the FDA's Center for Device and Radiological Health.

The conference set the stage for an unprecedented opportunity for diverse stakeholders that included electrophysiologists, nurses, the FDA, industry, and patients to discuss challenges, concerns and opportunities to deepen our understanding of the inherent complexities surrounding the issues of medical device performance and patient-physician communication.

In September, 2006, the Heart Rhythm Society published our device performance recommendations to improve the post-market surveillance system for cardiovascular implantable electronic devices.

On July 19th, 2007, FDA announced a new guidance for industry and FDA staff, titled Writing Dear Doctor Letters for recalls of implantable cardioverter defibrillators.

This guideline incorporated many of

the recommendations given our Heart Rhythm Society device performance recommendations.

In the guidance for industry and FDA staff, the FDA agreed to standardize public communications to physicians which would help patients and other health care professionals make the appropriate decision about explanting the implantable device, reprogramming the implantable device, or taking a watch-and-wait approach.

The Heart Rhythm Society commends FDA for incorporating important concepts from our guidance document. However, there was nothing in your briefing materials that showed this example, or that used the format that recommended how physicians and patients should be notified of a possible device performance malfunction.

ICDs present unique issues due to their life-saving nature, their lifelong use, and the patient risk versus benefit associated with device implantation.

The Heart Rhythm Society offers the following responses to the key questions from the Risk Communication Advisory Committee.

With respect to the pros and cons of standardizing different parts of the press release template, we advise FDA-regulated manufacturers and the FDA to use identical terminology when classifying device malfunctions. While recognizing that this advisory committee is under a tight timeline, we would like to request additional hearings to provide more input from physicians on the pros and cons of the press release template.

With respect to the second question regarding commenting on the degree to which the proposed template incorporates currently recommended risk communication practices, we strongly urge the FDA to establish a simple and more intuitive standardized format to communicate important information about device malfunction or failure of a device to perform according to specifications.

We also ask that the typeface on the press release template be proportional throughout the template. The title should be given the same text size as the subtitle that is being cited.

We urge the FDA to include the format given in the physician device advisory notice from the Heart Rhythm Society device performance recommendations.

The physician device advisory notice provides a template for delivery of centralized information to enable accurate interpretation of risk notification.

We urge the FDA to also adopt a standardized separate format for patient notification. This is also included in the Heart Rhythm Society's device performance recommendations.

Regarding the third question about commenting on any additional recommended risk communication practices, we recommend that the FDA eliminate the term, recall, for all public

communications regarding implanted devices.

Not all device system malfunctions or problems have the same safety risk for the patient. Change the term, class one recall, to class one advisory notice, or class one safety alert.

Change the class two and class three recalls, which are non-life-threatening malfunctions or potential malfunctions to safety notices.

The Heart Rhythm Society is recommending that FDA eliminate the term, recall, for implantable cardiac devices. The term, recall, suggests to patients and physicians that a device should be removed, when this may not be the case, and this can put the patient at an increased risk.

Regarding the last moment for comments, medical societies such as the Heart Rhythm Society can help disseminate information on their website and through their correspondence to members. Medical societies

are often used as the main resource by all affected stakeholders.

Thank you.

DR. FISCHOFF: Thank you. And members of the, I think everybody up here has a written copy of the comments and the suggestions. So thank you very much.

Our next speaker is Lisa Weddig from the National Fisheries Institute.

MS. WEDDIG: Good morning.

My name is Lisa Weddig. I'm the director of regulatory and technical affairs with the National Fisheries Institute. And we're a trade association representing the industry from all aspects from the harvesters at sea to the processors to regional operations.

And actually yesterday you heard my colleague, Jennifer Wilmes, speak about the challenges the industry faces as far as the benefits and risks, communications, for seafood.

And this morning I just want to share with you some specific examples that the industry has experienced with recent FDA releases that deal with the safety of seafood products.

And I'm just bringing these to your attention as more of a fuel for thought when you are deliberating your recommendations on press releases and the press release templates for a recall.

Earlier this month, February 5th, FDA issued a press release and the title of that release was, FDA Advises Seafood Processors about Ciguatera Fish Poisoning in the northern Gulf of Mexico near Flower Garden Banks national marine sanctuary. Agency updates guidance to seafood processors after recent illnesses.

And this news release was about seven paragraphs long, and the target audience of this news release was the seafood industry, the processors of the industry.

And I bring this to your attention because the way the press took this release was completely different than what we believe the intent of the release to be. In fact when we saw this release we were like, this is good news; we're going to share this with our members.

The next morning we wake up to headlines like, FDA warning, toxic fish. Toxic fish making people sick, FDA warns. Toxin from fish causes illnesses in humans. And the release says, and the stories in the press, were all focused on the illnesses to the consumer, not to the fact that this press release was announcing new guidance for the industry.

So we bring this to your attention because we want the templates to consider the purpose of the release. Is it to alert the consumer or is it to alert the industry, and to consider how these releases are used. And we heard that earlier today.

The press releases aren't used by the traditional media anymore. They are being used all over the place.

And this morning when I was Googling this, I couldn't find anything on the release that had to do with ciguatera. I only found hits when I Googled toxic fish.

And one website was particularly alarming. The headline was toxic fish making people sick FDA warned, and it was actually on the website of an attorney that litigates food poisoning cases.

And after their summary of the release was a nice little form to fill in whether you know your name and address and symptoms of illness if you feel like you suffered from ciguatera poisoning.

So again we bring this to your attention just to think about how these releases are being used now, and whether the message is really targeted towards the consumer, and whether that message will be

relayed in the media.

The second release that came out about seafood was at the end of the year, December 29th, and this headline was, FDA warns consumers not to eat raw oysters harvested from the West Karako Bay section of growing area #3 in Louisiana. Possible contamination with norovirus.

And we bring this to your attention just for your recommendations to FDA to consider the timeliness of the alert, and whether an alert or recall notice going out would really have an effect on protecting public health.

This release went out after the growing areas had already been closed, and after product had already been recalled. So the way the shellfish industry is regulated, the industry works quite closely with the state authorities within each individual state. And in this case the state of Louisiana actually recalled the product before

this press release went out.

So we are kind of questioning whether this release provided any benefit to public health.

And another thing to think about with these releases is how they are used. A month after the release came out, I'm on the subscription list for the National Food Safety Educators Network, which is an electronic newsletter from FDA, USDA and Centers for Disease Control and Prevention that gives updates on food safety to educators, food safety educators.

So a month after that release came out there was essentially another release on the same situation presented to the educators.

So again we have to consider the timeliness of these releases and whether they are actually providing any benefit for the consumer.

Thank you.

DR. FISCHOFF: Thank you very much.

And a third speaker is Marcella Gaitan from the National Alliance for Hispanic Health. Thank you for coming.

MS. GAITAN: Thank you very much for this opportunity.

My comment is not really a formal comment. It's just a follow up to some of the questions that the committee members had in terms of how the FDA is collaborating with national organizations, all organizations, in providing information, important information to consumers.

We actually are one of the organizations that work closely with the FDA. And we are a nonprofit organization based on Washington, D.C., and we work with a network of community based organizations around the country that serve the Hispanic community.

So one of the things that we started doing with the FDA was getting some of these consumer alerts and consumer advisories regarding some of the products that are being

recalled or taken off the market. For example last year we got involved with the recall of the Castleberry products, and also the contaminated toothpaste. There was also one, an important one if we look at how it affects Hispanics, the one that related, that was related to the Avandia drug in terms of some of the effects, the health effects, that were having in some of the patients.

So the way we do it is, we get the information from the FDA, and then we translate it, but also mostly adapt it into Spanish to distribute it to our network of community organizations, but also our publications and news media, mass media actually, network of organizations, and then it is distributed around the country. So sometimes it is picked up by Univision, Telemundo, which are the main TV networks that reach the Hispanics in this country.

And the interesting thing is, it's also picked up by the local newspapers, local

papers that maybe we don't even know they exist, but they reach a lot of the Hispanic community.

So try to make it as simple as possible, talking about the reading level of the population that we serve, and then trying to avoid any type of technical terms as much as possible.

And we also have another way, let's say people see the announcement in Univision about - let's go back to Castleberry - then they can call our hotline. We have a help line called Su Familia, a free number, 800 number, where they can call, and if they want more information, we can explain to them what's going on. And then that way they don't have to like panic and feel that they are alarmed about this recall.

It's more like to educate the consumers into helping them make informed decisions about their health.

So that is my contribution to the

committee, just to give you an idea of what's going on in terms of the collaborative activities that the FDA is doing with an organization like ours.

So if you need any further information, I'm here, and I'll be here the rest of the day. And I'll be glad to answer any other questions.

Thank you very much.

DR. FISCHOFF: Thank you very much.

We have a few minutes if members of the committee have any questions for our guests, we could do that now.

DR. KHANNA: Yes, I have a question for Ms. Weddig.

I was interested in what you said about how the effectiveness of the press release that went out was actually diminished, in fact you felt it did more harm because the recall had already been done, and the areas in Louisiana had already been closed.

What was the effectiveness of

closing those areas and having the recall already done? In other words you felt that this press release was unnecessary, I take it?

MS. WEDDIG: I think that the timeliness of the press release was kind of after the fact. The waters were closed. The recall was already in place. And the way the industry distributes products they track where it goes, all the product is tagged. So it's very easy to know where you sent that product to retrieve it.

So essentially the gears were in motion. The recall was happening. And this was kind of after the fact.

And any time there is an alert about a product, it impacts more than just the product that is part of that recall.

DR. KHANNA: Thank you.

Captain Elder, could you comment on that?

CAPT. ELDER: I'd be happy to. I don't recall the specifics of that particular

case. But when we have a contamination like that, and there as an oyster contamination in the Hood Canal of Washington State within the past few months as well, that things like that do happen. Growing areas get closed. Recalls get initiated. As the speaker pointed out, the state agencies are very active in the shellfish program and do a lot of the work in that area.

But if I was a consumer who happened to purchase those oysters that were recalled from the canal, I would want to see that public health advisory. It's true that the recall maybe underway. The shellfish retailers who are selling the product, and there is a requirement for tagging going with live shellfish at the retail location, may have gotten the notice through that system.

But if I was a consumer who happened to visit one of those and purchased some oysters to make my holiday stuffing, with my oyster and sausage stuffing, it presents a

risk of contamination of norovirus to my family, I would be very happy to see a recall notice that tells me I shouldn't eat these oysters that I eater just used and have left over, or I still may have in my refrigerator.

DR. FISCHOFF: Let me thank everybody.

Let's break now, and let's meet again at 1:00 rather than 1:15, okay? That will give everybody time. We have a few committee members who are leaving a bit early, and I'd like to move it up a little bit.

So I thank everybody.

(Whereupon at 12:05 p.m. the proceeding in the above-entitled matter went off the record to return on the record at 1:09 p.m.)

DR. FISCHOFF: Okay, let's start. I think we're all here.

We have time now for an open discussion. I think perhaps the most useful part of this discussion will be thinking about

the details of the proposal.

Behind us now that we've got this big picture of the context within which it's in, if anybody - we've had the - people have the alternative suggestions from the Heart Rhythm Society in case somebody would like to comment on that or peek at it while somebody else is saying, I think I know roughly when people are leaving. But if you are coming close to leaving and you want to make certain - two fingers instead of the usual discrete one, and we'll get you in.

Okay, Christine.

COMMITTEE DISCUSSION

DR. BRUHN: Thank you very much, and it has been a good day and a good morning.

I have a general comment, and then some specific comments as related to the food issue.

First of all in regards to the format, based upon my work with consumers as we have developed educational materials and

working with them, indeed, I think the choice we were shown here, of the bullets and the framing, that is consistent with what consumers have told met hat they found much easier to read, much easier to follow, much more attention getting.

And I would recommend that it's a good thing to start with. They like actually the lines around things and the bold print. They want their attention to be drawn to the critical words. They do not want to read an essay.

The concept of having a brief paragraph that is kind of an executive summary could be useful, but the approach that you have taken is consistent with what I've seen consumers prefer.

And then I have some specific comments about the recall that relates - actually the one on the Bravo that had salmonella for the dog and cat food.

And first of all - well, I guess,

my question would say provide more specific detail.

And the one that is written in kind of a box: consumers should thoroughly wash their hands with soap and water. Some people just think passing their hands under the faucet is a really good thing, and that's more than they usually do.

The fight back recommendations talk about 20 seconds, and I think that would be a good thing to add to make it consistent.

Within the box they say, people could find more guidelines on handling your pets by going to this web page. Not everybody who has pets is familiar with the web, and it's disconcerting to have them refer to something they don't have access to.

So it's grand to refer, I suppose, if you want to go into a lot of detail. But if there is something important people should read, put it there. Don't ask them to go elsewhere.

And then that particular handout, or that particular recall, was also presented to us in the FDA more textural format with the red lines and the cross on the top and so forth. And I would really appreciate rethinking some of these words, because I believe they trivialize foodborne illness.

It talks about both salmonella and listeria are organisms that can cause serious infection in dogs and cats, and if there is cross-contamination, in people, serious illness. Stop right there. Say, especially small children; well how about all children. Especially frail and elderly people? Centers for Disease Control says your immunity is decreased when you're starting to be over 55, and I tell you, even 80-year-old people don't consider themselves frail and elderly if they are physically strong.

So those words right away cause people to say, "ooh, that's not me", no matter who they are.

Then others with weakened immune systems, okay, what do we think automatically? AIDS. But you can be at risk for foodborne illness with other conditions too; for example, someone with diabetes is at significantly higher risk for foodborne illness in the general population.

So I believe these words are too narrow, and they cause people to assume that the warnings are not for them.

Furthermore, this says, healthy people with salmonella infections may only have short term symptoms. Who's healthy? Again, I think - unless you are a hypochondriac, you probably consider yourself healthy. Once more, people are bowing out to thinking that this might affect me.

So I would be much more all-inclusive. If you get a significant dose of salmonella, no matter what your age and physical condition, you can be pretty darn sick. And there are a lot of deaths from

salmonella. I don't think they are all people in their 80s and 90s. So I suggest that the wording be much more inclusive so people think, maybe that's me, and maybe I should pay attention as well.

Let me see, I think - I think this is it. So again I do applaud the idea of making it clear and easy to follow with the boxes.

Thank you.

DR. NEUHAUSER: Again, I have a shortened comment from something that should be quite long. So perhaps my main comment is just to draw attention to this issue, and then to figure out ways that over the longer term this could be worked out in more detail.

My short comment is that to write in plain communication is a science and an art. There is a lot known; many, many decades of information. But it has to be pulled together. There are people that study that and do that.

When it gets down to the detail of what type of type you have, whether it's serif or sans serif, or whether you change the type from the heading to the words that follow, the length of a sentence, the syllables in a word, using active or passive voice, how to explain a technical term when you have to put it in there, and there are a lot of techniques to do that that are accessible to people at different reading levels.

So the comment is that it's not something that is intuitive, and it's not only a science, because there are a lot of criteria that one can look for, a lot of research on this, but it's also an art form. And the art comes from working directly doing usability testing with the public, the various intended audiences. And that's the only way, as I mentioned earlier, to assure that the information will be understandable, meaningful, and perhaps we hope motivating.

So all of this is to say it's a

fairly involved process, but it's doable. And one question I have that could be answered by Dr. Bradbard, but I don't see him here in the audience, would be that I believe that this kind of usability testing might not have to go through the human subjects group that you have here.

I'm not sure about that, but for example when I do usability testing it does not have to go through the university's IRB. But that would be a good thing to have an exact answer to.

Nancy?

DR. OSTROVE: We can't self exempt. Any research involving human subjects, and the reason I can say this is I'm on the committee, any research that involves human subjects needs to at least go through a process of review to determine whether it can be considered to be exempt.

DR. NEUHAUSER: And the issue is whether this is research. It is a co-design

process. And so for example for our IRB, you can work with people in a co-designing process, which is what usability testing is, and that's not considered research on them.

So someone would need to get an exact response about this. I don't know, this may change from institution to institution, and if any of my colleagues on the committee or in the audience have information about that it'd be helpful.

DR. OSTROVE: It's something worth examining definitely. And you have brought up an interesting issue that I think I will raise with the head of the committee. Thank you.

DR. NEUHAUSER: The other side point would be that I think you could find at the FDA people of various literacy, cultural and ethnic backgrounds that you could draw from, employees here, and you could use them - you have 10,000 employees; I think you have a wide range of people - you could perhaps find enough diversity among your employees that

they could serve as good usability people. And I'm surmising that, but I'm not sure that that would work totally, but at least it would be one step.

DR. FISCHOFF: Okay, Betsy.

DR. SLEATH: I just want to say, I think your draft template is an excellent start, and I just have a few minor suggestions.

In a couple of the areas - in survey research we are always worried about double-barreled questions. You don't ask two things in a question. And some of your headings are double barreled. Like, what is the problem and who is the risk? And also you have, how to identify the product, and where is it distributed.

So I would suggest separating those, so if I want to know, okay, do I have to worry about this in North Carolina, that's what I'm going to look for.

The other thing is, someone earlier

said that the words, correction and market withdrawal, are universally known and accepted. Whereas if I think of my own family members, they would have no idea what a device correction means, or market withdrawal.

I think that because we are all - you know, work in the government or in academic settings, et cetera, we are used to a lot of words that the average American is really going to get confused by, just - so I would suggest trying to simplify some of the language.

And then also the titles in some of the examples are really long, so even as a consumer - because I have to admit I have a busy life and get lazy - if I see a long title, I'm probably a lot less likely to read it than if it's a bullet point that says, you know, "hamburger is being recalled."

So just some suggestions on how to capture attention. Don't be double barreled in sections, and really try to simplify the

language as much as possible.

DR. YAROSS: That's actually very close to my point. The words, recall correction, market withdrawal, et cetera, obviously there is a long and regulatory based context for their use.

But if we go back to what Commissioner von Eschenbach said yesterday, it's not what you intend to convey; it's what's understood.

And so from that standpoint I think that some of the alternatives that have been proposed by HRS and others really should be considered to make sure you are conveying to the intended audience what they will - that they will be accurately understanding what you intend to convey.

DR. PALING: I could go ahead and chime in, but I have basically the - kind of the same points that other people have, that the most important information should be earlier. People are going to read from top to

bottom; people are going to read from left to right. So in tables the more important information should be on the left if that's the way people are going to be finding it.

It should be organized in some way, ordered in some way, so that people could, for example if they are searching on a number, quickly be able to figure out what lot number - if their lot number is there as opposed to searching through an unordered set of numbers.

What other kinds of things? Identifying information the way the consumer knows it is really important here. Because if the consumer doesn't understand the words that are being used, or if that information is lost in a whole bunch of technical brand names or technical words for a disease that they are not familiar with, you are going to lose them. They are not going to read any further. Oh, this must not be me. I don't recognize anything here.

Communication has to be about the

person understanding, if that's your intention. Someone said that you have to communicate to your intended audience, and yet we heard also from some of the public speakers that there are unintended audiences too. As the world of communication changes, at this point you probably have to take that into account.

Thank you.

MS. MAYER: So I think there are probably multiple audiences for your press releases. And I think you can satisfy all the needs in some ways.

I think the most important thing, to reiterate what others have said, is that your brief statement, your fast facts or consumer abstract or whatever, be written in plain language for a fairly low grade level. And the simple declarative transparent and easily understood - I think that is the best way you can hope to keep control of the message.

Having said that I think you also need to meet some of the needs of the media who may want to do in-depth complex reporting pieces, and not make them have to fish for all of that.

So I see no reason why you can't follow the simple message with a much more nuanced message. I really don't see the need for it to be put in bullet format, but you could. I mean certainly that's the way newspapers are written. Every paragraph or so you can put a head. It does make it easier to read, because visually it's easier to read.

So I think that would be terrific. And I would really encourage you - now this is just in the wording that identifies what might be under the category, so I realize it's not really an example - but in the more expanded version of what's being communicated, I really think numbers are important. I think you have to quantify to some extent the use of words like rare, usually and so forth, are to

my mind problematic, because some of your - some - not only the media, but the educated public who wants to understand more in depth, or may have a personal interest in a particular recall, will really want to be able to drill down to that level. And I think it's good to provide that, or to provide a reference to that.

But ideally I think it would be good to provide it - I agree with whoever said that - in the document itself.

DR. FISCHOFF: I would just say that there are large research literatures on the problems of verbal quantifiers like rare and common. And the research also shows that people want numbers. They like to give words, because they don't want to have to sharpen their thinking or be precise or commit themselves. But people can process numbers.

The problems with processing numbers are much less than the problems of guessing what the words mean.

DR. DELAROSA: I echo the comments made by the committee.

The one point that I think is important in going out and going forward with recalls to the media et cetera, is that there needs to be really an education, an education in regards to that there is going to be a new template, what's going on, and also regards to also what exactly is a recall.

I'll tell you, many people think a recall is just removing something completely. And you've explained to us how, a recall from a type one, two, three, what it is. And again I think that is important from a media standpoint to do a story, to do a coverage, to do something in regards to explaining what a recall is. That's point number one.

Point number two is, I agree with a standardized template. But I think that again it's very difficult when you get into devices, and when you get into especially cardiac devices; that is my specialty.

And that is really a problem when I have people calling consistently asking about, do I have to have my pacemaker removed, a valve replaced, when the risks are so high.

And again I understand from your colleagues' points about why we use the term recall. But again I think it's an education about what exactly is a recall; it's not just about taking it out of the market, but what it is exactly.

MS. DESALVA: Yes, I would like to second those sentiments, and take it a little further to say that I also understand how this language has been codified, and it's well established.

But I do think we have to take seriously some of the recommendations that were made during the public hearing portion of today's meeting, and that it may be very disruptive to reconsider how we term recalls and devices. For certain kinds of devices that might well be warranted. And I'd just

like to posit that it may very well be that there needs to be a separate work stream that kind of draws down further to consider - engage more stakeholders in this area and really understand if the language needs to change.

And then the only other practical suggestion I have is -- and forgive me if this has been said already; I don't think so - but the kind of advice or the action items that are boxed on the second page, if there is a way to just build that into a subhead, or even box it right under the headline and still keep it in the body, and keep your full description about what different affected parties should do, but to have that immediate clarification right under the headline in terms of what consumers should do, what health care professionals should do, I think that would help tremendously, and also alleviate just some of the burden of trying to figure out what is a correction.

Because ultimately what you want to know is what should I do about this, or not do.

DR. GOLDSTEIN: Let me just ask the chair for a clarification.

Are we limiting our comments now to this particular item, the press release?

DR. FISCHOFF: I just want to make sure we capture your comments. You can talk about something else.

DR. GOLDSTEIN: Okay, well, just to put my comments into context, I would agree with some of the other comments about the importance of gathering systematically data about the impact of any of the tools including this one. And I certainly agree with the importance of usability testing as an important first step.

I agree with many of the other comments that have been made; I won't repeat them.

One other important consideration

especially for patients who may not be sure what this really does mean for them is to give them very specific help in asking the right questions of their health care provider.

I realize a press release by itself can't do the job of making sure that patients understand the meaning of what's in here, and they are going to need to consult most often with a health professional, hopefully their own health professional to get the answers.

So helping them to ask the right questions, and there are some specifics I could give, like how do I stop? That'd be a question they could ask their provider. Do I need to stop immediately, or cut down slowly? What else can I do besides - if I'm not going to be taking this medication or using this device any longer, how will this impact on the other treatments or other drugs that I'm taking?

What should I watch for, and when might I feel comfortable about being okay?

For how long should I be watching for it?

So there are some specific questions that we can help our patients to ask their providers. And then I do think we also need to help our providers, our professionals, answer those questions. And that may require a totally separate document, it could have a template as well, and we can talk about that at some other time.

MS. VEGA: This is just an observation. In Spanish, the word, recall, I have seen it used, it will translate to remover del mercado, which means market withdrawal. And so that's how it's being used when they translate a press release.

So if there is a correction it will still - they don't use those words. They will use the word, recall, translated equally to how we say in Spanish.

So that is why I continue saying the importance of also trying to find the

right words for the most common languages in this country that will at least reach the largest populations.

I don't expect and I know it's almost an impossible task given the number of languages in this country, but at least the most common languages, that we know what are the terms used in those communities, and we will give the message that the FDA is trying to give as opposed to us relying on others to do those translations. They might not give the right message to the public.

Thank you.

DR. KHANNA: Thank you. So when I was reporting for CBS television I had a rule that no matter how hard I was bombarded with press releases and phone calls from eager representatives, I really wouldn't report on stories where the product or device - the product or the drug was in phase one or phase two clinical trials, because it was so far out of being available to the public, what was my

point of doing a story about this cure for some incurable disease when those people who had it probably wouldn't be around to savor its effectiveness when it finally did - if and when it finally did get approved and come out.

So I read this great template, and I read the 37 lines on page one, and the 76 lines on page two, and then I got to the third page, the very end, and the second to last sentence says: its accuracy and comprehensiveness cannot be guaranteed.

And I thought, wait a minute, I just read this whole press release about how a product has been recalled, and in that sentence to me negates the whole thing.

Now I understand it's the FDA'S I guess version of a disclaimer. But I think we need to change that. We need to change that, because I immediately thought, well, what was the point of reading it all if its accuracy and comprehensiveness cannot be guaranteed. Maybe we need to take that word, guarantee,

out. To me it negated the whole thing.

DR. FISCHOFF: Other comments?

DR. GOLDSTEIN: I forgot to list one of the questions, might be the most important questions that again the patient should ask their clinician: when do I need to see you to follow up on this? Because as you recall from all our previous discussion, this is the beginning of hopefully an educational process that will help the patient to make the right decision with their clinician about the next best thing to do.

DR. FISCHOFF: While people are recharging, maybe let me follow up on that.

I had a bit of a feeling in reading these things that they were not written from the patients' or the consumers' perspective, so they are more from the industry's management perspective.

So if you tell me about, if you tell me there is a recall on spinach, you can have problems for the industry, I'll eat green

beans or burgers; I mean it's not a problem for me, because I have substitutes for that, you know, for medical device it's very different.

You know one of the things we always do is try to take the discipline of kind of looking at the decision, sketching a decision tree from the people who are getting it, figuring out what their options are and what they can do about it. And those may or may not be at odds with - they may be in the best interests of the industry or they may not be. And that's not hard to do. But I don't have the feeling that it's the routine in developing these that that is done.

And it's relatively straightforward, and if you talk to a few people, even people around the office, they can fill that out.

So that's one question.

Second one, this is kind of today's version of the topic that Musa brought up

yesterday that caught me - I guess other people did as well - is that I think that if people want some context in knowing where does this come from, how seriously should I take this. Is this some industry, government agency just covering itself? Are they just doing this under duress? Is this just the tip of the iceberg so that other things are just as bad, and they just caught these things?

So just like if I was taking a drug, I would want to know how many people are in these clinical trials? What do they pick up? Is there passive surveillance? And so on.

I really need to know - I want to know, and I'm going to make some inference about what the regulatory process is here, whether this is a required or voluntary recall. We learn that if it's one thing, most people would not know how limited FDA's ability is.

And people are going to interpret

this in the context of whatever they believe about the system in terms of how protective it is. And if the system is wrong, there's nothing you could do about it, you know, or that anybody in the agency can do sort of at the point of delivery.

But it's something that people can say, FDA only has a voluntary recall here. This is a political problem that somehow should be changed.

So for the short term it's important for me to know how this system operates. I know how serious to take this, and for the long term, maybe this is something I really care about, medical devices, or food, dog food, whatever, and I may get active some place else.

And so part of - there is a desire of course to keep this as simple as possible. But I think a suggestion we've heard from a number of people here is some kind of a tiered message, where you give people the few facts

most necessary along the lines of the Washington Post. I thought that was a great example. They can certainly know what you can do, and how fast you need to do it.

But then one can follow up with additional information. If I need to do something at the next level, I want a nicely organized set of lots. And then I could also say, well, what is this all about, not necessarily on the form or the website, but readily accessible, give me a simple version of what the regulatory process is, so I can put in the context.

So this is a multiple player game. I think the point you made about the Washington Post is really nice, because people are educated to see this problem in the way a risk manager would, and how simple it is. It's not an intuitive organization for people.

So each time they go back, they hear the same kind of story, they are going to be somewhat better. And I think over the long

run government and industry will have a more favorable relationship among the public, who will know, they are doing the best they can within their constraints.

So I would advocate having well tested materials. I would explain that somewhat different regulatory regimes in it so they know what's happening, because otherwise FDA is going to be held responsible for things that it can't possibly do, and you can't complain about the rules under which you are living, but you can't explain the rules, and somebody else complains to their senator.

Lisa.

MS. MAYER: Just to follow up on what you just said, I'm thinking about press releases that come from pharmaceutical companies and biotechs, and at the end of the press release, say it's announcing the results of new research, there is then a description of the product, and that is followed by a description of the company and a disclaimer,

right, that's the standard format.

It might be really worthwhile to have each press release, each recall release, end with a couple of paragraphs on recalls at FDA, and the program, how it's structured, some material. Because that just in very simple form, I'm talking about half a page's worth, of some of what we've learned today about the basic structure, and of course where to go to find out more.

I think that might have the result of educating press and public over time. It might be very useful.

DR. GOLDSTEIN: I would agree with both of those comments. And this gets us into thinking about other vehicles other than the press release. Because the press release can communicate the most important key messages, and what we expect people will do. But then we can have other kinds of tools to help the different audiences act on this information. And that might be something for

patients, that would include some of the questions I mentioned, maybe some of the others, that would include some other things about helping them to manage their condition, the condition that is affected by this release.

And we could have different tools for clinicians, and this is where industry can really help. Because industry spends an awful lot of time figuring out how to help clinicians use their products effectively, and I'm sure when they are sending their Dear Doctor letters, they are crafting them carefully.

But just saying there is a link, the doc should go to a website, isn't nearly as effective as including a tool with the release of this importance.

And maybe it doesn't come out right away, if there is a need to work on that, if there is some urgency. I wouldn't want to hold up the press release. It could be

followed a week later by a tool to help patients and clinicians have discussions and help them in the decision process about what they are going to do next.

So those are things that could be considered as additional risk communication tools. And there is a whole literature on decision making in medicine, and effectiveness of different kinds of tools. It's usually used in a different context, where decisions have to be made about a surgery, or managing a chronic illness. It could be applied to making decisions about making a change, one that is mandated perhaps by the recall of a product.

DR. FISCHOFF: That's your risk if you don't say anything, I'll talk. So while you are recharging - okay, thank you.

DR. NEUHAUSER: Anything but that, Baruch.

I have a couple of questions. One of them goes back to something Dr. Delarosa

suggested yesterday, and that was the idea of having a spokesperson from FDA, a recognized person like Julie Gerberding at the CDC makes statements, is understood to be the face of the FDA. That could be the commissioner, however it was played. So that's one thing that I think would be useful for this group to consider further, and I don't know if there are any restrictions for that.

The question I have that is somewhat related is, does the recall - is it only in a printed format, a text format? Or does the law say that the - allow for other formats, for example a video format for a recall?

If you think of something that is not going away like drug-eluting stents, where the public might really want some personalized information that's in a video format, especially because there are probably many people who will not understand this no matter how well it's done.

Is that a possibility to try a video, in addition to the recall itself, a short video that would be on the website showing the face of the FDA explaining something?

CAPT. ELDER: Certainly, if the question is as simple as are there any restrictions that prohibit it, the answer is no. There are certainly a lot of logistics in making it happen.

DR. KHANNA: And I haven't had the opportunity to check the site out yet, but Lynn Rice yesterday told us they have the patient safety news, and those were videos. So I haven't had the chance to check it out yet, but that maybe is where it could be placed.

MS. MAYER: Two words: Youtube.

DR. FISCHOFF: Isn't that one word?

MS. MAYER: There you go.

DR. FISCHOFF: Let me take this in a slightly different direction, and this is

actually not so much - I think this may apply to you all for - to Nancy and Felipe - is that it strikes me that it would be useful for all of these programs to have some kind fo analysis of sort of a risk based analysis of the market penetration, if that is the right word. So if I - Annmaria can tell us a lot more about this - but if I were trying to - there are certain audiences that I really want to target, and you'd like to know how many - the 15 to 24-year-old males, because they have the highest probability of buying something.

And here we have a kind of risk-based penetration, that there are certain audiences that are particularly vulnerable. It could be very poor people, people who are immunocompromised, people who think of themselves as immunocompromised, because they've got HIV-AIDS, or they've got transplants, people who are being treated for cancer who don't think of themselves as immunocompromised. There are other

complicating things in their identity.

And one should be able to model what is the effect - what percentages of those populations are being achieved through different media, and where media are defined as the electronic media, print media, partnerships, and it may be that - it may well be that some of the things you are doing really don't give you any additional risk based penetration, and they might be - you know, you might save some effort there and say, boy, we've got a real difficulty getting to people in food pantries at the end of the month and we need to develop that.

And that's something that could be formally modeled, and you could probably do a sort of - it'd be a great dissertation topic - you could - you know, the first one you could do it in sort of a non-time dependent way, just assume you've got all the time in the world. And then maybe a time dependent version of it where you need to get people by

a certain time.

We did a study, I have in mind maybe a concrete example will help, we had a project to design the perfect boil water notice.

And about 10 years ago, the microbiologist in our group developed a model trying to figure out what would be the health effects of getting a boil water notice into everyone's hands within 24 hours that was good enough to get them to boil water quickly enough to kill cryptosporidium. And discovered it had actually no effect whatsoever. And it took us about two weeks to figure out why. And it was because, people here will know this better than I will, that cryptosporidium it takes a week to culture it. It's an expensive, not very sensitive task; fairly specific - you know, fairly specific. So that by the time the perfect mass communication got to the target audience, irreversible damage would have been done.

So in effect the test is only good for forensic purposes. If you want to know what hit you, then the crypto test is good. So we had a communication system that could not possibly have worked because of the time concept. There was no way - even if you had the perfect penetration, you wouldn't be able to reduce risk.

One could imagine the same system working - communication system working quite well for some e. coli in the water, something in water where you are testing in real time, you got it out quickly you might be able to protect people.

And I feel like people, and not just here, are intuitively figuring out how the system works in a risk-based sense, and I think you've got the expertise, and with a little - you could figure out how to do that.

Thank you.

DR. YAROSS: That actually brings to mind a really good point. You know one of

the worries in all of this is the concept of warning fatigue.

And we talked - one of the speakers yesterday talked about sometimes less is more. And from that standpoint one can envision a number of situations where the warning would be moot by the time it could be crafted and come out, and from a manufacturer's standpoint, you might learn about an issue and understand that all the product has already been consumed.

Does FDA take that into account whether or not a warning is moot in determining whether or not something should be broadcast? And I think again about the oyster example we heard about this morning.

CAPT. ELDER: And my reaction to that example was that it wasn't moot because, just because the recall had been started and in this example the growing water is closed doesn't mean that there isn't any product anywhere where people would benefit from

getting that warning.

I don't think it was moot. But FDA does consider in other situations whether or not the warning is going to serve any purpose. It takes us some time and some effort to get these out, and there are plenty of other things we could be doing. We are not doing this for any other reason than reducing risk to patients and consumers who could be exposed to these products.

We are not doing this for our own benefit. We are not doing this to cover anything. We are doing this to reduce risk, and if it's not needed, we don't want to do it.

So yes, if it's going to be moot, there is no reason for us to go through the effort of doing it.

Just one other comment is that it could - and this might be worthy of discussion - suppose all of the product, suppose it was a perishable product and we learned of a recall

perhaps late into the expected life expectancy of that perishable product, and by the time it was issued and pulled back, in all likelihood, it's not a product that you might freeze and store or whatever, but in all likelihood is that that product is not in use, but there is a possibility that consumers could have consumed it and came down with an illness that may have gone undiagnosed, or they may be treating it for some other reason.

Would there be a benefit in one of these sort of retrospective press releases that might be helpful to that consumer or his or her doctor in better being able to diagnose what he may have or what he could have had in the past

And that's just another question, so that gets me to the point of wondering if it's ever moot to issue one in such a situation. But I don't know if I have a great answer for it.

DR. DELAROSA: The way I look at it,

you're damned if you do and you're damned if you don't. I mean that's the reality of what it really is.

And to answer your question, I think that you are obliged to really send that out. I mean I've seen on both sides, just for example this last week, an article on why did the FDA not act quick enough to stop the killing of these people undergoing open heart surgery and letting them - and at the same time that the counterpoint, why are they acting, because they are keeping this from the people.

So I think it's very difficult. You know what you have to do. And unfortunately we have to get the word out there.

CAPT. ELDER: I can say as a general rule of thumb, it's - if I had the choice between should I communicate and should I withhold, I have to communicate. I have to err on that side. It's - I think it's always

better to provide more information. And this is one of the commissioner's standing points is, provide consumers and patients with accurate and full information on which they can base health care decisions.

So I think it's always better to defer on the communications side. I can certainly defend that more than deciding not to.

DR. FISCHOFF: Thank you.

John is leaving at 2:00, so let me give John the last shot, and then Ellen, you sir, and Linda.

DR. PALING: Thank you, Mr. Chairman.

I have nothing substantive to offer other than to remark as someone who five times has made films on the science of pets, I'm wondering whether you, Captain Elliott, have in your pocket a picture of your pet?

And the reason I ask is, when that is asked statistically, most people have

pictures of their pets with them but not their family.

Now why is that relevant to this discussion? Because I'm constantly aware that any discussion of risks has an emotional component as well as a factual component. And in these surveys, there is this wonderful document where every other risk that was addressed was very factually addressed without any sense of sentiment, but when it came to diet, feline dry food, the announcement was made that the FDA recognizes that pets are very important to the American people, and our sympathies go out to those who have lost their pets. Only pets deserve that. And that to my mind was a smile, not in any disparaging sense, but the importance of emotionality on the communication of risks.

Thank you.

CAPT. ELDER: I'm embarrassed to say the answer to your question is I have neither a picture of my pet nor my family with me

today.

DR. PALING: True to facts to the very end.

DR. FISCHOFF: That is almost the perfect point to end, but we have more work to do.

DR. PETERS: I have pictures of both my pet and my child. But what I wanted to mention was, just with respect to the question you asked about things that have been recalled already, you think that probably nobody has it out there. It's probably past the expiration date.

But as you pointed out, there may be people who are being mistreated for something else as a result of that. So for that reason I think it's necessary.

I'd also add that the elderly are more likely to keep expired foods, they do not notice that they are expired. So you have a particularly vulnerable population with respect to foods at least where, again, that

may be important. Because even if they don't read it, some one of their family members might go and drag it out of the fridge.

MS. MAYER: I was just going to make the probably completely obvious point that such a press release could obviously be written in such a way that it could make it perfectly clearly why it was important to still release the information even though the immediate exposure was long in the past.

I mean if that was written clearly I don't see how anybody could take exception to it.

DR. FISCHOFF: Is there a follow up? Please go ahead?

DR. DELAROSA: Again I bring up the point that we made yesterday in regards to having a spokesperson. Many times I've received an email, or a card or a letter or a note or something, and what the hell did they say? And then you call them, and you speak to them, and it's like, I understand now.

And again, I think it's very important, because you have to follow from other programs. I mean the CDC goes around with a banner. So wherever she is she can put the banner up and all of a sudden it's an interview.

And I think it's important to find a spokesperson for the FDA, one figure that when it is something that is just an alert, it is something that is very serious, type one or type three, it could be easily explained and said, this is why we're doing it. It's been taken care of, recalled, but again, this is the point.

Because it's so much easier sometimes to talk to somebody directly versus just in written format.

DR. GOLDSTEIN: This is a specific idea built upon the idea of the video, what if it was an interview that was broadcast repeatedly with an FDA official or maybe somebody from industry about the meaning of

this product recall where these important questions were asked and addressed.

Instead of just having a video press release, it would be a video conversation, or video information session that would show a dialogue, where there were these - an opportunity in the interview itself to go deeper, to clarify the meaning, to make it personal for people who might be experiencing the impact.

Just an idea.

DR. NEUHAUSER: A couple of comments.

We haven't talked much about emotion. John brought it up in a semi-humorous way. But I'm struck that this really hasn't come up too much. Greg Baird mentioned it in his presentation.

But one of the principal tenets of risk communication is that you need to start with some acknowledgment of the anxiety that the audience might be feeling.

So it happened for felines, and I've been kind of thinking since Captain Elder talked about the potential I would call it maybe even a tag line of protect and serve that was used by the police, if there was a tag line on these press releases that had an emotional sense of caring about it that was on all press releases, I think that could go a long way to humanizing the FDA, making it less of a target.

Further a video would be a way to really humanize and use the lessons of risk communication. There is a lot of science about exactly - you have to start within the first 30 seconds of any communication to communicate your caring before people will even be tuned in to wanting to know any data. So you could do that with a video.

I did struggle over how you might do that with the press release, and it wasn't obvious other than a tag line. But perhaps some of my colleagues or people in the

audience would have an idea.

The second point was in response to something you said, Baruch, and that was, could we get some demographics about who is being affected by this kind of communication.

And I think especially now that the new amendment requires that NIH and FDA work together on clinicaltrials.gov, you might be able to put a few questions on the health information national trend survey, otherwise known at HINTS. This is the only population based survey of health information in the United States. It was last done in 2005. It really shows where the population is going for their media; what they are learning about health.

You could for example ask if anybody - it's quite a large survey with 6,000 people - you could ask if anybody has gone on the FDA website or has had some other experience through newspapers, whatever, press release, and then a few questions about how

that affected them, did they learn something.

Further, you could ask whether they've ever gone on the clinical trials website, and you could perhaps use this as a way to monitor whether the new work that NIH is going to be doing with FDA is going to work out.

MR. HANEY: I'm antsy because I have to leave.

I did want to make one sort of parting shot or comment. Most of the discussion about the press release has been about its effect on consumers. We talked about whether they are going to find it readable. Whether it's going to be something they can understand.

But I think we shouldn't lose sight of the fact that this is first and foremost a press release, and most people aren't going to find out about a recall in a timely way by scrolling the FDA website. They are going to find out about a recall that affects them

because they've read a news story on it.

And then if they want more information they'll go to the FDA site.

So I think this press release needs to be kept useful and comprehensive for the news media to do, put out the first alert, and then the press release serves a secondary purpose as backup information for people who want to research further.

MS. DESALVA: I wanted to touch on something that Dr. Neuhauser just referred to, also Dr. FISCHOFF, and it's directly associated with the discussion we've been having around brand.

And it's worth I think considering just for a moment branding method as a context for some of these strategic communications issues.

When we do a branding study what we do is we look at what do we uniquely need to stand for. What is our value proposition, and what position do we need to achieve in our

stakeholders' minds to be credible and effective?

And then we do the work to understand what do we really stand for, or what is the actual experience of our stakeholders, what do they think about us? Or as importantly what are their unmet needs, and how can we use insight into their unmet needs to refine and improve our own idea of our own brand?

And those two processes alone can be so illuminating. You can have great difficulty determining what is it that we should stand for, and then have great insight and even disruption in discovering what it is you really stand for.

And then there is all the work that you do then to determine how do we take that knowledge and move it into practice in terms of our communication strategy and the messages that we use.

And it's - sometimes I feel like

the queen of the obvious. I don't mean to keep saying the obvious. But it would seem logical that that kind of exercise as part of strategic planning at FDA would really - if it isn't in place already or if it hasn't been done recently, it would really help a lot in these discussions, because it would answer key questions about frankly how to just be much more effective in reaching audiences and part and parcel of that would include segmentation. There would be a fair amount of segmentation of priority audiences to understand how to reach them more effectively.

And it would probably end up helping the agency reevaluate and reinvent a lot of its communications vehicles, and possibly even streamlining them and making them more focused, and less proliferative. You always run the risk of having a lot of indiscriminate communication to meet information needs. It would probably tighten things up a bit too.

So I suppose that when you are a hammer everything looks like a nail. But I see some merit to looking at branding method also because it just came up very organically in the discussion that we had.

DR. BRUHN: I just wanted to build on what Dan had said, although Dan's gone now. But he mentioned that people are going to be reading the press release.

And a lot of people aren't reading anymore, not reading newspapers. He probably meant media in general.

But some of the interesting recent work shows many 30 to 40 year olds don't even get a newspaper subscription anymore. They are going to TV, and that is how they are getting their information. And then they are going to different groups, the Internet, exactly.

So that endorses again the comments that several have made about having a spokesperson, an FDA spokesperson that can be

the front individual to handle discussions and to present information, someone who is knowledgeable and credible.

And you might have a different spokesperson for different types of issues. Medical issues might be different than food issues for example. That's something that you might be thinking about.

And then in regards to use of the Internet, placing things on the FDA webpage is good and must be done, but it's a passive response. And can there be something that is more active where you are initiating something, or maybe where you are going to where the hot people who are Internet savvy are going now.

And I'm not really sure exactly where that is. I'm beginning to explore that myself, and we're going to be having a session at the Institute of Food Technologists on some of the new media people are using. But one of the speakers at that program, his webpage is

called BarfBlog, and it's might be a repulsive name to older people, but it is really a very cool name to the 20-year-olds and maybe even the 30-year-olds, and maybe also the 18-year-olds.

So I think we have to step out of areas where we're comfortable to explore some of these newer areas, and see what can be done to find out if there is a way that this very important information can be - reach our target audience in a timely fashion using new areas of the Internet. Thanks.

DR. GORELICK: If you're the queen of the obvious, I'm the king of the redundant perhaps.

I don't apologize I guess anymore for the branding, using the term. Because I see the value; I see the value in it.

But as you were speaking, I remember now what got me thinking about it. There really is a relationship between - and I wasn't sure when I came here that there would

be - between some of the work I've done with agencies that are fully and completely procedural and are law enforcement agencies, and that's that their brand is so fully associated - and I wouldn't want to predict what a good study would come up with - but their brand is so associated with the enforcement piece, and of course it's the main part of what they do, that it completely crowds out other aspects of their image, and it even colors the way they speak to the public. It's a whole organizational culture which then sort of leads them to use certain enforcement language, and to address the public in ways that doesn't always do the most important thing which I think you just mentioned which is to sort of acknowledge anxiety before you start - even your own anxiety before - not only theirs but your own.

And so some - with other kinds of agencies, I just began to think about the whole list of federal agencies, and what

brands they have.

And I did begin to think of a whole bunch of them that I know have a substantial service component and consumer component but are totally seen as enforcement agencies.

I guess we sort of are - individual freedom is a long term ethic in our society, and the idea of regulation, whether you're a Democrat or whatever your political - is something - people chafe against being told what to do.

So I think that that often is the master status of a lot of agencies is their regulatory and almost punitive side, to the crowding out of a substantial - you know who thinks of the EPA as a service organization. And yet it is. EPA is just the one that tells you, yes, you are not going to be able to drive that car anymore, because it went over - you see the point I'm making.

So I wouldn't anticipate what a branding study would come up with. But my

sense is, what got me thinking about it is that the brand is, at least to me in just listening to public talk, the brand is much too sort of enforcement saturated, and undeservedly so.

And interestingly - last point - the CDC - just an impression; this would be a hypothesis to pretest the testing - the CDC, which is - also has some enforcement responsibilities, to some extent, is not branded that way.

My hunch is, as essentially - and I could be wrong - but I think it's often seen much more as an information providing sort of thing, and their detective function which serves to root out illness, which is so similar to the wonderful work that FDA does in some areas, going off to factories and finding out why the heparin is done in certain - it isn't as publicized as the CDC's detective work is. Which is a shame, because this is a credible agency.

By the way I think you should be the spokesperson.

DR. FISCHOFF: At the risk of being both redundant and also obvious, in thinking about systems, and thinking about what FDA is trying to accomplish, and we've heard about the limitations of course in resources, it makes me think of another example. CMS, Medicare or Medicaid, when they first started to create physician review organizations I think they called them, PROs, it was all about enforcement and auditing and making sure there wasn't fraud going on.

That evolved over years so that now intermediary organizations are called quality improvement organizations. They are funded through Medicare, and they provide a service to hospitals, nursing homes, office practices, hoping then to improve the quality of the care that they deliver.

It's taken a long time for them to be seen as helpers rather than as auditors or

enforcers, but it's happening.

And this would mean an expansion of the scope of FDA, or perhaps some partnership with other federal agencies, but I think thinking more proactively and from a prevention standpoint, it would be wonderful to have a warning network and a response network that involved intermediary organizations, particularly for drugs and medical devices, where we could reach quickly the users, the prescribers of the products.

And through an intermediary organization that has some relationship with those organizations. The pharmaceutical companies do this through their academic detailers. They have people out there in the field who know the clinicians, who visit them, and there is obviously some pros and cons to that in terms of the influence that they have.

But the quality improvement organizations do that now too. They have outreach, educational outreach folks or

representatives that help get messages about quality improvement, guidelines, standards to clinicians. Those folks can be used to convey messages about responding to recalls about warnings, about pharmaceutical agents or medical devices.

And they've developed all kinds of tools and strategies for doing that. That's just one idea. You could set up a whole separate group of outreach people to do that, or work with industry to make that a part of what they do.

So there are ways I think to go beyond just the message, system, preparing, being proactive, and helping to raise the bar on responses to these sorts of problems that are going to happen as you pointed out hundreds of times a year.

DR. YAROSS: In fact those types of organizations are really appreciated by industry in the medical device world where I work. For example, ECRI is a nonprofit that

communicates well with hospitals. So if we have hospital based products, you know that you can communicate with them, and they are very, very quick in fact to pick up FDA press releases; talk to industry to make sure they interpret that in ways that are useful to their membership.

So I think that is a great suggestion, and clearly the more the different stakeholders work together, the better the job we can all do of helping people again get information out of data, and pick out the signals that are important to them above what is otherwise going to be a rising level of what for a given individual might be noise.

And if I could just go back a few moments ago to the comments about warning fatigue. My concern is all of us are human, and one of the principles that we try to use in developing warning language is to not have so much that an important detail gets buried in the middle. And that's really where I

think some of us are coming from in trying to make sure that we have a way to pick the important out for that particular individual versus the other information.

DR. FISCHOFF: One of the things that I wanted to see was to try to sort of see what the themes were that I was hearing, and I didn't write this in advance.

But let me sort of go through a few of the themes that I've heard, and people can object, and give you a chance to recharge.

It seemed to me that we had sort of specific - we had suggestions about the specific proposal, the concrete proposal, for dealing with recalls differently, and a lot of helpful discussions about that. And then that provoked thinking about what was the system. I think it seems like there are things changing in FDA that suggested EPA is - FDA is thinking about its brand, and maybe we can reflect on some of that, since I understood part of the reason - sometimes a vehicle for

helping stimulate conversation.

So in terms of specifics, I heard proposal - I heard a lot of support for the basic approach. For standardization that would lead people to see these problems in the same way; that would somewhat reduce the staff burden for having to produce this each time. It might give you an opportunity to do it once and for all, be a more predictable environment for industry who knows how things are going to come out, with a recognition that one size probably won't fit all.

So Mike Wogalter's work showed recall works pretty well except maybe in - there are terms that were - but generally speaking I think there was a lot of support, and if you need more supporting arguments, ask us, I think we can produce them.

Secondly, we had suggestions about both the connotative and denotative, or the substance and the feeling that comes across in the spoken or unspoken part of it.

I think on the spoken part we had quite a few suggestions about how to set it up for literacy, what kind of words to use, whether to use words or numbers if you possibly can, guidelines for things that we've done specific evidence on. So I think there were a lot of specific suggestions on how people could do it.

I suggested earlier, so I don't want to treat this too broadly, that a part of the backup for this would be a ready explanation for how the system works so people know what they're getting. It could be a kind of boilerplate slightly different by sectors. That might be part of it.

And perhaps the one place where additional work seemed to be is this feeling - is people's desire to know just what they should do, and people here from their own experience were sensitive to different people in different situations. So we like to know that that was covered, that we've done that

kind of a market analysis of people who got old stuff, or they are suffering from something. It seems like there is an awful lot of knowledge within the agency. You suggested some - things that were unintuitive to us about for example why you have a notice after the recall has been completed.

And so some methodology to ensure that we tell people - give people the information that they need on the denotative side, and what is this experience about. There were some suggestions about - well, there is research supporting most all of this, though not quite as specific as you would like. But there is what kind of affective relationship you have with people, how do you create an emotional tie with people with a piece of paper.

Second there's how do you establish a relationship of trust. And the statement that you repeated, from the commissioner, saying, we are acting routinely on an

obligation to tell people things. So that has to get across at some point, and maybe it's worth repeating the mission statement as well as - talk the talk as well as walk the walk, so people know this is part of the philosophy.

And then there were the suggestions about that it might help to have a human face, a Youtube human face if you will so people - because that evokes different things than a word or emoticon.

And then finally I think we had pretty good agreement here for empirical testing, that there just - the literature tells us at all, but it's not as specific as you'd want, and if you would have tracked our conversation, you got some conflicting advice on that, on various things.

So in terms of the strategic questions, these are the things that I pulled out.

One is that the standardization perhaps provides an opportunity to the

organization to look at the impact of its overall flow of messages, in terms of what is the workload on you all as well as how do we get that right balance between warning too little and warning too much. And maybe this is an opportunity for strategic planning.

A second thing is that - you might think of this as there is a - this would be a good time for some systems analysis of just how well this - the recall as a risk management method is working and probably there are some places where it's fine, other places where it's not. Some places where you may need to refine the communication. But some places where the difficulty of the communication suggests there is something wrong with the fundamental risk management. And either the inspection system or the self regulation or the - something that the communication is being asked to do the impossible, and that sort of systems analysis will help it to do the best it can, and then

kick it upstairs.

And then finally I think there were some suggestions of what might be thought of as, what's the business case for communication within FDA. It seems like that is under discussion; otherwise FDA wouldn't have created this committee before Congress acted. Congress presumably wouldn't have acted with all those specifications that we heard yesterday about the things that we are supposed to be advising you on unless this was up for grabs, and we heard suggestions I think probably most articulately from our people in industry that the communication is actually, it's not an end of the pipeline thing, it's a high level staff function, and those people need to be part of the strategic planning.

I think CDC's emergency communication has a model in which they are working - the communication and the risk analysis people are working much more in real time. It may or may not be suited to FDA, but

there may be an opportunity for strategic thinking to take best advantage of this opportunity.

And then let me just thank everybody for coming, and thank you for asking for help. I hope some of it was useful. I think it's a brave act to ask anybody for help, as somebody who never asked for directions.

Are there other people who'd like to say things or leave? Nancy? Betsy?

DR. NEUHAUSER: I just wondered, have you ever gone back and studied the people that have been harmed by these products to find out - I mean obviously many of them were harmed before the recall notices and that kind of thing, but have you ever retrospectively tried to go back to say, well, where would you have heard about it? Or had you heard about it? It just struck me, that that is something that a researcher could try to do.

CAPT. ELDER: I can't speak for our

product centers to know whether or not they did any type of work in that area.

It would be most enlightening to me to determine if people were harmed by the product after the communication went out, which would certainly tell a story about the effectiveness of that communication, and an opportunity to learn how it could have been done better to have prevented those injuries.

I don't know of any information myself. It could exist somewhere in the agency, but I don't know if it does.

DR. OSTROVE: And just in relation to your offer, we would like to thank you again. I mean this has been just incredibly helpful for us.

And I'm sure Lee and David would reinforce that. So thank you all. Before you all head out.

CAPT. ELDER: And if I may I would like to echo that sentiment of Dr. Ostrove. It is - it was enjoyable to be sitting here

all day yesterday and to listen to the conversation. It was even more enjoyable to be up here with you today and have the opportunity to talk with you and to try to address any of your questions, again, all of them extremely valuable and on point and the recommendations that you have now, and I don't know if there is a more formal mechanism down the road.

But we certainly have a lot already to set us off in a better direction. So I appreciate it.

And just truly, as a 20-year veteran of FDA, look forward to your continuing work across a myriad of issues that don't directly involve this, but everything that you have before you I think is a critical need that we have, and I look forward to seeing the impact of it.

Thank you.

DR. FISCHOFF: Thank you.

Well, let me thank everybody on the

panel, everybody from the staff, everybody from the audience, and to be continued.

(Whereupon at 2:29 p.m. the proceeding in the above-entitled matter was adjourned.)