very interesting to hear how you are struggling with very similar issues across the centers. So, I just have a couple of overall comments in response to some of your questions. And one common theme you had was how do we deal with an emerging issue where there is a lot of uncertainty or something that is changing quickly? And this is a simple response and an untested response but I would suggest that maybe one way to deal with this is not to run from uncertainty and to embrace it because one of the foundations of risk communication is transparency.

So, if you were to say something like, I'm just thinking of a quick template

here, what do we know, and equally, what don't we know? What should you do right now? And the answer may be nothing. And what are doing to find out more? How can you get updated? So much like you commented about the daily press releases when the information on the food contamination was unknown, that is a great approach, saying we are here, we are telling you what we know, what we don't know, what you should do right now, and we will be back to tell you more.

So, I think this will go along way to establishing trust about issues that are uncertain and very frightening to people. The caveat would be I am just doing this off the top of my head as a template but all of this would have to be tested with the kinds of audiences that you might want to impact.

Another general comment was that I had some questions about how do we get the information out through various channels. And one channel that I think is quite underused

are the public information officers that are at every state and in many localities. And I know some of your centers are working on pilot projects with what we call PIOs. So these folks' job is to get out information to the public about health risks, benefits, and so on. And if you could somehow work with them through their national organization to have a formalized relationship, I think it will go a long way to helping with what you would like to do.

We have, in past meetings, brought up the issue of having an identifiable humanized spokesperson for FDA, it could be the Commissioner or someone else, who would become a household name. And that could go a long way, too, to being someone who could appear on television and say here is where we are with various issues. And that would, again, respond to one of the other basic foundations of risk communication, which is to acknowledge emotional and human connection

that is needed for trust.

CHAIR FISCHHOFF: Thank you. We are going to take a break in one second. I have on my EPA's Homeland Security Advisory Committee, one of the members is a wonderful guy named L. D. McMullen, who is head of the Des Moines, Iowa Water Works. And I think he validates your theory that prior, I guess it was in '93 they had the largest loss of water in sort of modern American history, pre-Katrina, in those previous big floods on the Mississippi, Missouri system. And he followed your strategy. Every 12 hours he had a press conference, whether he had news or not. He said this is what we promised to do. This is what we have done. By the time it was done, people had, you know, like a mental model of how Water Works worked. He became a local hero and he even has a country and western song dedicated to him. So, perhaps that is our aspiration and evaluation.

So, let's break now and we will

meet again at 10:30.

(Whereupon, the meeting went off the record at 10:16 a.m. and resumed at 10:32 a.m.)

CHAIR FISCHHOFF: Let me welcome you all back. And we are very fortunate and honored to have a visit from FDA's new and I think first Chief Scientist, Dr. Frank Torti. And Dr. Torti will come and give us some introductory remarks, entertain a few questions, and then we will move on to some presentations and then he will get to ask the questions. Please. Thank you for coming.

DR. TORTI: I need all the communications help I can get. So, I am really glad to be here. You know, Nancy came and oriented me a little bit toward the risk communications efforts at the FDA and told me a little bit about this meeting. And I said, gee, I would just like a chance to sort of dialogue a little bit because this is actually very important to me and I would like to sort

of be here just first to say that, and to understand the dialogue that is ongoing, and to help in any way that I can to facilitate and implement the recommendations made from this committee and from the FDA leadership in risk communications.

And even in the few minutes that I have been here, I have learned some things that are important. You know, I have been here now almost three months and have already been thrust into an area of science that is relatively new for me but in some ways, therefore, really exciting for me, and that is the issues of scientific risk assessment, risk management, and, as part of that, risk communications.

And I have already learned from Dr. Fischhoff that risk communications comes at the beginning as well as the end of that adventure. And I respect that and understand that and want to work with you to being sure that we are able to provide that communication

at the beginning as well as at the end of these issues because they come before us in an interesting way, from my perception. And what I will do is give you just sort of one example of that and one issue that the FDA is wrestling with now. And then from there, sort of step back and give you a little bit broader sense of where I think the science and the FDA is going, needs to go, and to engage all of you to help me with that.

But you know, I came here really to confront a number but I will just choose one issue in risk assessment and that is with the issue of BPA and its presence in infant formula and the relationships there to potential toxicities that had to be sort of examined, and explored, and studied, and analyzed. And an enormous team of FDA scientists are in the process and will, very soon in the next days, be issuing a report to try and clarify if and what toxicities might be expected from such a product that is in

many of the devices and foods that we are exposed to.

Well, you know, without going in to the details, and I am certainly not an expert in any of the details, it struck me that in a broad sense, this was a dialogue that was incredibly complex scientifically. Very hard to wrap around even for a scientist who is not in that field, let alone for a lay person, let alone for a nursing mother who is confronted with the issue of potential product in formula.

So, how do we approach this? Well of course, we approach this scientifically in trying to as clearly as possible understand what that risk actually is. We must understand it scientifically. But then the next steps are how to communicate this risk. To everything there is probably some risk, at some dose, at some level. And you all as scientists yourselves understand that but the question is at exposures that happen in the

human environment, what kind of risk is there and defining that and exploring that.

So, we will be challenged with BPA and with many other issues about how to communicate our decisions, our findings, our collaborative findings with sciences outside of the Agency to the broader community how to take an incredibly complex scientific issue and bring it, and distill it to a way that people can understand and be advised appropriately.

So, we need you help. We truly do in such kinds of issues. And I am really looking to this group to help advise us and guide us as to what kinds of approaches and how in the future we can build our efforts in this area to even more deeply and completely communicate with the American public.

Let's start back from the issues of risk communication to the broader issues of FDA science and I think you will see why I started with the specifics and wanted to then

go to the general because it is really the specifics that define, sort of the general issues that we face at the FDA. There is an extraordinary amount of absolutely superb cutting edge science at the FDA. I think very little of it is recognized by the public and we are doing some things to change that. But we are also very cognizant of you know, other advisory groups, such as the Science Board who have advised on the science of the FDA and in some of the areas where we need to grow and we need to modernize and we need to improve. And part of what I have tried to do is work with the center directors at the FDA and others to begin to build a program to address the modernization of the science of the FDA in ways that will directly impact on the quality of the regulatory decisions that are being made by the Agency.

Well how do we do that? What principals guide the implementation of that strategy? The first is that the FDA cannot do

it alone, that the FDA needs to seek advice broadly from all its constituencies and do that even in a more, and we do that now, you are testament to that being here but we even need to do that in a broader and more complete way than we have done in the past. And I particularly want to be sure that we engage the academic community in thinking about some of the major problems that we face and looking to solutions. But I wouldn't limit it there, I think, even the industries that we regulate have things that they can teach us at a basic level and we need to listen very carefully to their thoughts, their stakeholders in this process as well. And we need to engage them on FDA-related issues where appropriate at the FDA.

The second thing we need to do, and again it relates, I think, directly to this committee, is for those things that we need to do in-house ourselves, because we are a regulatory agency and we can't contract out

our mission. We need to build and grow in those areas that are most critical to the Agency. And the Science Board defined many of those but the area of risk assessment, risk management, risk communication is one that I feel very strongly about and that we need to see growth in those areas building on the expertise. So, we are looking to your advice to help us think through what the right approaches are to do that.

Finally, I think it is a challenge for a regulatory Agency to be pre-emptive scientifically but I think that is where we need to be. We need to be out there and looking at where the risks are and placing our resources in areas of greatest risk. And that is what I mean by preemption, preemptive strategy for the FDA. So, in all three of those general principals, the FDA needs to move forward in the scientific arena and I think we are making great strides to do so.

So, that just gives you a little

flavor of where we are going, how we are thinking about things, how we are putting things together in a broad sense and some of the specific challenges that I think we face. But I would be glad to answer any questions that you have and also to sit back and learn a little bit about what you have to teach us. So, thanks for your attention.

CHAIR FISCHHOFF: Thank you. Mona?

DR. KHANNA: Thank you very much, Dr. Torti. Did I pronounce your name correctly?

DR. TORTI: Yes, you did.

DR. KHANNA: Okay. I am intrigued by when you said there is some extraordinary cutting edge medicine and science going on at the FDA. I would like to know why is it unrecognized? I would think it would be a tremendous strategy to build a credibility and expertise of the FDA in times of non-emergent conditions by raising the profile of some of that cutting edge science and I would like to

know what efforts have been made to bring these accomplishments into the spotlight publicly.

DR. TORTI: Well, that is a wonderful comment, so we agree entirely on that strategy. So, I will just give you one example of our strategy in this regard. We are reaching out to science writers to actually engage them in some of this cutting edge science that occurs at the FDA. And it is extraordinary and it is different than the other science that they will find because it is regulatory science but it is no less intriguing. So that in November of this year, we will hold the first ever symposia just for science writers, where they will have an opportunity for a full day to hear maybe six to ten of the most cutting edge and novel approaches that the FDA has taken in the scientific arena.

But I don't mean scientific only in the sense of laboratory. So I think you know,

science in the sense of epidemiology. Science in the sense of the anatomy of an epidemic. Science in the sense of some of the nanotechnology kinds of things which we do, in terms of biomedical engineering, as well as the biological and clinical sciences.

So, you know, we could fill many days with these kinds of stories. But I think we just want to whet their appetite to some of these issues and hopefully they will be engaged and come back and learn more about some of these issues. But it is something that has been done in the past but never in such a formal way. So, my intent is to do it formally and consistently. That meeting in November will not be the end of our efforts. They will be the beginning of those efforts.

DR. SMITH: Just a little more clarification on your comment. Do you see this sort of committee as a prototype for more of an outreach approach by FDA and a little less isolationism and reaching out to consumer

groups, and reaching out to industry, and sort of engaging in a high level discussion, as opposed to just dictating?

DR. TORTI: Well, I think these are the kind of committees that give us an opportunity to do that. I don't think, you know, I don't think the FDA has been isolationist. I think it has been difficult for the FDA sometimes to communicate its messages and we need partners in that communication. And groups like this would be very effective partners in advising us on how to communicate.

But it is constituencies that you can engage and raise to help us that will really make this committee, to my mind, go beyond, take the next step. So yes, I think is the answer.

DR. SMITH: Okay, Thank you.

DR. TORTI: Okay. Thank you.

CHAIR FISCHHOFF: Thank you very much.

So the program here is, I guess all you have, is we are going to now have four and perhaps five talks distributed between this morning and this afternoon, the fifth is dependent on how well David Moxley feels, trying to show you some of the science that might be applied or, to some extent, has been applied to answering the kind of challenges that we heard from Dr. Torti and from FDA this morning.

So, we are going to hear, first about two talks on non-persuasive communication from myself and Ellen Peters. Ellen and I have divided this up. I will be talking more about the interface between the communication and the risk analysis, risk management, trying to figure out what it is that you want to say. And then Ellen will be talking more about some of the basic science on how you say it.

But I thought the best way to organize my own was, rather than to give a

discourse on general methods, was to take four case studies of projects out of our research group, but you can certainly find other ones, and I think they are very much in the spirit of what a couple of, several of the speakers said this morning. There are lots and lots of different problems out there. There is one size doesn't fit all. And so we will give some examples of what the tailoring process would be that would take advantage of general capabilities that we have in risk analysis and in risk communication.

So, again, non-persuasive communication is addressing people's decision-making needs with in situations where you say it is, well I don't know if it is none of our business -- well, perhaps it is none of our business to tell you what to do. It is our business to put you in a position where you can make the best informed decision, given the limitations on the data that we have now.

One can think of this process of

non-persuasive communications having three elements. One is analysis. That is, determining what people need to know in order to make sound choices. In many of these situations, we could easily give them the fire hose treatment of all of the data that we have got but there is a limited window of opportunity.

Second, how do we design communications to effectively bridge critical gaps? And there we take advantage both of descriptive research, finding out where people are on a particular issue and the basic research saying well how do you get across issues of uncertainty or of conflicting opinions?

And then finally, how do you evaluate how well we have done? And as we heard this morning, the evaluation has rather different faces in different tasks.

So, I will talk about four examples, examples from these four domains.

If I could presage one of my last slides, this is going to look complicated and expensive. And you all are clearly overworked and I'm pretty sure under- budgeted. But I think most of this is actually, once somebody has done the basic science to adapt it to new situations or to do a fundamental work in an area and then to adapt it to specific settings, it is much more attractive than it may look. Most of these problems were dissertations but usually with a new problem, it takes a dissertation then somebody can confirm it with a masters thesis. Then you have a couple of undergraduate honors thesis and then anybody could do it.

And first a case in medical informed consent. This particular example, this is an older paper. This is John Merz's dissertation, along with Dennis Mazur at the University of Oregon Health Center. And Paul Fischbeck was a risk analyst in our group. And so John was, John is a lawyer and a risk

analyst. He actually worked in nuclear power. And he was interested in how is it that you -- basically, he was interested in how physicians can protect themselves against malpractice by showing that they have given patients the appropriate information.

For his masters, he reviewed the case record and found it really doesn't tell you what to do. Just hope nothing big goes wrong. So he said, well maybe as an analytical question, we can figure out what are the most important things to do. He picked carotid endarterectomy, which is a very well understood surgery. A very well understood surgery for which there was a lot of information about the risks. That is the surgery that probably half the audience knows more about this than I do. But this is the carotid artery and if it is hardening of the arteries, you scrape it out. It can extend your life. But they have got something sharp in your neck and lots of things can go wrong.

The analytical approach that we took was to say, well, imagine you have patients who are candidates for this surgery and you told them about the different things that could go wrong. Which things were important enough, in the sense of severe enough and frequent enough, that their decision would flip? We did this with hypothetical patients. This was more of an analytical than a behavioral exercise.

So, here are some of the possible side effects. And if you believe our methodology, what we did is we said, you took a population of hypothetical patients and said imagine you said them what the probability of death was. In this population, again a hypothetical population, 15 percent of them, the benefit of doing the surgery now would be sufficiently low and hearing the risk of death would be enough for them to say that is not for me right now. The possibility of stroke would affect another five percent and then

facial paralysis. Well you could tell everything. You wouldn't want to hide any of these things, but there clearly were three things that were at the top. This is in the common term, the supply curve.

If you wanted to design a communication, then we would say, well, shouldn't we just assume that people have no valid prior knowledge? There is no reason for anybody -- they may have beliefs but there is no reason to trust. So you need to assume that they need to be told everything.

Second, you would want to focus your communications on the few most critical facts. And you could think of these risks, each risk has a probability and an event associated -- has an event and a probability associated with it. You have to tell people the probabilities of death, stroke, and facial paralysis. People probably know what -- well, they know what death is as well as you are going to tell them. Stroke many people in

this population would know because it has been on their mind. And maybe you would want to tell them about the facial paralysis. There would be four facts that you might want to get across.

And then critically, it turns out, in this situation, as in many, people keep going after the facts but the real uncertainties are in themselves what kind of decisions they want to make. And you would want to legitimate that kind of value uncertainty and help people to think that through. And we didn't do any evaluation at all.

So, we think we would know how to do it. We think this is practical but John was a risk analyst an a lawyer and didn't want to do the work. But that would be the process. You could imagine how you might empirically evaluate it but you want be very careful in dealing. You would probably do it with a non-clinical population than an actual

population.

Second kind of task. There are also some parallels that, well, actually this was something that was brought to our attention by somebody at FDA, although the work is neither endorsed nor sponsored by FDA. So, as many of you, I think at least some of you probably have suffered through or dealt with is a court-mandated warning label a court-mandated disclaimer for dietary supplements.

And one of the interesting cases that we looked at, this was Sarah Eggers' master thesis was looking at saw palmetto. So, the top shows a kind of claim that might be made, might be legal under the law for saw palmetto for a dietary supplement. This is where you are allowed to make structure and function claims. And the bottom is the court-mandated disclaimer. So, the question is, is this good enough. Does this make it possible to sell this, to make this dietary supplement

available?

So, our form of analysis here was we decided to determine how sensitive consumers decisions are to the kind of information that would be provided with or without this disclaimer with other kinds of information. What we did is, we drew a decision tree, which is the point of departure for many of these studies. And if you have ever seen a decision tree, this is just a decision tree. If you have never seen a decision tree, it is just on the left are the different things you could do.

So, if you were a male concerned with benign prostatic hyperplasia, you might take saw palmetto, you might seek your doctor's advice, or you might do nothing. This is one of the dietary supplements where the evidence is relatively good. And if you believe our analysis, the critical question is whether people self-medicate, rather than going to a physician for a condition that

should be treated. So the real risks here are the opportunity costs of self-treating, rather than not being treated.

Here we did collect, we thought about how to collect some evidence. So we took a typical label, we took the disclaimer, and then we designed what we thought might be an ideal label. We think that an ideal label for somebody for facing this class of decision, in fact many classes of decision, would be you want to give them both the risk and the benefit information. You want to provide the information in quantitative terms. There is very large literature, which some of you may have seen, showing that people vary all over the place in how they interpret verbal quantifiers like common side effect, rarely causes a problem.

We want to give some indication of the data quality so people know how much you know what you are talking about. And you want to present the alternative options so people

know, well that is the trade-offs here, but I would like to know the trade-offs with other things that I could do.

Our vehicle for doing this was the kind of drug box that Gil Welch, Lisa Schwartz, and Steve Woloshin, some of you may be familiar with, they gave us some help in designing that.

So, our evaluation process was pretty straight forward. We just asked potential users. Actually, for those who know Pittsburgh, Sarah interviewed men at Ritter's, which is the classic Pittsburgh diner. And went through human subjects. It was okay. But she showed them the different labels and asked them what they would do with it and gave them as much coffee as they wanted, which was perhaps the stimulant of choice for this particular product. And then, based on what they told her, try to predict whether they would make the decisions that seemed to be appropriate for them.

So, the nature of the data are, you can imagine, you know, you could imagine there are some people for whom saw palmetto is right and some people for whom it is wrong. I imagine you could do this discretely, it is a little murkier than that. Some people who should consume it, some people who shouldn't consume it. You could ask whether they would consume it or whether they wouldn't consume it, based on different kinds of information. And then you can get a pattern like that and then that creates a regulatory decision or you are saying, well, how much do I value having people in each of these different cells? It could be false negatives and false positives might be weighted differently in different situations. Getting a few true positives might be worth a bunch of -- it depends on the decision. That is a regulator's decision not ours. We can just characterize it scientifically.

But, trying to guess what the

regulatory decision might be in this situation, we concluded that this was a terrible warning label, that people understood less with the disclaimer than without it. Some people read the disclaimer and said oh, they wouldn't put a disclaimer if this stuff didn't really work. So they exaggerated the benefits. Some of them said, oh, of course, FDA doesn't believe in alternative medicine, so the warning means nothing. They are just trying to divert us into traditional. But they also told us that they didn't really believe in dietary supplements enough that they would take it for very long.

So, it doesn't have much risk. It hardly costs anything and they wouldn't have the opportunity cost of self-medicating. So, in this situation, lousy label probably good enough.

Third example. Emergency alert. I think the example is outside of your domain, but we have several examples here, if you are

trying to get after people with information. We were asked a few years ago by the, actually about ten years ago by the American Water Works Research Foundation, when there was press, remember, to produce consumer confidence reports, if you pay your own water bill, you get them annually, talking about contaminants in your water, and they wanted to design the perfect boil water notice. How do you tell people if they have got a crypto intrusion that they should be worrying about it.

We did some formative interviews and we found that people actually wanted to know why this was their problem. They wanted to know more than just how to boil water but whether they should take this seriously, because there is lots of people trying to cover themselves by presenting information.

So, what we did is we created, Liz Casman is a microbiologist in our group, created a computational model to determine the

sensitivity of choices about whether or not to boil water as a function of how soon they got them and how comprehensible they were.

Her model looks a little better on a Mac than on a PC but it is in risk analysis, if you are interested. Try to take into consideration the whole public health system. So, the uncertainties that come from is it detected. Does the message get through? Is it interpreted appropriately? We made a distinction between people who are on public water and are not. Somebody said in the last session, you could have spillover from people. It could be the municipal water supply and people who are on wells or think that it has to do with them.

And this is a complicated model but the stakes were high enough so we thought it was worthwhile running the numbers. This is MM -- it turns out some of these, people if you want to do the modeling, the risk modeling, sometimes you have got hard data.

So there had been an MMWR report on people's response to notices. Other places, all you have is expert judgment we know a trick or two, in the literature found a trick or two about how to elicit expert judgment for modeling purposes.

We thought that the conclusion that we came from doing interviews with people about this situation was that it was important to establish communicator's credibility as part of any communication so people know why they were being asked to do this and whether this was just somebody in covering themselves. And in order to have credibility, people wanted to know where this problem came from, as best you understood. With crypto, it turns out a set of suspects in a local water supply is relatively small. It is perhaps feedlots or perhaps a breakdown in an aging system, like our area.

Second, they needed to know that they couldn't test by themselves because this

is a very hard test to do but you can probably buy test kits. You could think that you are testing. You could be testing for something else. So we needed to see that they couldn't really protect themselves and then they needed to know how they could decontaminate their water.

And what we found and we interviewed deliberately in Pittsburgh area communities that had had crypto intrusions and found no local memory at all that this had happened. But we also interviewed people who were recruited to the Pittsburgh AIDS task force and found that people who were immunocompromised were generally quite knowledgeable about this. So generally speaking, nothing that they could do about this but they were generally quite knowledgeable.

Independently, we found that people were immunocompromised for other reasons are often like people on chemotherapy and so on,

are not routinely told about water borne contaminants but that was coincidental to this project.

So the evaluation that we did, we felt that we had good, based on the interviews and other work that had done, a lot of people in food safety and elsewhere, we had a pretty good estimate of how many people would boil their water in a way that made themselves safe if they got a message. And you could think of how well if you got the message to everybody and everybody boiled their water right, what difference would it make. And when we ran the numbers, to our surprise, it made no difference whatsoever.

That is, the best available information has no practical value, however clearly it is presented because of the system properties with cryptosporidium, which take a week to culture. And the test is quite specific but not that sensitive. And by that time, it is only really useful for forensic

purposes. You want to know why. If you haven't otherwise why people have gotten sick or perhaps have died, then the test.

So, we had a communication system that was set up that could not work. This was a problem in risk management, not a problem in risk communication. But thinking systematically about the communication provided leverage into figuring out what kind of information the system was producing.

So, if they wanted, an example for making the case, if you had to start with the communication needs as a matter of strategy. It could be that for E. coli, you can test it quickly, get the message out, you might be able to save people by testing. And particularly for the people who cannot protect themselves, like the people who are immunocompromised, if you have got a vulnerable water system, it suggests you need an engineering solution rather than a communication one. And this is some of our

modeling.

And the final example would be one of health communication. Once again, we have heard that is part of what you all do to put people in a position that they can take care of themselves, perhaps not need some of your regulated products, or to understand why those products might be necessary.

So, the example I have here is a project that we had done with sponsorship from the National Institutes of Allergies and Infectious Disease trying to improve young women's behavior in STI prevention and treatment. We ended up we had the resources to do a randomized controlled trial with a group of high-risk adolescents. I think 17 percent of them had Chlamydia on our initial testing. So those that work in this area, you can characterize the population by that.

And again, the process was to analyze. The analysis that we did here was to try to figure out what young women's intuitive

framing was of the decisions that could conceivably expose them to sexually transmitted infection. So we particularly looked at what are the options that they see available to them and what are the options that they care about? And so clearly, they care about not getting STIs but they also care about having relationships, having fun, maintaining trust with young men in their lives, and so on. And then using that to identify the critical facts. And it turned out that some of the critical facts were -- oh I meant, it should be missing options. I will cover that in just a second.

So we had, here is, we made a couple of different models. I will just, here is a decision tree relative to choice of contraceptive methods. And you could think about how those decisions affected them. And then we sort of do what we typically, what many people typically do, is to have interviews with people asking them about this

decision and gradually getting more and more explicit.

So from this we had the resources to make and test an intervention. So, first thing we realized is you needed to reduce the complexity of the topic. Young people in Southwestern Pennsylvania, but I think this is generally true, they actually know a lot about HIV/AIDS and they know almost nothing about any of the other STIs. And then it is just a blur of different diseases. If you think of the matrix of diseases with treatment, prevention, detection, it is more than -- so, how do you make this comprehensible to them?

Secondly, we found that a recurrent theme in many of these interviews, the kind of information that was missing was that they, young women, naturally, wanted to preserve, believed that they could trust young men. Young men would often assert to them that they were clean. And conceivably, both the young man, that the young man exaggerates his

ability to tell whether he is disease free or not, even though there are some things where men are legitimately asymptomatic when they are carriers, and other places where they are symptomatic but it takes a physician, a healthcare professional to tell it. So we actually, this is an X-rated DVD because we thought we couldn't get this across any other way other than showing diseased genitalia, to show that you couldn't really -- only a couple of pictures but enough to make it X-rated.

The third thing, we thought that, we did this with the head of Adolescent Medicine at Children's Hospital of Pittsburgh, Pam Murray, that one critical issue was that it is just difficult to talk about many of these issues for many people, both for healthcare providers and the other side. So, we ended up with a DVD that simulated conversations.

And then finally and maybe most importantly of all of these things from the

perspective of making decisions, it doesn't matter if you don't feel like you have got decisions to make. And as people found, as we found and as people have found in other places, an awful lot of sex at this age in particular is coerced in one way or another. So, helping young women to see and create choice options was part of our intervention.

So, oh, no. But let me tell you what you are missing. I guess this worked better on the PC. I have three screen shots here, I thought. One shows how we tried to organize the world of STIs into basically viruses, bacteria, and parasites, for which most people have some kind of a mental model and if you are interested in Chlamydia or whatever, you could use that as basic. And we sort of broke it down into detection -- prevention, detection, and treatment. So, if there was something on your mind, you could quickly find it. It is on a -- I would be happy to send it if anybody is interested. It

is on a DVD.

Second, we had a dramatized pelvic exam to show how both for physicians and for kids, to sort of, to show how to talk about these sensitive issues. And the third, about half of it was choose your own adventure. You could pick a young woman that you wanted to follow and you could, there was a young man, either a steady or a pickup who was trying to get her to go as far as possible and you could stop it and say, like, "Mark would like you to go upstairs." Imagine you didn't want to go upstairs, what could you do? And this cognitive rehearsal. It is not from our literature but it is a field term, technique that is know what to do. And then had an actress demonstrating different ways of stopping it.

So, our evaluation here sort of compared to a print version of these materials and commercially available leaflets matched for topics, this DVD but the greater reported

condom use, less reported condom failure, less Chlamydia we did the test for, and less reported sex. This may actually be the only program that has reduced. You know, despite being sometimes very accepting, we think that it reduced the coerced sex. So you know, not everybody would want this, but in some sense the tone was, you know, this will help you to get the sex that you want. If you don't want any, then this will help you to reduce the pressure, and if you want, only under certain conditions. Okay, not everybody would want this but this was what the science was here.

So finally, so these are bigger projects, the last one was a really big project, the others were, you know, basically done by underpaid graduate students or people that -- anyways, underpaid graduate students. But it is not that hard or expensive to do. So first of all, there are many examples in the literature you could say, yes, mine, yes, the crypto one, that is kind of like mine.

Here is a set of things that we have done. Most of these have published papers, if you are interested in one of these topics or something that you think has the same properties, you know, I could be happy to talk to you. I think actually the analytical part tends to be the hardest and then once you see the analysis it is kind of straight forward.

Second, that the basic kind of analysis, even if nobody has done something like this, is not particularly -- anybody can draw a decision tree. Anybody can sketch out an influence diagram like we had in the model and the cryptosprodium, the discipline, it is mostly discipline common sense. Running numbers, doing computations, that takes special training. But actually sketching somebody's decision tree, having them check your work, not particularly hard.

Third, many of the design principals, in order to make this work, can be found in the basic research in the next talk,

Ellen Peters' talk, which will be next, will give you a bunch a those. And then finally, the FDA has individuals with a requisite expertise in order to do these things. And I think, you know, I think it makes an enormous difference in terms of institutional change having even a few people on staff who have this kind of expertise because you say, gee, I need behavioral sciences. You really don't know what you look for. You put out the word on the street that you are looking for behavioral sciences and lots of people will hang out a shingle asking whether it is spelled with or without a U or will claim to do the work. But having people internally and fortunately we do have some excellent behavioral scientists and so on, you know, enables you to build up a program, gives you what the economists call absorptive capacity to build up a program. And I think that FDA is really poised to do some really important work here. Thank you.

And maybe we should have thE two talks and then we can sort of like have questions, rather than structure -- let's do that. Okay? We are making our audience sit a lot. Well, I guess this part of the audience mostly has to sit but this part of the audience. Let me just say I believe that that part of the audience can asked to be recognized. Right?

DR. ZWANZIGER: Normally we don't do a lot of that.

CHAIR FISCHHOFF: In the open public hearing.

DR. ZWANZIGER: Yes. Maybe you could say if people want to speak at the open public hearing.

CHAIR FISCHHOFF: Okay. So, if you would like to speak in the open public hearing, please come to Lee. And then please come and talk to us on the break so maybe we can just work your topics into our questions.

DR. PETERS: Good morning. Is this

close enough so everybody can hear me? Better? Okay, good. Thank you.

So my name is Ellen Peters and I am going to take a slightly different tact in my talk today compared to what Dr. Fischhoff was doing. What I would like to do is I would like to talk to you about anticipating some of the barriers that exist to effective communication. And I am focusing in part, and in fact about half of my talk, will talk about some of the barriers to effective communication. Because by knowing those barriers, we can understand better how to motivate ourselves to work through them. And we can understand better how we might begin to start, how we might start to address those barriers, in order to make communications more effective.

So, I will talk briefly today about what is needed to make a good decision. And then I will start to address six barriers or six potential barriers, I guess to effective

communication of the kinds of critical information that the FDA needs to communicate. And then I will talk a little bit towards the end about some ways that we can begin to address those barriers.

First of all, to make decisions, you have to have information, of course. It has to be available. It has to be accurate and it has to be given on a timely basis. You also have to be able to understand that information, though. This is one of the basic building blocks of good decision making. In informed choice, you have to have the informed part. And so I am going to focus quite a bit on comprehension in the talk I will give today.

You have to be able to not only understand the information but you have to be able to understand its meaning as well. You have to be able to determine meaningful difference between options, if multiple options exist, of course. And you have to be

able to weight different factors in order to match your own needs and values. And that of course, by the way, means that you have to know what your own needs and values are. You have to be able to make tradeoffs. The FDA is often faced with patients and consumers needing to make tradeoffs between risks and benefits. And I will focus on that a little bit today, too.

Ultimately, the person has to choose. The person has to choose multiple options or has to choose to take a medication or not take a medication, to look at the food in their refrigerator and decide if it is part of a lot that is contaminated or choose not to do so.

So, I am going to talk today about six potential barriers. I am going to go through each of them in turn and I will highlight them with a red type as I go through each one.

There are a number of potential

barriers. The first of course is just the idea of the information that is available. It can be insufficient, like not knowing the source of a food contaminant. The information can be uncertain and it can often change. And these are barriers to effective communication. The second barrier that I am going to spend a little more time on is the idea that communicators in general, and this is not just the FDA, communicators, in general, overestimate what others know.

So, studies have shown that communicators overestimate what others know. And this is important because we tend to adapt what is said in order to communicate more effectively. And the better we adapt to what other people know, the more effective we are as communicators. To be able to do this, though, you need to have a model of what other people know. And for the FDA in particular, what they often need to have is a model of what most people know because they are

communicating about a wide variety of issues to a very diverse population of people.

Research by Raymond Nickerson and others suggest that the default model, the model that people use about what other people know, that the default model is ourselves. We use ourselves and what we know as an initial anchor to decide what other people know. And that generally works pretty well because people are often quite similar.

The problem that comes up though, is that then we have to adjust. We have to adjust for what the other person actually knows. And we tend to insufficiently adjust for what other people know, particularly, other people who lack the same specialized knowledge that we ourselves have.

When information is familiar, in particular, and people who are working at the FDA, for example, are quite familiar with some of the information about the various devices and the various medications that are out

there. And when information is quite familiar, it seems much simpler and it seems much more straight forward than that same information seems to somebody who is seeing it for the first time or is seeing it for the first time in a long time, maybe. And what ends up happening is this cursive knowledge, in a sense, leads us to over estimate what other people know. And that can end up being a barrier to good effective communication.

The third barrier I wanted to talk about is simply a lack of comprehension of information that you provide to other people. And I wanted to show you an example from our own work here. What we did, this was actually work that was being done for the Centers for Medicaid and Medicare Services, CMS. What we did is we devised a comprehension index that reflects the number of errors that were made on 33 decision tasks and these are 33 very simple decision tasks. I will show you an example. And it simply involves

interpretation of numbers from tables and graphs. We had two study samples. We had an elderly sample who ranged in age from 65 to I think 98 and we had an employed age sample who ranged in age from 18 to 64 because we were interested in how well people would be able to perform on these decision tasks across the life span.

This is an example of one of the decision tasks that we gave people. As you can see, it is a really simple decision task. We tell them, we actually gave them this table. There are four different health plans and we give them two pieces of information on each of the four health plans. And we simply ask, which health plan requires the lowest co-payment for a visit with a primary care doctor. Now, I know the answer, but I also have seen this slide a million times. I'm betting you know the answer but I will highlight it for you, just in case you don't. But the issue is that across the life span,

and you can see age on the X axis down at the bottom here, on the Y axis are the proportion of errors in each of those age groups, just on that one simple question. And what you can see is that the number -- that errors exist and the number of errors increase with age. And in fact, if you look across all 33 decision tasks, this is the average proportion of errors across the 33 tasks within each of the age groups that are shown. And what you can see are large problems with comprehension and large age differences in addition to that. People who are over 65 make many more errors on even these very simple decision tasks compared to people who are younger.

Oh, I'm sorry. And the correlation, by the way, between age and the number of errors made across 33 tasks was a 0.31, for those of you are interested.

The fourth barrier that I wanted to talk about is the idea that communicators also overestimate how effectively they do

communicate. It turns out that we are not really attuned to difference in the different perspectives that people have.

So, communicators tend to speak from their own perspective. We tend to communicate from our own knowledge base, from our own experiences. Remember the cursive knowledge that I talked about a moment ago, briefly. But listeners, as a listener, I also interpret from my own perspective again. And as communicators we are sensitive to these difference in perspective, we know that they exist and we do adjust for it, but not as much as we could.

I wanted to show you just a simple example that comes from a study by Boaz Keysar. I hope I am saying his name correctly. What he did is he gave subjects a simple sentence. The sentence was "Angela killed the man with the gun." And he told them that he had two different meanings. And then he said, okay, I am going to pick out

this one meaning for you and I would like you to speak it to the person across from you, this is just a third party, so that they can understand exactly which of the two meanings you are tending to communicate.

Well, the two meanings of course of this sentence are the man holding the gun is the one that Angela killed. That is one of the meanings. But the other meaning is she killed the man with the gun that she, herself was holding. So we have got two meanings here. A really simple sentence. It is really clear that there are two, people are told, very clearly, there are two meaning here. When the speakers were asked to be clear and when the speakers really truly believed, according to their reports that they had communicated correctly, 50 percent of the time they were not understood with that very simple sentence.

Similar findings are found with tapping a song. If you try to tap a song for

someone and they are supposed to guess it, it is very difficult for the listener to hear it because they don't share that same internal symphony of sounds that the speaker hears as they are tapping a song. Similarly in email, we think we can convey as well over email as we do in person and we don't.

Let's see, let's go on to another -- so basically, one of the ideas that comes out of this study is the idea that using intuition to clarify communication, using your intuition to figure out how to use intonation and tone in order to clarify communication isn't always enough. And in fact that brings us to another potential barrier to effective communications because intuitions about how to best provide information don't always lead to comprehension of that information.

And I would like to share with you an example that we have from a study in our own group that just came out last year. What we did, we were trying to help consumers to

understand a fairly new health insurance plan. It is a consumer directed health plan for those of you who know, with a high deductible. And it was a new product that consumers were not very accustomed to hearing. And what we wanted to do is we wanted to try to help them better understand what is different about this new kind of plan compared to other more traditional plans. And so we thought, okay, what if we were to provide them a framework. Let's provide them with a framework of kind of the overall gist of the differences, and then we will provide them with the detailed information afterwards. That should help them to understand. And this is what we thought.

And so what we did, for half of our consumers we gave them this overall framework and then we provided them the detailed information. For the second half of the consumers, we provided them just with the detailed information. And so we evaluated our message. We wanted to know, does the

framework really help or not?

And it turned out that we were partially correct. We help people like us. What happened was, highly numerate, people who are good with numbers, highly numerate consumers who are very good with numbers were helped by the framework. When we provided them with the framework, they better understood that detailed information that followed, regardless of what the detail was that followed. So the framework helped people like us. We used our own perspective and we helped people like us.

The framework also somewhat helped consumers who were less numerate. It helped them to better understand information that was related to the framework because half of our questions were related to the framework and half of our questions were unrelated to the framework. What happened though, providing the framework actually hurt their comprehension of other information. And so

what that said to us was one, you can't always count on your intuition. And two, if you are going to use a framework because sometimes it is quite helpful and you know that some of your consumers are going to be less skilled with numbers in particular, in this case, then you might want to make sure that any important information that you are providing shows up in that framework. So, that is an important thing for us to know because we didn't know that that was going to happen.

So, why don't we just ask the people receiving the information about what they prefer? How do you prefer to get information? Will that help? Can they use their own intuitions in order to help us figure out what to give to them? The problem is, of course, if this doesn't work either, studies have shown that preferences don't necessarily lead to comprehension and use of that information. Messages need to be tested.

The final barrier, though, that I

want to mention has to do with perceptions, risks, and benefits. We want consumers and patients to be able to trade off the risks and the benefits of pharmaceuticals and other products. The problem is, though, is that perceptions of those risks and benefits may be linked together. And let me show you what I mean.

In the real world, as well as in this slide, risks and benefits are positively correlated. For example, a medication with serious side effects, something that was highly risky, would have to have very high benefits simply to stay on the market or it just wouldn't exist. You are not going to get things in that upper left-hand quadrant that are high in risk and low in benefit. The market is going to push them out. People aren't going to purchase that product. However, in people's minds, they are actually negatively correlated. Perceptions of risks and benefits are inversely related. Things

that are perceived as high in benefit tend to be perceived as low in risk. Things that are perceived as highly risky, tend at the same time to be perceived as low in benefit. And the strength of that inverse or that negative relationship between risk and benefit judgments for a hazard or for a consumer good, depends on its affect, it depends on how good or bad it feels. Things that feel good to us tend to be perceived as high in benefit and low in risk. Things that feel bad to us tend to be perceived as high in risk and low in benefit.

An example of this is in chemical sources. Medical sources of exposure to chemicals like prescription drugs tend to be perceived as good overall. People feel good about prescription drugs overall. Whereas, non-medical sources, like pesticides, tend to be perceived as bad. Both are chemical but the medical sources of exposure have much more favorable benefit risk reading than do the

non-medical sources.

This inverse relationship between risk and benefit perceptions can be explained by the affect heuristic. This is a model that has been developed within the group at Decision Research. And research in our group a well as others, suggest that we use our feelings or our affect as information to guide perceptions of information and, ultimately to guide decisions in some cases. The affect heuristic predicts and explains how good and bad feelings about nuclear waste repositories or prescription drugs are associated with perceptions of its risks and its benefits. It predicts that we look to our feelings, we look to our affect as information to judge how risky and how beneficial something is.

Tests of the affect heuristic have demonstrated that when decision-makers are under time pressure and they have little time to deliberate carefully, affect and the affect heuristic play a larger role. And that

inverse relationship between perceived risk and perceived benefit grows. In other words, time pressure strengthens reliance on the affect heuristic.

The FDA and others sometimes choose to provide only risk information in a particular communication or to provide only benefit information in a particular communication. And the affect heuristic has something to say about this as well. What is also predicted by the model is that you can provide information to change an overall impression. So, for example, you can provide information only about the risks of a pharmaceutical drug that says the risks are high, for example. And because just that information is high, that alters the affect that is felt towards that drug, for example, increases negative affect in this case. And an inference is made that the drug is less beneficial. So there is this inverse relationship between risk perceptions and

benefit perceptions.

So, how can we disclose information so that people can understand it and so that people can use it? Because that is what we want to do. We want to effectively communicate. We can certainly do better than the nutrition facts disclosed by this guy selling fried stuff on a stick. For those of you who can't see it, the nutrition facts are it won't kill you, not right now anyway. We can do better. The FDA already does much, much, much better.

So, how can we address these? One of the things we can do is we can provide both risk and benefit information. We have been talking about this in previous meetings. We have been talking about this earlier today. If you provide both risk and benefit information in communications, what happens is is that if the public draws an inference about benefits when provided only risks, by providing both of them together, you can

actually better ensure that the tradeoff is going to be evaluated between risks and benefits. It also suggests, by the way, in evaluations of your communications, you may want to measure both risk perception and benefit perception, even though you are only providing one side of the coin.

What about providing it in numeric ways or nonnumeric ways? People tend to trust risk information more when provided numeric information. Providing numeric risk information, reduced fear of adverse events in one study. Providing numeric benefit information also reduced perceived benefit, by the way, in another study.

There is one issue with the studies that have been done on this so far, though and there have been a variety of studies. Most of them are hypothetical. Some of them have been done with quite non-representative populations like Stanford students, little non-representative. The issue is that not

everybody understands and uses numbers very well. And in addition to that, not every format of number communicates equally well to different people. These are empirical issues that need to be tested. And in fact, it needs more study in the context of pharmaceuticals to understand how to communicate these important sources of numeric information best.

Another thing you can do is make the information that you provide more usable. It turns out that how information is presented may matter as much as what information is presented. So, it is very important to get the information right, to get it accurate, to get it timely. But in addition to that, you also have to pay attention to how it is communicated, if you expect it to be understood and if you expect it to be used.

And so one thing that we have shown, one thing that we studied is the idea of less is more. And this is something that the FDA is aware of and it shows up, in fact,

in some other documentation. But I want to show you a specific example of it so that you can actually see it and see that it makes a difference when we did an evaluation of it. And the example that I will show you is showing only the most important information.

So in this study, we are actually studying people's ability to understand and use hospital quality information when choosing a hospital. Subjects were given information about three hospitals. They were given cost information, quality and other non-quality information. And we put subject in one of two conditions so that they saw all of the information in an unordered fashion or the other half of the subjects saw just he cost and quality information and the quality information was highlighted. I will show you what I mean.

So this is the condition for the half of the subjects who got all of the information and it was unordered. It actually

is quite similar to what is often presented on hospital quality websites. And in fact, I stole this basic format from a website in Minnesota that was presenting hospital quality information. And what you can see is that people get out of pocket costs. They get non-quality information like the number of general care beds. Jumping down a little bit, they get quality information like the percent of times that guidelines are followed. And then on that same page as this table of information, they answer question such as which hospital followed guidelines for heart attack care most often.

The other half of the subjects, we take out the non-quality information and we presented them only with the information that we considered most relevant, the cost information and the quality information because we were trying to help them to better understand the quality information. And we also, and then we asked them the same exact

questions that we asked the other group of subjects. Are hypotheses were that including less information would help comprehension. And in addition to that, that it would particularly true for more vulnerable populations, like people who are lower in number ability.

In terms of the evaluation itself, the dependent variable that I am going to show you is comprehension. We asked them three comprehension questions and then simply counted how many each person got correct. What I am showing you here on the Y axis is the average number of questions that subjects scored correctly. The less numerate people are on the left. The more numerate people are on the right. And what you can see in the red bars is that people who are given cost and quality information only. So they were given less information and actually understood more. It was true whether they were less numerate or whether they were more numerate. But it

particularly helped people who were less able, who had less skill with numbers.

So how information is presented may matter as much as what information is presented. These choices are judgments but these choices are quite important and they deserve study within the context of a particular communication.

So, in some of the studies that we have done, showing only the most important information helps comprehension. It also helps people to weight quality of care more in the particular choices we were looking at. Making key points easier to evaluate helps comprehension, if you can help people by ordering information, summarizing information, interpreting that information for them. In general, if you can require less cognitive effort from the person you are communicating with and require fewer inferences from them, they are ultimately going to understand more of the key messages that you are trying to

communicate to them.

We need to test information formats. This is the third addressing the barriers that I wanted to discuss. We need to test information formats. The intuition of information providers isn't enough. Sometimes we choose based on our own abilities and our own perspectives and we hurt people who are coming from a different perspective. Consumer preferences also are not enough, as what is preferred is not always what is understood best and what is used best.

In conclusion, who information is presented influences how well it is understood and it seems to be particularly true for people who are from more vulnerable population, people who are less numerate, people who are less literate. Careful choices of communications and how those communications are presented may promote wellness and ultimately may reduce some of the health disparities in our country.

Risk and benefit information should be communicated and probably in a numeric format, although I would suggest that more studies need to be done in order to evaluate across people who differ in age and across people who differ in numeric abilities, what formats for presenting numeric information will lead to the best comprehension.

In general, communications should be tested. The FDA has done a remarkable job communicating a vast array of information across a wide variety of populations but they need more resources in order to be able to do this better. The science of communication exists. The FDA is aware of this. The FDA uses the science of communication and they have some tremendous expertise within their group. At the same time, they should be using it more. And they should be in fact, developing that science. They should be a partner in developing some of the science of communication.

Thank you very much.

CHAIR FISCHHOFF: Socially defined, dynamically defined social norm of clapping. So, we have got jargon for everything. Thanks, Ellen.

Let's open up the conversation. We have about 20 minutes now an the conversation should be between and within the two tables. So let me invite people from there as well as people from here to offer comments.

Well, while you are warming up, -- go ahead, Mike. I think the last point, while Ellen was talking it occurred to me and I think it is about how this partnership goes. And I think it is probably unreasonable to expect FDA at any point to be a sponsor of basic research. And I think much of what we have been thinking about is just how to make what is out there more accessible to you, so you know about its existence, it is in ready form.

But I think that, thinking about

some of the challenges that you all particularly presented this morning, there are issues that you are aware of that are on your plate where I think that the research, the literature is probably pretty thin. And there ought to be some way to get us to work more on it. And I don't know whether that is just to put it out and for us to translate it into terms that our colleagues will understand or to talk to NSF or NIH about having, you know, about sponsoring research that particularly interests you. So this question of uncertainty or what is the quality of the information. I can think of things that are kind of relevant but I think we don't have as much to offer you as we might. So I put it out sort of, you know, both for us and for you to think about ways that we might get some of that basic science that you need most generally.

One of my colleagues, Alan Baddeley used to run the Medical Research Counsel's

Applied Psychology. And he made a distinction. He described what he called, he said that he thought that it was essential for the health of any science, and maybe in any society to have both basic applied psychology and applied basic psychology, where the applied basic psychology was taking things that we think that we know and seeing how well they work in the world. Do we even have predictions and what auxiliary assumptions we need to make it work. But conversely to see things that are going on in the world that we can then domesticate for systematic. So, I think we would be better off in learning from you, you know, as well as we hope that you will be better off in learning from us.

Mike.

DR. GOLDSTEIN: I just have a couple of general comments to make that are going on inside my head. So, I apologize in advance if they don't come out quite the way that I expect them to because I am not sure

how they are going to come out.

What I was hearing in these last few presentations, which really got me thinking was that it is really, really important not to make assumptions about the communication that we are trying to influence. And this whole notion that there is non-persuasive and persuasive communication to me seems like false dichotomy. Because, in fact, those last few presentations was all about trying to understand the meaning and the relevance of the communication to the audience that it is intended for. And if that is not an attempt to be persuasive, then it gives me trouble as a concept.

And the other point that is related to that is that both those presentations, both of your presentations underline the importance of seeking to understand the pre-existing notions, ideas, beliefs, preferences of the audiences that we are trying to reach. So, to answer some of the questions that were raised

earlier about how do we deal with uncertainty, Dr. Neuhauser said before that we have to embrace uncertainty, we have to understand uncertainty, too, from the point of view of the audience that we are trying to reach. What is their need for information? What is their comfort with knowing and not knowing? And that will help us to craft the messages, I think, that will address those needs. First, we have to understand the needs and we can't just divide information into facts and not facts. We first have to know the meaning in the audience that we are trying to reach, in order to reach them effectively. And that means we have to tailor our messages based on the audiences that we are trying to reach.

So, I will have more to say later. That is just a general comment about how we are asking questions about communication.

CHAIR FISCHHOFF: I have Betsy, Christine, Marielos, and Mona.

You yield your time. Christine.

DR. BRUHN: Thank you very much. Thank you. I have, you know, I think we all enjoyed the presentations and benefited from them and learned from them. I have a couple of comments.

First of all, actually in regards to the question of who should be doing the research or who does the research that relates to understanding and communication. I contend that it is fine if FDA has some small projects that they want to do and they want to handle in-house but I was appalled by all the restraints that you have on research that you are involved in. It looks like it would take one to two years to get through all of your IRB and other regulatory groups that have to approve what you do. I strongly urge that you keep in mind, keep open the opportunity to ask general questions and allow the academic and other community to respond to research calls to address these questions.

One of the projects that I am going

to be reporting on this afternoon is actually an FDA funded research project and I think we did a great job with it. So, I am looking forward to showing how we were able to collaborate together to show the actualization of some of the theory of communication.

And if I am thinking now of the forthcoming project that you have got on allergy labels and how people respond to some of the comments, and you have called for comments. That is good. That is appropriate. But wouldn't it be wonderful if there was someone who had done research with allergic patients on how they interpret and respond to the new allergy information so you are not hearing from anecdotal two, three, five, ten or fifteen folks, but you have a base of a large number of individuals.

And how are we going to get monies to do that, if not having a research call that academics or others are responding to or perhaps a group like FAAN, the Food Allergy

and Anaphylaxis Network, might have had a response from their members. But open the doors so that others can provide information to comment on effectiveness.

And in regards to the impact of some of the messages, Marjorie, I agree that the seafood advisory for pregnant women has been effective in that women who are pregnant or in child bearing age are limiting the amount of seafood that they are consuming, fish and seafood. But there is, as you mentioned, there is controversy in this. There is also the question of it appears as though they have limited it so much that they are now not going to have for their children the benefits that eating from this food group provides. There is very clear information that for infants as well as through children, and I believe it has been tested through nine years, those who had seafood in their diet have higher cognitive abilities.

And it appears that with the group

of pregnant women, when you say benefits and you say risk, and indeed in the FDA's communication benefits are listed first and then risks, and very reasonable and quite specific guidelines on how much people should be eating or rather how much, what their limit should be, the response has been, if I am pregnant and I hear risk, I am not eating it. And that has been shown by focus groups in a study that is in press, as well as by national surveys.

So, risk and benefit might seem balanced to us who are writing. But again, there is benefit of going to that target group because they don't see balance. They see risk big and benefit little and they are going to be protective.

Thank you.

CHAIR FISCHHOFF:Marielos and Mona.

MS. VEGA: This question is for anyone on the panel, the panel who spoke earlier. What is the reason why there is so

many difficulties to do evaluation at the Centers' level? Is it because of the logistics or because there is lack of funding?

And I also want to reemphasize something that Linda said earlier and is the need to have a unified voice. It is, as I was listening from all of the Centers, I mean, they seem to have a lot of similar challenges in terms of communicating with the public what is the best ways to do it.

It kind of remind me about the issues we are having with colorectal cancer screening, then there are so many tests offered for colorectal cancer screening, that there is a difficulty for patients to make an informed decision.

So, like for example mammography that is only one test and so it is easier for consumers to make decisions. I think there should be a unified voice to speak on behalf of all of the Centers. As a consumer and I feel like I am educated in terms of navigating

the web and it is difficult to go into a website. And I suppose each Center has their own website. It is cumbersome to search for that information.

So, when it comes to emergency communication, I think it will be very beneficial to have a unified voice. Also, I think it is important for institutions like the FDA to work with state governments and with organizations in each state that know how to communicate with their communities. We cannot expect the FDA to be able to get the message across to every individual in this country.

But I think that working with government, I was happy to see one of the Centers working with Rutgers University. I