I want to show you a picture of one of the groups, participatory design groups with whom I have been involved. These older men, and you can see that actually they are in a group of about ten people. They are sitting in a room. They are looking at a draft section of a guide on how to navigate your Medicaid system. Everything from how to get prescription information, to how to deal with problems that you might have in, you might counter in the healthcare system. And these men were part of hundreds of people that I worked with to design a guide that is intended to go out to several million people in California.

And I don't know how much you can see out of this picture but these men were involved in doing everything from selecting photographs, to looking at the small stories put under there, to looking at the tone of what is written there so it wouldn't be -- it would be considered welcoming and not

condescending, to look at the length of things to do, and make sure that list was not too long, that these things were actually feasible things that real people could do, and so forth, the placement of small chunks of information and the amount of white space around them. Every aspect of that, they were involved with doing.

This picture here shows usability testing for doing a website. I will not go into the details of this but in the references that I have to this presentation, there are lists of recommended usability guidelines for websites from the Department of Health and Human Services. And so this kind of usability testing, which is one-on-one, involves getting people to sit with the examiner in this case and look at a website, a draft of a website. And then, especially people who are in the lower literate group, can you understand that? Can you move around here? Can you find what you are looking for? Are the lists right?

So, any aspect of navigating a site or understanding a site. And then when anything is a barrier, that is marked down and revised and the whole process continues another time until it is completed.

So, I am going to enter with three recommendations for things I think that the FDA should consider to do to improve risk communication.

The first would be something that we have already talked about. And that is to assess what is already going on here, to look at the kinds of communication. And we saw that there are so many kinds of mass communication, the list is so long, I have to keep looking at it every time to try to remember which public health notification or advisory and MedWatch and so forth.

So, there are many kinds of communication. And I think the whole process of analyzing how people respond to this communication, in terms does it help them

improve their knowledge, attitudes, confidence, their behaviors, etcetera, for these diverse kinds of groups that we are talking about.

The second one, we talked a little bit about this morning and Deputy Commissioner Torti also alluded to this and that is the need to build capacity within the FDA around communication. This is a big job, so we have various comments here. And I will just go through a few things here.

Internal expertise. There is internal expertise in the FDA and we have had the privilege of listening over the last few months to a number of people who have communication skills. But that needs to be surveyed and identified and then brought to the fore and those people could serve as expert consultants within the FDA. As we have heard, staff will be added. We talked about the need for an FDA humanized and publicized and, perhaps, trained spokesperson.

The third one I would like to emphasize here. I think there is a need to do a strategic planning meeting. That would be different than having a committee like this convene, having all of you come, but actually, an intentional strategic planning process, which might take perhaps six months or a year to figure out exactly what is in the Agency's -- what the Agency's goals are and how it is going to accomplish this, all of the resources needed, all of the resources available, etcetera, and how to fill those gaps.

Forming partnerships we have heard about. Certainly there are a lot of possibilities within the CDC, NIH, DHHS, Office of Homeland Security, all kinds of places could be supportive to the FDA in its work.

And then, seek federal funding. We did see a lot of smiles this morning when people were being asked about the resources available.

The next recommendation is to improve communication. And one of the things I think can be done is to set some standards. I would suggest a sixth grade level for anything textual or on the web be a good goal. Sixth to seventh grade to meet the needs of the average person in this country.

To meet the Department of Health and Human Services usability guidelines, there are about 16 guidelines, I would add another four for usability for lower literate people, and then set some standards for linguistic and cultural relevance. There are a lot of standards already for accessibility for people with disabilities. Section 508 of the Workforce Reinvestment Act, etcetera, those things I would assume the website is probably already being designed with those.

I was very happy to hear that Dr. Sanjay Koyani is heading that process. Not any more? Well, he started the process. Oh, well. More communicators there. Anyway, he

was one of the authors of the Department of Health and Human Services usability guidelines.

And finally, in case you didn't get the message before, design and test with diverse groups.

So, I thank you very much for your attention. There is a number of references. And anybody who is interested in having a copy of this can get it off the website, I guess. Thank you.

CHAIR FISCHHOFF: So thanks very much. We have had talks and if they will, I would like to invite the FDA panelists from this morning to join us again. And we have, really actually have the rest of the afternoon for open discussion. So, I am taking names.

Well, as bashful as usual. Okay. AnnaMaria. Wait until they sit down and then we will get started.

MS. DESALVA: Thank you. I just wanted to ask a quick follow-up question to

the discussion that was held earlier on the subject of device recalls. And I, of course, well remember as everyone else did, I am sure, the discussion we had on the same subject in February. And I am just wondering that stands and if anyone from the Agency can maybe clarify what may or may not be under consideration in terms of supporting that particular change in referring to recalls specifically and renaming recalls, as appropriate.

MS. RICE: Well I do know that there is a group in our Office of Regulatory Affairs that have been working for a couple of years on looking at verbiage, terminology, format for recalls but I don't know, I don't have any particular details of what is going on lately regarding that. I can tell you that the Center for Devices and Radiological Health did do focus testing on the term recall for medical devices. We had about six sessions in different locations with different types of

individuals with medical devices ranging from walkers, you know, non-life sustaining life supporting all the way to implants and we did put out a number of different terms. And the word recall did not seem to alarm them to a great degree when they indicated they were getting the information from a trusted source.

What we did see and again, I don't have the report with me, that some of the other terminology, such as safety advisory and safety alerts to them did not get their attention as much. And again, as I indicated we do very limited numbers. And so six groups of about 15 people is not a lot of people and it was done locally. So, you are getting people out of the Washington, D.C., Baltimore area. So we do get different -- we get this area perspective, which I don't believe is the national perspective that we need to get.

That information is all with Office of Regulatory Affairs and part of this process. So Nancy, I don't know if you know

any more about it.

DR. OSTROVE: I think I can add a little bit more detail. You probably also recall that in addition to the focus group research that was mentioned at the meeting back in February that Mike Wogalter talked about the work that he and Jennifer Cowley did, which was not with local, I mean, which was done down in North Carolina where they specifically asked about, you know, use of the term recall with regard to implanted devices.

My recollection is, and I don't have it in front of me, is that there seemed to be a fair amount of consumer preference for using a term other than recall, in that particular situation. We are currently in the process of preparing like samples of the template that ORA has put together for testing, for kind of an internal testing process. And I think that is one of the questions. I think we need to have a sample, basically, that uses the new template that we

have presented to you and which we have revised somewhat based on the feedback that we got from the committee. And I think we probably need to have an example that specifically deals with an implantable device and ask that question specifically because I think that is really --

But here is the problem. I mean, we are using, for a number of reasons, we are using kind of an internal group, but I think we can probably get a reasonable number of people who really don't have, who -- well, the trouble is is finding the right audience. I don't know how many people at FDA have implanted devices. And obviously, that would be the most appropriate audience to use.

So, it is a question that still remains. It is still out there and I think that it is something that, you know, we are going to have to hit head-on fairly soon. But I just can't give any more feedback than that right now because we are still in limbo.

MS. DESALVA: Thank you for that. That is really helpful. And just to quickly close off on that, who have been involved in communication around actual corrections or withdrawals of products of implantable devices, the burden of communication, as you know, is just incredible because of the potential for misunderstanding and anxiety, the fear. And I will talk about that a little bit tomorrow. But it just seems that that would be just an enormous step forward if, as a result of the work of this committee, or some of the discussions that have been held here, that that could be addressed simply from a terminology standpoint.

CHAIR FISCHHOFF: John has a comment.

DR. PALING: I was just going to suggest that as a default, it would seem preeminently logical to always make communications to the public with the understanding those words -- with the

understanding that the public will take those words to mean what they mean to the public in general.

In other words, the default thing should be we shouldn't be trying to find whether this is a good way or not but we are going to let's make the default because we don't have time and money to do all of this and then, I think, try and attack a series of things. Like, safe and defective we will come onto later and try and find alternatives that really do communication as best we can see in simple words that mean what the public in general expect them to mean.

DR. OSTROVE: Well, can I? I mean that is a very good point. But I think what the question is is do we even know what the public -- you know, we can take words out of a dictionary and say this is how people generally think about them but that is not necessarily the case. So, you know, you run into that problem where there may not be data

that specifically look at how people use the term or, in fact, there may be, you know, you could postulate that in certain circumstances people understand this term differently.

As in the case where Lynn was talking about, where people get the term recall in a context from a trusted healthcare provider, it has a different meaning, in some ways, to them. So, without kind of looking at that empirically, I mean, I am the biggest fan possible of empirical investigation, you really need to work at it. Because I think that you will find, if you talk to people at FDA, you will have one group of people who will say, and they are experts, people understand what a recall means and they understand that when it is an implanted device that it doesn't mean it should be taken out. And you will have another group of people who will say exactly the opposite. And then the question is well, what is actually the case.

So, it is not clear what the

default would be in some of these circumstances, although the point, the general point I think is a really good one.

DR. GOLDSTEIN: To take off on that theme but to get back to what Dr. Neuhauser and Dr. Bruhn said, the important step of assessing the needs of the population can't be overstated. And we know that there are certain populations that are more vulnerable, they are more vulnerable because of their illiteracy, they are socioeconomically vulnerable. But then there are those discreet populations of patients with conditions that are using either pharmaceutical therapies, devices, where we know there is not only a professional organization that may be able to link to them but also there are advocacy organizations. And the importance of assessment and then utilizing the constituencies, the stakeholders, the partnerships with the professional organizations, the advocacy organizations,

within those targeted populations specifically when there is a known risk or a category of risk. That would allow you to target your efforts in developing these messages. And it would start with some assessment but it would also be important in designing a system that includes them to get feedback about the channels for communication.

So, it is not just about knowing what the message is. It is about knowing what the channels should be. And also knowing how to evaluate the impact of the messages. It actually is relevant at all three levels, assessment, design and evaluation.

So, to answer those questions that came up from each member of the panel earlier, there is always going to be some uncertainty. But especially when there is a lot of uncertainty, the strategy is to involve the specific target audiences as much as possible in the assessment, design, and evaluation of messages to that group. And that means

utilizing groups like the one we heard earlier about, the Heart Rhythm Society. I can't think of an audience that may be more relevant for those kinds of devices, to have a registry. You can access every single member of that population. You need resources to do that. That is where the federal government could be helpful, perhaps. Yes, another part of the federal government.

And I agree that this can't be FDA alone. FDA has some limitations on its scope. So other organizations have to be partnered with within the federal government, as well as outside the federal government to do this job right.

CHAIR FISCHHOFF: Okay. Linda, Mona, and then Musa, was it? Oh, Paul, please.

DR. SELIGMAN: I am just going to make a quick comment regarding the issue of targeting because we have spent a fair amount of time this last year talking to our MedWatch

partners. We have about 160 some odd organizations that are partners. And one of the messages we hear over and over from them is, you know, all of these alerts go out every day to all of these various organizations.

Is there a way we can tag or hone our, or tag these messages in a way that if it is drug related, if it is a product that only dermatologists use or rheumatologists use, or a cardiologist might primarily use, are there ways that we can be smarter about using these dissemination tools, it really goes, this is really in advance of assessment, design and evaluation. This is just taking what we produce now and being smarter about getting it into the hands of the right audiences. We have just been talking to professional organizations. The same goes as well for consumer groups, and patient advocacy groups, and others. They have, again, a great need for information that is relevant and valuable to their constituents as well. So we spend a

lot of time beginning to think internally about how to be able to do that smartly.

DR. GOLDSTEIN: And there is another group that I mentioned before and that is the health delivery organizations. And that includes the insurers, and that includes the biggest insurer of all, Medicare, and the second biggest, the Department of Veterans Affairs.

And by the way, nothing I say is related -- I have to say this, I forgot to. I am an employee of the Veterans Affairs Department. So nothing I say has anything to do with them. I am here as a member of the committee.

But we have these health delivery organizations or healthcare provider organizations that can also help, that have their internal systems for communication and messaging that can help shape the process, not just the message, but the process for delivering the message, and evaluating it.

DR. SELIGMAN: And we currently have an agreement, memorandum of understanding with the VA and are now actually engaged in a pilot with them where we take our drug advisories and share them with the VA, usually 24 to 48 hours before they are made public, so that the VA can begin to prepare their own messaging and their own bulletins that they distribute nationwide through their, I think it is called a PBM bulletin.

DR. GOLDSTEIN: Right.

DR. SELIGMAN: So we are going to do this, we are doing it now, as a pilot, with a thought towards if it is successful, ways in which we might broaden or engage a greater audience so that relevant organizations can be prepared at the time that FDA makes an announcement to, you know, be in the position to share with their constituents the information and their interpretation and the appropriate response to that.

DR. GOLDSTEIN: That is a fantastic

example.

DR. SELIGMAN: Yes.

MS. MCNEILL: I have one additional comment. Paul noted that that is done through a memorandum of understanding. Oftentimes what we are doing when we are developing our messages is dealing with information that is not disclosable for any variety of reasons. It might be pre-decisional. It might have to do with an ongoing investigation.

And so, in the absence of such an agreement, we may not be able to share that information. And we may not be able to share that information with some of our target audiences to help us develop that message. So that is another barrier, if you will, the constraint to what we have to do, you know, that limits the type of collaborative work we can do.

CHAIR FISCHHOFF: Thank you. Linda, Ellen, and members of -- well you heard but if anybody from there has a comment, you

go to the head of the list.

DR. NEUHAUSER: My first comment was related to the issue of using the term recall. And one of the things I have found working with groups who may have a different, I mean many groups have different understandings of meanings of words, but especially lower literate groups who may have heard a term only in a vernacular sense and not understand a medical sense, say, like recall.

And one of the things that they have recommended doing is not getting rid of the word, particularly, unless there is a better word, but they like the word explained. So, if there is, an alternate suggestion here would be to take the term recall, put it in a box on an advisory or whatever. Anything that is going to a consumer or to somebody who is going to be in contact with a consumer and may need to take that information and give it to them. And have it explain what recall means

for an implantable device. And in this case, the advice would be that you would want to say that there are some issues around safety and of the device that the FDA regulates. And of course, clear language in that. And that you want the person to see their physician to get advice. That is the action that they need to take. Not necessarily to understand what FDA means by recall but that is what they need to do.

So, I think you could solve a lot of problems that had to do with meaning. The word safety and effectiveness. We will discuss that maybe today, tomorrow. The same things. Those have different meanings for people. But as long as you explain it in a way that gets to the point you want to make with them, especially if they need to take action, I think you have done your job.

The second comment is related to Dr. Seligman's very good idea about working on delivery of messages by tagging, segmenting

these for audiences. I think it is a terrific idea. And this goes back to another reason to have strategic planning processes that are more intense and in-depth than we can do here in a committee meeting that has a lot of issues.

So, I would say if you got together people, the right people, including members of the various delivery organizations, you can think of many of them, many you might already have initial partnerships with, for two days. You should be to come up with a terrific and very low cost way to do, you know, you could catapult the value of what you are doing to the public and to providers by a factor of ten, I think.

MS. RICE: I wanted to comment on the term recall and the fact that we should explain it. We actually do that. In the very second sentence, what we do is, if it is a recall for an implant, we explain that this certainly does not mean that we need to talk

your implant out or that your physician does. We say right away, please contact your physician. Before we get into any of the details of what the real problem is and what the suggestions are.

DR. NEUHAUSER: And just one comment about that, getting back to the emotional thing. Sometimes, when people see a word like recall they may associate with something deadly, they may have an emotional reaction as Dr. Peters and others were explaining. So, it may not be enough to just explain what a recall is but might have to put in some language that acknowledges the emotions that people might be feeling. We know this might be difficult or might be confusing. You know, whatever it is that can say we are here with you and here is some reassurance, and then here is what to do. And again, those all need to be tested with various kinds of people.

DR. KHANNA: Here is the headline.

More bad news for patients with heart disease. The tease before the commercial. If you have a pacemaker, your life may be in danger. Stay tuned. We will explain on the other side of the break.

(Laughter.)

DR. KHANNA: After the commercial, the story. The FDA has issued a warning for people with implanted devices to control their heart rhythm, etcetera, etcetera, etcetera.

So you all remember it wasn't too long ago that the number of cardiology that had to practically shut down their phone lines after the media picked up the story about sudden death and calcium channel blockers. Or what about the number of OB-GYN offices that had to shut down their phones after the media picked up the story about the increased risk of breast cancer, heart disease, strokes in patients on hormone replacement therapy, etcetera, etcetera.

So I just want to have us all keep

in mind that however many iterations we go through or the FDA goes through, fine tuning our message and esoteric, what may seem like esoteric definitions, that the number one vehicle for disseminating these messages through the public, whether we like it or not, is in fact the media. And that is when our careful words that we have chosen are basically out the window when the producer, the reporter, the editors, and the managing editor decides how they are going to phrase it.

So it has to be simple enough that somebody who is on deadline for the 4:00 p.m., 5:00 p.m., 6:00 p.m., 7:00 p.m., and 10:00 newscast has to write it very, very quickly. And I am not voting for which way to say something. I am just saying that we have to keep in mind that we are not the ones who get the information out to most people.

CHAIR FISCHHOFF: And you were implying, as all they hear is etcetera,

etcetera, etcetera. Right?

DR. SELIGMAN: May I just make a brief comment? And this is just an observation but based on our work now over the last couple of years with public health advisories, you know, one thing we can't seem to control are those who write the headlines. But generally, the content underneath the headlines seems to be generally fairly balanced and reflective of what we want to say. And we can't write the headline, as much as we might like maybe to write that headline.

I mean, it was certainly true around our early communication related to Prilosec and Nexium. I mean, the headlines are all talking about heart risk associated with popular drug. But the content of the articles basically said well, you know, there isn't a risk out there that we are highlighting here. We are talking about a process of evaluation.

So, I think what you just pointed

out were the sort of the screaming headline. You know, behind it, of course, may have been coverage which may have been perfectly balanced and well nuanced and truly reflective of what it is that we were trying to say.

DR. KHANNA: I think that is okay because I think when you write a headline or say it, you want to cast a wide net. You want to cast a wide net of everyone who has that condition who then looks at the story.

So, I think it is okay if the headline is a little looser. It is just the content, like you are saying, the nuts and bolts. The nut graph, we used to call it in print, that needs to be an accurate reflection of what we are trying to say.

DR. SELIGMAN: I couldn't agree more. I agree about the nuts and the bolts.

DR. GOLDSTEIN: Can I just make a point on that? Can I respond just to that one point? Because actually it was Dr. Maisel who made a point that I think is really important

and that is how we prepare the population for the warnings ahead of time.

So, even it comes over the TV, if that population has been informed, if that specific target audience through their communication with their clinicians, with other forms of communication from the government, etcetera, prepares them that this is what recall means, and this is how to respond, go to a website, you can go to your doctor, too. But then go to a website because you are patient with a device of this type. And this information is going to be on that website and you can be sure that it has been cleared with the group that your doctor belongs to that designs and works with these devices. Then, you are at least mitigating any fear factor and emotion that is going to drive people to want to have their devices out right away because you prepare them ahead of time.

So, it is worthwhile to invest in

these, when we know the target audience, how they might access these other resources in these times when they get news that may be important for them to hear.

MS. MAYER: I think it's me. Yes, I have to respond to that. I don't think anything can really be done about the media's need to grab the attention of its viewers, readers, and so on, but I think there is an enormous amount of harm done. A recent example in breast on MSNBC. You know, this was the headline: "What if hundreds of thousands of women with breast cancer were getting a toxic chemotherapy that didn't help them?" And the real story behind that was far more nuance. Only a small proportion of women actually have a preferential benefit from this particular chemotherapy drug. It wasn't that it didn't help them. You know, it was more complicated. The headline was incredibly misleading.

But that wasn't really why I raised

my hand to speak in the first place. I am back with something that you were talking about before. I am sitting here getting a little concerned about our continued discussion of the recall issue, of the use of the word recall with regard to implanted devices, because we are not really hearing a full consideration of that question. We are not hearing the FDA's position, most notably. We are hearing the position of a professional organization.

And I don't know what the background in this case is but I do know that it is not at all unheard of for both professional organizations and advocacy groups to be industry-funded and to, you know, have a very strong representation of a particular point of view. And I want to say that I am not meaning to suggest that that is true in this case. I am just saying that I don't think we should continue to press for changes on this particular issue because we are not

here to discuss that and we are not getting a full presentation of all of the issues on that. It is really not our -- in my opinion, it is not what we are here to do.

CHAIR FISCHHOFF: Okay, thank you. Ellen, then AnnaMaria and then Marielos.

DR. PETERS: I would like to switch the focus a little bit off of recall and onto an issue that has been brought up a number of times, by a number of different people. And that is the idea of simply the importance of testing communications and particularly in vulnerable populations.

And you can test communications and after testing decide that you want to target communications, like Dr. Goldstein has brought up. You can even choose a strategy of do no harm. So for example, sometimes you may end up wanting to choose communications that maybe they don't help people of high ability very much but at least they don't do any harm to people who have low ability. So, there are

different strategies you can choose, basically.

But the pink elephant in the room I think actually might be OMB. I think it actually might be a huge obstacle that the FDA has to actually being able to do this testing.

And I wonder whether part of what we could talk about as a committee is are there ways that, are there things that we, as a committee can do to help facilitate things for the FDA around this issue. So that there are -- it is a political issue and it is a huge political issue. And that is not something that probably people in this room can approach. Are there other people who can approach it? I mean, that is the huge one.

If the FDA sponsors research, does OMB have to be involved? I think the answer to that is, if the FDA gives a contract to somebody, OMB does have to be involved, but if they do a grant, they do not have to be involved, I think. I am not positive about

that. Okay, and Nancy is shaking her head. So she can answer and say everything that I am saying wrong in just a moment.

What about, and I believe it was Dr. Seligman and Neuhauser who started this conversation. If there are agencies who are involved as partners in this communication effort, is it possible that those agencies can be encouraged to put some of their resources to bear on testing these communications? So basically what I wanted to start with a communication about, how can the FDA do away with some of the resource commitment that they currently have to use, in terms of having to go through OMB clearance all the time, which is a two to three year process?

DR. OSTROVE: Well, if I could just provide, maybe a little bit of context there. I think one of the things that I do want to point out that Lee made very clear to me is that we shouldn't completely blame OMB. I mean, OMB is following Congress' intent. I

mean, the OMB admittedly, there is some flexibility in there but the Paperwork Reduction Act of 1990 and them some later ones, I think, are kind of what led to the regulations that require that information collection, as well as lots of other stuff, needs to be reviewed by OMB and the regulations kind of lay out the general process. And they also have guidances out there as to what is covered under this requirement, so that, you know, if you are doing research with nine or fewer people, you do not need OMB clearance, for instance.

Similarly, there are exemptions. So that clinical research, for instance, is exempted. Research that we might want to do in pursuit of a compliance action, some kind of investigation having to do with compliance of industry with the regulations, with FDA regulations, would also not be something that would have to be publicly disclosed. There is a number of exemptions, and I can't possibly,

I just can't recall them because those are the major ones that I know of because we have had to, you know, we have done research specifically, kind of under that compliance exemption in the past.

And over time, kind of the scope has been unclear in some cases, and OMB has clarified because of that lack of clarity so that many years ago we operated under the assumption that we did not generally need to get focus group clearance, clearance for the focus groups that we did. And then over the last, I don't remember how many years ago it was, probably about seven years ago, everybody was told no, that is not the case. That is considered to be kind of a type of survey research, as long as you are doing it with more than nine people and you can't get around it by saying well, each focus group is different. You know, as long as you have a moderator guy that is basically the same and you are asking the same kinds of questions,

making the same kind of focus.

If we have a contract with someone, that is something that needs to go -- if we have a substantial interest, if we are substantially involved either by providing funding or we are interfacing with the group and it is not like a clinical research study, then it needs OMB clearance. I mean, I should probably go back to the guidance and get that information, kind of, and send you the pieces that are relevant.

Grants, you know, I am not going to be positive about grants by my expectation is is that some of them probably are supposed to get cleared but I would not say that for sure. Okay? Contracts definitely. And again, you know, there may be exemptions.

So that is kind of the basics and, oh my goodness, I hope that I haven't said anything wrong there because sometimes the rules get a little unclear, which is why OMB periodically puts out guidances to make let us

know what they are.

However, they do allow for emergency clearances and there are what we call generic clearances that we can get by going through the whole process of the 60 day notice and the response to comments and then the 30 day notice, and then the 30 day review. Because technically, those are the major time frames. You have to give the public first 60 days to respond to your notice and then you have to go out again and give another 30 days at the same time you submit your request for clearance to OMB. And then on top of that 30 days that the public gets the additional 30 days for notice, OMB then gets another 30 days.

But we have a number of clearances that are generic in the sense that we have gotten clearance for that general type of research, which is one of the things that I mentioned earlier with regard to the customer satisfaction surveys. So now, we can, you

know, we can select from a bunch of questions that we have sent into OMB. You know, and we can even add some that are specific to a site and send it in. And presumably within ten working days, once we get it into them, they will give us an answer. So, that can be done quickly. We can also do that for focus groups.

CDRH has had some rapid response surveys that they have a generic clearance for. Again, they are kind of limited in the kind of questions that you can ask. Because once you go outside of the realm of what they have given approval for, then it starts getting more problematic.

But in cases that are really, really significant, we can ask them for emergency clearance as well which, again, in that case, you don't get the 60 days. You just get the original 60 days. You just would kind of send it in and ask for the 30 days and then they would take another 30. So, there

are ways to get around it.

I am not defending and I am not attacking them. They are fulfilling what they believe is a congressional mandate and they are doing it in the best that they believe possible. And I am sure that they are aware of the issues that it might cause. But you know, they have their mandate, and we have ours.

DR. PETERS: And I am simply trying to point out the idea that I know you are fully aware of, that there are benefits to the public in testing these communications. And there are some fairly large benefits because, to some extent, part of what you do doesn't matter until it gets communicated. And so through the testing of communications, you can become more effective communicators.

And generally, at least at the universities when we are dealing with what we would call IRB issues, rather than OMB, we talk about the risks of conducting the

research and the benefits of conducting the research. And there is a tradeoff between them.

And here the benefits don't seem to be weighed as much. Although perhaps, just based on what you were just saying a moment ago, I wonder if part of the strategic plan that Linda was talking about earlier, part of what goes into that strategic planning perhaps could be what kinds of generic clearances can we get in order to wrap risk communication around more of the process.

DR. OSTROVE: I think that is an excellent point. And I think that is one of the things that we need to think more about is how we might be able to expand this kind of group of generic clearances to allow for testing, for kind of rapid turnaround testing of messages that will allow us to learn more over a period of time and, as well, to kind of allow us to build a better foundation on which to do -- and also to test the stuff that we

are doing at that time. I have already dealt with that one, right.

So, I completely agree. And I think that from a strategic planning standpoint, that is one of the things that we probably do want to do. That in and of itself becomes something that takes resources because you have got to go through the initial process. But is something that is doable.

I think what we need to do is to talk more, you know sit down with OMB, basically, with our people over there, with their people and our people and see if something can be worked out. And in that sense, that is something that the committee may very well be able to help with because when we go out with the initial public notice that we are kind of asking for this generic clearance, that is something that we will be asking for public comment on.

DR. SELIGMAN: Let me talk a slightly different tact to your question,

Ellen. And this involves what I would call partnerships and leveraging. I think there are extraordinary opportunities out there beyond the realm of OMB cleared research which could involve healthcare organizations, associations, and a variety of groups who have their own robust research programs and whose interests there are in working with and communicating with their own professional, as well as patient population. I hate to keep looking at the VA but the VA is a perfectly good example of what can be done. You can look at the private sector as well, whether it is the Blues or HMOs or others.

So, I think those opportunities I really think do need to be explored to the fullest because I think there are those opportunities for other groups taking our messages and looking at how they play in their own populations, amongst their own constituents.

The second point I want to make is

that there are opportunities, and we have used one of them in the last couple of years to basically work with outside researchers and how you translate their research work into applied public health. And yes, actually, they were part of references in your presentation to Schwartz, Woloshin and Welch at the Dartmouth Medical School and the White River Junction VA, where we, I was particularly intrigued by a presentation they made two years ago on the prescription drug facts box, which is a way portraying numerically information about the benefits and risks of a drug modeled after the nutrition facts box and others. And they have done, as you have pointed out in your presentation and others have done a lot of research to indicate that patients of all sorts can understand numeric information and interpret it and use it properly if it is presented in a careful fashion.

So, we actually identified about a

half a dozen of our experienced clinical reviewers in the office of new drugs over this past year and actually had them work with the Dartmouth group to create drug facts boxes for ten drugs. And we looked at a whole range of drugs from oncologic drugs to symptomatic drugs. We looked at all of the problems related to -- and this was because these were the experts on the clinical trial data. They really new these drugs backwards and forwards probably better than anybody else in the country, except for those who develop the drugs on the sponsor side.

And you know, we hashed through all of the problems related to when there are multiple trials, some were the drug against an active comparator, the drug against a placebo, multiple doses. What do you do with studies that have composite outcomes, like a lot of the rheumatologic drugs or psychiatric drugs that the outcome that they are measuring is laboratory data, and x-ray data, and patient

symptom reports and a whole bunch of things. How do you kind of put that together in a fashion?

Well, we worked through a lot of those and actually over this past year, created a reviewer's handbook which sort of talks about how you kind of work through a lot of these issues. So, we are still working internally within the organization. But here again, this is research that is being done external to the FDA. They get their research grant monies from Robert Wood Johnson Foundations and others. And they do all of the work related to testing these boxes and seeing whether they can be utilized properly. And our role at the FDA is basically to provide some expertise and to do some feasibility work and to provide some thought into how one might be able to construct and create these.

So, I use that as an example of not only translation but also an opportunity to

again, in this endeavor, partner with an organization.

So, I didn't mean to give you a long-winded answer but just to make you aware of that.

CHAIR FISCHHOFF: Thank you. That is very helpful.

It strikes me that, I mean we have heard that the system, as it works now, my personal opinion is that the system as it works now with OMB is broken, that you are under two incompatible directives. One is to protect the American public and the second is to satisfy the Paperwork Reduction Act. And in some places by hook or by crook, you have managed to get an exemption for this, to get something for that. But in fact, a large portion of the things that you would like, it seems to me that FDA would like, to test empirically to see how they degrade under pressure, how they interpret it by different organizations. You are simply not able to do

that.

And it strikes me that either much of the work needs to go outside so somebody else does it and then you use best practices or else there needs to be a cabinet level negotiation to say let's rewrite these rules within the constraints of the negotiations for having you, you know, fighting this kind of gorilla warfare. You know and point by point, where things just don't happen and you end up responding in emergency just seems like really unfair to you and unfair to the public that you are trying to serve.

And this is bureaucratic politics. The law has been in place for a while. These are not electoral politics and it seems like there is a cabinet level solution, which is what you need. And maybe you know, out of your strategic planning a commitment could come and somebody could bash the appropriate heads together and get you the ability to do the kind of testing that you should be doing.

As you may know, there was a National Research Council Committee. You may need to go to this but there was a National Research Council Committee issued a report about 18 months ago that said OMB was incapable of monitoring, it basically said, could not do risk analysis. It put out a general guideline and it said this was something that really needed to be left to individual agencies, within some general philosophical guidelines. So, the fact that there has been a bureaucratic war that OMB has been winning over a period of time, doesn't strike me as something -- you may not be able to say it but I think, you know, if we believe it, it is our obligation to say that you are trying to help the American public with one and a half hands tied behind your back.

DR. OSTROVE: I think I am glad that Paul brought that up. Because it seems to me that what we need to do is to tackle this on many fronts because sometimes the

academic researchers' interests and our interests coincide.

We had, for instance, Mike Wogalter was very interested in having one of his students do this research that was directly relevant to the development of this template. Clearly, the Dartmouth group is very interested in working with the information that FDA puts out. So when it coincides, it is like, it is beautiful and it is fantastic.

But sometimes it doesn't. You know, sometimes there is just some mundane stuff that we would like to test or something that somebody else is just not that interested in because it doesn't have a theoretical basis or whatever. So it really does help for us to have, you know, some of that capacity to do it internally.

So my own sense is, it isn't one or the other. It is like both or more. And we have partnered with a number of different groups, sometimes in a kind of very careful

position over the years to get the information that we need. Sometimes we need to get it ourselves. Sometimes we need others to get it. Sometimes it is bet that others get it. Sometimes it is best that we get it. So, I think we have to kind of put all of that together in figuring out strategically where we should be going.

CHAIR FISCHHOFF: AnnaMaria. And we will stop at 3:30 and pick up then.

MS. DESALVA: I was just going to briefly revert back to something that Mona said and something that Musa said and to say what I know we all know. Which is, that as more emerging risk information becomes available in real time, obviously, that is very stimulating to the media who do need to cast a wide net and are reporting news. And when the Agency comes out and says that there is something to be aware of, it feels like news and it gets reported that way. And I think we have all seen the negative downstream

affects of headlines that are either sensational or inaccurate. And none of us want that to pose a danger to people.

So, I am just wondering, and I am sure it has been discussed at length but what the Agency has considered by way of media education about emerging risk information and what you have already done. I just don't know the current state of play.

DR. OSTROVE: I think we will have someone here tomorrow. Heidi Rebello will be speaking tomorrow and I think she would be the best person to raise that with because I know that there is media training that gets done. But I don't know enough about it. Do any of you?

DR. SELIGMAN: Yes. In my time here, we have done some sporadic things. We have actually invited the representatives from the major media outlets to spend the morning with us and sit around the table and ask questions and learn a little bit about us.

But I don't think we have ever really done it in the sort of coordinated, consistent regular way. And I know that yes, the Idea has been considered many times. And I think that my hope is that we will get to the point, as an agency, where we do do that. Because I think there are actually federal agencies that do do this on a regular basis. And I think the benefits from that have, I think, been pretty well recognized.

MS. DESALVA: Absolutely.

MS. VEGA: One of the things for me, in my opinion, that makes the issue of communication more complex and difficult in this country is the diversity of populations in this country.

For example, I am from Costa Rica. I was born and raised in Costa Rica and I spent 19 years in there. And the population there is more homogeny and so communication is easier for agencies. But we come here and the diversity is tremendous.

There are organizations and industries in this country that are very successful communicating with consumers such as the car industry, the pharmaceutical industry, the fast food industry. I mean, they get the people to do what they want, which is come and get our products. But again, they also spend billions of dollars in advertisement. Unfortunately, I know the FDA doesn't have that amount of money.

Recently I came across, I was looking for some data on childhood obesity and I came across, I don't recall exactly where the information came from, but 93 billion dollars is spent in advertising to children by food industries.

So, the bottom line is then if we are going to be successful in communicating and testing all of these strategies, we need money. I don't know where that money is going to come from but we also perhaps can learn from what others are doing successfully.

I am not sure if anybody has ever looked at also how communication is done in other countries where the people who are coming here are coming from. I don't have any knowledge of that but perhaps we know where people are coming from through the census. So perhaps we can learn from how other countries are communicating to the public and then try to use some of those strategies for the people who are from those countries in here.

CHAIR FISCHHOFF: Thank you. Let's take a break now for 15 minutes and then we will pick it up again.

(Whereupon, the meeting went off the record at 3:33 p.m. and resumed at 3:49 p.m.)

CHAIR FISCHHOFF: Okay. Thank you all. Let's continue the conversation. I have Linda who is not back yet. And then Mike, did you want to wait until Linda gets back?

DR. SELIGMAN: Could I say something just in response to what Marielos said right before the break?

You know we are very much aware of what other countries are doing by way of communication, you know, particularly in the European union. They have actually a whole different set of structures and regulations regarding particularly consumer-related information, where it is basically required to be produced by the drug manufacturers and sponsors to be distributed. It is material that is reviewed by the European Union. They have a pretty, I guess I could describe it as robust program, evaluative program as well. So they do a lot more. I should say a lot more but it is very different in this country. I mean, there are certainly a lot of lessons to be learned from the Europeans regarding good practices.

And as a result, I mean, the other thing about the European Union is that they regulate a number of countries where lots of different languages are spoken. And as a result, there materials that are, you know, in

Spain prepared in Spanish, and in Italy, in Italian, and in Belgium, probably in German and Flemish and who know what else. So a lot of the language issues are dealt with in Europe, just by the diversity of the membership and the union and the fact that sponsors, indeed, are producing consumer friendly information probably in that whole range of languages spoken in that sphere.

CHAIR FISCHHOFF: Linda and the Mike.

DR. NEUHAUSER: I wanted to go back to the issue of testing and all of the challenges to get that done.

I wanted to mention that participatory design is not a form of testing. So, it is exempt from needing to go through OMB. And it has, that is one of its great advantages. The second great advantage is that, if you do a participatory design, you don't have to do as much testing. You might cut your testing down by two-thirds because if

you don't do participatory design, you are likely to have to go back and revise several times. So, it is a time saver, a money saver, an OMB avoider, lots of advantages there.

The second comment is that Dr. Ostrove said that there is often a synergy that works between universities doing research on issues of interest to the FDA and sometimes not. Sometimes the issues may not be that interesting. But as a professor in a university, I can say that I have plenty of students who would love to work on something of value to the public, in which there is a huge scientific gap. I bet you can't find anything that those student's wouldn't be interested in doing. And if you just took those of us around the table who have connections with universities and Dr. Fischhoff gave very good examples of how students have done FDA relevant type work.

So, my suggestion, my practical suggestion here is that as part of strategic

planning or just a suggestion right now, if you could develop a research agenda of things you want done and then you would have to think about how to get it out. But there are, I would say, for example, public health associations. There are a lot of different lists serves and ways to get this work out. You probably have your list serves. I see Dr. Seligman with his mind full of list serves over there. I think you could come up with ways to do it.

CHAIR FISCHHOFF: And the suggestion might be that some other agencies would say NSF or NIH, which is part of the same department, might give extra, either have a competition from its own money, or give out added credit to proposals that were drawn from this list.

DR. NEUHAUSER: Yes, and there is so much overlap with FDA issues with say the USDA because you share regulatory authority in different areas. And I could see that it

would be very efficient to have some of the research, is abundant at the USDA and which does operate at the level of many diverse audiences and relates a lot to communication. It probably wouldn't bee too hard to piggyback some extra questions onto things that are already being done. And that also saves you having to pay for it.

DR. DAVIDSON: I would like to address one of the more successful exchanges with the USDA that we have had as put our issues with the extension service grant and have been getting enormously available information through that mechanism.

I would also like just to speak to a moment about the research involving groups from other countries. An example of what we have been doing in that area involves a recent risk that we have had with unpasteurized -- cheeses made with unpasteurized milk that were particularly popular in certain groups in the Latino community. And we did formulative

research in East LA and in certain parts of Texas talking with them about how they actually recognized or how they described a certain kind of cheese. And one of our findings was that we Anglos always thought it was queso fresco and they didn't recognize that as a particular term of art to encompass all the different kinds of cheeses that we wanted to reach them.

But we used promatoras going out in the communities, as well as the Latino media to reach the audiences with our messages about cheese and found that very successful. One of the problems that someone had mentioned earlier, however, is that it is a population that turns over for obvious reasons and it is very challenging to keep the messages constantly out in the community. Promatoras are costly, for example. The media needs to be reminded over and over again to keep the messages out front. So, it has been a particular challenge of ours.

DR. GOLDSTEIN: So I really appreciated the presentations today. It was particularly nice to hear from members of the committee and I resonated with all of them but I particularly resonated, Linda, with your recommendations at the end. And particularly since we were talking about this earlier, the recommendations for the strategic approach to a research agenda.

So, I wondered if you would be willing to read that to us again and to see how other members of the committee felt about it, whether we can all endorse that as a strong recommendation because I think that is all central to the need that we are hearing about in the FDA. Could you read us those, that particular one again?

DR. NEUHAUSER: Well, the suggestion was a simple one and that would be to set up a strategic planning process and I suggested, you know, it could be six months or a year. And this is an idea that I am putting

out there without any knowledge of how strategic planning operates in the FDA. So there may already be strategic planning processes that you have. So I am the uninformed here. And maybe what I would suggest is putting it back out to people, FDA staff, and seeing what people have to say about how those processes work now within the Agency.

Obviously, you would need leadership from the top and you would need leadership across centers. I mean, there would be a lot of just the process of trying to define the process would be one that would take some thought here. So, I wouldn't probably go any further now because I know how those operate in organizations in which I am involved. But I am not sure, maybe some of you would have comments if you have been involved in these processes and how it works.

DR. OSTROVE: The FDA does have a strategic planning process. And it is often

kind of built around the budget and that cycle. But actually given that I am in the office of planning, it probably, you know, I think you are doing what you can in terms of suggesting that. Well, both Lee and I are in the Office of Planning and that is something that we will raise.

It is something that we have considered doing is setting a research agenda. Oh, yes, absolutely. But it has not been the highest on the priority list. But with all of the ideas that I think are kind of coming out now, I think it is something that deserves a second look, in terms of moving forward on that to the extent that we can.

DR. GOLDSTEIN: And we could actually combine that bullet with the next bullet because the strategic planning meetings should involve partnerships with other relevant, federal, state and professional organizations. And I would add consumer organizations to that list and healthcare

delivery organizations to that list to create that agenda together because that would make it so much more powerful and would actually lead to potential joint funding for that effort.

DR. OSTROVE: Well, I will take the recommendation back. I mean, I don't make guarantees about whether we would do it internally, whether we would involve other government agencies, whether we would involve outside groups. If we involve outside groups, it might in the context of having a meeting. We discussed this. We in fact, years ago we had a meeting looking at a research agenda for direct consumer advertising that was actually funded by the Assistant Secretary for planning and evaluation. So it's not as if this kind of thing has not been done. But I do have to say that not very much substantive ended up coming out of that. So, you know, I think we have to make sure that we do it in a way that we would get the most bang for whoever's buck

goes to funding. But I think it is a great idea and it will be brought forward.

DR. GOLDSTEIN: Yes. Well you have to be strategic about how you do the strategic planning.

CHAIR FISCHHOFF: My feeling -- oh, go ahead, Paul.

DR. SELIGMAN: No, I was just going to say the only other thing that I might mention is, you know, by way of engaging organizations and developing an action plan, there is one that is twelve-years-old now, which is the Keystone Group out of Colorado actually convened a broad range of representatives to develop and action plan for the Secretary around what constituted useful consumer information that really brought together a wide range of professional and consumer, and industry organizations. And I think out of that came a document that I thought was pretty powerful and pretty useful. It certainly withstood the test of time in my

mind, in terms of how one defines what the elements of useful consumer information should be. So it is the only model that I am aware of where we have done that kind of planning in a sort of broader audience. I know I think you are pretty involved with that, I presume, Nancy.

DR. OSTROVE: Yes, that was a process that was actually Public Law 104180 that there be that process. And we funded it but then we took a kind of hands off arms-length and said here is your mandate from Congress, go for it. And it did come out with an action plan that has withstood the test of time. But what a lot of the public doesn't know is how controversial the discussions were.

DR. SELIGMAN: The discussions were difficult.

DR. OSTROVE: Yes.

DR. SELIGMAN: But it was a certainly thorough process and I wasn't aware

but it may be one way of doing that, to be able to sort of you know, giving a group like that a charge, and then be stepping back. But anyway --

MS. LAWSON: Just to piggyback on what has already been stated, I think there is such a wealth of professional expertise that exists within the organization, both the professional groups and consumer groups, and the organizations certainly would rally around the opportunity to collaborate with the Agency. And I know it has been done over the years for different projects, but I think you should further explore the ways that, there is such a resource out there and they would be willing to work with you. And then you could capitalize on that to get a lot of things done. And it is all under the umbrella of partnerships that they would become partners in whatever the effort is. But I do think that you have such a rich resource available to you.

DR. PALING: Dr. Seligman, you are the first person I have met at the FDA who has expressed knowledge about what is going on in the EEC. It is not that you are the only person. You are the first person I have been able to speak to.

As you will know well, in the European community, it was thought that communicating probabilities was so important and the ability to confuse the public, typically, with descriptive words was so great, that it was hugely important to try and define some limited vocabulary to go with levels of probability. Several of us have discussed this in private here. I still believe it is potentially a very useful thing.

Will you share your personal opinions about the value of that and whether it might apply here in this agency?

DR. SELIGMAN: Well you know, I have -- I will just give you my personal opinion. I have never been a fan of use of

the words like rare, or common, or likely. It is why I really found the approach that Woloshin and Schwartz and others were taking about just, you know, give them the numbers. So, that is just my personal bias. You know, those kinds of descriptive terms are, in terms of how one interprets them and uses them, are so particular to the particular drug and the context and the individual who is making a choice about their own healthcare and what risks they are willing to take, and what competing issues they are confronting in making a decision.

So, that is just my personal -- I know that much vocabulary and many words have been spilled on the battle field of trying to characterize these things and I, that is sort of where I have settled on that issue.

DR. PALING: I find that helpful. Thank you.

CHAIR FISCHHOFF: Me, too.

Let me take us in a slightly

different direction which, and I am particularly interested in my more academic colleagues thoughts on this.

I think one of the things that makes this area kind of difficult coming in from the outside is there are these different approaches. And you say, well, should I go with the collaborative learning? Should I go with the health belief model, the theory of reasoned action? The stuff these decision-making people do and so on?

So, this is the way I think about it. And if you got into this, you would find it is more, you know, the internecine warfare is a little nasty. The review panels that are controlled by health belief model. People will not fund anything else. On the other hand, for those of us who study decision-making, that whole approach to decision-making vanished from the literature in the mid-1970s. I think nobody in decision-making thinks of that class of linear model as actually being

capable providing much insight into people's decision-making processes, that we believe there are a class of linear models that if you have some substantive insight, they are guaranteed to give you weak correlations and can't give you a whole lot more.

So, how do you sort these? But people are very committed to their approaches. So my thinking on this is that if anybody is really, that these things are so complicated, that if anybody has a theory, then you should ignore them. You know, there couldn't be a theory that applies to these complicated situations. What you want is somebody who has got an approach that will help you to respond to the complexities of the task, the complexities of the people, the complexities of the situations, the communication channels that you have.

And I think if you got -- so among the people who use the theory of recent action, or the health belief model, or the

stages of change theory or model, among them you will find people who use that as a calling card. It inspires confidence, gets them in the door, and then they are very eclectic in what they do. You know, they listen to people. They do things that are not all that different from the kind of collaborative approaches that you have heard from Linda, or from Christine, or from Ellen, or myself. And what you really want is somebody who will listen to the problem, you know who really cares about the science, or some things matter and some things don't, will listen to other people. And that is really sort of the critical screening characteristic.

And I am wondering, I guess I would sort of be interested in what we look like to the people who are actually solving problems. And I would be interested in knowing what my colleagues think.

DR. KHANNA: There is your headline.

DR. GOLDSTEIN: I don't want to defend any particular model but I do think there are some frameworks that are really helpful. The framework that you articulated. The framework that Linda articulated, the socio-ecological model, which is really a multi-level approach to understanding a complex set of behaviors that cuts across the different influences that come from those different circles, those different sets of factors.

So, because it is complex, I do think we do need a multi-level analytical approach to addressing the problem. And that is one of the reasons I think to have some bringing together of groups that are stakeholders, so that they can identify not only the important questions that have to be asked but also the necessity of having multiple different levels of both intervention and analysis in order to address the big problem. Because no one, there is not going

to be one study that is going to answer all of the questions that need to be answered. There is not going to be one level where we are going to find all the variances accounted for. It is going to be spread across all the different levels. And we need bigger models or models of models in order to fully understand this kind of a complex set of behaviors and issues.

DR. PETERS: Just to follow up on it, there are some benefits, though, I would say, Baruch, in terms of some of these models. They remind you of things that aren't easily available to you. So, similar to your earlier work on car problems and auto mechanics, sometimes different frameworks, and maybe it is really taking, thinking about multiple frameworks, rather than just a single one, wills sometimes remind you that you need to be asking questions that are down that route, in order to help you better understand the problem.

And so starting off with the model perhaps does give people, whether it is your model or the health belief model or another one, helps people to have a starting place to remind themselves to ask different questions. Because in the end, I would agree with you that in the end what you have to do is you have to listen to the problem and you have to understand who it is relevant to and what pieces of information are relevant and not relevant.

MS. DESALVA: I have spent a lot of my life just tearing down the models that seem very ineffective. And when they are tested, a lot of the communication models, I am thinking of an article by, a study by Weinstein 1993 in which he says that the linear communication behavior change models are just strong enough to avoid being thrown out all together. That is not a very strong support.

But I would suggest and I have been actually thinking about what combination of

models, like you were saying, Ellen, might be ones to put together. And this conversation, to some of you in the audience who were thinking of very practical things might seem esoteric. But I think if some day we could make progress here, it would be a good basis of guidance upon which to do more effective activities.

So, what I have been thinking of more recently is that the translational and trans-disciplinary research models are probably in combination with a social ecological multi-level model. These are three dimensional type models, in that they combine, they look over time, they look from molecules to society, etcetera. So, they really have a lot of dimensions to them.

And what we are talking about here at the base is trying to translate research findings into better health for the population. And so a translational research model that cuts across disciplines and sectors

is the only way to really accomplish that. And there are some very interesting models by Abrams, Sussman, and a few others that have been put forward in NIH conferences about these issues.

So, I would suggest those would be some. And then combined with perhaps some models that have something to say. Diffusion of innovations. I think that model still has, I think it still holds water in terms of adoption of new ideas. So there are things but one would have to combine a lot. And I do think it takes thinking that we haven't really been bold enough to do, because it means stepping out of a discipline, stepping out of a comfort zone.

DR. BRUHN: In applying for grants, we frame our research around a model. If you don't, you are not going to get approved. You are not going to get your money to do the project. But I think once you are in the project, a guiding principal that seems to be

effective is keeping in mind what is in it for me. What they teach us in media training. Why do I want to listen? Why do I want to care? Why would consider changing my practices? And however you frame that, that is the most, however you frame what is in it for them, I believe that is the most powerful factor that will lead for understanding, possibly changing, possibly adopting a new behavior. You have got to show that it has merit in whatever value structure that people that you are working with is.

Your headline writer is always going to write sexy headlines because it gets people to look at their paper or to listen to their program. And their business is staying in business. And they want to be important. If you can give them something that also makes them appear credible, relevant, maybe get them a few Pulitzer Prizes. Well a Pulitzer Prize won't necessarily keep them in business. They have got to be able to grab the public and we

have to be able to appear risk communication messages. We have to be able to show that this is important for the public and it is going to help them achieve a higher quality of life. And I think that is where we need to be aiming in our communication strategies.

MS. DESALVA: I will just collect my thoughts.

CHAIR FISCHHOFF: Okay. Somebody was trying to volunteer somebody else who wasn't quite ready. Mike?

DR. GOLDSTEIN: At the risk of again getting too esoteric, it seems like the kinds of questions we are asking are about translation of research into practice or about trying to understand the needs of populations and sub-segments of populations. And in some cases, we need to look at models that go beyond traditional, empirically has to randomize controlled, trial-based research. We have to look at public health types of approaches, dissemination research,

translation research, and intervention research. Don Berwick, who is the, I guess he is the President of the Institute for Healthcare Improvement has written recently in JAMA about the importance of new paradigms for testing interventions, where the interventions are focused on improving the quality of care. And in some ways, we are talking about improving the quality of messaging, of warning, or communicating about risk. So there is linkages there. It is a very complex phenomena.

So I think we can learn from some of the practice base models, the testing that may occur in a sequential way, an iterative way, to help build our knowledge. It doesn't have to be just in the traditional sense of a controlled trial, testing one message against another message, and looking at other variables that may be covariant, and may be an incremental approach to testing and looking at the impact of what we do, what we are testing.

CHAIR FISCHHOFF: We got less disagreement than I was hoping for there. So let me just make a final comment, try one more time to provoke something.

I think what happens is that people are trained in a particular way, they get good at a particular way of looking at problems and I think your probably want somebody who is really good at doing something. And some people are really good talking to other people, some people have their discipline in looking at things analytically, and if that is all they do, then you don't want to have anything to do with them.

And the core is, as I think Christine was saying, the core is trying to find some disciplined way of getting what is on people's minds, what do they care about, and then matching that to the science of what they can conceivably get or have dumped on them.

And so my preference, I am sort of

an analytical guy and have my appointments in engineering, and I am often trying to sell the social sciences to natural scientists or engineers, I find being kind of analytical helps because then we have got models, too, just like they have got models. But it is a different discourse when you are working with other people. And if we were just stuck there, we would be in big, big trouble.

But I would say, you know, you sort of start at one of these cores and then he just had a checklist. You know, make certain you thought about culture, about language, about affect and so on. That might the next tier, that might be as far as the theoretical structure needs to go. You know, something you do well that basically talks to people and listens to them. And then a checklist of other issues and then get people who are really, you know, either your audience or other specialists who can inform you on that.

That is about as fancy as I would

like to get.

Okay. Yes, John.

DR. PALING: I took the fact that you were seeking someone to be provocative as an invitation to speak.

I would like to toss out a hypothesis. We are all rightly interested in a scientific approach to risk communication. And I would like us to put a thought, that I don't know whether it is valid but I would like to get the view of my esteemed friends in the FDA and my colleagues around the table on. It is this.

Scientific principal is that you really can't run before you can walk. And one of the things I am just questioning is whether a lot of our attention is being given to try and advise on risk communication in these of the more difficult categories; vulnerable populations, emerging issues, complexity. And I am wondering, without trying to be provocative,

what would happen if we put together ten items, five items from each of the Centers which were not vulnerable, which were not emerging issues, which were not overly complex, and we were to devise our recommendations for what, in the best of our knowledge, might make practical risk communication strategies.

Because I am just wondering whether we could be addressing the more intellectually challenging and perhaps overly difficult things for the stage we are at. I would be glad of your input.

(Pause.)

DR. PALING: I rest my case.

MS. DESALVA: Actually, I will add to that or just comment. I think that is a very good point. And I think, you know, sometimes from where I sit, which tends to be sort of more in the real world of trying to communicate in an effective way in real time when issues are breaking, you can have the

best intentions in the world and have actually very good resources, you know, tangible and intangible resources to apply to the problem and it can be very difficult to deliver an incredibly crafted message that has had the participation of stakeholders in its development.

It is difficult when you have a breaking situation. You know, and so sometimes I think that when the situations are less urgent and when you have more of the daily obligation of just being thoughtful about the way you are communicating about any particular product and its risk benefit profile. But that is often where, at least from an industry standpoint, where the more thoughtful work can be done simply because you are not in a vice. You know, you are not under extreme pressure to deliver information to a wide range of stakeholders in a very complex environment.

So, I think that is a terrific

point.

MS. MAYER: I have some hesitation, John, in looking in that direction and here is why. Most of the communicating I do about risk is online. And it is to patients who are, by virtue of their even being there, information seekers. That is they are already proactive in terms of reaching out to other patients and healthcare providers as well about making sure they are making the best treatment choices, for example.

And I often feel like I am doing a good job communicating to them but I am preaching to the already converted. And I think that knowing how to do that doesn't really -- I think we all know that there is only this small area that has -- the internet has distorted my perceptions, in a way. Because it is the internet and it reaches around the world, there are hundreds and hundreds and even thousands of people who respond.

So, that makes it seem as if we are reaching a lot of people but in reality, we are reaching just a tiny fraction. I am convinced of that. And we have no idea how to reach all of the others, who may be defined as being minority populations, or more vulnerable, or any of those words.

But I think that there is even a broader category which could probably be better defined in a psychological dimension. And that is, people who manage issues around healthcare primarily by thinking about them as little as possible, until they are forced to do otherwise. I don't mean to say that in an insulting way but there are the anxious information seekers and there are the avoiders. That is a reality.

So then the question is, if, as I believe, the majority of us are among the avoiders, how in the world do you reach people whose spontaneous psychological makeup leads them to not want to think about complex,

difficult, painful, risky, unsafe, issues that we are talking about. How do you even begin to communicate to them when what they are trying to do is not communicate, not be communicated to. You know?

To me, it is a huge barrier to overcome and I think it is a barrier that transcends all population groups. At least that is what I have observed.

DR. BRUHN: Well John, I think I would like to see what that list would look like. And that might make your suggestion really exciting, depending on what is on that list.

And again, looking at my area of interest is in food, we don't want to tell them things that are mundane. Because who cares, really? And there is a lot of things on people's plate, and they only have a limited amount of time and attention, so why look at something that is not important? I think they have to know that what they are

looking at is important. That this is information they need and they don't have.

Now, we have the challenge right now in food safety because people think they know what to do and in actuality they probably don't. They know in general what to do but they don't know the details and how important some of the details might be.

So, whatever that short list is, it would have to be an exciting list, where your communication is telling them something new and something interesting. And then you are saying it in a way that they can remember it and apply it to themselves.

So you said things that were not as complex and perhaps that works. But I would say it something that can be so exciting to them that they care about finding it out and they find out something that is new.

CHAIR FISCHHOFF: Nancy.

DR. OSTROVE: Here is the rub about walking before you run. When we have time,

you know, when there is something that we can do thoughtfully, actually we think we are pretty good at that, in terms of putting together the nutrition facts panel, in terms of the recent revisions to the physician labeling, in terms of the drug facts, the OTC, the standardized label that we put together a few years ago. Kind of we are less concerned when we actually have the time to do it. It is the complex issues that are really causing, getting us the criticism and causing the problems, which is why we are coming to you.

So, yes, I agree that from a logical perspective you definitely want to walk before you run, but in this particular instance, I think we are running. The walking part I think we are doing okay. It is the running part that we could use a little help with.

So, that is just kind of my feedback on the issue.

MS. DESALVA: So in light of that

insight, I can agree with all of that and understand it completely.

I suppose it is relevant, isn't it, in terms of layers of complexity because it is all complex. And you have hyper-complex situations and then you have other types of situations that are important or urgent with drugs or devices or vaccines.

But they are more chronic. They are more, you know, if you are dealing with the aftermath of a major problem and there is a population at risk that needs to continue to be managed, there is a mandate there to do that work on an on-going basis thoughtfully but your pants aren't on fire. That is sort of a marathon. It is not a sprint. You know, so I guess it is relative but I can certainly understand what you are saying. It does feel like a constant sprint in many respects.

DR. SMITH: My first reaction to John's comment was pretty similar to Christine and Nancy. And then as I thought about food

some more, yes, you know, I think we do have a nutrition facts panel but the American diet is pretty poor. So yes, it is there and if people want to use it, they can, but they don't. And they don't really follow it and they don't.

So, I don't know that that is not a bad suggestion to take something as mundane as the nutrition facts panel and really test some assumptions and learn how to communicate it so it is effective. Because communication is great and if people -- everyone understands what it is but they don't do anything. So how do you take it to that next level, where it is more than just, gee I know what a nutrition facts panel is. And when they have dinner with somebody like me who lectures them on what they are doing, it is oh, great, it is there. But then they still don't change.

And how do you change that behavior? Because that is what you want to do in a crisis situation but much faster and at a

much more accelerated rate. So, I don't know that that is not a bad thing to pick something like that and really get it to the different level than we have seen recently.

MS. MAYER: I am reminded of the community, is it in Denmark, who actually managed to change a whole city's dietary habits by means of -- there was an article in The Times not long ago about this community. But they just sort of took it on as an issue at every level of the city government, all of the restaurants, all the foods suppliers, families, and so on. They brought it to a community level, it is sort of like "it takes a village," and were able to do some major alterations in behavior.

It is clear that, I mean, I guess I would like some clarification from FDA about what they are looking for. Is it effective communication that actually leads to behavioral change that you are looking for? Or is it, we are doing our part the rest is up

to others? Which is sort of, it is a very different thing.

Because I think what it takes to change these fundamental behavioral and psychological and emotional issues is far more than the FDA an hope to take on.

DR. OSTROVE: And I would welcome, also please, don't let me hang out here to dry. I think it is a little bit in between those. Because clearly, if you put out all of the communications and it doesn't have any impact at all, that is kind of a waste of the taxpayers' money, essentially. So, we don't want to do that.

Ideally, would we like to be able to impact behavior? Absolutely, because there are instances where, for instance, a product has had to be taken off the market because the healthcare providers' behaviors would not change. Now, it may be that nothing we could have done would have changed that behavior but I am not sure that we are certain about that.

And you know, so that is kind of like what we, I think, like to get a little bit better at doing is at least moving in that direction. And even if we can't necessarily change the behavior, maybe we can have an impact on the way people think about it. Because once again, once you get, you know in the whole risk communication thing, it all is in there with peoples' values.

You know, and it may be that we want them to do something. And they just feel like, okay, I know what you want me to do and I just don't agree. I am not going to do it. Well, fine. You know, then the consequences are that A or B happens. But at least we have gotten them to think about it and we have done our best to improve the situation so that we don't have to remove a tool from the environment because under its current conditions of use, the benefits don't outweigh the risks.

So, you know, that is kind of my

sense, that I would love.

MS. RICE: I would agree with Nancy, that is probably a combination and it depends on the situation. I think we would like to be able to use both types of communication or improve both types of communication, both those to have people change their behavior and the use of products, and the ones that are just more effective in overall understanding, as part of a bigger picture.

As you said, we can't do it all. In certain cases, we are not responsible for doing it all, you know, as I alluded to earlier with the kind of dual vaccine safety responsibilities of FDA and CDC. So, I think that somewhere in the middle, you know, I think there is a little bit of all of that that we would certainly like some help on to improve how we do it.

DR. DAVIDSON: I would say from the sense of CFSAN, we really do want to change

behavior, both from encourage greater label usage, have people have safe food handling practices, in the event of an emergency, stop eating a certain food. That is definitely what is within our interest and our scope.

DR. SELIGMAN: Yes, one of the initiatives currently within CDER focuses on safe use. And that gets directly to the whole issue of how we can effectively influence the behaviors of those who prescribe, dispense, and ultimately use the products that we regulate. So, I agree with the commenters. You know, there are clearly things that are within our circle of control, you know, what we write and disseminate.

And then there are things that are what I consider to be our circle of influence. And clearly the safe use of products that we regulate, I think, will continue to be in that circle. I think we all care deeply about it because that is ultimately why we at the FDA are here doing what we do on any given day, is

to ensure that the products that we look at are ultimately redounding to the benefit of the public.

MS. MAYER: So just to be provocative, throwing out another question to the committee, do we feel like we have all of the needed expertise around the issue of influence? Like to influence. How to get people to do what you want them to do. Is all of that expertise represented around this table? And if not, then could it be?

CHAIR FISCHHOFF: I have a point of order. Linda, Ellen, the mike. We won't forget that question.