MS. MAYER: Thank you.

MS. VEGA: My question is also related to labels, and advertisement. When you talk about the FDA having -- viewing and approving labels, and advertisements, are you talking exclusively about English language, I mean, advertisements in only English, or labels in English? Because you talk about, also, certain words that are prohibit, and certain words that must be used in labels and advertisements. So my question is, is this specifically related to English language?

MR. McCONAGHA: I think that the rules, as we discuss them, talk about advertisements in the English language. That said, the Agency would certainly have a concern if misleading speech, or legal speech were being offered in a different language. And, so, I think what you get at is this issue of the different ways in which drugs are promoted, and the need for us to have a comprehensive policy that both addresses

foreign language labeling, and promotion, and encourages it in appropriate situations.

There is a requirement in our regulations, at least that labels and labeling be in English in virtually all circumstances. There are exceptions, like for areas that are predominantly Spanish-speaking, like say Puerto Rico. But with respect to the advertisements, I think the general rules that we discussed would apply whatever the language was, if it was being promoted in the United States, because what we're fundamentally concerned about are the issues about consumer fraud, misleading statements, et cetera, and less concerned about the precise language in which it's delivered.

DR. FISCHOFF: Let's take one more question from Steve, and then we'll have a break.

DR. GORELICK: I don't think is splitting hairs. I have a question for you, when you refer variously to Direct-to-Consumer

advertising, and then television advertising. When you say television advertising, are you talking about jurisdiction over that part of television that is considered the public airwaves under the jurisdiction of the FCC, or are you talking about any sort of television that comes into the home?

As you know, when it comes to other areas of regulation of television, there are some things that the FCC, for example, can do when it comes to public airwave network television that it can't do with regard to cable television. The reason I ask the question is that if you were working at a network today as a researcher trying to figure out your audience, you'd be looking at a graph that's moving as we speak of declining viewership over the public airwaves of their programs, but not of their programs. So the question has to do with the channel, and how -- and to what aspects of television does the jurisdiction apply?

MR. McCONAGHA: It's a great question, and our regulations speak to kind of broadcast media, generally. So I think we would take the view that the rules apply whether this is over the television airwaves that, as you make reference, are regulated by FCC, whether it be over the radio, whether it be over the telephone, whether or not it be over cable television. And, so, we're talking about broadcast, generally.

The bottom line is that the Agency has a regulatory interest in all of the advertising. The distinction it draws between print and broadcast has more to do with the way that kind of information about side-effects is delivered. The obvious difference is that when you guys, I'm sure you've seen print ads in magazines, where there will be an advertisement, and then on the back page will be the professional labeling in great detail that is part of what's required in the print advertising regulation.

The idea is, I think everybody recognizes, it's impractical to have that information scroll up on a screen, whether it be on television, or on satellite cable. And, so, the broadcast regulations allow for kind of a summary of side-effects to be offered, and then reference to be made to some kind of print, journal, ad, or something of that nature where the consumer can then, in turn, get more information, the professional labeling with respect to the product.

Bottom line is that while there are distinctions drawn between broadcast and print, at the end of the day, the Agency is concerned with all advertising, regardless of the medium which it appears through. I don't know, Dr. Ostrove, if you have anything to add to that.

DR. OSTROVE: We, actually, we have guidance concerning broadcast advertisements, as well, which came out initially in 1997 as a draft, and was finalized in 1999, which is

what kind of prefaced the people seeing advertisements on TV. And the difference in some ways is in the ephemeral nature of the beast, so, actually, the bill did a good job of explaining it. The only thing that I would clarify is that with regard to broadcast ads, in addition to including the most important risk information in the ad itself, there also has to be a provision for allowing people to get to the full product labeling through numerous sources, so that they can get it in a convenient fashion; so not necessarily just referring to it in a print publication, but also providing, for instance - and, again, this is not a law, this is a guidance - also providing, say a website that people can go to to get it, making clear that they can get the information from their healthcare provider, website, print, ad, and there is a fourth. Oh, an 800 number that people can call to get the information, as well.

DR. GORELICK: I would just say,

the only reason I asked the question is, the declining amount of viewership on public airways, and the growth in cable consumption, and the tendency of some product, some content producers to move to cable to escape various forms of regulation, not generally in this - just concerned me that we are thinking broadly about it.

MR. McCONAGHA: It's a great question, and from our perspective, there's no escaping these regulations by moving to cable. The same rules apply.

DR. FISCHOFF: Let me thank everyone. And, particularly, let me thank the three speakers for staying with us, and for these really helpful presentations.

(Applause.)

DR. FISCHOFF: And I think having them in writing I think will be really helpful, so we will be starting promptly at 1:00. Let me remind the Committee members that there should be no discussion among us

about matters under deliberation here, and this is not an endorsement. I see whether I'm doing this legally correct, but the restaurant here has a buffet. Thank you.

(Whereupon, the proceedings in the above-entitled matter went off the record at 12:07 p.m., and resumed at 1:04 p.m.)

Dr. FISCHOFF: Okay. Let's start with the Open Public Hearing. Before we start, we have -- Nancy Ostrove has one announcement that she would like to make.

DR. OSTROVE: Did you just tell me that it was turn?

DR. FISCHOFF: Yes.

DR. OSTROVE: Thank you. I'm so sorry. Mr. McConagha asked that I clarify the answer that he gave to Musa's question concerning off-label use and promotion of off-label use. We wanted to make sure that people understood that we take the position that prescription drug advertising should not promote off-label use, so that's the bottom

line.

That said, using his terms, we, nevertheless, acknowledge that some people suggest that substantial evidence, or substantial clinical experience may be achieved even in the absence of FDA pre-approval. So that some people have suggested that. We take the position that prescription drug advertising should not promote off-label. So does that kind of clarify that? That was the intent. Thank you.

DR. FISCHOFF: Thank you very much. So this is now the Open Public Hearing. We have four speakers, and there's things that -- a paragraph I need to read.

Both the Food and Drug Administration, FDA, and the public believe in a transparent process for information-gathering and decision making. To insure such transparency at the Open Public Hearing session of the Advisory Committee meeting, FDA believes that it is important to understand

the context of an individual's presentation. For this reason, FDA encourages you, the Open Public Hearing speaker, at the beginning of your written or oral statement, to advise the Committee of any financial relationship that you may have with any company or group that may be affected by the topic of this meeting. For example, the financial information may include a company's or a group's payment of your travel, lodging, or other expenses in connection with your attendance at the meeting.

Likewise, FDA encourages you at the beginning of your statement to advise the Committee if you do not have any such financial relationships. If you choose not to address this issue of financial relationships at the beginning of your statement, it will not preclude you from speaking.

And now I'd like to have four speakers, Kathryn Foxhall, Michael Negrete, Jeffrey Seconda, and Jennifer Wilmes - I hope

I pronounced those correctly - in that order. And I invite you to come up and share your comments with us. And please speak into the microphone at the rostrum here. So first, Kathryn Foxhall. They have a microphone back there, sorry. Thank you.

MS. FOXHALL: My name is Kathryn Foxhall. I'm a freelance reporter. I don't have any financial interest in this, other than I'm paid by magazines that like to communicate with FDA.

I've covered the Washington health scene for specialized health publications for over 30 years. I write for physicians, nurses, pharmacists, biotech professionals, and others. Among earlier positions, I was editor of the Nation's Health, the newspaper of the American Public Health Association, for 14 years.

Not too long ago, a host of reporters covered federal agencies in standard reporting fashion. We talked to people in the

agencies. We got to know staff. We developed source people. We called and we got two minute educations that vastly improved our stories. A very quick interview often turned an empty shell of an article into a solid piece.

Some specialized reporters regularly walked a beat in the halls of the agencies in time honored manner of local reporters. We often got story ideas faster than we could scribble them down. The agency experts were our graduate schools. No one ever quantified these communications. Usually, they were just a routine part of a staff member's day.

Then about 12 to 14 years ago, some agencies began instituting a control mechanism. Staff members are strictly forbidden from speaking to any reporter unless the reporter first makes application for each conversation with the Public Relations office, and is tracked by that office. FDA is one of

the most strident agencies in the use of this control.

The permission to speak system is simply the worst thing I have seen happen in the governmental process in all my years of reporting here. It is severe censorship and it is very effective censorship. Agencies track, monitor, control, and chill our conversations with staff.

The permission to speak mandate has probably killed about 90 percent of communications between agencies and specialized reporters. It goes like this. A reporter who wants to talk to a staff person, whether it's for five minutes or two hours, must call the Public Relations office. An assistant tells the reporter that someone will call back. The reporter waits. The Public Relations officer calls back, maybe in two hours, maybe in a day, maybe not ever.

When the Public Relations officers call back, they want to know what the

questions are, what your deadline is, et cetera, et cetera. Why you want to talk to the person you want to talk to? Then they often try to answer the questions themselves without allowing you to talk to the source person. Sometimes they just say you just can't talk to the person, because of reasons like the Agency doesn't deal with those kinds of questions. If the process does go forward, the Public Relations officer says he or she will get back to you again, and then hangs up. What happens in the meantime, we don't know. Does someone else have to bless the conversation?

The Public Relations officer gets back in two hours, three days, or never. There's no set time. I have sat at my desk all afternoon while a physician expert sat at his desk after he had already told me he would love to talk to me about a technical medical provision of a Federal Register Notice, but our permission to speak never came.

If permission to speak comes, often the Public Relations officer mandates that he or she will listen in on the conversation, so the officer goes away again to set up a time when all three parties can be on the phone. And increasingly, Public Relations officers, those people whose job it is to make the organization look good, listen in on every word. But, usually, reporters just don't call any more, because they cannot devote the absurd amount of effort and time to the application process just for a few words with a staff member.

What business or other endeavor could survive a mandate of a multi-day permission to speak application for every five-minute conversation? What would that do to anybody's work?

The burden by itself is severe censorship, but that is not the worst of it. The chill from the fact that the Public Relations officials are tracking and listening

in is nearly universal, and it is devastating. The communication is nearly always different, much less fluid, much less informative than it is if reporters can ever get people away from the monitors.

Ironically, the great majority of the communication that has now ceased was benign and useful from the agency's own point of view. It was exactly the kind of information an agency wants to get to the public. Reporters want to know, does this rule apply to this population? What does this term mean in this Federal Register Notice? Can you tell me what this is about in English? But there is also a critical need for those conversations that some officials are not comfortable with.

In addition to untracked conversations, off-the-record conversations are often absolutely indispensable. If the permission to speak rules had been in effect and adhered to in the early 1970s, Watergate

would not have been reported. An example, before the time of the permission to speak system, one day I was talking with an agency staffer, an expert, a head of a program for 30 minutes. I had gotten my obligatory quotes, and I was about to hang up. Then just on chance I said, Dr. XYZ, is there something you could tell me if your name weren't attached to it? At that point, Dr. XYZ exploded with information. It was as if a klieg light had come on in a totally dark cave.

Everything he told me was quote "public information", but not in 100 years would a reporter, or a member of Congress, have understood without inside help. Had I not gone off-the-record, the story would have been sterilized to the point of deception. How often does my profession serve to lull the public into thinking the official story has been confirmed, and there's no need to question further?

Something happened a couple of

years ago that told me how much trouble we are in. An agency held a major media event to announce an initiative, but there was no initiative because there was nothing new, no new funding, or no new activity. This almost assuredly had to do with politics.

The media gave the initiative major play. No reporter understood the inside workings enough to question things, and no reporter could call staff without being tracked. Of the numerous staff people who understood the situation, no one tipped off a reporter, because they are forbidden to talk to us off-the-record. And staff people and reporters don't know each other any more. How confident agencies seem to be that they can just put a story out and control the public information.

Some of the reports on FDA recently have been about the Agency not functioning well, or about the Agency not having the resources to work properly. Some things I

know from having been around for a while about those kinds of stories. Usually, a number of staffers have understood the issue for years. And some of them would have laid out a map for it, a map of it for a reporter if they could have talked away from the monitors. From there, the reporter could have gotten a balanced story by talking to other people, but agencies are getting bolder about using this blockage.

Recently, an FDA Public Relations officer told me, "I decide when you can talk to him." I was trying to negotiate a five-minute conversation to find out if a particular staffer knew anything. I never did get to talk to him.

This Committee's charge is to look at FDA's communication, particularly, risk communication. But if the press can't freely talk to people in the Agency, then the trust in the information, whether it's about risk, or about the Agency itself, must be very

limited. Thank you very much.

DR. FISCHOFF: Thank you. Our next speaker will be Michael Negrete.

DR. NEGRETE: Thank you. My name is Michael Negrete. I'm a Pharmacist, and I am the CEO of the Pharmacy Foundation of California. We're based in Sacramento, took a red-eye actually out last night to be able to be here for the beginning of the meeting this morning, so if I stop making sense, just blame it on that.

Our foundation is a 501C-3 public benefit organization. We were created 30 years ago by the California Pharmacists Association with a purpose of improving and protecting public health by collaborating on pharmacy-related research, education, and information dissemination initiatives. In the spirit of full disclosure, I just want to say that we still rely on the Association for about 15 percent of our revenues, the balance of our income is basically through grants and

contributions from Pharmaceutical companies, drug wholesalers, pharmacies, foundations, public and private foundations, and just private contributions, as well.

One of the things that we do to fulfill our mission, and it's actually become a big focus for us over the last few years, is to work on the issue of medication errors. And I don't know how big of an issue -- how well many of you understand the issue of medication errors, but it's a growing public health crisis, quite frankly.

Last summer, the Institute of Medicine came out with a report with a conservative estimate that said 1-1/2 million Americans are harmed or killed every year by their medications. Three hundred million Americans, that's one out of every 200 Americans being harmed or killed by their medication. If there's 100 people in this room, there's about a 50 percent chance that one of the people in this room will be harmed

or killed by their medication this year.

This is just mind-blowing to me. Here we have cures that are unnecessarily turning into killers. And this should and could be stopped, quite easily.

One of the most significant things my foundation has done over the last year to help fight this problem was to help facilitate the creation and release of a report on medication errors in the out-patient setting. This report came from an expert panel that was created by California Senate concurrent resolution to create the panel to study the cause of medication errors in the out-patient setting, and come up with some recommendations as to how they could be addressed.

Why did we pick the out-patient setting? Well, errors in the hospital systems have been something that people have been looking at for quite some time. There's a lot of good work being done to fight errors in the hospital systems, but there's not much being

done in the out-patient setting, so we wanted this panel to take a look at that.

Now, when a lot of us think about medication errors, we think it was a problem with a prescriber didn't prescribe the right drug, didn't do it appropriately, maybe prescribed the wrong dose, or a pharmacist, potentially, didn't fill it correctly, or a nurse, potentially, didn't administer it correctly. That's only part of the medication use system.

Other parts of the medication use system which are particularly relevant in the out-patient setting are errors related to how the medication is actually used by the patient, and how it's being monitored for efficacy and toxicity. Is it doing what it's supposed to, or is it causing untoward side-effects?

It's hard to get a handle around the scope of the problem in the out-patient setting, particularly related to use and

monitoring, because it's not an institution, so we don't know really how big the financial cost with the whole global issue of medication errors really is, but estimates have been made that put it well into billions of dollars. In fact, I think it would be reasonable to say that a reasonable size chunk of the $177 billion that we spend, that's been estimated that we spend every year taking care of problems that result from adverse events to medications, I think a good chunk of that $177 billion is preventable in the result of medication errors, but it's hard to say exactly how much.

So the report came out just over a year ago, and the report came out with 12 different recommendations. And, unfortunately, only one of those recommendations has had any significant work on it done to-date, but I think it's one that might interest this Committee.

Based on one of the

recommendations, a legislator in California created a new law in California that requires our Board of Pharmacy to spend a few years studying the prescription label, not the labeling that's on the box of a drug, or the labeling information that comes with the drug, if you go to a pharmacy. This is the actual label that the pharmacy prints out and puts on the vial; the idea being that there's a lot of variation. Is the right information there? Is it readable, is it understandable? So the law mandates our Board of Pharmacy to investigate this over the course of the next couple of years, and come out with eventually maybe some regulations that could serve to create a standardized patient-centered prescription label. After the talks this morning, whether or not it would stand up to any First Amendment arguments I don't know, but at least that dialogue is being started.

Now, obviously, this is one recommendation that related to patient

information, basically. And this whole patient education, patient empowerment, patient engagement into their medication therapies, and medication use process, was a very big theme in the report. In fact, half the recommendations related in some way to those issues.

I know Dr. Sleath mentioned earlier in her dream segment this morning that - and I share the same dream - we need to find a way to create an appreciation for a level of concern for among patients and caregivers that they demand the right services and support they need to become those active participants within their medication use process, and their medication therapies.

I believe until we get patients to develop a sufficient level of demand, that we're never going to drive the dollar allocations in the healthcare system to where they need to be to support the physicians, and the pharmacists, and the nurses to be able to

have the time to sit down to talk with the patients, to be able to get that information across, and provide the support systems. Incentives are just completely misaligned right now. Every time I spend as a pharmacist talking to a patient, is time away from doing something else that actually generates revenue, but that's a discussion for a different day.

So how do we change the level of concern among medication users? I'll talk only about medication users for a second. What --

DR. FISCHOFF: Could I ask you to tie it up? We have a number of other speakers.

DR. NEGRETE: Okay.

DR. FISCHOFF: And we'd like to give the panel a chance to interact with our other speakers.

DR. NEGRETE: And that's just where I was going to come back to you all. I think

patients have a perception that medications are safe, or that somebody else is looking out for their benefit. A lot of people think, my belief only, that the FDA approved it, they saw it on TV, their neighbor is taking it, they think it's great, their doctor prescribed it, the pharmacy filled out. How could this possibly cause me any harm?

We need to, on one hand, use experts like you, and I'm so excited to have this Committee together. I'm looking very much forward to seeing the work that you do. We need experts like you to come up with some strategies, recommendations to be able to raise the level of concern among medication users. But at the same time, not shoot ourselves in the foot and create too much concern among medication non-users, who should be taking medications but don't, because they're overly concerned about side-effects, and under-appreciate the benefits of their medications. So very difficult challenges,

they're challenges that my foundation is pursuing. I hope, I don't know if this will fit as a specific issue on your agenda. At least I think it serves as a backdrop for many of the issues you will be discussing. Good luck. I'm going to be watching your work with great interest. Thank you.

DR. FISCHOFF: Thank you very much for coming, and for the comments. Our next speaker is Jeffrey Seconda from AdvaMed.

MR. SECONDA: Good afternoon. My name is Jeffrey Seconda. I'm an Associate Vice President at Technology and Regulatory Affairs at the Advanced Medical Technology Association, AdvaMed. AdvaMed is a leading trade association representing manufacturers of medical devices, diagnostics, and health information systems. I appreciate this opportunity to present the device industry's perspective at this, the first public meeting of the Risk Communications Advisory Committee.

AdvaMed applauds Commissioner Von

Eschenbach for establishing the Risk Communication Advisory Committee to advise FDA in effective communications to the public, to help facilitate effective and safe use of all FDA-regulated products.

Risk communication is a core activity in the device industry. The industry seeks to communicate risk and benefit information about our products to enable people to make informed independent decisions about these products. The industry goes to great lengths to develop the expertise necessary to evaluate customers' ability to understand complex information and instructions. Our customers include healthcare professionals, as well as patients. In fact, medical device communication stakeholders include all those who prescribe, purchase, use, and assist in the use of our products.

For these reasons, we feel that the industry representatives, with appropriate

risk communication credentials, should be available to the core Advisory Committee to provide experiential insight on communicating with device stakeholders.

Although the charter of the Risk Communication Advisory Committee does allow for the inclusion of industry representation by invitation, the available representatives are limited to existing members of other FDA Advisory Committees.

The industry representatives on these existing committees are chosen on the basis of their knowledge of FDA regulation, and the products under consideration by the particular committee. Restricting the pool of industry representatives to those from existing committees will severely limit the Risk Communication Advisory Committee's interaction with risk communication experts from the device industry.

AdvaMed recommends that FDA develop a pool of risk communication experts

representing the unique knowledge and experience of the companies who develop and market the various products represented by the five main centers of the FDA. These representatives would be vetted in the same fashion as other industry representatives to FDA committees. Risk communication experts from industry would be non-voting, and available to the core Committee on an as-needed basis.

We urge the Commissioner to consider this recommendation to identify industry representatives using the same thoughtful criteria that has been applied to identifying the other members of the Risk Communication Advisory Committee.

As regards the standard template for press releases, and I apologize, I won't be here tomorrow, so I'm making these comments today. As stated earlier, risk communication is a core activity of the device industry. When it becomes necessary to inform device

users of a problem, the industry strives to develop useful information that is directed to the affected population. To be useful, the communication should include the nature of the problem, the likelihood and severity of the problem, and actions needed to ameliorate the problem.

In those instances when no specific action is indicated, the communication should be carefully crafted. Exaggeration of risk to the target population, or misinformation to unaffected populations could discourage appropriate use of beneficial devices, drugs, or biologics.

Press releases and other vehicles of communication should use accurate and understandable language. Terms such as "notice", "correction", "removal", coupled with appropriate adjectives, such as "urgent", or "critical", are precise and widely understood. Although the term "recall" may have its place in the Agency Lexicon, it is

understood by the public to be synonymous with removal. Recalls affecting foods and drugs, which have a limited useful lifetime, generally do mean removal. Devices, however, fall into several use categories, such as patients with long-term implants, such as hips or pacemakers, patients who use devices without medical supervision, such as blood glucose monitors, patients having a transient experience with a device operated by a health professional, such as imaging equipment, and patients who have no direct contact with a device at all, such as in the case of in vitro diagnostics.

I urge the Committee to consider these use categories when considering the structure and content of press releases intended to inform the affected public of device problems.

A press release is an effective tool useful for reaching a very broad population very quickly. Press releases

should not be the automatic response to every Class I problem, unless the affected population cannot be reached effectively by more precise methods, such as letters to the patient, or prescribing physician.

Furthermore, delayed or repeated press releases can undermine the effectiveness of a focused communication plan. For instance, a company may send letters to the affected population in one month, only to have a press release required by the Agency several months later. The result is confusion amongst all segments of the patient population, whether or not they are affected by the problem, and a tidal wave of inquiries to physicians and companies who similarly may not be involved with this specific device problem.

In summation, I urge the Committee to consider the very real danger of discouraging the appropriate use of beneficial devices due to the overly-broad communication effect of the press release. Thank you.

DR. FISCHOFF: Thank you. Thank you for coming, and thank you for the comments. If anybody has written comments, please leave them with the Committee. So, for example, you had some detailed issues about wording. I guess we have a copy of your comments, and we'll be able to look at those when we have our discussion tomorrow, so thank you. And our final speaker is Jennifer Wilmes for the National Fisheries Institute. Please.

MS. WILMES: Good afternoon. Thank you very much for allowing me to chat with the Committee today. My name is Jennifer Wilmes, and I am registered dietician, and have expertise in the area of nutrition communication. I work for the National Fisheries Institute, which is a non-profit organization dedicated to education about seafood safety, sustainability, and nutrition. And my particular role at NFI is to help our staff and member companies effectively communicate about seafood nutrition.

Each and every one of the thousands of food choices a person makes weekly is a mini benefit-risk analysis. For example, some foods are delicious, but high in saturated fat. Some foods are nutrient rich, but inconvenient to prepare, and some foods are healthful and scrumptious, but expensive to purchase. Tallying the list of pros and cons associated with each food, drink, and drug that we put into our bodies is a complex process; yet, we often manage to come to a verdict in minutes or seconds.

The U.S. Food and Drug Administration is in a position to improve the outcome of these verdicts on a macro level through balanced, well-crafted benefit-risk messages.

Before providing my recommendations on how FDA should craft their messages, I'd like to underscore the importance of the Committee's counsel on this issue by illustrating the impact that FDA

recommendations have on public perception of a food using seafood as a case study.

In January of 2001, FDA released a document entitled, "Consumer Advisory: An Important Message for Pregnant Women and Women of Childbearing Age Who May Become Pregnant", about the risks of mercury in fish. The advisory recommended that women of childbearing age can "protect their unborn child by not eating shark, swordfish, king mackerel and tilefish. Numerous media reports followed.

To estimate how pregnant women changed their habits after this advisory, Dr. Emily Oken of Harvard Medical School looked at the diet of over 2,200 pregnant women before and after. Her study published in the August 2003 "American College of Obstetricians and Gynecologists Journal", found that after the advisory women ate less total fish, including dark meat fish, canned tuna, and white meat fish, with ongoing declines through the end of

the study period. Because these fish confer nutritional benefits to mothers and infants, the public health implications of the FDA advisory were questioned.

In March of 2004, the Federal Advisory was revised and re-released as, "What You Need to Know About Mercury in Fish and Shellfish - 2004 EPA and FDA Advice for Women Who Might Become Pregnant, Women Who are Pregnant, Nursing Mothers, and Young Children." Benefits of seafood are given four sentences in the second advisory, as opposed to two in the 2001 version.

To gauge how consumers were responding to advice about eating seafood after the second go, the Center for Food Nutrition and Agricultural Policy at the University of Maryland conducted a survey of over 1,000 Americans in 2005. More than one-third of the respondents mentioned that "fish was contaminated with mercury or other contaminants".

When asked to name fish higher in mercury, tuna and salmon were the most common answers. When asked to name fish lower in mercury, the top three answers were salmon, shrimp, and tuna, suggesting terrible confusion.

A 2006 University of Delaware Sea Grant survey gives further insight into consumer knowledge, two years into the latest federal advice. Initial results of more than 1,000 consumers in this survey, both men and women, show that 79 percent of people did not agree, or were not sure about whether pregnant women should be eating seafood at all. Of the consumers who indicated they had heard negative messages, 57 percent, an all-time high, mentioned mercury.

As a dietician, FDA advice is simple. Eat 12 ounces of a variety of fish, of which 6 ounces can be canned albacore tuna, avoid just four predatory species that are rarely consumed or available, anyhow.

Unfortunately, the University of Delaware survey shows that only 16 percent of consumers get their information about seafood from dieticians, and only 9 percent think this is the best way to get information about seafood.

Media is by far, at 63 percent, where consumers currently get their seafood facts. It ranked number one as the best way to get information about seafood, above health newsletters, dieticians, and blast physicians. For this reason, I spend a large portion of my time working with journalists to get the FDA advice correct.

A LexisNexis search of the last month produced at least 10 articles that specifically refer to the federal advice about eating fish. In many cases it plays out like this. "For pregnant women, the Food and Drug Administration's warning is clear. Too much mercury could damage a fetus' developing nervous system." And this is from a news affiliate in Charlotte on just Friday,

February 22nd, 2008.

The health benefits of eating seafood range from optical and brain development in babies, to heart health for moms and dads, to reduced risk of dementia in grandparents. At the same time, minimizing mercury exposure during pregnancy is prudent, so what can FDA do to clear the waters about eating fish and other foods?

First of all, it is important to recognize that the fish story is more than a benefit-risk situation. It is a prime example of benefit-risk-risk issue. There are proven health benefits of eating seafood, inclusive potential health risk of mercury from seafood, and proven health risks of not eating seafood. All three should be communicated in proportion to the risk or benefit that science shows they offer.

Second, the focus should be on do's as opposed to don'ts. The University of Delaware Sea Grant Survey shows that only 22

percent of Americans broadly, and only 19 percent of women of childbearing age are eating seafood twice per week as recommended by the U.S. Dietary Guidelines of the American Dietetic Association, the American Heart Association, and on all major health authorities.

With heart disease being the number one killer of both men and women, and obesity and diabetes on a rise, Americans must know that they need to be eating more fish. Emphasis must be shifted to encourage consumption of the large and exciting variety of seafood that exists.

Third, and lastly, considering the overwhelming impact that they have on public perception of foods, the media must be held accountable by FDA for misconstruing the Agency's recommendations. Something as simple as an FDA phone and email contact number for confirmations of accuracy could and should be offered.

The Federal recommendations for seafood during pregnancy are an example of how well-intentioned risk communications can give life to a whole new set of risks. The FDA's job is to protect and advance public health, and that means leaving families with not only the confidence, but the drive to eat a range of nourishing foods. Thank you.

DR. FISCHOFF: Thank you as well for coming in, for your comments. We have about 20 minutes now for comment, if there are questions from the panelists for our guests, members of the Committee to take advantage of their presence. Anybody have follow-up questions? Please.

MS. LAWSON: I have a question. This goes to, I think it's Kathryn, is it Kathryn Foxhall?

DR. FISCHOFF: Yes.

MS. LAWSON: About the internal -- the controls over the communication with the media. I just wondered, you mentioned having

discussion with the Public Relations person who allegedly said to you that you -- she or he was in control, or made the decision. I just wonder if there had been any attempts to have communication with senior level personnel at the Agency beyond Public Relations staff?

MS. FOXHALL: I personally have not done that at FDA. I wrote Secretary Leavitt and got a letter back from Public -- well, I shouldn't say this is how we do things. There are reasons given like well, we have to tell reporters who to talk to, because reporters apparently can't find out who to talk to, or that you don't understand the Agency's expertise, et cetera.

MS. LAWSON: Okay. Thank you.

DR. FISCHOFF: Are there other -- yes?

DR. NEUHAUSER: I wanted to thank the speakers for their very important information. This will be very helpful to the Committee.

Something that Kathryn Foxhall and Jennifer Wilmes said, seems like they're interlinked, so Jennifer Wilmes was talking about the need for a quick or efficient way for the media to contact the FDA when there's an advisory, or some other kind of communication that would clarify what is meant by that. So I'm wondering, perhaps, if Jennifer Wilmes could say something more about what she thinks would be helpful. And if Kathryn Foxhall could say if that is something that, as a journalist, she has found to be an issue.

MS. WILMES: Sure. In my comments, the example I gave is, perhaps, just an email or phone number associated with particular area of expertise within FDA. And I think, ideally, it goes beyond FDA being available as the source, but I think that as much as able within the resources of FDA, they should hold the media to a standard of accountability, because that's what I'm doing right now on

behalf of FDA in my role. And I'm happy to do it, because it contributes to public health, but I would greatly appreciate the support and ability for FDA -- the support of FDA, and the ability of FDA to be vocal.

MS. FOXHALL: Yes, her comments struck me when she first made them. We don't -- basically, reporters don't feel like we can get through on any kind of a reporting time line. We have to go through an almost ceremonial poobah process for a five-minute conversation, so we look -- we oftentimes, unfortunately, look at the release, maybe go to an outside expert to try to find more comment, but we're very discouraged from trying to get through at FDA, even though we know there's a treasure trove of expertise there.

DR. SLEATH: Just because I'm unfamiliar with it, when did that change, that the media started having difficulty talking to the FDA?

MS. FOXHALL: I can't tell you precisely about FDA. I remember being in newsrooms like `94, `95, `96 maybe, and it becoming a factor in one agency after another. And we in the newsroom, just really not knowing what to do about it, because we're not supposed to lobby the agency, and we're oriented to just moving on. If somebody doesn't want to talk to us, just move on to the next source person. So communication is very closely collapsed.

DR. FISCHOFF: Please, Christine.

DR. BRUHN: I want to thank each of the speakers. Each of you had something very important to share, and we were all gratified to hear your perspective.

I wanted to follow-up on Michael Negrete's comments about your pharmacy group, and you said your report came up with 12 recommendations. And would you be able to share those recommendations with the Committee, so that we could review them, and

they may well pertain to some of the issues that we'll be addressing. Certainly, communication seems to be a central part of it, and we'd like to have the insight your group has developed.

DR. NEGRETE: Most definitely, I will send them along. They're also available on our website at www.pharmacyfoundation.org/medication errors, but I'll send them along, as well.

DR. FISCHOFF: Thank you. John.

DR. PALING: We're so much in a learning mode here, speaking for myself, particularly. Many of the things that the four of you said, I would like to know more about it. It's not that you're wrong, very much the reverse. I don't know enough to properly assess them. I almost wish that this was the second meeting, and we've been introduced to some of these when we could have had a little more expertise to try and make a creative and positive evaluation of how your

remarks fit into what we should be doing.

I have two specifics. Jeffrey made the point that others have made about the word "recall" being deceptive to the general public. Would you please tell me if you have other suggested words, and we'll be glad to hear those. That will be very helpful. That will be one thing.

The second thing, for Jennifer, since the media is intending to get public to listen, and look, and read their works, we, the people, tend to follow negative news, rather than positive news, as you know full well, so perhaps at another time I'd like to explore the ideal of we should - we, the FDA, only temporarily associated - should be talking about the positives, and not the negatives. I think it should be both, and I think you will probably agree with that.

Jeffrey, the other thing for you is, I don't know the way within this Committee that people who wish to make us aware of

things can provide us with information. Clearly, this can't get out of hand, and there must be a million groups that would like to have our ear, but at least two of you have things that I would love to know more about.

DR. FISCHOFF: So we have an answer to that. The procedure is to send it to our Designated Federal Official.

DR. PALING: Well, thank you for clearing that up. Thank you.

MR. SECONDA: Thank you for your comments. In terms of the language, I think it's fairly logical which terms would be more effective. It's really the issues that recall is a defective term. It has a certain legal status, I understand, but in terms of actual communication it fails, especially in those examples, such as an implant where, what does that mean? And I know that the Heart Rhythm Society has a statement which they left, printed statement where they very strongly say that the term "recall" should not be used.

But I think in terms of actual communication, that, again, the adjective urgent or critical gets one's attention, and notification, if it is just information, or correction if it's something that has to be done, or removal if, in fact, it does have to be removed from service. So I know some people feel that well, if you don't say recall, people won't take it seriously. But I just don't think that's the case.

I would also like to point out that the Global Harmonization Task Force has come out with recommendations as to various terms that should be utilized, and I believe they are similar in nature; field safety correction, safety notification, these are the terms that they recommend.

DR. FISCHOFF: Nobody has a question? I have a question for Kathryn Foxhall. If when you see a situation, when you perceive a situation like the one you described, and you say well, you just go on to

your next source, who are the sources that you are going on to? You describe kind of a vacuum, from your perception. Who fills that vacuum?

MS. FOXHALL: Professional associations, many times, industry associations, hopefully also academic people at universities, according to what the subject matter is. FDA -- I mean, the federal agencies should be there, but they've almost trained us not to call.

DR. FISCHOFF: Thank you.

DR. NEUHAUSER: Just a follow-up question for Jeffrey Seconda. You mentioned a task force that had come up with other terms. Could you say more about that, and direct us to the source of information?

MR. SECONDA: Yes. That's the Global Harmonization Task Force, GHTF. And, in fact, I believe it's Study Group II that has to do with the reporting of adverse events, whether it be removal of a product, or

informing the public. I don't recall the precise language, but I believe that it's fairly well described in their documents.

DR. NEUHAUSER: And could you direct us to where to find those, unless somebody here knows that?

MR. SECONDA: I believe it's www.GHTF.org, probably /SW2, but just go to the C- I'm sure, or very simply, I'll email it to Lee.

DR. NEUHAUSER: Thank you.

DR. FISCHOFF: Thank you. I was hoping for a very long web address just to test our short-term memory. Thank you. Are there other questions from the Committee?

In that case, let me thank our guests for their contributions to our education, willingness to stay through this interaction. And let us now call the Open Public Hearing to a close, and move on to our next session, which is Existing Risk Communication Programs. I'm sorry. Yes. One

of our guest panelists, Greg Baird, is here now. Would you like to introduce yourself, and take a couple of minutes to tell us what you do, the way we did this morning. Thank you. Even if you have a bit of a dream, that's the time for that.

MR. BAIRD: Thank you. I enjoyed the meeting even from the back of the room this morning. It's okay. My name is Greg Baird. I have been in the pharmaceutical and biotechnology industry for the past 30 years. I've worked at Pfizer, Cyril, Genetech and Novartis, and on the agency side I've worked at Burson-Marsteller, Hill and Knowlton, and Porter Novelli. So I think it's given me a pretty broad cross-section of risk communication relative to products, devices, biologics. And the gamut of those communications and the situations is remarkably different, challenging, competing interest. And what is fascinating to me now is the literal war that's going on over the

timing, extent, and balance of communications regarding risk.

Billions and billions of dollars are at stake, and being played out, and a CEO can be as easily sacked by a class action lawsuit of patients as he is by a shareholder lawsuit for inadequate risk information to make a prudent investment. And I think that the FDA is sort of in a cat bird seat, I hope, to be able to have clarity and authority on this topic, because so very often the communications professionals within the corporation are the tail on the dog when it comes to decision making and timing. And many voices are heard from legal to regulatory, to operations, that can drown out a communications professional. And if this Committee can come forward with standards, clear standards, and with a clarity and a force, and authority that's needed, I think you could make a tremendous difference to what communications professionals within these

enterprises could actually do in the timing and clarity of their own communications that come forward. Anyhow, I look forward to the discussions. I don't want to take any more time.

DR. FISCHOFF: Could you say a little bit more about what you -- what the form of these standards would be?

MR. BAIRD: Well, I think that the gray area is what's frightening here in the sense of what's the right amount of time, what's considered material to a company. And when do they have the fiduciary responsibility to discharge that information? What's the difference between discharging information and actually assuring that the need-to-know population receives the information in a time, and in an extent to make rationale prudent decisions of their own? And it is a gray area, and it's currently being, basically, decided by courts. And it would be great to get ahead of that curve, and have that more

wisely decided as it happens.

And to the extent that FDA could generate a protocol, a standardization, and an expectation that has real authority and teeth to it, I think it would be great. And I, actually, frankly, think that the corporations involved would be relieved at that point, because the sort of tension behind the decisions with competing interests, there's shareholders and their interest, and there's patients, and ultimate consumers and their interests, and you've got to acknowledge and be deferential to each. And sometimes that seems to be a tremendously conflicting battle. And I think that if there was that clarity of like these are the teeth of the procedures that you have to follow, and what's expected, it would be a tremendous boon to them. Because it's funny, as much as they seem to be in the short-term conflicting interests, in the long-term, there's a tremendous congruity of interest between corporations,

manufacturers, providers, patients.

Everybody ultimately wants to see medical progress achieved. It's good for business, and it's certainly good for health. But in the short-term, there can seem to be tremendously competing interests, and that's where it gets bollocksed up. And I think a voice of this Committee could have a lot of clarity.

DR. FISCHOFF: Thank you. Well, welcome, and let us move on to the next session. And our first speaker will be Lorrie McNeill, who's the Director of the Office of Communication, Training, and Manufacturer's Assistance at FDA in the Center for Biologics Evaluation and Research.

DR. ZWANZIGER: Could all the panelists come forward? And it might be easier if you stand at the podium.

MS. McNEILL: Thank you very much. I'd like to thank the Committee for the opportunity to come present today.

In the short time that I have to speak to you, I'd like to present some very specific communication efforts that we have taken on in the Center for Biologics in FDA. One of the things that we've started to do more recently, and when I say recently, this started in 2006, are public health notifications. And these are very specific communications to the healthcare provider community, where we've had information that was considered early information, but that we wanted to communicate because we felt it was important for folks to know.

The three that I've listed here are three very different, or two very different situations; Biomedical Tissue Services was a donor, excuse me, a tissue recovery organization that processed donor tissue that did not -- where the donors did not meet eligibility criteria. There was a tremendous amount of information in the press about this, because there was an ongoing criminal

investigation in Brooklyn by the District Attorney there, and so there's a tremendous amount of interest in this.

The first communication that we did on BTS was actually a press release, because it was very broad. We wanted to make information available. But after further investigation into what was going on with the firm, we had some additional information about the risk and what we felt was important information that needed to be communicated, not only to healthcare providers, but to potential tissue recipients. And, therefore, we issued a public health notification. It was the first one that we had done. It was in March of 2006, and the purpose of it was, essentially, to communicate to the doctors that they should inform their patients who may have received this tissue that there was a potential risk. And while we believe that the risk was low, because donor tissue, unlike blood products or organs can be processed

further to help reduce the risk, reduce infectivity. The risk is not completely zero, and essentially is unknown. And so we felt it was important for patients to be aware of this, and for doctors to offer testing to their recipients, or to the tissue recipients.

So we took this form of communication, because we wanted to target healthcare providers rather than again issue another press release. We wanted to get to the specific community we felt needed to hear the message the most. We distributed this through our website, which is not terribly targeted, but also through MedWatch. And you're going to hear a little more about MedWatch from Paul Seligman, but they have a tremendous reach as far as their partner organizations, and their listserv, and so we thought that that was a very effective way of reaching our audience.

In addition to MedWatch, the Center also did some specific targeting with

physician groups that we felt, just in the event that they weren't on MedWatch, would be users of this tissue, like dental organizations, and the American Academy of Orthopedic Surgeons, that kind of thing.

Donor Referral Service is a very similar issue, it's about six months later, also the issues there had to do with the appropriate donor eligibility not being done. In both cases, there was no reliable way of determining whether or not the test results on the tissue samples could be matched to the donors, and that was the big issue.

We did a similar public health notification, again targeting the healthcare community, so that we could get the information out. The issue with Donor Referral Services was not quite as large. I think it only involved eight donors, as opposed to between seven and eight hundred tissue donors with the BTS recall.

And the third public health

notification that we've done was last year, last February, on Rotavirus vaccine, or RotaTeq by Merck. The vaccine had been approved 12 months earlier, in February 2006, to prevent gastroenteritis caused by Rotavirus in infants. In the 12 months following licensure, there had been 28 cases of intussusception reported to our vaccine adverse event reporting system or VAERS, which is the vaccine equivalent to MedWatch.

It is a serious, and potentially life-threatening condition, causing a twisting of the bowels or blockage of the intestine, and it can occur spontaneously in the absence of vaccination. So while a report to VAERS is important, and it's a safety signal, it is not a determination of a causal effect between the product and the event. But because we had seen this, we felt it important to communicate this information again to the healthcare provider community to make them aware of the event, and to encourage reporting of other

potential cases.

Again, none of the specific cases were specifically tied to the vaccine, but we wanted to make sure that the providers were aware of the event, and could then report appropriately.

Another communication, and I say communication on this because it's my specific area of focus, but an effort on the Center's behalf are our interdisciplinary safety teams. These are also fairly new. We have three, and they cover three product areas, tissue, blood, and vaccines. The Tissue Safety Team was the first one that we established back in May of 2004, and the others followed.

The purpose of these teams was to identify the appropriate staff across the Center, not just in the Program Office, in this case the tissue program, but also product manufacturing folks, clinical folks, and communication staff so that we could improve communication across the Center, rapidly

respond to emerging issues and the like.

I think the most important thing that we have learned from this is that the makeup of these teams has really improved how we communicate information within the Center between the folks who are dealing with a particular product issue, and the communication staff, as opposed to in years past where the communications folks were brought in later in an issue. We now have a seat with the team from the beginning, so we hear the information the same time that all of the review staff hear it, and the subject matter experts hear it, and can advise early on how we should consider communication efforts. And, so, from my standpoint, it's been a very successful collaboration.

Another very specific communication effort that we've undertaken is a risk assessment on variant Creutzfeld-Jakob Disease in plasma-derived products. CJD is a fatal neuro degenerative disease, and human

infection is generally caused by consumption of infected beef with BSE. There is no screening test for CJD, and so the actual risk from blood donors is unknown, whether or not it can be transmitted. We do know there are some circumstances where it can be transmitted in cellular products, but with plasma derivatives, it's really unknown.

So questions arose from this potential risk from products such as clotting factors, immune globulins, and albumin, so we undertook developing a computer-based risk model to try to evaluate the risk of these products, or the risk CJD posed to these products, and to the recipients.

The Center had put into place in 1999 some blood donor deferral policies that we believe reduced the risk of having blood products enter the system by about 90 percent, but then what happens with the other 10 percent?

The conclusions from the model that

our staff developed suggest, essentially, that the risk of infection from manufactured U.S. source plasma derivatives, and we're talking specifically about U.S. products, not products that are made elsewhere, the risk appears to be extremely low, but may not be zero, and so, how do you then communicate that to the recipients?

Part of this risk model was to engage in the stakeholder community the affected hemophilia community, and hemophilia treatment centers, and healthcare providers who deal with these groups. We brought them in to discuss the results, and get their input on how we should communicate this information to that community.

We also presented it to our Transmissible Spongiform Encephalopathies Advisory Committee, and got their input, as well. So we tried to do this in a very public manner, and we thought it was a very successful effort, and collaborative effort

with the affected community. And we disseminated all of the information on our website, which brings me to our website.

As Dr. Von Eschenbach said this morning, we view this as a very critical communication tool, and as he said, we are, as an Agency, undergoing a major transformation right now, and so what you see today will look dramatically different come December or January of next year. What we post on our website is product approval information, safety information, such as public health notifications, frequently asked questions on products that we approve, whether it's a new product. The first time we approved FluMist, for example, the nasal flu vaccine, we posted FAQs on that. We also have some on blood donor deferral to answer questions about if somebody is deferred when they go to donate, why were they deferred? And try to explain the reasons for that.

We also have information posted

that we develop for specific target audiences, whether it be healthcare providers, or consumers. And healthcare provider education is an area that is going to be a focus for my office and the Center for 2008 and 2009. So with that, I turn it over. Thank you very much.

DR. FISCHOFF: Thank you. Our next speaker is Paul Seligman.

DR. SELIGMAN: Good afternoon. In my seven minutes, since I can't capture the full breadth and depth of communication efforts in the Center for Drug Evaluation and Research, except at the most dizzying and superficial levels, I've chosen to focus on a few of our current initiatives to communicate important, and often emerging safety information about medicines that are marketed in the United States.

The MedWatch program serves the Agency, and has been in existence for over 10 years. It has two primary functions. The

first, it serves as the means for health professionals, patients, and consumers to report adverse events, and medication errors associated with drugs and devices. Reporting can be done through our website, where a web fillable form is now available, or through our toll free number. A current Agency-wide initiative that is underway, which we dubbed MedWatch Plus, is looking at ways to facilitate and improve this reporting function.

The second feature MedWatch is to communicate new safety information as it is released by the FDA, about the whole range of medical products and changes in label warnings, to recalls, to letters that are issued to healthcare providers, to medication guides for patients, to any of the safety messages and public health advisories that I'm going to be talking about in just a minute.

The information comes out on a daily basis, and goes directly to the 75,000

individuals who have subscribed to our listserv, as well as to 160 professional and consumer organizations who participate in our partners program. These organizations then take our alerts and announcements, and further distribute and disseminate them to their constituents and members, as appropriate.

As a member of this Advisory Committee, I would encourage all of you to, at the very least, look at our MedWatch website. And if you don't already subscribe, to consider subscribing to our listserv. It will give you a real flavor for the types, as well as the breadth of communications the emanate from the FDA every day.

In December 2005, DHHS, the Department of Health and Human Services Secretary Leavitt announced an initiative to provide important and often emerging safety information to practitioners and the general public. Prior to this initiative, most new information was communicated via changes in

the professional drug label.

In 2006, we published a draft guidance, and in March 2007, a final guidance that describes why and how we communicate new information to the public. We developed four new vehicles for communicating the safety information that we believe to be valuable to clinicians, and patients in weighing benefits and risks of medicines, and in making informed therapeutic choices.

Before you is the cover of the Drug Safety Newsletter, which we launched this past fall, which provides articles that summarize the data for selected post-marketing reviews completed in the previous quarter, and presents case studies in that newsletter that we believe are illuminating to practitioners and the public about the kinds, as well as the complexity of cases that we face in assessing the post-market risk of a product. The newsletter is issued quarterly. The winter issue is actually poised for release any day

now, and it is available by electronic subscription.

Last fall, in response to concerns that FDA should be more forthcoming about issues that we are currently -- that are currently under review, we began issuing what we call an early communication about an ongoing safety review. The intent of these announcements are to inform the public that we are in receipt of data from sponsors, academics, through the medical literature, from foreign regulators that we are reviewing the data, to inform the public as to whether we have any preliminary views on these data, and to communicate clearly the time line that we have established for completion of our review, and further communication.

Since 2005, we have been issuing both public health advisories, as well as healthcare professional sheets. The public health advisories, or PHAs, are directed to the general public, and are issued when we

have a safety issue to communicate, and actions that we can recommend that patients and/or providers can take to mitigate or minimize the risk from a particular safety issue.

Healthcare Provider Sheets, there's an example of one here, often accompany the public health advisory. They're written at the professional level, and are organized with an alert or a summary, a section that provides clear recommendations for clinicians, another section that describes what patients should know, and then provides a data summary at the end, which was the basis for the alert.

The feedback that we have received to-date from representatives of professional organizations is that they like what the FDA has done in speaking directly to them through these communications, and that the format, using a summary alert bulleted recommendations and a concise data summary have all been very appealing.

We've also done some modest focus group testing of patients regarding the patient portion of these communications, and, again, they have found them understandable, valuable, and informative.

As always, whenever we do more in response to a concern that we are doing too little, it sparks concerns about too much information. Our goal is to foster transparency, and to provide factual, clear, balanced, timely information about what we know, and what we're still uncertain about. We believe that -- and information that we believe will be valuable to both patients and providers in making important therapeutic decisions.

In this past calendar year, 2007, we issued 20 healthcare provider sheets, 10 public health advisories, and 3 early communications. These 33 items are against a background of over 900 professional labeling changes that occurred to the warnings,

precaution and adverse event sections of the professional labels, as well as more than 60 new boxed warnings. So rather than engage in the too much/too little dialogue, it is more informative, I believe, to learn whether what we are doing is of value, and is well-communicated. And to this end, I look very much forward to engaging this Committee and its expertise in providing advice to us on the conduct of our communication efforts.

Finally, in the past year, the Center for Drugs has taken a comprehensive look at all of its communication efforts in response to a recommendation made from the Institute of Medicine a little over a year ago. We completed an inventory of all of our tools, and communications channels that we use, and are taking a close look now at the best way to resource and organize our program that ultimately leads to better communication, and more appropriate use of medicines by the American public.

With that, again, I look forward to our subsequent panel, and any questions and comments that you have. Thank you.

DR. FISCHOFF: Thank you very much. We have four more talks. We're going to go through the talks. Please keep notes on your questions. I think we could probably occupy each of these speakers until the break, so thank you.

MS. RICE: Good afternoon. I'm going to share some information with you. A lot of what I will say sounds very similar to what both Lorrie and Paul have alluded to, because we do have similar tools, similar documents that we use for our risk communication processes. But I will give you some unique products that the Center for Devices and Radiological Health provides that we collaborate with the other Centers on to help get our risk messages out to our various stakeholders.

So, first, a glimpse of some of our

websites. Our products clearly talk to different audiences, as well as some that are developed just for specific types of products. And then some that we work on in regards to disease-related, where we do collaborate with the rest of the Agency, and try to provide reliable information about all FDA-regulated products, and you'll see a glimpse of that.

One of our pages, our medical device safety page, is geared towards our health professionals, and provides information on recalls, alerts and other safety information. Our medical device recalls page was developed for consumers to provide information about our most serious recalls, and try to explain to them a little bit about our regulatory process, which isn't so easy to understand when we talk about our Class I, II, and III recalls.

We also use the MedWatch system to push out a lot of this information for us. The web is a great, wonderful tool that can

reach tons of people. However, it's a very passive system. We have to rely on people to find us, so the one nice thing about our MedWatch system is it does reach 75,000 subscribers, and we can get the information out that way.

Our medical product safety network, known as MedSun, this one of the newer websites. This is, again, directed at healthcare professionals. It's actually a program that the Center for Devices runs. It's an adverse event reporting system where we collaborate with over 350 hospitals, and try to identify and solve problems around medical device use. The website, in particular, was put up to start sharing the information a little more broadly.

From our consumer aspect, I did mention we try to stick to some product-specific sites. This is actually one of our largest visited websites, between 60,000 and 100,000 hits a month. This where we try to

provide guidance on risks and benefits, and the approved products out there for Lasik eye surgery. I think this is only first or second to our breast implant page, so it gives you a glimpse into our industry, and consumers. Another example is a tanning website that we have up to help people understand about the skin tanning, UV products, and skin protection.

I did mention sort of our collaborative efforts, and the Heart Health Online was the Agency's second disease-related website that the Center for Devices collaborated and pulled together with the help of all of the other centers. The first one was our diabetes site, and this one is taken to the next level with a lot of very specific information and diagrams, and videos to help people understand how products like pacemakers actually work.

You've heard about public health notifications and/or advisories. These are

very similar across the centers. They are directed to the healthcare community. We have just recently in the last couple of years started to take that similar information, and when the issues span into the patient world, tried to again write at an appropriate health literacy level with the same information, so we're giving similar information at different levels of understandability. An example of our public health notification page.

We also have newsletters. These are electronic newsletters. When we go out and do exhibits at various trade shows, we bring hard copies of this. This is another example of our collaborative efforts. The "FDA and You" is a newsletter targeted to secondary school health educators, as well as students, and we put this together in a way to direct young adults into taking some responsibility for their healthcare, so we pick, obviously, topics that could have an interest to them; contact lenses, the

decorative lenses that people see during the Halloween time, tanning is very big, because we are trying to get to the youngest, and give them advice on how long-term exposure to UV radiation can affect them, as well as medications, acne medications, and a lot of things that will affect their life, and hopefully get to them. We do attend, we have about 16,000 subscribers to this. We also developed lesson plans for the teachers to try to get them motivated to get the kids involved.

Our newest is "Maturity Health Matters", which is, again, the flipside. Our health news for older adults, families, and caregivers. What we're really doing is pulling information that exists from a lot of other places, and trying to pool it to where we can push it out to various organizations. We have partnered with AARP on this initiative, and it's been very successful. Examples there of our sites.

And, lastly, we have the opportunity actually do some video broadcasts. We have a broadcast quality TV studio in the Center for Devices and Radiological Health, and we do a monthly health news TV show. And we've been doing that since about 2002. We collaborate with the other centers, as well, and so this is an FDA patient safety news show. And we've done 73 shows that have actually been broadcast, with over 580 stories.

The nice thing about this is the shows are broadcast over four to five hundred hospital and nursing home networks, but it's also webcast, so you can go back in at any time and view just one story, view a whole show, try to get the story on a particular issue, and catch up through all of the years that we've been doing this. There's an example of that page. So we do push this out, also these stories through MedWatch, and we have about 18,000 subscribers to this site, as

well.

And the last thing I wanted to mention was some of our initiatives to improve communication, because I think that's the reason we're all here, and all of the centers have as much desire to do the best job we can communicating risk-benefit information to the public. This is similar to, it sounds like Lorrie's interdisciplinary safety teams.

In 2006, our Center started to look at how we could improve our post-market safety across the board. And one of the outcomes was to sort of formalize some of our informal networks, and really pull the people from the very diverse function and skill set into one group.

Now, January we kind of stood this organization up with team leaders, so we have 13 product-specific teams, and hopefully by April, we will have the centers office liaisons pulled together, and these teams will start looking at various post-market safety

initiatives. And the communication is clearly a huge part of this, and so we believe there will be more information coming out to the public, since we do have people that will be dedicated to solving post-market issues, as well as we put together a Risk Communication Steering Committee. It sounds very similar to what Paul's group has done based on the IOM recommendation, but we saw this as an important part for our center, as well, to evaluate our current products and processes. And, hopefully, after we get our own house in order, to move forward into working with our stakeholders to see about improving their risk communication products. Thank you.

DR. FISCHOFF: Thank you. Our next speaker is Marjorie Davidson.

DR. DAVIDSON: It's a pleasure to be here today to talk about the Center for Food Safety and Applied Nutrition's Risk Communication program. I think you'll notice a pattern, and a theme as I proceed through my

presentation.

CFSAN, as we recall, deals with a wide range of issues, microbiological, chemical, and physical contaminants in food, nutrition and obesity issues. There's food defense, we have dietary supplements, and allergens, just to name a few of the issues that confront our Center.

There are a variety of communication methods we use to get information out. Media outreach is one of the -- actually, the primary use that we do use, because we find that when we do our research, we find that there's where our folks are going for information. First and foremost still is television and magazines, that kind of thing. We do use all kinds of media outreach.

We have education conference and education programs. We have a toll-free hotline, 1-800-SAFEFOOD, which consumers can call and speak to a single individual at the Center with questions they might have. This

hotline also allows us to kind of measure informally issues of interest that are out in the consumer population you may be unaware of.

We have email inquiries. We do constituent updates to our stakeholders. We have over 20,000 names now on our constituent update list. This is mostly industry consumer groups, folks that follow our particular issues. We have listserv and EdNet, we call, which is for Food Safety educators who subscribe throughout the country. There are over 5,000 people who subscribe to this, so they can keep up on the latest educational programs that people are taking in food safety.

Advisories are also a method that we use at CFSAN. Recently, we have - what has been addressed earlier today, our risk-benefit messages, we're finding we're increasingly dealing with in our advisories. Mercury and fish and shellfish is one, acrylamide in food, listeria in refrigerated ready-to-eat foods is

another one. We also, as much as possible, do educational programs associated with our advisories.

For example, on the listeria advisory done recently, we did an extensive outreach to the Hispanic community because of the risks of queso fresco cheeses that are made with unpasteurized milk that are popular in that community. We developed an entire community outreach program that Public Health Departments can use to do outreach to that community, with training programs for promotoras, as well as issued a lot of extensive media outreach to the Hispanic media, and with advice and information on how they can do that in their communities, as well.

Product labeling is another risk communication method we use. We have safe food handling, for example, information on shell eggs, warning labels on pasteurized fruit and vegetable juices. We,

unfortunately, as everybody, deal with recalls and public education campaigns. And since time is so short, I'd just like to highlight a couple of issues we're dealing with now.

You'll see in front of you a list of just some of the recalls we've been dealing with the last year to two years. It's been a very challenging time. We've learned a lot from this experience. Amy Landow will talk to you tomorrow more in detail about what we've learned from our recall processes. But just, for example, we learned from spinach that people didn't know when the recall was over. We may have had a massive outreach with the information there was a spinach recall, but they didn't know when it was finished. The botulism in Castleberry brand canned foods was a lower, received less publicity than some of our other recalls, and we found, to our chagrin, that there was long after the recall a number of canned products that were still on consumers shelves.

FDA just recently issued a comprehensive Food Protection Plan. It addresses both food safety and food defense for domestic and imported products. And the importance of improving risk communication is addressed in this Food Protection Plan. It calls for the design and conduct of consumer communications and behavior response studies, so that we can learn the very most we can possibly learn on how better to improve our communications about recalls. And I feel certain that this Committee will be called upon to help with that.

We plan on using the study information to update our risk protection and risk communication plans to, as I said, effectively communicate better with consumers. And, also, there will be an enhancement of the website about recall information.

Another risk communication and entirely different component we've been dealing with is obesity. Sixty-five percent

of Americans are overweight now. We have an interactive program on our website with a Label Man, "Make Your Calories Count", that is a tool that educators can use to teach about making healthier food choices on the nutrition label.

Since 15 percent of young people are also overweight, nearly twice the number of a decade ago, we have recently launched Spot The Block, which is a label education program for tweens, ages 9-13. We're here the medium, we're addressing - considering the audience, the medium on air spots where the Cartoon Network has been our partner in this effort, which also includes community outreach programs in the summer in areas targeted with the highest obesity rates.

There's a Spot The Block website with streaming videos, and widgets and all the other things, games that interest kids, get them engaged in the process. We have evaluated the effectiveness of this program,

for those of you who are interested in greater details, I can tell you later, but it has shown to be effective.

As we're going out through our programs at CFSAN, we have two underlining themes. One is that we believe very strongly that our efforts should be based in research, not just the science-base of the message itself, but also the science on how we can best frame that message, and the best methods of reaching our audiences. We work very, very closely with Steve Bradbard and his consumer studies group in developing our programs.

And our second governing theme is that as much as possible, we like to work with partners to leverage our information. And I'd like to conclude my five minutes but just showing you a number of the groups and associations that we're working with on risk communication programs, just this year. Thank you.

DR. FISCHOFF: Thank you. Our next

speaker is Laura Bradbard.

MS. BRADBARD: I think I should make a little change in my presentation to let people know that I'm a Public Affairs specialist. I spent the last 16 years talking to reporters, setting up interviews. And yes, I'm the dreaded monitor. However, I do that so I can help the reporters when they call. I can send them subsequent information. I run down documents that might be referred to, and I make sure that any follow-up questions are answered that come to me from the reporters. So I also want to say to Ms. Foxhall, if you're still here, anything you want to know about the Center for Veterinary Medicine, please call.

As an example of risk communication, I'm going to walk us through a brief description of how the Center for Veterinary Medicine recently communicated with the public about agricultural cloning.

Media attention to cloning reached

new heights in February 1997, when Scotland's Roslin Institute announced they had successfully created Dolly. As you can imagine, this caused quite a lot of activity in the press office of CVM.

In early 1998, less than a year later, CVM published an article in the FDA Veterinarian, "Biotechnology: Putting Clones in Context." So as cloning is becoming more and more in the media, we, in the communications office, needed to keep up with the information that would keep things in context.

By 2001, it had become apparent that animal cloning may become a commercial venture to help improve the quality of herds. There was a lot of money to be made from these perfect animals, and there was a lot of interest in agriculture to improve the meat and the animals, themselves, and cloning was the way to do it.

Because of the greater interest in

cloning, FDA requested that the livestock producers and researchers keep animal clones, or their offspring out of the food supply, and that is still true, although it's not at our request.

Plans needed to be put in place to gather information, and to better understand cloning, so CVM contracted with the National Academy of Sciences to identify and evaluate science-based concerns associated with animal cloning.

The NAS Expert Committee came out with their information, and CVM announced that their report was ready, and we came up with a public meeting. The experts had information to share with the agency, and we held a public meeting, also asking industry to contribute.

CVM in the Pew Initiative on Food and Biotechnology co-sponsored a symposium entitled, "Animal Cloning and the Production of Food Products Perspectives From the Food Chain", so as cloning is becoming more and

more advanced, we're coming up with more opportunities to get together wit the public, and with the experts, so that the public knows what's going on.

In September 2003, the FDA Veterinarian Newsletter, and FDA consumer magazine, featured an article, "Cloning Revolution or Evolution in Animal Production". The next product CVM produced was the Draft Executive Summary of its assessment of safety of animal cloning, and this risk assessment was discussed at a public meeting. I think there's a trend here.

December 2006, FDA issued draft documents on the safety of animal clones. We put out a draft risk assessment, a proposed risk management plan, and a draft guidance for industry. Afterwards, there was a public comment period. FDA requested public comments on the cloning document, and at the risk, or the request of members of the public, the initial 90-day comment period was extended for

an additional 60 days, and it closed on June 3rd, 2007.

FDA received approximately 30,500 comments, this after you take out any duplications, or things that didn't make a whole lot of sense, literally. Approximately 17,500 of these were form letters, 13,000 were directed text comments where there was a cut and paste from associations, and 100 were substantive, providing detailed analyses, recommendations, or opinions either supporting or opposing the Agency's draft documents for cloning, in general.

January of this year, FDA issued the final documents on the safety of food from animal clones. And you notice it's the safety of food from animal clones, that was our risk assessment, safety. The Agency concluded that meat and milk from clones of cattle, swine, and goats and the offspring of all clones are as safe to eat as food from conventionally bred animals.

Additional information that we put out for the public, "Myths about Cloning"; a second document, a primer on "Cloning and Its Use in Livestock Operations"; and a consumer update, "Animal cloning and Food Safety." We also have online transcripts that were made available from the Cloning Press Conference held at the HHS building to announce the findings, a media telecon for reporters to ask questions about the announcement, and stakeholders telecon for industry and consumers. Frequently Asked Questions were also provided. They're online, also. We have FAQs about cloning for consumers, and we have FAQs about cloning for livestock managers. As a result, over 1,500 news stories were produced about cloning in the days and weeks that followed the announcement. Thank you.

DR. FISCHOFF: Thank you. And Nancy Ostrove.

DR. OSTROVE: Okay. I am here to talk about the risk communication and the

Office of the Commissioner. You all heard from our five product centers. We also have a sixth center that you have not heard from. It's the National Center for Toxicological Research. They don't really do communications, per se, except within the Agency, so we felt that it probably made more sense to stick with the five product-focused centers for today. But the Office of the Commissioner has a number of offices itself, sub-offices, that do do risk communication. We have some focus programs and activities, and we have cross-agency activities. And to be perfectly honest, even the focused one tend to be cross-agency, so let me -- what I was hoping to do today is basically give you kind of a flavor of some of the key activities that the Office of the Commissioner does in the area of risk communication.