that ultimately the stories, you know, the reporter will be better informed, the coverage will be more accurate and so on.

MS. BRUHN: So, do they usually make it?

MS. REBELLO: Do they usually make it?

MS. BRUHN: In other words, do you keep track? Do they --

MS. REBELLO: Yes.

MS. BRUHN: Do you keep track of your success so that within a timely fashion, you know, reporters are often on deadlines. Are they usually able to speak to who they want to speak to within a reasonably short period of time?

MS. REBELLO: I can say we certainly try our best. We don't do 100 percent, you know, we're not 100 percent effective at that. Just from the sheer volume of calls that we get, and you -- if you couple that with, when we're dealing with an

outbreak, unfortunately, we're not going to get to all the media inquiries.

But we've just added a mechanism last year for our website. So, if you're a reporter who doesn't really know FDA, and you have a device question, you can send an email online, and it goes to the two press officers that handle those inquiries.

We also have been really trying to develop our media lists -- or better -- to make them better and trying to reach out as much as we can. But, there's certainly room for improvement.

CHAIRMAN FISCHHOFF: David.

MR. SMITH: I've got sort of a two-part question, I guest the first is, for Heidi, and maybe Nancy. Do you share the perspective that John showed in, you know, clearly there's a desire and we heard from yesterday from everybody about transparency and better communication. And, you know, do you share that there's some more modern tools

to use that John talked about to do that in a better way?

And then secondarily I guess for everybody, in light of some of the perspective that Ellen shared yesterday, and the horrible mathematical acumen of the general public, how do you deal with these things of probability and even my guess is, bar charts and pie charts are going to be a struggle for a significant part. So, yes, the verbal communication is tough, but I don't know that -- I guess we have to test it, but how do you look at that?

And is there any plans and would there be an action plan from FDA to actually look at that? And is that in your -- or may be part of the strategic plan part we talked about. I don't know.

MS. REBELLO: I can -- okay. Well, I certainly really enjoyed your presentation, Dr. Paling. And we are looking at ways to be -- to better communicate. Like when we have

announcements of agency initiatives, and where we have time, we really tried to do a multi-media package and you know, not often, but we have done in the past where we have a senior official whose -- you know, we have a studio over -- that they can go to and tape a message to, as a different form of communication.

We have the Commissioner, has Andy's Take on the website now. And it's a forum for him to once a week, speak about an issue to consumers. He also tapes it. So you can hear his voice.

And then your second question was about the numbers. And that's why I was talking about context. Without context, I think numbers, at least you know, we have a very hard time sometimes explaining the context around the numbers. And we would really -- that's an area I think, we would really find useful, if you could provide us help with, maybe coming up with analogies.

Is there any way to provide

analogies of risk to explain complex information? We have risk assessments that come out, and during the melamine in pet food, we issued a joint news release with USDA. And on a risk assessment that concluded essentially that there was very low risk to human health from consuming meat from hogs and chickens known to have been fed animal feed supplemented with pet food scraps that contained melamine, which was -- and that was you know, during the melamine and pet food.

And so, we tried to -- and actually we don't have any credit from this. USDA came up with a way to try to explain it. And so what we said in our news release was, translated to consumption levels, this means that a person weighing 132 pounds would have to eat more than 800 pounds per day of pork or food containing melamine and its compounds to approach a level of consumption that would cause a health concern.

It's a little wordy, but it really, you know, it helped to translate the risk. And we need to do more of that.

CHAIRMAN FISCHHOFF: Let's see. Betsy, Marielos, Mike and then Ellen.

MS. SLEATH: I just had a comment related to John's talk. One of your -- it was excellent, by the way. One of your comments was that telling patients they should communicate with their healthcare professionals about risks and benefits. And I'm not convinced that healthcare professionals have the adequate tools to discuss risks and benefits.

I work in a pharmacy school. I've studied communication for years. And so, I would argue that we also have to think about how do we educate healthcare professionals to talk about risk, and at the same time, for the public to feel as though they need to be empowered on, How do I understand risk.

Because I think it's very grey

area. So, I know that each of your agencies, or divisions has a website and showed us what they do. But one question I have is, do you have a risk communication section of your overall web page, you know, that may be advice for providers, advice for consumers. Is there anything like that? And if not, I would suggest that's something that should be considered.

MS. REBELLO: I don't think that there's a formal one-stop-shopping on risk communication. I think it probably is throughout the website. But not a centralized place. But I'll definitely take that back. That's good feedback.

MS. SLEATH: Because actually, I tried to use your website before I came here to find information to use in my class to teach first year pharmacy students about the FDA. Because at one of these meetings, someone told me there was a curriculum. And even though your website's getting better,

when you search things, it's still very hard to find stuff. So, I would give that feedback as well.

It just -- it's almost -- it's impossible. For me, it was impossible.

MS. REBELLO: I'm sorry to hear that. We are trying to improve upon that.

MS. MCNEILL: Hi. Good morning. As far as the website goes, oh, I'm in the wrong place, aren't I. Excuse me. Lorrie McNeill. My office is responsible for managing the Center for Biologic's website. And so my staff are actively participating in the agency's efforts to move to a new content management system.

And they've been doing extensive usability studies with a wide variety of stakeholders, not only FDA staff, but they've gone out to consumers, healthcare professionals, industry representatives and folks from a variety of organizations that have an interest in the information that we

post.

So, I think once we do this transfer, which I think is supposed to happen by the end of December, you will see a vast improvement in the agency's site as far as being able to navigate and find the information that you're looking for.

So, we're getting there. But you know, it's a very painful process and it's very time consuming. But I think it's supposed to be done by the end of the year.

CHAIRMAN FISCHHOFF: Marielos.

MS. VEGA: I do also agree with what just Betsy had to say. I work in a medical institution. I went to nursing school. And I have never seen any formal training in risk communication, so I think your point is very well taken.

This question, I think, is for Heidi. In this meeting, and over the past meetings we have discussed the importance of perhaps having a single voice, or a

spokesperson for the FDA when communicating to the public, especially emergency situations. Is there a reason why this hasn't happened? That there is one spokesperson for the FDA?

MS. REBELLO: I mean, I know that I've heard that in the past meetings. And it's you know, it's been brought to management and considering. I will tell you that our issues are so diverse, that it's oftentimes, we go to the best technical expert to be able to bring that person to talk to reporters, to the public. But I understand your need and suggestion, and we'll explore it.

CHAIRMAN FISCHHOFF: Mike.

MR. GOLDSTEIN: I too want to thank everybody for their presentations today. And I want to start with John's because I think there's so many opportunities we have to make something simple, and do it effectively. And your recommendations, every single one of them, I can endorse 100 percent, something FDA could start to do tomorrow.

And the very first one, I think it was the first one, letting people know that all drugs have risks and benefits. Yes, the effort is to make drugs and devices and foods that's safe and effective as possible. And that's what FDA is trying to do. But all of these devices and drugs have risks and benefits.

And then to explain it in ways that folks can understand. So there's some very basic concepts that are really, really, simple and effective, I think, easily applied.

And then, AnnaMaria's presentation just blew me away. The preparedness that was demonstrated in how you work with industry, really, to -- it's mostly industry, I guess, to prepare.

And I think there are lessons learned there. And I know they're resource limitations, but you have talked about them before. But to the degree that you can approximate a process that is in place in the

commercial world, I think would be fantastic. To think about the preparedness.

And part of the preparedness has to do with others have mentioned, Betsy mentioned just before. The need to help our clinicians have these conversations with patients when an event occurs. And they need help. Training, yes. And I do training in this area. So I know some training occurs, not enough. We need to use, and I think, some core principles like the ones that John mentioned, as the starting place.

But then, we also need the tools. And AnnaMaria talked about the effort that they put into helping those affective clinicians who already had some training, use some specific tools and have some specific language, so that they can help patients to address both their fears, to make the right decisions together, so that they can mitigate any risks.

So, I think all those things are so

important and so valuable. And we can learn some lessons from them. It does require some shifting of resources, some more resources, perhaps some more partnering with the commercial side, so that those things can be put in place.

But I don't think there's any -- what's the right word -- excuse comes to mind. If the FDA really wants to -- and this is not for the FDA. This is for above the FDA, whoever makes the decisions. If we want to be as safe and effective as possible, then we need to be prepared. And then we need to adopt the kinds of principles and strategies and processes that industry is adopting in order to do the best job that they can.

So, somebody needs to get that message. We need to have the same kind of processes in place. Because we're -- where FDA is dealing with so many more important risks, when we talk about the food supply, when we talk about the millions of people who

are taking -- hundreds of millions of people who are taking pharmaceutical agents that can't be reached through industry as easily, it really requires this kind of preparedness.

And I think we have to invest as a country in the preparedness. So, I'll get off my soap box.

CHAIRMAN FISCHHOFF: Thanks. Ellen and then Linda.

MS. PETERS: I wanted to return to a topic that Dr. Smith brought up, around numbers are difficult. And the importance of communicating numbers. One thing that sometimes comes up in the risk communication literature, and this is something that Baruch has actually written about, is that sometimes it seems that some communication is so difficult that we shouldn't bother.

That it's just too difficult. There's not a way to get around people who are innumerate, who aren't as good with numbers. And I wanted to actually point back to one of

the analogies that John showed. One of these great visuals, but make a slightly different point from it.

He brought up the point of the bees being an incredibly efficient, very efficient as a hive. But then when you slow it down, and you look at all the mistakes, they're making a lot of mistakes. They're bumping into each other. But the point I'd like to make is, that they keep on trying. They might have gotten knocked down to the ground, but they got back up again and they continued to try to get into the hive.

And it worked eventually. Just like the little engine that could, eventually made it over the hill, if we keep trying to figure out ways to communicate the numbers, we will in the end, end up with better informed patients, and hopefully with better health in the end. And that's what we're looking for.

A couple of other points just along that same line. We know a bit at this point

about how to communicate numeric information. We don't know everything. I believe that we need more testing with less numerate populations who aren't as good with numbers.

In particular, I think we need more testing with elderly adults, who as a population, tend to be less numerate. But in addition to that, because of declines of cognitive processing, they're also less flexible with change. They're less flexible with new types of information. And I think we need more testing specifically with them.

In addition, I think we need more testing with them, because they are the ones that consume the large proportion of our pharmaceuticals. And so in particular, it's important to understand how they would react to this kind of thing. We actually don't know much about that yet.

Some of the things that we do know, though, in terms of how to communicate numbers is, we need to use judgments. We need to use

judgment in what format to present a number in. So, some things we know already, are that if you use verbal labels. Some of the verbal labels that John was talking about, in communicating risks, that is going to lead to probably the greatest risk perception of the side effects based on the studies that have been published so far.

You can use frequency presentations. One out of 10,000, for example. Or you could use percentage formats. I can't even do that translation quickly, but one percent versus one out of 100. We know that highly numerate people, there's not going to be much of a difference, regardless of what format you present that number in, unless you use the verbal labels, by the way.

But if you use actual numbers, it's not going to make much of a difference to people who are good with numbers.

For people who are less numerate, if you use a frequency presentation, it

actually will connote greater risk perceptions. It will effectively deliver more risk is there if you use one out of 100, than if you use one percent out of 100, for people who are less good with numbers.

And so, it's not that one is better than the other, it's that there's a choice to be made. If it is deserving for a greater risk to be communicated there, then the FDA, or whoever the communicator is, needs to make a choice. If it appears as if people are fearful and anxious, and you want to quell some of that, some undue fear at that point, then using a percentage format may be the better way to do that. But it's a choice. It's a judgment call.

John brought up the idea of framing. And whether you frame information in a negative frame, the proportion of people who will get the side effect, or a positive frame, the number of people who will not get that side effect. And he suggested using both

frames.

Again, there's an issue with numeracy here. If you use a single frame, people who are more numerate, it's not going to make much of a difference. The frame isn't going to effect them as much. It affects them some, but not as much.

People who are less numerate are much more affected by those frames of information. I would claim, it's actually not clear what's going to happen if you present both frames of the information though. It needs to be tested. It could be that what will happen, is if you present both frames of the information, you're going to help the less numerate to better understand the complexity really that's involved in a single number. And they'll get more meaning from that.

On the other hand, there's other data that suggests that the more information, the more numbers you provide, and particular to less numerate people, the less they

comprehend. And so, it's not entirely clear what's going to happen. And as far as I know, it hasn't been tested. So it's another case, where there's an empirical investigation that needs to be done. It's not quite that simple.

And what it comes down to again, and I always hate bashing the FDA over the head on this over and over, is we need testing. We need testing to make sure that what we're doing is going to deliver the best health to our patients and our consumers. And in the end, we need testing to be able to ensure that the U.S. public is getting what they deserve.

CHAIRMAN FISCHHOFF: Let's see. Linda, Marielos and then Christine.

MS. NEUHAUSER: I too wanted to thank everybody for the excellent presentations. And I'm still trying to digest what Ms. Rebello talked about. Because the enormity of what you're faced with as far as challenges, the lack of resources to carry it

out and the questions that you have, you have a whole list of questions. And I really can't think of anything that is more important to the charge of this committee than trying to answer the questions.

We just heard from John Paling and Ellen Peters, that even coming up with an answer to something like putting out risks and benefits and probabilities is something that needs a lot of thought here. So, my question to you is, have you ever had an internal, strategic assessment of your office? Because the list you have is so long.

I mean, you could pick any one of these things like we need to do better at evaluating, and each one of those would require an assessment of what you're doing now, your resources, your ideas, who else you could call on in the agency. So, moving ahead strategically to do better, would require something like that.

And then, I would suggest a

strategic plan to figure out how each one of these things that you would like to accomplish, each of which is enormously important for the public, is going to be carried out and by whom.

MS. REBELLO: Thank you. For your question about the internal strategic assessment, I'm actually, I'm not sure if we've done anything formally. I know that when we -- after an event, or after an announcement, or we roll out a major initiative, we do take the time, not always, but we do do it as much as we can, to go in and to reassess where our strengths and weaknesses were.

We did that with the Heparin. Actually, the CDER lead that. And I think throughout the agency, folks do that as well, in terms of for communications.

But you know, like I mentioned, we need to do a better job at that. I feel like a broken record. But your insights are very

valuable, thank you.

MS. NEUHAUSER: Well, just to clarify a little bit, you can do sort of piecemeal assessments of this issue and that issue, but that kind of approach is probably not going to get you where you want to go. And it won't really respond to what Congress is asking in terms of improving the risk communication capabilities and activities of the FDA, which relies so heavily on your office.

And so, my question is really an agency-wide question. Rather than necessarily a question for your office.

MS. REBELLO: I see.

MS. NEUHAUSER: And maybe one for the committee to consider in the light of the Congressional requirements under the new Act.

MS. VEGA: Something that Ellen said, it reminded me in terms of the issue of framing. It reminded me of a case in our institution where first we don't have enough

staff who is multi-cultural. So, there was the case of this patient, hispanic patient, monolingual, who had a test for colon cancer, a blood test. And the test was positive

So, a letter was sent to the patient, saying the test was positive and that she needed to come in. The patient never came in, and there was no followup. Eventually she came in, but it was already about two and a half years later. And to the patient's understanding, the positive in her culture meant something good.

So, she was under the impression then everything was fine, she didn't have to worry about it. Of course, the symptoms persist. She continued bleeding, and eventually she came in. But that is when the framing that I need to state, it is more with difference of groups, it's very important. Because we have no -- we know how we understand, positive and negative, but we have no clue how different groups understand it.

So, it can mean life and death for some people. So I'm glad you brought that up.

CHAIRMAN FISCHHOFF: Okay. Christine, Mike, and then Musa.

MS. BRUHN: John, I want to thank you especially for that last list at the end. And I'm sorry we don't have it in our papers, but I will look forward to seeing it on the minutes as we get posted. But when you went through it, I was thinking right on for each one of them. So, thank you for putting that together.

Now, I wanted to make a comment on relative comparisons. Should you compare risks from one topic to -- from one category to another. I know it's often in the literature they suggest don't do relative comparisons. My colleagues and I tested this in the area of pesticide risks with parents of young children. And we compared the residues that could be on fruits and vegetables with driving a car under certain circumstances, or

eating a peanut butter sandwich on certain circumstances.

We had six or seven relative comparisons. And the results form this where people appreciated having additional information. Because it put the risk in comparison. So if that showed them that the risks for many residue in, on fruits and vegetables was indeed very low, and even though it was still there, it was low. They didn't find all of the risks credible.

They didn't believe there was any risk from eating peanut butter sandwich, other than perhaps choking. And this again goes to one of Ellen's points about people come from a different context than you. I did this with a toxicologist, and of course, we were thinking of apple toxin and mold. But the public didn't know about that.

So, but the main thing from the comparison was, that was additional information and the people wanted all the

information they could get. So that was useful for them.

Now, one of your things that I thought was very interesting, and you gave us even slides on it, was the visualization of a risk. Like the pie chart, and then in your diagrams here, you have like two people with -- two people lines with lots of other lines. And I wanted to have a question for Ellen.

Has anyone tested visualization as far as, does that give people a better concept of relative risk? And does -- how does it impact numerate and the less numerate populations?

MS. PETERS: There's been some very nice work done by Angie Fagerlin and Peter Ubel, Brian Zikmund-Fisher, and a few other people at the University of Michigan, looking specifically at things like comprehension of numbers from tables, versus comprehension from what they would call a pictograph.

Where a pictograph is basically, if

you can picture sort of a 10 by 10 table of squares. And you can then mark the number of people at risk of a side effect, for example. And what you can see is, you can see in that pictograph, the number of people at risk, and the number of people not at risk within a single, fairly small space on a piece of paper.

And what they find is, that people tend to believe that tables are more effective if you ask them. But they actually understand more of the gist of the information if it's -- if the information is provided in one of these kind of graphical formats, like a pictograph.

And it's fairly new research. I don't remember if they looked at numeracy. My expectation would be that it makes a bigger difference for the less numerate people, and that for the highly numerate, it doesn't make as much of a difference, but maybe still, makes some difference because it does provide some of that context for them.

MS. BRUHN: That's very useful. Thank you. And I'm wondering, do we know that much? If we -- are we ending up perhaps misleading the public if we show a pictagram that's based on averages, if there's a situation that people with certain circumstances are more at risk? And you know, we're always making decisions here when there's not complete certainty.

MS. PETERS: Yes, a very good question. So, I mean, you're bringing up sort of two different issues here. One is, we give a precise number, but there's almost always uncertainty around that number. So, that's one issue. It's a very big issue. There's actually a working group at the National Cancer Institute that's just starting up looking at these ideas of ambiguity, and how do you communicate ambiguity and how do people understand ambiguity.

There's actually not a lot known about that. There's a little bit. And you can

-- we can talk about it offline. There's just a little bit known, and it's kind of in sideline literatures. Unless Baruch knows more about this. I'm hearing him down there mumble a little bit. Did you want to kick in there?

CHAIRMAN FISCHHOFF: No.

MS. PETERS: Okay. The second part of your question was, we often present information about the average person, or you know across this Group of 100,000 that were tested. But it may be that people who have a particular physiological profile are more at risk, or less at risk.

And you know, it gets at the idea of using the best information that you have available to help this particular patient make the best informed choice. Sometimes what we have is only that average. And I'm ignoring the ambiguity at this moment. Sometimes what we have is more targeted information, and you know, I would claim, that if we can provide

that more targeted information, we should.

It's some times quite difficult to come up with though. That's easier said than done. In terms of a federal agency, they're also often trying to provide information to everybody. And they're trying to help people as best they can. So if you're talking about having the resources to send a single communication out, that average is probably what you should send out.

Maybe with a little additional information if there really are some big differences around physiological profiles or gender or something like that.

MS. BRUHN: It's like Maria's presentation. It worked well for lots of people, but there were some specific groups that it didn't work well with.

MS. PETERS: Right. Yes. Great questions though.

CHAIRMAN FISCHHOFF: Okay. Mike and then Musa.

MR. GOLDSTEIN: This is great. I love the interaction and the discussion. Because I learn something every round. And it's been -- I raise my hand, and I have something say, but it's very different now after hearing people. What I've learned from Ellen is that, all methods of risk communication have risks and benefits. That there's no one way that we're going to find that's going to work for all people.

And actually, I learned this from reading Howard Gardner, who's a cognitive psychologist. We have a cognitive psychologist in the audience who may know him. And he's the person who came up with the concept of multiple intelligence and there is evidence that people are different in terms of their way in which they learn and understand.

Some people are more visual, some people are more verbal. Yes, in general, we can study population and learn the best way. But it's not going to work equally well for

all people because of their differences. On the other hand, he also showed, that when you show information in multiple formats, comprehension increases and actually, that gets translated into taking that information and acting on it.

So, my view would be that we want in the current level of understanding, we want to provide as many different methods of helping people to understand the meaning of the information we're conveying as possible. We want to continue to test to see what's the best way. But it's never going to be the best for every person, because there are differences.

So, there's only so much that the FDA can do. The FDA can gather information, they can put it into formats that are understandable and make those available for patients and providers. But then, I do think it's up to providers to fully take into account, the specific needs of a given person,

given their culture and background, to help them to understand so that they make the choices.

That kind of a conversation, communication, is only going to take place in the context of a relationship. And the FDA is never going to be able to recreate that. They can only promote that. So, I would argue that we need to, again, take what John's core statements have helped me to realize, that this is what the risk is, this is what the benefit is. There's risks and benefits.

Different people have different levels of risks and benefits, because there's uncertainty about that. So, here's what we know. Refer people to credible sources, so they can have the conversations that are likely to enhance understanding and decision-making. And train people who are having those conversations to do it effectively. That's my simplest way of putting this all together so far.

And I'm sure it will change as we go around the room again.

CHAIRMAN FISCHHOFF: Lorrie had a comment, and then Musa.

MS. MCNEILL: It gets in part to what the last speaker was saying. But to get back to Dr. Bruhn, when it comes to reporting information in terms of numbers, it's a real challenge, based on what we know and what we don't know.

A very good example is an article that appeared in the Wall Street Journal today. I think it was posted on line last night. It was an interview that one of the subject matter experts in my center did, on RotaTeq vaccine, which is a Rotavirus vaccine. A similar vaccine was withdrawn from the market, back in 1999 because of an increased rate of a specific, serious adverse event, following administration, vaccine administration.

So the reporter from Wall Street

Journal had submitted a Freedom of Information request for adverse event data and had gotten all of these numbers and wanted some help understanding what they meant. The interview itself was highly technical, because Dr. Ball, who heads our biostatistics office, had to get into the weeds of explaining relative reporting rates of the current vaccine, versus the previous vaccine, and all of the caveats of what we don't know.

We know how many doses are distributed by the manufacturers. But what we don't know, is how many are actually administered. The numerator in the case, or excuse me, the denominator, of the number of doses distributed, is considered confidential commercial information by the manufacturers. So, while we know what that number is, we can't tell the reporters or other stakeholders.

So, it's really difficult to put this type of information into context and

explain it why we say, we don't believe there's an increased risk based on what we see, what we've seen. Dr. Ball was able to explain this very well to the reporter, but he was a highly educated, you know, on this particular issue, it was as Bob said to me afterwards, the most technical interview he's ever done.

We often don't have the luxury of time to do that with reporters. In this case, he worked on the story for a couple of weeks. He spoke with us, he spoke with the Center for Disease Control. He spoke with the manufacturer. He spoke with the World Health Organization. So, it was somebody who had time to develop the story and really get the story right.

And Heidi could comment on this more than I could, but oftentimes, when we hear about an interview request from Heidi's office, it's with about this much turnaround time. The reporter has a deadline. They want

very specific, detailed information. Our subject matter experts may not be available to provide that kind of context.

So, it's an added problem for us. We want to get that information out there. But it's hard to do it in a way that's meaningful.

CHAIRMAN FISCHHOFF: Thank you. Musa and then Linda.

MS. MAYER: So, I'm sitting here trying to absorb and sort of filter everything that we've heard through what I know best, which is, how breast cancer patients understand the risks and benefits of the treatments that they choose, and what the sources of their understanding really are.

And as best I can determine, apart from the information which is usually -- I say usually - incomplete, that they get from their healthcare providers, they are also making decisions based on anecdotes, stories that they hear from other patients, and media

coverage of treatments that are emerging. And to some extent, from advertising. That's probably more an issue for women with advanced cancer.

But you see, breast cancer is always in the news. I don't know -- I mean, I'm aware of it because I follow it. But there's a constant, sort of media attention, on emerging breast cancer treatment, like other major and common diseases. It's just always there. It's also very feared. So that creates a certain climate as well.

As a result of all of these factors converging, and as a result of out not quite being there in terms of what science understands, we over-treat primary breast cancer to a degree that's probably unimaginable to most people. About three-quarters of women diagnosed with breast cancer do not need any additional treatment past their surgery and possibly radiation to the local area.

And yet, most of them are receiving very toxic drugs -- chemotherapy and hormonal treatments -- that have a both very short, serious -- short and long term consequences. In -- and how they make those decisions is often based on their emotional state. It's based on their perceptions of safety, which may or may not be true, on their perceptions of effectiveness, which are almost always exaggerated, and on their perceptions of what everybody else is doing. That is, this is the standard of care.

If ever there is an areas where there is a lack of truly informed consent, I think this is a perfect example of that. And there are a lot of reasons. It's too complex an issue to really talk about in detail here. But all of the factors that all of the speakers have brought up, in a way, come to bear. The lack of numeric communication, the lack of visual aids that might help patients understand what their risk of recurrence is,

and what their benefit for choosing these treatments, the way in which treatment choices are framed, the use of absolute versus relative risks and benefits of the treatments -- all of these factors come into play in the most intricate way.

And so I'm sitting here thinking, how could FDA have a positive influence in these factors? And it just -- it seems to me that to the extent that FDA can communicate clearly in all these areas, and discuss -- I suppose it's really in terms of individual drugs I'm talking about here, and also procedures, devices and so on, that are used. As clearly as possible, that will offer so much benefit not only to patients, but to physicians as well, who are also at a loss.

We have one tool that is sort of like a light -- it makes use of many of these things. It's called Adjuvant! Online. And it's a way for -- and it offers a visual aid and clearly quantified information. A way for

an oncologist and a patient to sit down together and look very clearly at information -- which is abstracted from the latest clinical trials data -- at what the actual benefits are from selecting treatments.

However, there is no risk information incorporated. It's all benefits. That -- so it's only, in a way, half of the picture. And I'm just thinking that FDA could play a really significant role, in providing the real tools that would enable the scientists who are constructing tools like this to take it the extra step.

And that there really isn't any other honest broker, if you will, who is in a position to do that. To actually help provide the numbers in a way that's transparent, both to patients and to physicians. I was so heartened to hear Paul Seligman say that with ten drugs, they are trying the drug facts box. Because that's exactly the kind of tool we need, desperately need, I think.

CHAIRMAN FISCHHOFF: Thank you. It's 10:30 now. So, I'm going to take a break. I've got the names of people down. When we come back, we'll have an opportunity for our open, public hearing. Again, if anybody would like to speak, please see Lee during the break. So, let me thank our speakers and thank our panel, and we'll continue this discussion in a few moments.

(Whereupon, the hearing in the aforementioned proceedings went off the record at 10:32 a.m. and resumed at 10:48 a.m.)

CHAIRMAN FISCHHOFF: Okay, we're now going to have the public comment part of the meeting. But before we start, I'd like to have a thank you to Nancy 's daughter for the brownies she's made available to the committee, written into the official minutes of the Food and Drug Administration's Risk Communication Advisory Committee. Thank you.

And now, an official announcement. Both the Food and Drug Administration, FDA,

and the public believe in a transparent process for information gathering an decision making. To ensure such transparency, at the open, public hearing session of the Advisory Committee meeting, FDA believes that it is important to understand the context of an individual's presentation.

For this reason, FDA encourages you -- the open public-hearing speaker -- at the beginning of your written or oral statement, to advise the committee of any financial relationships that you might have with any company or group that may be affected by the topic of this meeting. For example, the financial information may include a company's or a group's payment of your travel, lodging, or other expenses in connection with your attendance at the meeting.

Likewise, FDA encourages you at the beginning of your statement, to advise the committee if you do not have any such financial relationships. If you chose not to

address this issue of financial relationships at the beginning of your statement, it will not preclude you from speaking.

And I have two speakers and I'd like each of you to state, or state your name, and then speak directly into the microphone. And the two speakers in order will be Cindy Evans from Health Canada, and Jeffrey Sekondi from AdvaMed. Please.

MS. EVANS: Thank you. Again, my name is Cindy Evans. I work at Health Canada and in the Marketed Health Products Directorate. I'd like to thank Dr. Fischhoff yesterday. He asked if I could just give a few comments on the Canadian context.

And it's been my pleasure to be an observer at this meeting. I've really enjoyed listening to the conversations, both from the expert advisory members, but as well as the FDA panel members.

In addition to that, we've had the privilege of having on-going dialog with Dr.

Ostrove and Dr. Zwanziger with regard to sharing our best practices, our informations and the challenges that we're having around the issue of risk communications.

Just to situate myself in Health Canada, Health Canada is made up of a number of branches, one of them being the health products and foods branch. It has a scope of responsibilities similar to what you heard yesterday from the centers, in that it ranges from foods, veterinary drug products, pharmaceuticals, biologics, medical devices as well as natural health products.

Within that branch, I work in the marketed health products directorate, and the scope of our responsibility is post-market surveillance for pharmaceuticals, biologics, natural health products and medical devices.

We've made risk communications a natural priority area for a number of years. Some of the things that we've been working on are to make risk communications. Both our

products and our processes more consistent and more transparent. A number of years back, we issued a guidance document for industry on the development and issuance of health professional communications and public communications.

So, that was outlining Health Canada's expectations for both form and content and the nature of distribution for Dear Doctor letters, and notices to hospitals that are issued by the industry. And as well, we put forward the principle that there should be a companion piece for that called a public communication that in lay language is the same messaging, but designed for the public. Because those dear healthcare professional documents were made available on our website, and we felt that that companion document was really necessary.

In addition, last month we issued a guidance document which explains the -- it has a very long name. But it's essentially the

current risk communication document. What they are, and how we use them. So, for the 13 different types of risk communication documents, risking -- arranging all the way from a public warning, down to an "It's Your Health" letter, what we wanted to do, was to bring some transparency and also some predictability to the process.

So, what are the documents, what are some of the considerations for when we would use one or the other, and what are the typical ways in which we distribute those. So, again, we were quite pleased to be able to issue that and we feel that's an initial step for us in laying out a baseline of what we do. Because we're also very interested, like the FDA, in looking at those processes and products, and how do we challenge them.

One of our important outreach initiatives is the MedEffect Canada Initiative. And that consists of, we do have the MedEffect Canada website, and that's both

for information in and information out. So, it has the advisory's warning and recalls that are issued are posted there. You can also get the Canadian Adverse Reaction newsletter. It's also to get information in, where people can find information about adverse reaction reporting, the ways in which they can report why it's important, and provide their online reporting there as well.

An important aspect as well is the MedEffect E-Notice. So, that's our list-serve, where we're actively, proactively sending stuff right out into the hands of Canadians. And we're quite pleased that it's a subscription over 18,000 subscribers to that list-serve. A little smaller scale than on the U.S. but we're pleased with that.

Another initiative just to share with you. We have, in the branch, set up an expert advisory committee on vigilance of health products. And they're to have their third meeting coming up the end of September,

and examining risk communications is one of the items within their mandate. So, we're quite interested to follow the discussions of this group as well, and we'll be bringing some questions to our EAC in the Fall, and we're quite pleased that Dr. Ostrove will be joining us at that meeting.

So, as I said, we have similar challenges to those that you heard yesterday from the centers. We see Health Canada as one player in the healthcare system. We don't do everything, and we can't do it all ourselves. Health care is delivered provincially in Canada, and the practice of medicine is outside of our federal jurisdiction. And that can bring challenges when you're getting into the specific details of risk communications and what you would want someone to do with what you're communicating.

We also believe quite strongly that risk communications is a shared responsibility. So, it's Health Canada, it's

industry, it's our healthcare professionals and it's also consumers, have an important role to play. Some of the things that we're looking at is as I said, we'd like to challenge and examine the effectiveness of our risk communications. And that's a three different levels. It's the documents themselves, it's how we distribute them, and that's both our primary distribution but also there's a number of different ways of secondary distribution that I don't think we've look adequately at in terms of how we could use our, and work with, our healthcare organizations and consumer and patient organizations to better get our messages out.

And the third is the uptake. So, not just enough to say we sent 200 things out, but was it received, was it understood, did it result in any change in practice. And that's easier said than done. And we're again, quite interested to hear what the ideas are around examining effectiveness. Because it can be a

challenge to say, what would success look like. Because success wouldn't always look like a drop in prescribing patterns. So, again, how do we figure out the best ways to assess the effectiveness at all of those three levels.

We're very interested in the topic of emerging risks as well. What do we communicate. How soon do we communicate and how many messages would be too many on a single topic. So things like, you know, on the pet food, or on the Heparin, when the situation is unclear at the front end, when do we come out with information and what information is helpful to share at what stages.

And just lastly, we're also very interested in the issue of relativity of risk, or how do we best put risk into context for Canadians. And again, these are not simple questions. If they were simple, we would have solved it on both sides of the border and just

shared our information.

So, again, I'm pleased to be here as an observer at your meeting and we really look forward to hear the recommendations of the committee as well.

CHAIRMAN FISCHHOFF: Thank you very much. Would you be willing to take a question or two, or if we have a question or two?

MS. EVANS: Absolutely.

CHAIRMAN FISCHHOFF: Please, Madeline.

MS. LAWSON: Thank you for your presentation. I'm just very interested in how you work with the health professional and consumer organizations in aiding you to get your message out to the public?

MS. EVANS: We do have on-going, regular, what we refer to as bi-lateral meetings with these groups. So, for example, we would meet the Canadian Medical Association, the Canadian Pharmacist Association and there's other patient groups

that we would meet with.

They, themselves, have good relationships within their own organization. So, for example, their secondary distribution, they will point to the advisories on our website. They will often redistribute. So, there are organizations like NAPRA, who are the National Pharmacy Regulators, who will take our e-notice, and also share them with their groups.

So, there's a full range of secondary distribution that's effective. But also, we do get on-going feedback from them on our -- for example, when we're developing guidelines on risk communications. They're input is extremely helpful to us. Again, to bring that practical perspective.

CHAIRMAN FISCHHOFF: Okay. Thank you very much. And our second speaker is Jeffrey Secunda from AdvaMed.

MR. SECUNDA: Good morning. My name is Jeff Secunda from AdvaMed. AdvaMed is

a trade association that represents the medical device industry. And I want to give my compliments to the committee and to the FDA for their participation. It's been very insightful and I think in some ways, in a very positive way, provocative discussions.

I hadn't intended to say anything, but again, the discussion was interesting and provocative. And I do want to make three points. The first is, I believe Ms. DeSalva's prevention was marvelous in describing the best practice of corporate response to crisis and risk communication. However, I also want to point out that -- and I believe that Lynn Rice from FDA pointed out also -- that 75 percent of the medical device industry is made up of small manufacturers, with as few as 30 or less employees.

And whereas, the portrait that was portrayed is absolutely the pinnacle, it is absolutely beyond the means of the vast majority of manufacturers. And I think this

just goes to, you know, reinforce the necessity for effective risk communication and that it starts at the lowest level, goes to the highest level.

And the second point I would want to make in that regard, in reference to Dr. Paling's concept that the FDA has a responsibility to shape the communications: I think this is absolutely a key point. And I would direct this to FDA. The FDA mission is well-known, is to protect and to enhance the public health.

And I think that the effective risk communication is the absolutely integral part of that process. When it comes to FDA putting out the message, that's important. But as we've been hearing time and time again, and as citizens of the media age, we all know that the real communication doesn't take place -- doesn't come necessarily from the source of the information, but rather from the transmitters of that information.

And I think that FDA should take a special responsibility in training the media as to what FDA means, what are the terms mean, what are the relative priorities and risks, and this can't be a casual thing. This has to be part of the core mission of FDA, in enhancing and protecting the public health, to be able to have effective partnership with the media to get a real message out.

And I would also say that in addition to the media, the financial community is, I think, not necessarily well-understood as being a very, very important communicator of information. When there's a crisis that goes out, you know, you might read about it in the newspaper and run around and say, "Oh, my gosh."

But, if you're an investor and there is a crisis statement that goes out, then that's going to have a material effect on you and therefore, the financial community is a critical part of the dissemination of this

risk communication.

And finally, I want to refer back to the statement that Dr. Maisel made yesterday, representing the Heart Rhythm Society. And AdvaMed is completely in concert with Dr. Maisel's presentation in terms of the term "recall." I think that it's a barrier to effective communication. And I -- and honestly, I -- all the metaphors that we've heard and means of communication, I had in mind a particular metaphor for the concept of the term "recall."

And that is, if you have a bump in the sidewalk, and you want to warn people not to trip on it, then if you put a barrier up that covers the sidewalk, then you have an option of either going around by stepping into the street, or you can walk around, up on private property. And the fact of the matter is, that very often, if it is in fact a bump, then you don't need a barrier to prevent people from passing over it. You can put up a

warning sign. And I think that's, when all is said and done, the term "recall" might be part of the FDA lexicon, and it might have some legal ramifications. But that doesn't mean that it can't be changed, either from a legal perspective in regulation, or very practically, in the nature of the way that FDA communicates and uses that term.

Instead of putting the recall in red letters in a box on the paper, it can have urgent safety notification, which are very communicative terms that are well understood. And then if you have to put into the footer, you know, pursuant to, you know, Part 7, is a "recall."

It all depends on how it's framed. And I just think that it's a unnecessary impediment to effective communication. Thank you.

CHAIRMAN FISCHHOFF: Thank you. Are there any questions for the speaker? Okay, AnnaMaria.

MS. DESALVA: I'll just quickly say, thank you so much for your comments. And I should have actually acknowledged, and your comments remind to acknowledge that what I presented certainly was sort of a broad best practice. I certainly do understand the points that you're making relative to the scope of the activity that a smaller company wouldn't really be in a position to undertake. But for demonstration of, you know, how we apply these strategies broadly in the time that I had, I just wanted to look at the fullest illustration of it.

But your point is extremely well-taken.

MR. SEKONDI: It wasn't a criticism. It's was just an observation.

MS. DESALVA: I understand. No, I understand, thank you. Thank you.

CHAIRMAN FISCHHOFF: Thank you very much. So, we have the rest of our meeting to come up with -- to continue to come up with

recommendations for FDA. We have particularly in our two talks today, we had a number of quite concrete proposals.

Let me just direct your attention. This will be in the folder for all of the committee members. I guess it would -- I guess it's probably on -- I don't know, is this out there for...?

So, we have four questions here. Rather than read them, I'll allow them, just sort of take a look at them and see some of the classes of recommendation that we might come up with. But we're also free to think of other -- of other things.

So, let me, before -- to kick this off, let me -- I'd like to make a comment, some sort of "to connect" comments that David and Musa and Ellen and some of the others made just before the break. So, I think we've had -- I have to make certain that a half an hour doesn't go by without talking about evaluation. But I think we've had an hour go

by without talking about staffing.

And so let me say I think that, so the question of how do you deal with evidence -- I mean, we have common sense evidence. You know, sort of every day evidence of people's difficulty with numbers. We have a growing research literature about forms of innumeracy and its correlates, and its extent. We see that there's -- that we're sort of dead in the water if people don't know how large the risks and the benefits are, and how good the evidence are.

And so how do we reconcile that? And I think that a necessary, but not sufficient condition is to have as part of the research group, people who are intimately familiar with the research literature. It gives you a few things. One, is it gives you access to whatever else is out there.

So, you see, we have several experts here, and we're checking with one another, whether or not you've heard of

anything. So, if you've read a few papers, you've just seen a tip or less than a tip of the iceberg of what's out there. So, you want access and you want people who can call up other people who can bring that in.

And without people who are trained, there's really no way that that can happen. And they have to be there, you know, in real time as the projects are being developed, you know, in the same way that you need your collaborators to be there in real time to see where you've gone astray.

Second thing that people who are familiar with the research literature can give you, is they can give you the context for understanding the research that you're seeing. So for example, a standard technique, particularly in psychology, is to create conditions that magnify biases. That is, much of psychology is built on finding ways in people, in which people make mistakes. Because those tell us something about the

systems in which -- that generate their behavior.

So, if you think about -- a lot of perception research has been informed by optical illusions, because it shows you things you wouldn't already see. The fact that you can generate reliable, theoretically informative optical illusions, doesn't really tell you that much about how good people's perceptual systems are in everyday life. And a perceptual system, you just don't know how often we're challenged. You don't know what kind of prosthetics we've developed, or aids we've developed to overcome things, how we've engineered our surroundings so that they don't mislead us.

So, one needs people who know the literature, who can tell you whether, you know, this is a robust, theoretically informative experiment, hothouse phenomenon. We can show you problems, but they may -- sometimes they're big, or sometimes they're

not. You really need somebody who knows the literature and will look at it candidly.

And I would say that people, as one of them, you know, people who scientists are totally enamored of their phenomena, and we do tend to get carried away with the importance of whatever we study. And if we study biases, we see biases al. the time. They're really robust to us. And people look -- can look terrible if we don't catch our breath and think about the context within which they are.

Second thing, something that we -- the behavioral researchers can't do by ourselves, is to understand the sensitivity of the context to the kinds of problems that we have. So we can give you a best estimate of you know, a lot of uncertainty, but imagine we can give you a best estimate of how numerate, how well people are going to be able to process quantitative information in a setting.

You, who know the, you know, the experts and the decisions will tell us whether

or not that's good enough. You know, sometimes the gist will get you to the right answer, and sometimes you need really precise, precise information. So you need not only to have the people who know the research, but to have them in a context that will discipline them.

The third thing is that you need people who know the research to tell you how good -- whether people have been given -- how good the communications have been. So, people can perform badly because they've gotten lousy communications. And you know, as I guess Ellen began her talk, we all believe that we all exaggerate how well we're communicating. It applies to me right now.

We all exaggerate how well we're communicating. So, we put out a message. It makes sense to us, and if people don't understand it, we think, "oh, they're innumerate, they have low health literacy, they just can't handle it." So, you need

-- you need to be, need to look hard to see whether the problem is with the receiver, or with the transmitter. And you know, you really need the expertise. You need the empirical evidence of evaluation, but you also need people who have that kind of expertise.

And then finally, you need -- if you find the situation where individuals are not, you know, you've given it -- you're in a situation where you've used the best of the science to produce the communication that will provide the information that's essential to people's decisions, and people can't reach the level of proficiency that you would like for them to give informed consent for whatever product there is, that they're being asked -- decision they're being asked to make, then you need to think about, what's the system within which those people are embedded?

So that is, maybe I can't understand the, you know, the financial disclosure that I get from you know, my

pension plan. But am I one or two degrees of separation from somebody who can decode that for me? Or, if I can't understand Medicare Part D -- the 50 firm by 80 option matrix that's been created for me -- am I within one or two degrees of separation for somebody who can do that?

And for that, you need somebody, say like David Moxley who's not here today, who understands the social context within which people actually make decisions, to see whether you can engineer it. So, we're in big trouble. Medicare Part D maybe one of those examples, where nobody is within the ball park of anybody who can make any sense out of it.

But I think that with a lot of situations, you know, as Musa was saying, if you can get the quantitative risk and benefit information that people need -- they've got a friend, they've got a confidant, they've got a physician, they've got an interpreter within the medical press who can make that

comprehensible to them. So, I thought your point was very well-taken, and we require good research and a systems approach to get as far as we can in expanding people's envelope of competence. And then, you know, being ready to help them where it's too much, or to find people who will help them.

So, let's -- Marielos.

MS. VEGA: This question is for Nancy. Is there a regulatory issue for the FDA not to accept help offered? For example, when we were talking about having the students at universities help in the FDA with the research agenda, is there a regulatory issue in accepting the help freely?

MS. Ostrove: There may be -- I don't think it's a -- actually with FDA, there may be regulatory issues. It depends on who the help is coming from. Okay? Because there are sources that are allowed, and sources that are not allowed. You know, it gets to problematic if the help is being offered by a

source that we regulate, like industry.

And there are all kinds of regulations that are not necessarily FDA regulations, but are government regulations that kind of go around the ethics and the conflicts of interests, and the appearance of conflicts of interests. So, we have a whole ethics group, you know, that is there to help us kind of navigate those waters.

So, I can't give you a real solid answer on that, except to tell you that, you know, that's my general sense. Lee probably has more about -- knows a little bit more about this than I do.

MS. ZWANZIGER: And I would just say, that it -- as Nancy suggested, it would depend a lot on what the details are. I wouldn't -- I would say, it's always worth bringing up a specific case to think about so that we can get some more specific answers.

CHAIRMAN FISCHHOFF: Madeline.

MS. LAWSON: I, just along the same

line. I just wondered if through the IPA, and I forgot what that -- Interpersonal Government Act, that governs exchange or details a personnel from the agency to other institutions -- and then on the other hand, you can receive experts from academic institutions to come on assignment to federal agencies. I think that's still in effect.

I wondered if you could accomplish some of this with maybe not necessarily students, all right, well, probably still students, through the academic institutions, if you could -- if this could be governed through the IPA, where you could bring in experts from academic institutions to work on some assignments?

DR. OSTROVE: I can tell you that I know that the Federal Trade Commission, you know, brings people in to work say, for a year or so. I believe that Craig Andrews, for instance, worked on an IPA with the Federal Trade Commission at one point. And actually,

I think FDA has done that as well, at least in the past. We have also had, and they become special government employees, we have a couple of researchers now from American University, who are working in, with different parties of FDA.

One you guys heard about in our last meeting, Jack Swasy, works with the Division of Drug Marketing, Advertising and Communications on research they're doing. And I believe Anna Mitra, also from American, is working with the foods group. So we do have the capability. Those people then become special government employees, though. And then, they're kind of separate, in terms of from their organization.

So, if you're looking to get someone who can -- I mean, in some ways, they can come in, and then they can go back out again. And then do stuff that they know is helpful, you know, within the context of their academic positions. So, there are different

ways of doing this, and there are different ways of getting that expertise in. And I think that we need to explore that more.

And that's kind of the bottom line, is that we -- and that should be part of a strategic plan as well, you know, to explore how to get that external expertise in for specific projects, or for specific time frames. And we'd be very interested in talking with any of you who are interested, you know, or have people who are interested in doing that kind of thing. Because as Lee said, we need the details in order to figure out how to work things out.

CHAIRMAN FISCHHOFF: And I would say, that if there's -- we would hope -- increasing demand for people who can do that kind of work within FDA, having somebody work here and then go back to the academic community is a way of producing some of the supply. Because people can do the work in a better, informed way. So, that's really good suggestion.

I have Linda, Ellen and Mike from before the break, if you remember.

MS. NEUHAUSER: So, I've got a comment and question. But first, Baruch, I first wanted to ask you, I thought that was a very good idea about thinking about real-time research help. And I wondered, did you have a specific idea for how you could put together a group of researchers that would be relevant? And I don't know, if you had an idea of what process could be used to get this real time help.

CHAIRMAN FISCHHOFF: Hiring.

(Laughter.)

MS. NEUHAUSER: Okay. Thank you. That was very succinct. You know, hiring, okay. Done.

On another issue, I've actually two other things. And unfortunately Ms. Rebello from the Office of Public Affairs had to leave. But she did mention a problem that is very common among federal agencies, and that's

the problem of being able to translate or adapt information in other languages. And so, as I understand it, the problem here is that, for example, that office does not have a specific person who does translations or adaptations in Spanish.

And then you, the further problem is, that Spanish is made up of many linguistic variations, so you have to take those into account when you produce a final document like a press release or any of the other documents that FDA produces.

So, what I wanted to suggest is, this is a solvable problem. Again, it's a strategic issue. But, that I have not seen this in the agencies that I've been involved within in the federal government, I have not seen any of them address this problem in a really effective way. And I've only been involved with health-related agencies, so others may have done this well.

But I do want to suggest, it's

solvable without a lot of money, and two things are needed. One is, either internal again, hiring. Hiring a person who is experienced in translation/adaptation. And in particular, in Spanish. And secondly, setting up a process for dealing with linguistic variations. And I don't want to go into detail about that right now, because it would take time. It is a strategic issue. But there are ways to bring into concert the people with skills in -- let's say, across various Spanish linguistic variations, and produce a neutral Spanish document without a lot of problems and expense.

But it would take a process that's put into place. So, wanted to recommend that.

And I think it would be great if the FDA took leadership on solving a problem, and then becoming a model for other agencies on how to do this. Like I say, you have so many problems that are so complex, this is one you could deal with, at least in Spanish, and

relatively quickly, I think.

I know the hiring -- new budget will be coming up. And so there's possibilities of making that a priority. So that was one thing.

The other is, I wanted to ask -- AnnaMaria DeSalva, I really enjoyed your presentation. And the best practice issues that you brought up are so important. I wanted to ask you if -- how you view what you described as best practices, or good practices, as being relevant to changing anything at this agency.

MS. DESALVA: Thank you. It's a great question. You know, I think the -- the central question with respect to the case I presented is, you know, what's the opportunity for industry and the agency to work together in a way that's incredibly constructive and really serves the interests of the patient.

You know, so I know that's what everyone wants to do, and that happens in a

lot of cases. In my own, strictly personal experience, I've had very good experiences. And I think that that has a lot to of with the kinds of organizations I've worked with, with the quality of the people I've worked with, with trust. Trust is very important. And I think when there's you know, prior working relationship and kind of people are known to each other, it makes things a lot easier.

But you know, I know that there's room for improvement. And so, I do think there is, if Heidi had been able to stay, it would have been wonderful to have this exchange with her. It is to understand, what should best practice be? What should the state of play between the agency and industry when communicating around emergent risk, around, you know, major events.

And I don't think that's been well-defined. I think it's very much a work in progress. I think that there's a lot of opportunity to get the right people together

to explore that very issue and define what best practice is.

I mean, I think with respect to the case I presented, it's a nuanced point, but nonetheless, a very deliberate point, that when you consider that moment in time when it's time to take the field action, you'll -- and if you remember, the sequence of events is such, that the strategy is basically baked before the company communicates it to the agency.

And there's several points in that time line, in which there's very substantial exchange with the agency in terms of the investigation, in terms of the letter that goes out to surgeons to describe the investigation. I think technically that letter, because it talks about adverse events, adverse events, and talks about investigation, I think technically that's a recall. I don't -- Nancy, I don't know. Maybe you would advise differently. But I

think that, according to the regulations, "recall" is a broad term.

In the medical devices world it actually does relate to any change, correction, you know, or change in notification about adverse events experience. But so there are several points in time where there would be very significant exchange with the agency. But when it's time to actually initiate the field action, and mobilize all those risk communications, you know, a company may feel like it's really important to have everything basically ready for execution.

And the reason for that is, by the time that exchange occurs, it's going to move very rapidly. And there may be reasons to revisit that. I mean, in certain situations, it may be wise to stage the communication or to be able to have a window of opportunity to you know, communicate with surgeons first, before a broader public communication happens.

I think those questions are on the

table. It's like, how do you get to the right outcome? What's the best way to get to the best outcome? And I'm sure that there's a lot of discussion that that could occur around that.

So, I don't' know, you know. I think that there are always opportunities between the private sector and the public sector to exchange best practices. And I think that I've always greatly enjoyed my work in the public sector and I've taken many of those lessons with me into the private sector, and vice versa. So, you know, I think that resources being different, circumstances being different, it isn't always apples to apples.

But I'm sure that the commitment to preparedness, I think, is to answer your question more directly, is paramount in communication. There is -- you don't always know what you're dealing with. But if you can anticipate to some extent what you're dealing with, you know, 80 -- 70 or 80 percent of what

you need to do can be started, you know, well in advance. And that means the quality of your communication is going to be that much better when you're not having to invent it right in the heat of the moment.

So, those are just some thoughts in response to your question.

CHAIRMAN FISCHHOFF: Yes. Maybe I could followup on that. How do you make -- maybe you've just done it, but so how do you make the business case you know, that in terms of the, you know, there's a public rather than a private firm, that the business case that it is, you know, the agency's -- it's products, it's product is the protection of the American -- protection of the health of the American public --

MS. DESALVA: Yes.

CHAIRMAN FISCHHOFF: -- the well-being of the industries that try to serve the American public, and as a means to those ends, it's own reputation?

MS. DESALVA: Absolutely.

CHAIRMAN FISCHHOFF: And that communication is strategic communication, is essential to all of those you know, how do you -- maybe you just made the case. But how do you -- but it sounds like you're not always successful in making the case.

MS. DESALVA: Sure.

CHAIRMAN FISCHHOFF: What are some of your strategies for that strategy?

MS. DESALVA: Your -- it's an incredibly relevant question. And there -- earlier in my career, I'm not so old, but I'm old enough to go back far enough to think about the times when communication wasn't that central in the industry, or it was sort of a peripheral discipline. Or, it was -- if it wasn't peripheral, it was thought of second, or third, or fourth or fifth in the process. And you know, I see a change where it's thought of first, and it's really prioritized. And it's because the industry for the most

part, understands how central it is to the business.

So, the way that those cases have been made, have a lot to do with failure. Have a lot to do with just, you know, painful experiences where you know, there's been undue risk and pain and suffering in many different ways, either to patients, or to the business and to corporate reputation.

So, the equivalent, if we think about it, from FDA's perspective, I mean, for the agency to have some wild successes and to be able to clearly demonstrate the power and impact of its communication in terms of protecting the public safety and health, and interest, and to be seen as you know, just very effective agent for that kind of change and a partner, you know, to the private in managing major risks, would be very powerful.

And it's why I asked some of the question. I mean, we're all asking questions about evaluation. I know it gets very

tiresome, because we all know what the challenges are there. But especially this area of emerging risk communication, I just think for the agency, if somehow it were possible for the agency to blase a trail there, and to really make that a priority and say, you know what, we are in a new age of transparency and accountability in communication.

And there is going to be much more emerging risk information. And we're not just going to you know, put it out there and allow all the downstream effects to occur. We're going to proactively manage it, and we're going to demonstrate and show, you know, how we can contextualize it, and help a variety of stakeholders interpret that risk and use it in an intelligent way, and really minimize the potential disruption it can cause.

And then, we're going to describe that and in such a way that you can advance knowledge and practice. And that becomes

broadly valuable to other parts of the government and then also certainly to the industry.

But you do need some experience and some data I think to be able to do that. To be able to demonstrate the value, otherwise, it's vague. And I think on the industry side of things, I think that's -- they were just very tangible experiences and data that have allowed these best practices to develop.

MR. SMITH: Baruch, if I can share some personal experience. Because in a couple of different companies that I've been with, we had the situation where we weren't prepared. And in my role in heading up quality, that, I felt like that sort of fell in my area. And I think the same rationale and policies would hold true for FDA.

And it really is, look at it as an insurance policy. Because that's what it is. Because it's going to happen. It's going to happen on a Friday afternoon at 5:00 o'clock.

And if you're not prepared, it's going to be much worse.

And if you go and look at case studies, and see which companies were prepared, or which agencies were prepared, and which ones weren't you know, time and again, you see people sailing through it, in the classic historical one is Tylenol when they had that horrible contamination. And you know, they handled it perfectly well. And that's sort of the state-of-the-art.

And then there's many cases of, and I'm sure AnnaMaria has many more, of just disasters where leading to some companies going out of business for some things that just weren't handled very well. So, you know, between looking at the case histories of what preparedness can do for you in making a difference of survival or not, and looking at the philosophy of, it's an insurance policy, when you look at it, it's a pretty cheap insurance policy.

It is a pretty easy case to make when you're talking to rational people.

MS. DESALVA: It really is.

MR. SMITH: So, there are ways to do it.

MS. DESALVA: I've had some experiences with some smaller clients, you know, clients who don't have lots and lots of resources, or who maybe are earlier on the curve of applying best communication practice. And you know what can be challenging, is that when you -- in working in that environment, you know, your reward is, what doesn't happen.

So, you convince people to invest, to spend the time and effort to have a high level of a state of readiness, to implement certain strategies and tactics that are great insurance policy. And then your outcome is, you averted a problem. And that's a challenge in answering your question, which is, how do you make the business case. It's -- you probably do need to do some side-by-sides of

what happens when you don't have that state of readiness compared to what happens when you do -- or doesn't happen when you do.

CHAIRMAN FISCHHOFF: thank you. I have Mike and Ellen from before the break.

MS. PETERS: I was going to followup.

CHAIRMAN FISCHHOFF: Okay.

MS. PETERS I'm curious what you think, and maybe what some other people, Dr. Smith, and maybe Dr. Ostrove think as well, about communicating on-going risks, versus communicating emerging risks. What are some of the similarities, and what are some of the differences?

If you've ever thought about this, because in some cases, improving our communication about on-going risks, will probably also help our communication about emerging risks. But there are also some differences and probably some very important key differences around time. But I'm curious

what your thoughts are around those similarities and differences?

MS. DESALVA: I think it's a great point. And it's one that I've alluded to a couple of times. You know, when you have like an on-going situation to manage, which the industry often does. I mean, all of these products have risks. Some of them have a more grave you know, risk-benefit profile than others.

And I think that's the opportunity to probably do the most thoughtful work. And I think that's where oftentimes, sort of the -- a lot of the theory and principles and strategies that we've discussed in these sessions, that's where the opportunity is, I think, for the industry to mine those even more than they currently do, and apply them over a longer time horizon, and to understand, or describe what their impact is.

You know, the industry is trending in many cases, towards risk first

communication. I think that the industry is finding its way very much now in sort of shifting the paradigm of how it communicates and markets products. And in certain categories, the pendulum has swung all the way to risk first communication. And where the emphasis is on making sure first that the target understands the risk profile, and discussion of benefit really happens strictly within that context or as a secondary or even tertiary you know, message.

And that tends to be in categories where there's been very visible or difficult risk issues. So, I think that there's you know, a lot of progress being made there. The difference, obviously, does tend to be circumstantial. So, I think that moving those practices and it's why I referred earlier to the best case scenario, you have -- when you get into tough situations like the case I presented, you already have a repository of knowledge. You've prior experience from the

on-going work you do in less acute situations. And you have those relationships in place that you can draw from.

But the circumstances are very different with emerging risk. And I don't think best practice in emerging risk communication has been defined. I think that -- and I'd invite other people to comment who may know more on this subject than I do. But I think that that's a big priority both for the agency and for the industry. And it has a lot to do with what others and with what John's talked about earlier about providing context and making sure that people understand what an emergent risk is, and what it's not.

And so I think that the opportunity to educate there, and to educate at the level of influencers and people who amplify communication, like the media, you know, and other key people, and the advocacy community and certainly in the professional community, so that emerging risk can be interpreted.

Because the burden on that information is going to I think, become, you know, much more significant and much more problematic if we don't really create some focus there. But Nancy, I don't know if you have anything to say about that with respect to how the agency's looking at best practice around emerging risk communication.

MS. OSTROVE: That's what the agency is looking for.

MS. DESALVA: Yes.

MS. OSTROVE: I mean, clearly we know that it's a challenge, and there's a lot of room for improvement in terms of what we can do. And you know, that's one of the reasons that we're kind of bringing this topic to the committee is to try to figure out where to go and where there are some -- and we heard some of this today. In terms of, maybe here are some simple things that can be done. Here are some things that we can think about and that we need to do more research on, and here

are some things that whoa, we really need to think about, just think about and talk with people more about and perhaps start more of a wider dialog about.

But this has all been very useful. Don't get me -- there's been some incredibly useful information that's come out of this. But I think that is the problem, you know, that we don't have that yet. I don't think anyone has that yet. And to the extent that any kind of best practices, or good practices or you know, some practices that have at least some empirical basis, that we can bring to our centers, to the rest of the agency, is exactly what we're looking for.

MS. DESALVA: Could I ask -- go ahead. You go ahead.

MS. PETERS: Actually, could I just ask a followup question?

MS. DESALVA: Yes, please.

MS. PETERS: What I think I heard from what you were saying, in terms of

similarities and differences between ongoing risks and emerging risks, is that you can start with sort of a base of knowledge that you can build up in a more thoughtful way when you're looking at on-going risks. And that's a lot of what we've talked about today.

Then, what's different in terms of the emerging risk profile has to do with the circumstances in the moment, which include really important timing issues and things like that. But those circumstances are often surprises. So at that point, how do you come up -- how do you prepare? You talked a lot about having a preparatory strategy for this. Other than the base knowledge that you can come up with, how do you prepare for circumstances?

MS. DESALVA: You know, in the best case scenario, you know, there is enough surveillance, there are enough systems in place that you are aware -- you kind of know what you don't know. You have a sense of what

could happen. Not because you have foresight into specific safety issues that are going to happen in the future, but because you know your business well and you know the nature of the challenges and of the risks that are fundamental, you know, to the business.

There's a lot of very incredibly rapid work in the moment that happens. And it comes together very quickly. And that's why in healthcare communication, you know, it's a little bit like being a firefighter. Because you do get into these situations where you have to extremely quickly, assess and collect the right knowledge, and then consolidate the right strategy. And it's not perfect. And it's not, you know, you can apply all of these principles and methodologies that have been so well developed by the experts.

You have to hopefully have a base of knowledge there, and then do what's very practical in the moment. And put it together, you know, very rapidly. So, in my own

personal experience, and I did mention this when I presented, I mean, I have kind of a short list of people I know and trust. Some of them are in my own organization, some of them will be in my client's organization. Some of them are external experts. And when things are really breaking fast, and you know that the communication if its not right can be a big problem, it's a very consultative process. And you just consult as rapidly as you can, and use your professional judgment and your prior knowledge.

But then also, be ready to course correct. I think that's very important. So, if you communicate about something and your best efforts can still be a problem, just one or more stakeholders. And then you have to be able to shift and correct. So, it's fluid. And you know, it -- there's a lot of judgment involved, I think, professional judgment involved in -- did you? Sorry.

CHAIRMAN FISCHHOFF: Let's see.

Marielos. No, wait. Yes. No, Mike, and then Marielos. And, Nancy rather, you still?

MS. OSTROVE: No, I --

CHAIRMAN FISCHHOFF: Oh, okay. We'll do the clarification and then Mike and then Marielos.

MS. OSTROVE: AnnaMaria, what I kind of have written down in terms of repositories. Repository of knowledge and on-going relationships. I wanted to clarify --

MS. DESALVA: Yes.

MS. OSTROVE: -- if that's kind of what you're talking about, that in terms of this repository of knowledge, are you talking about kind of understanding your, say your consumer audience, your patient audience. Understanding what they understand about the product, what their needs are? Kind of, what you've learned in terms of your marketing and other things? So that you have a sense of how they're likely to react to you know, emerging information?

And also, with regard to on-going relationships, you know, again, having a repository of groups that you would use to get information out, or to potentially serve as a third-party credible sources of information? Is that -- because that's what I got, you know, that's a piece of what I got out of what you were saying.

MS. DESALVA: Yes.

MS. OSTROVE: And is that accurate?

MS. DESALVA: It is. It is. I mean, on the commercial side of the business, hopefully there's a lot of knowledge in the organization, you know. And you just work it. You just -- when you've got a tough situation, you mine for the relevant insights from the people who have them. You know. So that may be certainly in the medical affairs group, certainly in the marketing organization, or sales, or even sales organization certainly, where there's a lot of customer insights and people will understand how information will be

-- what kind of a reaction new information will elicit.

All the market research that's been done to understand what the unmet needs and sensitivities are of patients. You know, Musa asked the other day, how do you get people to do what you want them to do? Well, it's -- that's insight-driven strategy. It's understanding, you know, what people's rational and emotional needs are, and how they react in certain circumstances. And that data doesn't always exist, but you're lucky when it does and you should use it if you've got it.

And so it's sort of just a common