So, for instance, let's start with the Office of Women's Health. It's focused, but it's also cross-agency, because what the Office of Women's Health does, in addition to funding research that is designed to advance our knowledge about women's health, one of their major activities, or health, they put together health information campaigns. For instance, they have a campaign called, "Take Time to Care", specifically focused on women, but not necessarily women as just patients, women also as caregivers. "Take Time to Care" about they have diabetes, they have information about safe medication use, they have information about non-prescription drugs, over-the-counter drugs, about generic drugs, and about buying over the internet, and a lot more than that.

They have put out "My Medicines" brochure. I'm going to show you kind of an example, I'm going to show you that in the next slide. And these are brochures that they

put together, basically, that are designed to help -- for women to have, to carry around so that they have a record of the medicines that they're taking, and they can bring out that record at any time. I'm sure many of you are aware of the fact that kind of having that personal health record is something that has been kind of held up as a really important thing for people to do in order to take better control of their health.

Now these are brochures. Associated with this, they tested these brochures. Many -- both "My Medicines," I think "My Medicines", but certainly the other brochures that I'm talking about, many of them are in English and Spanish, and some of them are in other languages, as well. In fact, some of you, I think you were given kind of an example of some of the information programs that have been developed by the Office of Women's Health, so the "My Medicines" brochure, this is a piece of it. This is the

other piece of it, so you can see it basically says use medicines wisely, read the label, avoid problems, gives very, very simple straightforward instructions, and then says ask questions. In other words, ask questions of your doctor, and keep a record of what medicines you use, including, for instance aspirin, allergy medicine, antacids, and you've got the little chart there where the women can, or anyone who chooses to use this, can write down the date, the name of the medicine, how much they're supposed to take, when they're supposed to take it, what they use it for, and how many refills they've got. And they can have this as a handy brochure to carry around with them, which can be especially useful if they run into any kind of emergencies where they need emergency medical care, and they may not necessarily be coherent enough to provide this information. So that's some of the information that's coming out of the Office of Women's Health.

We also have the Office of Special Health Issues. That office is responding to one of the recommendations that came out of the December 2005 public meeting, public hearing on how we communicate drug safety information, which you may recall this morning I mentioned that one of the recommendations coming out of it, saying we should be engaging more with healthcare professionals. Well, the Office of Special Health Issues has been given that mandate of increasing the outreach that we do with healthcare professional communities, in addition to the work that they've been doing for years and years with patient communities.

As part of this, in addition to kind of managing these relationships, they hold stakeholder teleconferences, whenever there's big issues, to actively communicate important risk information. They are able to rapidly target the communication of risk and benefit news, again, important stuff through

electronic listservs that they keep. And, basically, they also have websites that are community-focused, so that they may be focused on a HIV community, or breast cancer community. And these are meant to provide people in those communities, the patients specifically in those communities, to information that is of particular interest to them, so it's targeted information. And, as you all know, targeting our risk communication efforts is a good thing.

Now, they also are in the midst of increasing and preserving relationships between MedWatch, which Paul has talked a little bit about, and providers of electronic content to healthcare professionals, Epocrates, Medscape and WebMD, and others, those of you who are physicians, of course, I'm sure you all know about Epocrates and just the incredible amount of information that they provide on a regular basis.

By the way, the Office of Special

Health Issues is now within the Office of Scientific and Medical Programs, which is why it all kind of flows in, and I forgot to make that association.

What we have also done, which has come out of the Office of Scientific and Medical Programs, is we've been encouraging and facilitating healthcare providers to use electronic resources. A little while ago, we put out first a draft guidance, then became a final guidance, on electronic communication of product safety information, that basically told the industry that it's okay to communicate, for instance, recalls and other kind of product safety issues. It's okay to communicate those to the people who need to get the information, which in many cases is the healthcare provider electronically. You don't have to do it using snail mail. And this is something we actually had to make clear to the industry, because of the way the regulations are written and how conservative

many of the groups within the industries can be in terms of how they interpret the regulations, for good reason, because they're concerned. They want to make sure that they stay within the confines of the law. So we put out this guidance to make sure that they understood that they could use electronic means. And we gave them some kind of guidance on how to do that.

In addition to that, we relatively recently sent a letter to many, many healthcare organizations that asked them to encourage the healthcare providers that belong to their organizations to use FDA electronic tools.

Both of these things, we believe have had an impact on at least one private sector group that is trying to put together this healthcare notification network, that is designed to be a way to get by electronic means, get important product safety information out to healthcare providers. Now

that's one group that's doing that. We, of course, will work with any group who is out there and says we want to do this. This is something that we're trying to facilitate, we're trying to help FDA to do that. So, again, we're trying to make the environment easier for electronic communication, and to facilitate that.

There's also our FDA website. As you all know, you've heard everyone here talk about the website and how we use it. As you also know, one of the things that we heard in the December 2005 meeting is that our website was not easy to navigate, it may have wonderful information, and, in fact, we had the policy wonks there saying I love it, but I'm a policy wonk, and so we definitely got the message.

We just recently launched an integrated consumer health information page that pulls together on one page all of the various kinds of information that have been

made available over the years in kind of a fragmented way, because each one of the centers has put out different information that's on their websites. This kind of pulls it all together, so consumers can go to one place, and they can find that information about foods, about drugs, about medical devices, about anything basically that FDA regulates.

Just recently, I believe it was in November, we launched GovDelivery, which is a way for people to come to our website and sign up for electronic notification of various different things. Again, it's very targeted, you can sign up for as few or as many, or none, as you want.

Since that's been launched, subscriptions have more than doubled, and that's been in less than three months. On average, I've been told that we have 500 to 600 people signing up daily. That's an incredible increase over what had been the

case.

We are also working on incremental site improvement. As you've already heard, we plan to redesign the entire site by the end of 2008, putting in place a new web governance system that will improve coordination of cross-agency response and information, which is absolutely critical to effective risk communication.

We are planning for a March launch a redesigned FDA Home Page. This whole thing is going to be done on an evolutionary, I think we called it revolutionary/evolutionary, or something along those lines, basically, on an incremental basis. We're not going to be able to do the whole thing at once. It will be done over the course of a year, but what I wanted to do was to show you briefly, this is what the new -- this is the draft new Home Page.

You can see -- well, for those of you who have been to our website, it is

extremely different from what we currently have. And the information is going to be organized in a way that has been looked at through usability testing, and other kinds of research to make it more accessible to the public, to allow people to get to the information more easily. And I would especially point out to you, if you look on the right-hand side, there you go, just outlined it in red, that is kind of the little safety, not little, because, in fact, if you go back here, you -- well, I don't have a pointer. It's around here somewhere. Here we go, right around here, what it says is, "Report a problem with medical products, MedWatch in parentheses, Medicines, medical devices, food, vaccines, all FDA-regulated products." Right under there you have a category headed "Recalls and Alerts", and you've got approvals. So we've got the risk information, and the benefit information all in one place that people can get to easily, so

we're actually planning on launching this next month, which next month starts in about two days. So some point in March, this should be available. I've been assured of that, otherwise, they wouldn't let me show this. And we're very excited about that as a first, another step toward improving our website. Thank you very much.

DR. FISCHOFF: Thank you. We have about 25 minutes to take advantage of our speakers, of our guests. Let's go around this way.

MS. VEGA: Thank you all for the wonderful presentations. I keep bringing this issue up because it is a big concern for me, and it's the issue of -- I was trying to see in any of these centers in the programs, for example, that Ms. Rice and Dr. Davidson were talking about, if any of these programs are available for people who have poor English or non-English skills. And I know that it's wonderful the hits, and to see that many hits

in the sites, but what does that mean? And in terms of subscribers, who are these people who are subscribing to these sites? Are they people who are disseminating the information, or just happen to be by the site. So I don't know who can answer those questions, but it's something that -- I mean, I know that Dr. Ostrove talked about many brochures in English and Spanish, but how are we going to narrow the communication gap between a large segment of the population, because, as we know, and I said it earlier, the demographics are changing rapidly.

DR. DAVIDSON: I'll answer for CFSAN. And the simple answer is, virtually all of our educational materials are translated into Spanish. Do I think that's sufficient? Not at all, but we do do at least that, and make it available to the community.

What we've been trying very much to do is target our information so that it will be received in a manner appropriate to the

community. As I mentioned, listeria is an example of that program. Everything was done, the photo novellas, use of the training programs for promotoras, and things like that. Everything was done in focus group testing with the audience itself to make sure that this was the best way we could get the information out to them, and communicated to them.

Rather than having those folks come to our site, all that information is on our website, but we distributed it to Spanish-speaking health organizations, as well as community health departments throughout the country so that they could, in turn, use this program in their own communities.

MS. VEGA: I don't want to sound like I'm just talking on behalf of Hispanics, because that's not what I'm trying to say, because I know there is a lot of segments of Portugese, or French-speaking people, so that is what I'm trying -- I mean, I know there is

a lot in Spanish, but I don't know if the website, for example, the FDA website is going to -- I don't know if it had -- I was looking for a little icon for the Spanish or something else, or any of the other websites. So for not just Spanish, but --

DR. DAVIDSON: We do have them in others, as well.

DR. OSTROVE: I think I mentioned that we had, the Office of Women's Health free publications are in Spanish. In addition, they're tested so that they're at fourth to sixth grade comprehension levels. And I think that -- I have to admit that that kind of provides a high bar for the rest of the Agency to try to meet. It's difficult to do that with all of the materials we put out, and I have to admit that it's unusual. It's not something that we're unaware of, that we do have a very large population, patient population, consumer population with whom we need to deal, but we're kind of taking it a

step at a time. And it's something that we're aware of, that we acknowledge. When we might be able to kind of improve that, get to that point, I'd like to say soon, but anybody who knows me will know that as soon as I say the term soon, I say that's in government terms, and what that means is your guess is as good as mine.

MS. PERRY: May I respond to that? I'm Susanna Perry from the Office of Women's Health. Nancy, would that be appropriate, to her question.

DR. FISCHOFF: Okay. Please. Consider yourself recognized.

MS. PERRY: I apologize for the interruption. As Nancy had mentioned, the "My Medicines" brochure, it is in both English and in Spanish. It's also available in 11 Asian languages. We also take pains to work with national organizations throughout the country, and offer our materials for their translation. And if they adopt these materials, they

provide the translations. They work with university-level professors to verify the accuracy and the comprehension levels are maintained at fourth to sixth grade comprehension levels. Then we sent it up through the Department, and it is cleared, and it maintains Department-level clearance and public domain status. Is that helpful?

DR. FISCHOFF: Could you just give your name so we --

MS. PERRY: I apologize. I'm Susanna Perry, Senior Program Manager with the Office of Women's Health in the FDA.

DR. FISCHOFF: Great. Thank you.

MS. PERRY: You're welcome.

DR. FISCHOFF: Ellen, and then Mona.

DR. PETERS: I wanted to bring up an issue I've been curious about since signing on for this Committee, and that was also brought up by I think a couple of our public speakers. While we've been talking today, we

talked a bit about risk, and a bit about benefit. And when I think about risks, I think about what might go wrong, and how likely is it that that thing might go wrong. When I think about benefits, I think about it in much the same way. How is this thing going to help me, whether it's a food or a drug, and what's the likelihood that it's going to help me? Both of them are important.

In general, we seem to be emphasizing risks over benefits. And, as I said, both are important, and for a number of reasons. Knowing more about the benefits can be helpful in a couple of ways. The benefits might be small, and they might be smaller than consumers think they are. And as a result, and informed choice might be not to take it because the benefits are small. Research in risk perception would suggest that an emphasis on risk may decrease benefit perceptions in the absence of any mention of benefits.

Benefits also may outweigh risks,

but the risks are here, and they're scary, and they're perhaps either being experienced at the moment, or they're easy to imagine. While the benefits might be abstract, and maybe they'll happen sometime in the future, benefits can also be sort of unseeable a lot of the time. And, certainly, probabilistic in terms of whether patients will experience them or not; like, for example, with statins, people may not know if they're experiencing a benefit or not. And so, I guess, what I'm looking for is some understanding, and maybe some insights into the FDA's emphasis, because I'm sure there are reasons for this. The reasons for the emphasis on risks over benefits, and what you think the advantages and disadvantages of that emphasis are.

DR. SELIGMAN: They're looking at me.

(Laughter.)

DR. SELIGMAN: Well, the decision to approve a product, of course, is always

based on whether we believe the clinical trials support the -- and the data submitted in the context of clinical trials supports the efficacy of the product. And that, indeed, in our assessment the benefits outweigh the risks for the population in whom the product is indicated.

Historically, in our society it's been the role of the clinical or the learned intermediary to discuss with a patient why the product is being prescribed, and what the benefits are that the patient should accrue from that product.

In the post-marketing environment, we -- most of the information we learn about has to do with risk, and in part has to do with the nature of the kinds of information that we collect, and we're collecting adverse event reports, we're collecting medication error reports. And we're constantly at the Agency weighing and factoring that new information in our own calculus regarding what

should be communicated to patients, both about the indications, the appropriate use of the product, which in many ways is a reassessment of benefit and risk. But I think you raise a very important point.

One of the things that we're currently looking at by way of research at present is ways in which to summarize the information that is available at the time a product was approved in more easily digestible terms for patients that describe what the benefits might be from lowered -- I shouldn't say might be, are from lowering your cholesterol, reducing your blood pressure, having your diabetes under control, or any of the other indications for which prescription medicines are prescribed.

Clearly, this is certainly an area that we constantly struggle with, particularly in an environment, in the post-marketing environment we're always learning about new information as to how to continue to

communicate that appropriate balance. And I think that's certainly an area that we would be interested in gaining your guidance and expertise, and thought on as a potential topic for this Committee, which is how do we communicate both benefit and risk at the time of approval, as well as when new information comes to us in the course of the product's use in the general population. That's a great question. I don't think we have a simple, direct answer for you.

MR. BAIRD: I think a little bit of seemingly disproportionate focus on risk is quite simply that nobody is being sued for an unexpected benefit. And I think it becomes an almost terrifying responsibility, because best information is a moving target. And it could be a global challenge in the sense of a study done in Europe that one hand doesn't know what the other hand is doing, and there's no mal-intent, but there's information being generated, and it's not sufficiently

distributed; yet, it's involving a product of a global manufacturer. And there can be a seemingly overly aggressive diligence in trying to collect and distribute that information so that it prevents, at least, a successful lawsuit from patients, providers, or so on. And I think that sort of answers the question as to where the focus is, and how do you really try to address that.

DR. SELIGMAN: Just one other comment. We're very attentive, and actually very concerned about what we often called the "unintended consequences" of a lot of our post-marketing information. And we do observe, clearly, changes in prescribing and drug utilization of products following these safety announcements. And we don't know whether this is because the product is now being more narrowly, and maybe more appropriately used, or whether people who actually should be on the medications have stopped using the medications, so these are

issues that we confront, and we struggle with all the time.

DR. KHANNA: Thank you. When I was doing my medical reports for CBS, the way I would decide on a topic to cover that day, since I was responsible for two newscasts and medical coverage was I would do so from what I considered a public health approach; that is, the number of people that would perhaps benefit from the report. So if I had the opportunity to report on a new medication for fibromyalgia versus stem cell, progressions in congestive heart failure, I would choose the congestive heart failure story.

And, Lynne, you mentioned breast implants and Lasik were some of your most popular topics. How do you, of the hundreds of thousands of medical topics -- this is open to all of our speakers - create, decide which topic to create an information page for? Why did you pick tanning as opposed to crush injuries? Do you do it based on the subject

prevalence in the populations, the incidence, the number of inquiries to the FDA, the greatest risk-benefit, or some other method?

MS. RICE: Since that microphone doesn't reach over to me, I would say that we do look at the number of inquiries that we are getting on a topic. We also have an 800 number for industry, health professionals, consumers to call in and ask questions. We monitor that on a monthly basis, and when a new product comes out, or an old product that we're getting a lot of questions on, a post-market safety issue or recall, we kind of say it's now time to put our subject matter experts, and our communication people in a room, and let's try to get the information. And it is risk-benefit information.

I will say we try very hard to make sure both sides are out there. And I do think that one of the issues that we face, as being an Agency that approves or clears products, just having that out there gives the public

the sense that this product is free of risk. And I do think we find ourselves on the other side trying to make sure that the balance of that information is provided, because you do hear through advertisements, and lots of things that this is great. And we just want to make sure the other side is heard. But I would say from our end on the device side, it is what we're getting asked on a daily basis, and that tells us we need to get it out there.

DR. KHANNA: And one quick follow-up, please? Who vets the information that you put on the website? Do you have a panel of medical experts, or do you contract with physician experts?

MS. RICE: We start with all of our experts in our organization, in the Center for Devices. We do, obviously, use the experts around the Agency. For most of our consumer stuff, we are using our internal expertise. However, we do focus testing. We do lots of other outside research, not so much with

experts for content.

MS. McNEILL: I'd like to follow-up real quickly to a question about how we make decisions about what goes on the website. For the Center for Biologics, for a number of the safety information pieces that we posted, it often has to do with the signal that we get. And we review them, we feel that we need to communicate that.

With vaccines, in particular, and certainly childhood vaccines, the population that's going to receive them is extremely large, and so, therefore, it's important for us to get that information out to both healthcare providers and to parents so that they understand if there is a new potential signal, if there are specific things that they can do in advance of receiving the vaccine, what kind of decisions they need to make with their providers and whatnot. So part of it has to do with the size, I think, of the population affected.

DR. FISCHOFF: We have, I think -- is this a follow-up? So if it would be all right with you, this is so valuable, I'd like to let -- the session is supposed to be over at 3:15. Is it okay if we continued it a little longer? I think we have two follow-ups from Musa Mayer and -- okay. You're not a follow-up. Okay. Then Michael Goldstein, then Jacob DeLaRosa, and then we'll sort out the next few names.

MS. LAWSON: Well, in addition to your question about what goes on your website, or how you determine what the topics are, I was interested -- by the way, I think it's all very good information, and you've done a great presentation, all of you. But I was very interested in how we get it out to the target audiences around the country. And my question about the newsletters, there was one, I think it's in Center for Foods on "FDA and You" newsletter, the one on "Maturity". Are those only done electronically, or are there are

other means of getting them out to the community?

My question is really how are we getting the message out? How do we look at getting all of the beneficial, the essential materials that you're coming up with, how do we insure that it's reaching a very broad spectrum on a population?

DR. SELIGMAN: Our drug safety newsletter and all of our advisories are only available electronically.

MS. LAWSON: Only?

DR. SELIGMAN: Only. We don't provide any print or disseminate -- we use our listserv and the MedWatch program to send them out electronically, but that's the way they are made available. If anyone wishes a hard copy, they can download it and print it from our website.

MS. LAWSON: Is that true of all the other centers?

DR. DAVIDSON: We actually don't

have a newsletter, as such. This is Center for Foods. It depends on what the issue is, what our distribution mechanism might be. If we're looking at a huge nationwide kind of thing, we'll target not only just the media, which is an obvious one, through press releases, but we'll go through associations, we'll go through community health organizations, all kinds of different kinds of organizations that we think will be effective in reaching the audience that we need to reach.

DR. OSTROVE: Paul is here from the Center for Drugs, but we have another group in the Center for Drugs, the Office of Training and Communications that we don't have a representative from. And I can tell you that they will collaborate. They try to leverage the relationships that they have. They work with the National Consumers League, for instance, on procedures, and helping to disseminate things. They will use public

health announcement. I've been in movie theaters when I've seen the drug facts public service announcement, for instance, come up, so they try their best within the constraints of the resources that they have to get out the information even beyond our website. They make available all of the public service announcements that they put together on the website, but they also work to get them out in other ways.

DR. SELIGMAN: Yes. You'll see our public service announcements in pharmacies regarding what should you know about generic drugs, and how does the FDA approve generic drugs. I've seen these announcements in the Metro in subways about what you should know about non-prescription drugs and how to use them safety. So Nancy is right, for many of our other public service announcements, we do work with organizations. There have even been these announcements on billboards in some states where organizations have worked with

us, so yes, there are other means for getting out different kinds of information beyond just the electronic means.

DR. FISCHOFF: Let me -- so Michael Goldstein and Jacob DeLaRosa. And what I'd kind of like to do is to get the new thread started rather than have follow-up questions, so we'll at least get the issues out on the table.

DR. GOLDSTEIN: This is, in a sense, a follow-up. Although it's a new way of framing follow-up, and that is how do you actually utilize the feedback that you're getting in terms of in some systematic way pulling it together, looking at it carefully? I realize that you have limited resources to do that, but I think it would be really helpful for us, as we're contemplating recommendations to know what feedback you're getting, and to know how your current efforts are actually reaching, as well as affecting people. So if someone can comment on the

current strategies you're using to gather information about the impact of these communication tools, it would be great to know.

DR. SELIGMAN: I'll speak for the Center of Drugs. We don't have a systematic way for getting feedback.

DR. GOLDSTEIN: So it's just coming in, and you're collecting, and not --

DR. SELIGMAN: We get email messages, we get comments from professional organizations. We look at them, we weigh them. Many of them, actually, the majority of them are usually very valuable, and they guide us in terms of any modifications that we make. But there is no formal program for assessment or evaluation of our communication efforts.

DR. DAVIDSON: The Center for Foods has quite a number of extensive survey mechanisms among many other mechanisms that we will track over time our success with, for example, how the nutrition label is being used

is one, how safe food handling practices are being adopted, at least purportedly adopted, that kind of thing. We have a number of measures that we do in that respect.

As far as immediate communications that you do, immediate response to breaking stories, if you will, that's harder. A number of organizations will send information, and we do have tracking, media tracking.

DR. GOLDSTEIN: So it seems like it would be useful. It sounds like you'd welcome the opportunity to more formally evaluate the effectiveness of all the tools that you're putting out there.

DR. SELIGMAN: Yes.

DR. DeLaROSA: Dr. Seligman, how long has MedWatch been available?

DR. SELIGMAN: I think since the mid-1990s, `92, `93, something like that.

DR. DeLaROSA: I guess with that being said, the numbers that you gave are very small, and that's sad. That's sad because

it's not being communicated. I mean, I'm a practicing surgeon. I mean, I operate every day except while I'm here, and I see patients every day, and I've never heard of it. And I know that --

DR. SELIGMAN: You're not the only one.

DR. DeLaROSA: I understand that, but that's sad, because that's a lot of -- that's a lack of communication that's been going on, and I hope that this body will be able to help that, because there's a lot of pertinent information that was presented by you and Ms. Rice that's not hitting us. I mean, it's not getting to the target audience. And if I'm a representative of it, then it's very sad.

DR. SELIGMAN: The only comment I can make is that we are currently engaged in discussions with the American Medical Association, and many of the sub-specialty societies fall under that umbrella, to address

just your precise concern, which is how can we communicate better, not only through professional organizations about the existence of our MedWatch program, the existence of the kinds of information that will be valuable to practitioners, as well as the role that practitioners have in helping us, as a public health agency, learn more about how these products are being used, and any problems that might occur in the course of their use.

But I always, I shouldn't say always, I frequently in many of my presentations to professional organizations ask for a show of hands of people who have heard of the MedWatch program, and most professionals aren't shy about raising their hands, and very few of them ever do, so you're not alone.

MS. McNEILL: I think one of the challenges that we face, though, and Paul is talking about a very specific activity that we're doing, we met with the AMA and their

sub-specialties, and by a show of hands around the room, each group wanted the information a different way, and so that's another challenge that we face. One group wanted us to contact them directly via newsletter, others wanted listserv, they wanted to be able to filter it themselves versus they wanted us to filter it for them, and so that's also an extreme challenge for us as an agency in trying to figure out how do we craft the messages for our target audiences when they're not necessarily entirely sure how they want to receive the information? And this is strictly from the healthcare provider group.

DR. OSTROVE: And if I can add to that, I think the Agency is aware that sometimes it's hard to make decisions about where to go when you don't necessarily have the information to work on. And one of the things that we're actually in the process of beginning, of getting into the field is a survey of healthcare providers -- well, not of

healthcare providers, of physicians -- a national survey of physicians which will actually be looking at the extent to which they're aware of some of our efforts, including MedWatch, that will ask them kind of how they would like to get information about emerging risks. This is going to focus on emerging risks of medical products, but this has been something that I think as you heard from Steve Bradbard earlier today, it's taken a while to get through the system, but we're at the point where we should be able to be fielding that survey in a fairly short time.

DR. FISCHOFF: Is it fair to shift gears here and open a new subject? All right.

MS. DeSALVA: I can be quick, because I had the same question that you had, actually. I was wanting to listen to all your presentations, which were so helpful. Thank you. To understand the thread of the research that you all use, both in the formative phases of developing your programs, what kind of

insights do you use to develop your strategies. And then, of course, from an evaluation standpoint, which is so important. And I think I understand what the status is from your prior answer.

So the only other comment I would like to make is that clearly, one of the major problems that we've solving for, all of us, is that currently there is this tremendous trend towards disclosure, and increasingly real-time disclosure of clinical information and new data. And there's also tremendous emphasis, appropriately so, on post-marketing surveillance, and so there's this incredible burden on consumers to interpret new information.

And, Dr. Seligman, when you were talking about FDA early communications, I was just very curious to know what's been the experience? How would you characterize what the impact is? What are we learning? How can we begin to take some those insights to

improve practice, and the ultimate result in terms of consumer understanding?

DR. SELIGMAN: Too early to tell, just to be honest with you. Particularly, with the launch this fall of our announcements that we have data in-house that we're looking at a particular issue, and that we will be getting back to the public in three months, four months, whatever time it takes for us to complete our work. I think we've done four of them now, and I just don't think -- as I indicated in response to an earlier question, we don't have formal mechanisms to really assess the degree to which how well they're being received, how well they're being valued, and their impact. And I, to-date, don't have any anecdotal information to share, as well.

DR. FISCHOFF: Thank you. So I next have Musa Mayer, Christine Bruhn, Marsha Yaross, Don Haney, Linda Neuhauser, and Michael Wogalter. Okay? Anybody else? Okay. Thanks. Where was I?

MS. MAYER: I think with me. So, I'm thinking about the ways that patients seek information on-line, and most, I think, would start with a search engine. So I am really not aware in all the years that I've been working with breast cancer patients that the FDA is even seen as a resource of any kind for patient information, especially on risks of treatments. So is that because FDA accepts a much higher level of risk for cancer treatments? It's probably related to that.

But one of the things that doesn't exist at FDA, and that certainly is a tremendous benefit on, say, the NCI website, are specific pages that gather together information from different parts of the website, and even external links that are vetted for patient communities to go to and make sense of.

The women that I work with really have no way of knowing what the potential risks of the drugs, biologics, and devices

they use. And no way of beginning to find out, certainly no way of putting that information together. I'm not sure that this falls under the purview of what FDA ought to be doing, but I don't see why it would not. In a way, you've become the premier public health information provider in the United States. Maybe that should not be true, but that's, nevertheless, so often the case, particularly with regard to risk. So I'm just sort of putting out there that there may be other ways of organizing this incredibly rich resource you already have, and are updating so well, that directly interfaces with how patients seek information about health and disease.

MS. McNEILL: I think what you see now with the Agency websites is each center has a site, and a consumer does not know whether they need to go to devices, or drugs, or biologics. We have a handful of pages, as Lynne mentioned, that are around a specific

topic, like diabetes, or heart health. What you will see as the website transforms is information collected more along the way that people look for it. We are going through some pretty significant testing now with categorizing information, and trying to put information together from different parts of the Agency. There's going to be, Nancy mentioned a new governance policy, but what's driving this is a new content management system. And from a technical standpoint, what that means is the information will go into the system, and then it will be a more dynamic site to the end-user when they go to do a search for information from the main page. They'll get it from all sources. They'll see it collected in one place, essentially. And, so, I think it will get at part of what you're talking about, that people look for the information one way, and we're providing it a completely different way right now. And we know that that's a real problem.

And I think the other issue, of course, is the FDA Amendments Act, and the type of information that we'll start to post and make available regarding approval information and post-marketing information, and so we're still wading through what FDAAA means to us, as far as what we need to post. I think we know very quickly what action packages and things when we approve a product, what that means, but as far as the post-marketing information, and the information sharing that we'll be doing with the National Library of Medicine for the Clinicaltrials.gov site, there's going to be a lot of collaboration there, as well. So I think you will see a dramatic improvement in the quality of the information in the coming months.

DR. BRUHN: Research has shown that consumer perception of the credibility of a group is often based upon their perceived competence of the group, and the history of reliable information. And in that stent, I

have felt that the FDA consumer went a long way in increasing the confidence of the public in that decision making and the expertise of this organization. It's simply written. It's good for the general consumer, and addresses a range of things that an everyday person would be interested in, not only backaches, organ replacement, safe food, but all of them.

No one here mentioned how widespread the FDA Consumer distribution is, and it seems that some of the articles that each of you spoke about could be linked to the FDA Consumer, and might be an effective way of awakening the expertise that one could find here, and sharing information, building both the consumer's knowledge, and their confidence in the Agency. Could someone comment on the FDA Consumer?

MS. McNEILL: Well, I think -- the magazine itself is gone.

DR. BRUHN: That's why I've had trouble finding it.

MS. McNEILL: That's why you can't find it.

DR. BRUHN: But I can still type in FDA Consumer in the search engine.

MS. McNEILL: Exactly. There will be a page that Nancy mentioned, there's a Consumer -- and I don't remember exactly the title of it -- Consumer Health Information page is intended to replace the FDA Consumer.

DR. BRUHN: Yes, electronic.

MS. McNEILL: Electronically. And the folks in the staff that worked with the FDA Consumer still work with the centers to develop content for that, and they'll mine our existing sites, and try to convert that information into consumer-level, the more understandable, and from a health literacy standpoint, usable information, than perhaps what we're posting on a more technical end on the center sites. But that is the main reason why you can't find it, it's gone, it's been replaced. And I think that was - I'm

guessing. I think it was a financial decision.

DR. BRUHN: But it's still electronic.

MS. McNEILL: Yes.

DR. BRUHN: So my question is, are you all linking to it?

MC. McNEILL: Yes. All the centers, I believe, link to it.

DR. BRUHN: And can you subscribe to it?

MS. McNEILL: Yes, you can. And I think with GovDelivery, which is a new way of doing listservs, Nancy mentioned the increase in the number of subscriptions. Essentially, you can subscribe to a page like the Consumer Health Information page, and every time that's updated, they'll push out a message to you. Just in the Center for Biologics alone, we had three listservs on general information, blood and tissue that total, I think, 8,300 subscribers. Since GovDelivery went into

effect, we now have 46,000 subscribers to our content and our pages, so the jump has been dramatic.

DR. FISCHOFF: Marsha, Don, then Mike, and then we will have exhausted the topic.

DR. YAROSS: Thank you. My question builds a little bit on the discussion we've already had about the framing bias, if you will on the risk side of the risk-benefit equation. And we've talked about some of the possible causes, the litigious society, the risk averse nature of our society in that Commissioner Von Eschenbach talked about desire of people to have products completely safe, the assumption that an approved device is completely safe. And I recall seeing years ago in a major American newspaper that the American public has a right to expect its drugs to be completely safe.

So the first level question would be what is the role of FDA versus industry,

consumer, academia, et cetera in righting that balance if we believe there should be more emphasis on benefit, probably, and so maybe I'll ask the FDA speakers to address that.

The deeper question may be if we are a risk averse society, and the society, therefore, puts greater value on avoidance of risk, are we going to be successful, or should we even be trying to do that shift?

DR. OSTROVE: Sorry. I'm not sure how we can answer. Certainly, I'm not sure exactly how to -- it's one of the reasons I think you're here. We recognize that the way that we've done things in the past is not, necessarily, the most effective way to do things in terms of communicating. But there is an entrenched culture in some ways that I believe is changing, and there's a recognition that communication is C- I mean, if you have information and you don't get it out to the point where people can understand it, and can put it into use, then you're not doing the job

you're supposed to be doing.

But, on the other hand -- well, it's not an on the other hand issue -- we have historically not done the benefits. The industry does the benefits. I think Lynne mentioned, well, you see all the benefits out there, and I think that that's kind of a general sense across the Agency. And I'm not saying everybody believes that way, but I believe that people have been doing this for a long time. I'm being completely honest here, and hopefully I'll still be here tomorrow, believe that, as well. I mean, that's not our job. People have perceived it that way. Our job is to give people the balance, because the producers, the manufacturers give them the benefits.

Well, but that doesn't recognize the fact that there's a variance in credibility of those different sources, the vested interest of the manufacturer has an impact on how people are going to understand,

how people are going to process that information, and that if a higher credible source, for instance, hypothetically, focuses on the risks, while a lower credible source focuses on the benefits, then you may very well end up with an imbalance in terms of the risks and benefits.

That's why you're here. I mean, these are the kinds of things that we need to hear about, and we need to have discussed, not just among a few people within the Agency, but from the experts who really have a better handle on these issues. Does that kind of get at your question?

DR. YAROSS: I think it's a great start, and it's something that I think we may want to discuss more today and tomorrow.

DR. FISCHOFF: Please bookmark that. Don?

MR. BAIRD: Speaking of tomorrow, one of the things that's going to be on our agenda is food recalls, among other things,

and my question here is for Dr. Davidson. You brought up the spinach recall, and mentioned that no one knew when the recall was over with. And I'm wondering what happened, or what didn't happen. Did FDA put out a press release, or not? And what you would suggest doing in the future to let people know when it's safe to resume eating or using whatever the recalled product is.

DR. DAVIDSON: I want to stress that not no one knew, many -- we were surprised that many people didn't know that it was over. We did announce that it was over. I think as we're talking about further research into recalls, that's one of the things that we need to think about and address, how do we insure that people do know when things are done, and it's over.

MR. BAIRD: Did you have any suggestions?

DR. DAVIDSON: We're looking at the -- I'm not being evasive, at all. We're

looking at that now, as how we can best communicate that kind of information. And that is also -- we said it. It seems like an obvious answer, but it didn't permeate everywhere. Perhaps you have to say it many more times, many more ways; although, we did do it on a number of occasions, so that's one of the things that we're looking at very closely.

DR. SELIGMAN: I'm surprised you missed the headlines in the New York Times that said, "Spinach Recall Over." Maybe that makes the point, I guess.

DR. NEUHAUSER: I have two questions. The first is for Dr. Ostrove, and I wanted to say to everyone who has spoken today how much I appreciate all the good efforts to make the communication more accessible and understandable. And my question is about the website, and about the documentation, the procedures that have been used to develop the website. And by way of

introducing this question, I'll just comment that a major USDA website, which has many good features, had a few problems when it was launched because even though the reading level was intended to be at a seventh or eighth grade level, it was several grades higher due to some problems with the procedures of developing it. And the navigation didn't meet many of the established accepted criteria, again a problem with being explicit about the procedures. So my question is, could you make available to this Committee the documentation about whether there's a standard for readability that's being applied to the website? That's one. The usability, whether that is involving any low literate populations? And, third, what navigation criteria are being used to develop that website? So it would be very helpful to have it at this time.

DR. OSTROVE: I don't have it at this time, I mean right now. Certainly, and I

don't know if there's anyone in the audience from FDA, for instance, who can provide more information. Actually, I suspect that Lorrie knows more about the fit process that we're going through, that's designed to improve the website than I do at this particular time.

I do know that what we're doing is research-based. Our new Web Director comes to us from HHS, was actually one of the authors, Sanjay Koyani is one of the authors of the readability guidelines for web access that came out of NIH. And he is directing this process, so if you know him, which I get the sense that you do, I think you have a sense of kind of the high-powered force that we have behind this evolutionary process that we're going through.

I can certainly get you more information to the extent that we can make it available. I mean, that's something I can work with Lee in doing. I just don't have it with me right now.

DR. NEUHAUSER: Well, I just wanted to say that's terrific that you have Sanjay there, and using the DHHS guidelines, because they are very good. They do not right now explicitly include standards related to readability levels, so that's a gap, but for the navigation, they're very good.

My second question is for Lynne Rice. And I notice that the Center for Devices and Radiological Health has its own Risk Communication Steering Committee, and I wondered if you could tell us what this Committee is, and is there some way to have some synergy between this group and that group?

MS. RICE: The Committee is similar to things that the other centers are working on. We just happened to name our Committee the Risk Communication Steering Committee. It came from a very large center post-market transformation initiative where we were looking at that part of the life cycle when

things on the market were not doing as expected, and one of our nine major initiatives was to improve our Center's risk communication efforts.

We have members from various offices with varying expertise in risk communication, and initially, the goal for us is to look at all of our current products, and current processes, and current distribution methods, and all of those things that have sort of been around for 30 years, and no one has taken a look at those in this larger perspective. And as people come and go, and different expertise comes, and the importance of different parts of our regulatory obligation happen, we finally -- it was finally recognized across our Center that this was very important for us to do. So the first pieces that we would be looking at are internal processes, and clearly information that we get out of this Advisory Committee, as well as information sharing we do with Paul

and his effort. The goal is to do best practices from what we're hearing. And then, hopefully, down the line, more like next year, our next step would be to look at how we can leverage our various stakeholders on getting best practices out within their communication products that, as you heard earlier today, we don't have regulatory authority over. So that is what we're doing. And, clearly, as we get things we could share that information with you.

DR. FISCHOFF: Thank you. Mike, Steve, and that will be the end of the session.

DR. WOGALTER: Earlier today, and in this session we were talking about the benefits and the risks, and the fact that this Committee seems to be, or a lot of people seem to be emphasizing the risks. And having done some research over time, and having looked at drug websites, magazine advertisements, television advertisements, people get the

benefits, the indications, or -- it's the risks that are much more difficult, that you have to almost, at least emphasize, at least we found in our research that they get the benefits right away if you just -- it's sometimes in the name of the drug, or first lines of the information. But what I wanted to ask about was the usability of the website, as was just mentioned.

Were there actual human subjects, people involved in the testing, or was it just examination? The reason I'm saying that is that earlier Steve Bradbard was telling how difficult it was to test human subjects. And some of that usability, at least in the human factors area, and human computer interaction, they use people to test how easy, and whether they can do the tasks. And I think those things could be applied to let's say recall notices, or any of the information to go out to the target population, see what information they glean from it, is it appropriate

information, and so some iterative design quickly, not just running 300 subjects on what you have, but actually doing the testing and evaluations early on just with even a few subjects.

MS. McNEILL: Nancy mentioned the -- I'm sorry, Nancy, mentioned the FDA internet/intranet improvement team, the FIT Team. And they've done very extensive usability testing. Now I can't give you specifics on who was tested, but I know they had different groups of subjects. They had consumers, they had healthcare providers, regulated industry, and I can't remember what other categories there were. A lot of it was done under contract, and I'm not so sure how they did it, but I've sat in some of the presentations, and it was -- the amount of testing that they've done has been very extensive. They did card sorting activities for both internal staff, who are actually working on the web, and internal staff who

have nothing to do with the website, and then external users and trying to figure out which category of things goes together.

The object is, obviously, to make navigation and usability much simpler, so that you don't have to go and drill down six times to find what you're looking for, but to get to where you need with one or two clicks. And all of that information is feeding into this entire website transformation. So I can't provide specifics, because I don't know them, but there is a lot of data-driven information going into this.

DR. OSTROVE: With regard to the research issue, which is the only part I was going to answer, so thank you, Lorrie. If you use nine or more people on a particular topic, and they're outside, so you can actually do research with internal, with government people without getting OMB clearance for that. If you go to nine or more people with the same topic on the outside, that's when the

Paperwork Reduction Act kicks in, so it's entirely possible that -- and I don't know the numbers, that what was cobbled together is -- and you can get a lot of information from nine people when you're doing kind of individual in-depth things, where you're actually having them look for information on the website, which is why I think usability testing can be a little easier to do under the Paperwork Reduction Act restrictions.

For all I know, there might be a generic clearance for that, but I couldn't swear to it. And, again, since I haven't been involved in the process, I can't say for sure.

MS. RICE: And I have to say that in the Center for Devices, we have been doing usability testing of our websites for at least four years. And some before some of these new requirements came into play, we did 1,000 people on our home page, and I think, Dr. Wogalter, you know that we actually have a human factors program in the Center for

Devices and Radiological Health, and we work closely with those individuals on usability, understandability, plain language on our various documents, so they work with us to help us understand. So it's not, I would say, as new to our center, as it is to the Agency's website as a whole, but we find this very important in getting the right information at the right level out.

DR. FISCHOFF: Thank you. Steve Gorelick, and this will be our last comment.

DR. GORELICK: As I listened to the various people talking about the extent to which they either did or did not know about various aspects of the website, something struck me. And I apologize in advance for using a buzz word that I've made fun of in the past. I'm wondering in the larger sort of arena of public information what the FDA brand is, in a sense. Is it primarily a regulatory brand, which, by the way, then I was going to say, or is it a patient brand? Those are not

-- as we know, those are not distinguished from each other, to have a regulatory agency making sure that his stents are in good shape is a good thing for me.

So I began to think about when you put FDA in the constellation of places that I might turn, I actually was imagining myself sitting talking to a heart surgeon, and hearing about the differences between angioplasty and whatever, and then coming home. I began to then all of sudden, what the various brands are of the places I might turn, from CDC, to FDA, to WebMD, to my dad, and on and on. And I'm just wondering if there have been any studies that sort of look at where people in their sort of cosmology of health information, where they place FDA, because it may be a matter not of -- it may not be a matter of getting the word out about various things. It may be that you're fighting against a history, which is so rich in sort of regulatory successes, that that dominates

public perception of what goes on here. So, a thought.

DR. SELIGMAN: I'll give you my opinion. I think our brand is FDA-approved, and that's a regulatory -- that's our regulatory brand. I mean, when people look at drugs, devices, any of the things that we regulate, our brand is we approved it.

DR. GORELICK: You see then, all I'm trying to say is you may -- you're doing a superb job, but it may not be a matter of the kind of communication you're putting out. The guy who needs to get it, me, after I talk to my doctor, may not think of you that way. I may think back to all the examples of times when you saved me from eating tainted this or that, but I may not think of you as a place to look about geez, what -- have there been any certain stents recently that have shown to be problematic?

DR. FISCHOFF: Okay. Well, let me thank our guests for the talk. I hope you'll

come to us with additional things, and we'll be able to continue this conversation. Let's take a break. We'll meet again at five after 4.

(Whereupon, the proceedings in the above-entitled matter went off the record at 3:50 p.m., and resumed at 4:08 p.m.)

DR. FISCHOFF: Okay. So what I'd like to do in this final session is to -- let me, again, thank everybody who's presented, and everybody who's come to watch us talk. We have now until 5:00. Several people have come up to me in the break with things that we didn't manage to get through, because I didn't allow any follow-up questions. And so what I'd like to do is just have an open-ended conversation now with the group, things that -- so this will be just for the panel -- the Committee to speak now, for us to talk about things that are on your mind, things you want to make certain end up on our agenda in the future. And we'll start with Marsha Yaross.

DR. YAROSS: Thanks. I just wanted to comment a little bit on the statement before the break that it may be reasonable to focus on risks because the benefits of the products are clear. And much as I wish that were the case, I'm not sure that I believe that is always the case. I think we heard examples today about how benefits of eating seafood were not clear based on perceptions of risk.

I know from discussions within my own personal experience with friends and family, people who avoid recommended medical therapies because they've heard of the possibility of very rare side-effects. So I think we just need to remember that communication is, again, as was said today, what's heard, not necessarily what's said.

DR. PETERS: If I could follow-up on that just for a moment. I wonder if we can go ahead and just start collecting some evidence, though. It sounds like Doctor --

I'm afraid I'm going to butcher your name.

DR. WOGALTER: Wogalter.

DR. PETERS: Wogalter has some evidence. I know of some other published papers that bear on this topic, and I wonder if that would be something we could go ahead and start collecting some data on.

DR. WOGALTER: I was saying that I can make available a number of papers where we've shown, and I'll send it to Lee, or at least the citations. They're already published. Where you almost have to enhance the risks for them to get it a lot of times, but I heard the same thing about the seafood, as well.

MR. BAIRD: As I listened to all the really helpful comments and presentations, one of the things I think that dawned on me is just how primitive the times we live in are in terms of risk communication, because when we talk about the proportion of communication about risk, how much are we talking about

benefit, what you have to realize is almost 90 to 95 percent of the time, we're communicating risk to the wrong people. Most of the time, the risks that are associated with the products are what, 3 percent, 5 percent of the patient population. So when you start to engage them in dialogue about the risk, 95 percent of the people are the wrong people, don't need to hear the information, aren't interested in it. And it becomes a huge communications challenge, and a huge challenge to any sort of standardized protocol as to how do you get people to listen to you about a risk that has that low an incidence, and yet for the 5 percent, 3 percent, 2 percent of the people it could mean life or death. And when we don't have personalized medicine, and maybe at that point in time we'll have a much better communication record with the right patients, this is what we're operating in. It's just an interesting observation.

DR. FISCHOFF: Christine.

DR. BRUHN: Well, I think we need to respond to some of the things that we've heard from our speakers this afternoon, the public forum, as well. And I guess what pops up to me first is that there needs to be initiated something that's going to track responses. For example, we heard some messages were well received -- well covered. For example, the issue on cloning animals got a lot of coverage, but we really need to know what that coverage included, because I've looked at it, and it might say -- it does say what the FDA said, but many of the pieces also say but they sure missed the mark because they didn't consider X, Y, and Z.

Now you might say it's not appropriate for them to consider X, Y, and Z, but I believe a monitoring system needs to be in effect so that the Agency is looking systematically, and evaluating how their information is being received and presented to the wider world. And, perhaps, a follow-up

communication might be appropriate by the Agency, or perhaps not. But at least knowing what's being covered, so it seems to me the first thing is tracking how many people are getting in touch with the Agency on these risk and benefit messages, and what they appear to be hearing.

And is this more jobs for FDA to do? This is when partnering, I think, comes in, because some of FDA's partners on these women's health issues, as well as some of the other partnerships that Marjorie showed us in the food area, some of these groups periodically track LexusNexus all the time. And I would imagine if FDA asked, they would be delighted to provide a copy of their report to FDA just as part of their good-neighbor partnering thing.

So I believe we need to look at, or need to advise the Agency to be looking at specific issues, but tracking effectiveness, tracking extent of your outreach, providing

suggestions on how that outreach might be broader, and then evaluating what that outreach contains are important components in getting the message out, and testing how it's received.

MS. MAYER: One of the things that always strikes me whenever I see an advertisement for a drug usually on television, is the enormous discrepancy in format between how the benefits are presented, and how the risks are presented. The benefits are usually presented in rather vague terms, in the context of a story, a character, a scenario that's very appealing; whereas, the risks are presented as a very rapid list that just goes by very quickly, clearly to satisfy requirements at the end of the ad.

It seems to me that we have to -- if we are going to ever ask consumers to weigh benefits and risks, we have to give them the information in the same kind of format. We have to allow a story to be told about

risk, if stories are the form, or we have to give quantified information about both, if that's the form. Whatever we decide on, and it could be a multiple -- many different kinds of communication might be important, since we know people hear and learn things in different forms, and at different levels. But I think it's sort of naive to assume that well, industry gives the benefits information, and so FDA can supply the risk information, because the same level of sophistication with regard to advertising and marketing does not exist within FDA, and is not likely to exist here. So we really have to look at who's selling what, and in what form, I think.

DR. FISCHOFF: Thank you.

DR. GOLDSTEIN: Just to follow along on the same theme, it's also important that we assess and evaluate systematically the impact on health professionals, not just the public, because I'm reminded of a recent publication, I think it was New England

Journal, that reported on the impact of the black box warning about anti-depressants among children. And there's been a significant decrease in prescription of anti-depressants by pediatricians to young people. We have no clue as to why that's happened. We think we know, it's because of the black box warning, but what's beneath that? Is it because they're being more careful in making choices about use of anti-depressants, or are they over-responding, if you will, to the risks, suicide that have been associated with the use of these drugs?

How much of it is based on misinformation in terms of their interpretation of the black box warning? How can we address that in a way that's going to meet the needs of patients, families, and hopefully prevent another negative impact that may be associated with the warning. So I think we owe it to the public, we owe it to health professionals to evaluate the impact

that may be extremely significant from a public health standpoint, as important as the research that supports the efficacy of the drugs in the first place. And I'm not sure where the funding should come from, and maybe it's not FDA that should be supporting that research. Maybe it should be NIH that's supporting that research, or CDC that should be supporting that research, or AHRQ that should be supporting that research. That research has to be done in order for us to give answers to the questions that are being asked of us as a panel.

DR. DeLaROSA: It was nice to see something, to hear from the FDA from the last panel that we had, and in the change that's ongoing, because that same change is going on in medicine. And medicine, there is no longer strictly the heart surgeon, the cardiologist, the vascular surgeon. There really is what's the term that's being used, or what's the sexy term is the convergence of technology, and it

really is a convergence of the heart specialist, the one that can do vascular, the one that could do surgery, that could do stents, and can do it all together.

And it was interesting to see as this new web page is coming forward this next month, and in the next year, it's also a convergence of technologies, because before we had many different sections going forward, and now they're all going to converge. They're going to be able to cross, and just like members of the Committee noted, that there is other people that are doing good things. And it's nice to see that the website, hopefully, will be able to get that technology, because that is one way of communicating. It's very important. And we're just realizing in medicine, and that's the way we're going, so it's nice to see that the FDA is moving that way, also.

MR. HANEY: As important as it is to develop direct outreach through the

internet and publications, the FDA is still going to have to rely on the news media, I think, to get out word of risk, especially when something big is breaking. And Kathryn Foxhall raised some, I thought quite eloquently, comments about the responsiveness from her point of view of the FDA press office.

I can say as an old journalist myself, that her views are shared by at least some other people. And it seems to me that at some point, this Committee should be looking at how the FDA press office works, as one very important piece of this communications process.

I doubt that the clock will ever be turned back to 1995, when reporters could really call up Dr. Jones whenever they wanted to, or maybe it can, but there must be a way to streamline this process, and establish some standards so that reporters can get answers on deadline, and they won't feel as though they

are -- there's just no point in calling the FDA because you won't hear until days later.

MR. BAIRD: You know, a previous conversation that actually discussed the FDA brand being FDA-approved, the challenge I'd like to present is that perhaps it is the FDA's job to better communicate their brand in terms of what FDA-approved really means. FDA-approved, in that context you need to legitimize bad results, because within the labeling, within the black box, there are legitimate bad results with the use of a product or a device. And I think patients tend to breeze passed what they consider fine print in risks. They want to try to reap the benefit, and yet it's a nasty task to legitimize harm, death as the result of the use of a product, or a device. And yet, that was in the fine print, as it were.

And I think if more of that were brought forward in the sense of the seriousness of any medicine or device, or its

use, and the fact that you may be one of that unfortunate small percent that's referred to, and just a better cognizance of that on the part of patients.

I mean, I would give a quick analogy to good risk communication. When does that happen? Pre-op. You're going to be operated on tomorrow. You're listening to your doctor, and you have to sign forms releasing the hospital, the physician and the surgeon from liabilities related to certain risks. And you probably go into that procedure with a keen awareness of okay, there are some possible bad outcomes here that I may have to face. Whereas, with the delayed risk of I'm an arthritis sufferer. I take NSAIDs, I take them for decades. There's some heart disease risk I've heard about, NSAID-induced ulcers, small minority of patients. I'll play the odds, so how do you then communicate effectively to the people in that broader, more diluted audience who still need to pay

attention to the risk? And that's a huge challenge. And like I say, maybe it's more legitimizing where, and to the extent appropriate, bad result.

DR. PALING: I'm almost overwhelmed with new ideas, but during the course of the day, nothing was more impactful than the reply to this question about the FDA brand. I think brand is a wonderful concept in its meaning and marketing to apply to this issue of how do the public view the FDA? And the answer we got back revealed a great schism between what the FDA really does. Partly, it is an FDA-approved; namely, we have made a decision, notice who's made it, we have made a decision that there should be a recall, or this procedure should take place. I think the FDA does that incredibly well, given the resources it has available.

Many of us here, certainly, I put my hand up as being one such person, is trying to investigate the degree to which the FDA can

provide data in context for patients and doctors to themselves we're making the best decision. And this insight, for me, is something quite relevatory, that the immediate answer of the FDA is the FDA-approved really is giving data information about a decision they've made, and there's a whole world that is more difficult, and is ill-addressed about how they should be providing in the best way possible the data in context that enables people to make their own decisions.

DR. SLEATH: I wanted to make two short comments about what we heard earlier this afternoon. One was, it was Paul Seligman that talked about people not knowing about MedWatch, and meeting with the AMA, and the sub-specialties. The problem that's happening in professions is that there's so many professional organizations that the power of the AMA has kind of dwindled, as well as the same things happening in the pharmacy world, and I'm sure nursing. So one idea I had was

maybe making things like MedWatch or suggesting it become part of the curriculum of medical schools, nursing schools, pharmacy schools, because these eventually become the practitioners, and these are often the change agents in professions when they get out in practice.

And then a second point I'd just like to make is kind of, I'm always amazed at the People's Pharmacy, and Joe and Terry Graedon, they happen to be based in Chapel Hill, where I live, but they are on national public radio. They have a column. They're like the idols of a lot of older Americans, and just what -- I think we need to figure out what are they doing that's appealing to the public, because it's very appealing to the public. And one of them is an anthropologist, and one is a pharmacologist, and it's just always been amazing to me, and maybe perhaps in the future partnering with them. But I just find it an interesting phenomena.

Working in a pharmacy school, I always say to my students, "You need to be out there telling people what you know, and having people come to you for information", not that the People's Pharmacy doesn't serve a great purpose, but I just don't think we market the knowledge of health professionals well, or want patients -- making them want to approach them.

Can I make one -- okay. The other thing was, Lynne Rice talked some about they had a program for secondary schools about tanning, and something about the safety of medicines. I remember the United States Pharmacopeia was involved with educating children at a young age in elementary schools about medicine, and I just want to raise that as an issue, because I think that's where you start learning health behaviors, and certainly in other areas, it's taught about at a young age. And that may be risk communication, or just communication about products, you can start introducing concepts at a younger age

for children to start -- because they become medication users. And at the young age they learn medicines are bad, and this kind of thing, it's just going to continue throughout -- could possibly continue throughout their life cycle.

MS. DeSALVA: I just wanted to pick up on the thread earlier about what does FDA stand for, and the insight that we all gained from the answer. And I think that, as Greg said earlier, if you begin to have a more intelligent discussion, a more complete discussion about what does it mean to be FDA-approved, that leads to a much more balanced discussion about relative benefit and relative risk. And then that neutralizes that lack of balance that we seemed to talk about earlier, about how the Agency talks about risk, and the manufacturers talk about benefit, which is not sustainable. And I think that as a consequence of FDAAA, and as manufacturers really begin to take on board the guidance of

the risk evaluation and mitigation strategies in the REMS programs, and those become more widespread, I think you'll see that there is a tremendous recognition in the industry, and desire, and appetite to balance those communications more.

And, so, to aspire to have more balanced communication both on the regulatory side, and on the side of the industry is a very worthy, I think, place for us to go, but we will need the best practices. And I really do hope that that is something that we're able to get to, not in this meeting, obviously, but soon. And I think that will be very well received.

And I would have liked to have heard, frankly, and if any of the Directors come back from the centers to speak to us again, it would be very interesting to kind of get to the next level of experience, because I'm sure they have wonderful stories to tell about when things went well, you know, when

there is a horrible risk to manage, but a tremendous benefit that balanced it, and the Agency was able, working with various stakeholders to make sure that the baby didn't get thrown away with the bath water.

DR. BRUHN: I think the concept of a brand, FDA-approved, is really too simplistic for the variety of products FDA evaluates, and for the different requirements for each of these products. It might work for medical devices. I don't know that area, but even then, I would say it's probably FDA approves for accuracy the information on risks and benefits that would be on a medical slip for medication, or for surgical devices, or something like that.

In the area of dietary supplements, they are prohibited from stepping in ahead of time. The supplements industry puts it out, and FDA could only come in if there is a danger that becomes apparent after-the-fact. That is definitely not FDA-approved, and to

have that as the FDA brand would be inaccurate.

In the area of food processing technologies, there are very few they approve. Irradiation is one of them, and there are many who believe that that technology, which could save lives, is being not widely used because it has to go through all the evaluations that FDA requires, and has to bear a label that it's been treated that way.

I've been doing some work on newer technologies, pulse electric field, high-pressure processing and so forth, and developing information sheets for the consumer and health professional. I wanted to put down the FDA has approved this process, and our FDA collaborator said no, no, no. We've looked at it. We read about it. We've evaluated it. You can say that. It doesn't say that it's approved. And the other foods, as well, it's not approved, these cookies, or that kitchen, though there might be an inspector who's

approved it. But it's not an on-site, I'm watching every move process, so using that general term I think would be misleading to the public, at least for all products.

MS. LAWSON: I concur with, I think it's Mr. Haney that talked about revisiting or reviewing the role of the press office at the Agency, because that is an important vehicle for getting messages out. But I would like to see how the Agency determines your network of partners and supporters, and those who you go to to get information out to the widespread population. I think it would be important to see. I looked at the list, and there are some organizations listed, but for an Agency the size of FDA, and the responsibility for the public health, I think it's enormously important to expand the network. So I'd be interested in hearing more about the organizations that you really consider to be those that you would share information with.

For instance, I heard the American

Medical Association mentioned, but there are so many others, like the Hispanic Medical Association, and National Medical, just as an example. So I think the network of organizations that you could share information, that would get it out to their constituents would be an enormous service for the Agency. So I'm really interested in hearing more about the network of supporters and providers, because I think collaboration is certainly key. And there are many organizations that would welcome the opportunity to work with the Agency.

DR. GOLDSTEIN: To follow-up, because I think that's such a good idea, can we make a request that we gather information, best practices, if you will, from other government agencies that we know are involved already in communication about risk, like CDC? And if yes, well, what's the next step to make that happen? Should it be one of us, should it be somebody from the FDA? How can

we gather what we already know are best practices from some of the other agencies that are communicating about risk?

DR. ZWANZIGER: I guess one avenue is for you to let me know that you want that. I would then have to ask within the Agency what can we do to pursue this information. And I'd certainly be happy to do that.

DR. YAROSS: Mine is not a follow-up. I was going to introduce a new thought. Do you want to follow-up?

DR. DeLaROSA: Mine is a follow-up. Is it time that we -- that the FDA has evolved so much that it's time for a daily press conference. Is it time that we treat this like the Department of Defense, or as the White House? And from -- there is no public relations, as we learned, but there's only a Public Affairs Office, but should they have a daily press conference to let others, the media know of the issues that have come up, what's going on, what happening? And all of a

sudden that's information disseminated, and it would be a way that media would have access to the FDA right away. I mean, are we at that point now?

DR. YAROSS: This is a bit of a follow-up, but the risk there is, again, we've got a tension between newly breaking ideas, and investigated and verified facts. There was an issue this morning about early communication, and these are issues that I think many of us deal with, certainly in industry, on a daily basis. You hear about something. Is it of such importance that you communicate before you've had a chance to investigate, or do you wait until you have it verified? And, so, I think that that tension between transparency, which is certainly another societal good, and verified fact to avoid scaring people about things that don't turn out to be true, is one that has to be looked at carefully.

MS. MAYER: Over about the last

seven years that I've been a patient representative with the FDA, one of my responsibilities has been to communicate to my constituents, to the patient community and the public about the organization, about what FDA does. And I can tell you that there are two consistent messages. There's not a lot of understanding on the part of the public, that's clear. And there are two consistent messages I hear from people I'm in touch with, and I see in the media. And they're very different, but they're inter-related. One is, FDA has failed to protect us from whatever the latest safety issue is. And with the assumption that that should somehow have happened, and it's FDA's fault that something has occurred.

The other is, and this is probably because I do work with cancer patients, FDA is standing between us for purely bureaucratic reasons and the treatments that will save our lives. We should have treatments faster.

Now, I don't think there is any overall public recognition of the dynamic relationship of those two issues, that the less evidence FDA requires, the more safety issues there -- before approval, the more safety issues there are likely to be. Nor do I think there is an overall understanding of how we know what we know in medicine, and how the whole process of drug safety is established, how efficacy is established, what clinical trials are, and all of the surrounding issues.

Now, maybe you wouldn't expect that from a public that has not had that as part of their curriculum growing up in the educational system, but the thing that always shocks me is how absent that is in so much media coverage. It's like it's being written not from that comprehensive understanding that would put things in context, so I guess I don't know exactly where this is leading, but somehow in all of this, there's got to be an educational

function in FDA communication about the whole endeavor in the larger sense, to somehow let the public and the media understand in a more in-depth way just what it is, just what is at stake, and what's being done at FDA.

MR. BAIRD: The comment was made before about possible other examples that we could learn from in the sense of risk communication. And given human nature, people I think tremendously care about their health, and their money. I think generally they tend to take better care of their money sometimes than their health. And I think in the financial industry, if you look at risk communications, it's actually a very good model to look at.

If you understand how diligently companies need to communicate with stakeholders regarding any emerging risk, about a possible downside in the stock, or any upside in the stock, there are analyst calls, there's analyst briefings. I mean, a

tremendous amount of regular diligent effort and communication goes into communicating precisely what the upsides and downsides of a company's outlook is. If some sort of parallel could be shaped between these same corporations and the medical community, and the practicing medical community that actually manages distribution of the drugs, it might be interesting.

And in so far as the comment made, maybe the FDA should be doing daily press conferences, well, maybe that's a little bit too shotgun, but if you could refine that down to specific information, specific physician populations that really need to know that, I think that might be a good model.

One other real quick comment, and that was that who's -- FDA-approved. Does the public really just rely on the FDA to put its confidence and trust in what they put in their mouths in terms of drugs or devices, or anything like that? I think it's not. I

think it's a shared responsibility. It's FDA-approved. It's doctor-approved. I mean, the old concept of learned intermediary was that the physician was, indeed, the primary person to that specific patient, and who the patient would rely on most that manufacturers literally could stand behind and say we can't get sued, but sue the doctor. The doctor prescribed it, and this was before DTC. And I think so it's doctor-approved. I think nowadays with DTC, it is manufacturer-approved, but then it's also media-approved. And it's a tremendous swat, and I think some of the statistics we heard earlier today about where people -- whether it's fish intake, or food intake, most people are learning more and relying on that information more from the media, than many other possibly more credible sources. And I don't denigrate the media. It's just with the other authorities out there, it seems to be they're not paid as much attention to as you might think.

DR. DeLaROSA: Thanks for those comments, Mr. Baird. Just a point of fact, just like you said, that it's your health and your finances. And I think that there is a lot of physicians out there that think the same way. It's between your health and your finances. And it's between giving the right medication sometimes, or giving something that's maybe questionable or not, but it will increase finances. That does happen, so I think the FDA is still very important in stating what should be done, or what's regulated, and what is not.

A case example, drug-elating stents. You know, we know now it's for use for a single vessel, but that doesn't matter. There's still a lot of cardiologists out there that are putting in multi vessels, so I think, again, it's not just the physician to make the decision, but it's also the FDA, it's important to have that regulation that's there.

DR. NEUHAUSER: So a follow-up to a comment about resources. There are a number of federal agencies that are quite a bit further ahead than the FDA in developing risk communication, and we had a suggestion that how we might gather some of that information.

I would suggest, for example, that the National Cancer Institute has done a lot of work in this area, a lot of research, a lot of development, very, very fine work. And that information could be leveraged. The National Library of Medicine, so forth and so on, so just organizationally thinking about how we might bring existing resources to help the FDA, who obviously doesn't have a whole lot of resources to develop whole new areas. So that would be something that I think would be very useful.

The other comment is that it seemed to me from the presentations of the different centers that the resources related to good communication and risk communication are

unevenly distributed in FDA. Some of the centers seem to have the capacity to do information for low-literate populations, others may not. For example, perhaps the Office of External Affairs does not have that capacity. Some of the centers have done an inventory of their communication tools, others have not, so I think it would be very useful to get a sense from the centers, again an organizational question for Dr. Zwanziger, how we might get a sense from them of where they are with respect to their capacities. And could some of those capacities be shared across the centers, so if there's somebody who can write in a more accessible understandable way, perhaps that person could be a resource to the entire Agency.

DR. BRUHN: We were told that anything we wanted to say, we had to say here. I notice we've got 15 minutes left. I want to be sure that I don't just want to talk to someone in the hallway and find I have to be

mum because I haven't said it.

Getting the message out, someone said go to the medical schools for getting the medical message out about the med alerts and so forth, and I certainly endorse that. And as a general philosophy, if there's a training area that relies heavily on some of these different areas that the FDA has jurisdiction over, then FDA might focus on getting -- writing letters, or talking to the administrators.

Certainly, in food science area we have groups of administrators in food science, and I'm sure the others do, as well, so getting the information about what FDA is doing, their new web page, what access and what resources they have on their web page, so use the professional societies, use the training institutes, and use the journals.