And the key with our education campaigns is partnerships. That's how we get the additional reach that we can't do alone, and it's a multiplier. If we can gather these stakeholders together and have them use their vehicles of dissemination and their resources with us, that's how we're going to be successful.

This is a public service ad where the goal of this is to get people to go to our website, and what's important about that is there is a lot of good information. All of these materials are available on our website for anybody to download, reprint or use.

And in addition to the website, we have podcasts that we put out. We work with the field public affairs specialists around the country. We do radio and television ads. We have, let's see, partnerships now going on with National Consumers League. We're doing an education campaign on adherence.

Institute of Safe Medical

Practices, we're working on education on acetaminophen.

Partnership for Drug Free America, we're doing a campaign on teenagers and the misuse of prescription drugs.

Web MD is going to work with us. Safeway is going to be putting our brochures in a new rack that they have up in all the Safeway stores.

Cough and Cold, giving cough and cold medicines to children is a new subject, and that's one we're working on at the moment.

And the transition of CFCs to HFC inhalers is something that's going to come out in the next couple of weeks.

And then we do e-mail blasts regularly to all of our stakeholders when we do have information. So it's a little bit of this, a little bit of that. You know, hopefully over the long term we make a difference.

Thank you.

CHAIRMAN FISCHHOFF: Thank you.

That's really, really remarkable. We're trying to get in four talks within an hour. So could I ask you just quickly what would be your sort of bottom line for this on our topic, you know, which is direct-to-consumer advertising, if that impacts the direct-to-consumer pharmaceutical advertising for these under served populations?

I mean from all of the experience you've learned, the evidence you've collected, could you just give a quick summary relative to what we're trying to advise FDA on?

MS. FRANK: Well, my thoughts are I don't work in direct to consumer. I work in just educating consumers about the safety of medicines.

CHAIRMAN FISCHHOFF: Right. So I'm asking what did you learn from that rich experience relative to this topic.

MS. FRANK: Just keep bombarding the consumer with as much information about

using medicine safely as you can. Just keep getting it out there in a variety of different ways and don't give up, and continual education in as many vehicles.

CHAIRMAN FISCHHOFF: Okay. Thank you.

I'm going to cut off the conversation because we do have these three other talks, you know, to get through, and then we'll have some opportunity -- not "get through." That's not a nice way to say it -- that we're going to hear. Time management, that was a reflection on time management, not on interest.

So let's hear the other three talks and then we'll take a break and we'll have a chance to ask direct questions to the speakers.

MS. HITCH: Good afternoon. I'm Mary Hitch, Senior Advisor, Office of External Relations.

I want to thank the Chair and the

members for giving me the opportunity today to discuss methods of effective communication for racial and ethnic under served populations.

I'd like to start off by stating for the record that we need to define health disparities as it relates to racial, ethnic, and under served populations. Health disparities are inequities and not the diseases, and that's how I'm going to focus my presentation today.

Health disparities are persistent gaps between the health status of minorities and non-minorities in the United States. Despite continued advances in health care and technology, racial and ethnic minorities continue to have more disease, disability, and premature death than non-minority.

The specific causes of health disparities are two: inadequate access to care and substandard quality of care. Barriers to care can result in economic, geographic, linguistic, cultural, health care

financing issues. Even when minorities have similar levels of access to care, health insurance, education, the quality and intensity of health care they receive are often poor compared to other populations.

Substandard quality of care, lower quality of care has many causes, including patient-provider miscommunication, provider discrimination, stereotyping or prejudice. Quality of care is usually rated on four measures: effectiveness, patient safety, timeliness, and patient centeredness.

This graph shows the 2006 Census supplemental report. I want to point out two things, three if I may. The Hispanic population has exceed African Americans or blacks. The Asian-Pacific Islander population is now the fastest growing population, and they expect by the year 2050 that population will nearly triple.

I point out the ten leading causes of death in comparison to health disparities

because several of our major education campaigns do focus on heart disease, cancer, stroke, accidents, and unintentional injuries. And I want to point to accidents and unintentional injuries because the Native Americans have a high incidence of accidents, and it's from substance abuse using methamphetamines which ultimately leads to a high degree of mental illness and suicide.

African Americans, Latinos, American Indians, Alaskan Natives, Asian Americans, Native Hawaiians, and Pacific Islanders have higher rates of cardiovascular disease, diabetes, HIV infection and AIDS, cancer, infant mortality, and lower rates of immunization and cancer screening.

Heart disease, cancer, stroke, unintentional injuries and diabetes are recognized health disparities in racial and ethnic and under served populations.

I will now focus on the primary consumers of ethnic media and the popularity

of that. Racial and ethnic populations prefer ethnic media. Fifty-five percent of Hispanics, 42 percent of African Americans and 40 percent of average American. The reliance on mainstream media for information would be something like the Washington Post, Los Angeles Times; think of any popular newspaper that you could buy at a media stand at the Metro, and these are the percentage of interest. You'll find that African Americans rely on mainstream media the most, Hispanics the least.

The percent of populations that visit ethnic websites in the home I felt was striking. Elder Americans use ethnic websites the most, Hispanic Americans the least.

Percent of populations that have low use or no use of the Internet, and I find that Hispanic Americans have a striking figure. This does not include libraries or schools.

FDA basically has three types of

communications: care communications, basically dealing with risks that we know how to manage. Most of our education campaigns fall in that particular category. Ms. Frank just gave us a wide array of care type communications.

One I would like to mention is Take Time to Care. That is a program that focuses on, let's say, two health disparities: cancer, safe use of medication, and diabetes. That is a particular education campaign that dealt with Asian Pacific Islanders, 11 to 13 different languages, Hispanics, African Americans, and Native Americans. It has been a program that has been quite popular I'd say for at least 15 years, not exactly, but I'm sure at least 15, with millions and millions of copies of publications that have been distributed throughout the United States and Puerto Rico.

Methods of communication, there are very many designs of consumer publications.

If we have consumer publications, we try to have them as easy readers and making sure that they're translated.

Education campaigns you can see are varied. We have public affairs specialists that do any number of exhibits reaching thousands and thousands of consumers, say, in a year. I'll mention two. I'll mention this because it's sort of nontraditional. It's Bronner Brothers Hair Show that's held in Atlanta, Georgia, where there's about 50,000 barbers and cosmetologists gather annually and literally distribute thousands and thousands of easy reading materials there.

We also participate in the Tofu Festival in South Los Angeles where literally thousands of Asian American attend that particular exhibit.

We have fact sheets. Our formal official notification to the public is the Federal Register. We have notice and comment, rulemaking. We have media briefings, media

interviews, press releases, stakeholder briefings and round tables, testimonies, speeches, and websites.

As you can see from the statistics, ethnic and racial populations do not use traditional modes of communication. So we do have to be creative. We use partnerships in the federal agencies: Indian Health Service to reach the 1.5 million Native Americans that receive hospital services only from that institution.

We work with the Office of Health and Human Services through our National Partnership for Action, which is currently holding listening meetings throughout the country trying to map the health disparities' impact across the nation region by region. So far there have been about eight listening meetings held. There are about two more to go before August of this year.

The Administration on Aging, we have access to more than 256 area health

agencies and more than 16,000 caregivers in our distributions to get information out to the elderly.

We work with the U.S. Department of Agriculture, Cooperative Extension Research Service, and there are usually community-based groups that work in rural areas.

We work with your tribal colleges, historically black colleges and universities that are usually located in the southeastern part of the United States, and also your reservations.

We work with nonprofit national community-based organizations, in particular, the National Alliance of Hispanic Health, which is the leading Hispanic organization in the United States. If we were to have, say, a crisis in product safety, for example, heparin, the blood thinner used by heart patients and dialysis patients, we had to get the word out to the public quickly, and particularly to the Hispanic community. We

would work with them to have information translated. We would have access to over 600 radio stations, all of the Hispanic newspapers.

If there were an outbreak, say, of E. coli in fresh fruits and vegetables, we can get the word down to the community-based level quickly.

We also work with historically black colleges and universities and tribal colleges and some of the institutions of higher education for the mainstream because I wanted to mention HBCUs, historically black colleges, because most of those are located in the lower income neighborhoods, and they do have outreach and the communities normally would trust the officials that work in those institutions.

With the private sector, Ms. Frank mentioned the partnership with the National Council on Patient Information and Education. We have enjoyed that relationship for more

than 30 years. That enforces the patient-doctor communication initiatives and campaigns that we have.

The National Association of Chain Drug Stores is a great sponsor of our marvelous program, Take Time to Care, which I say has been in existence for about nearly 15 years.

Challenges to communications. I heard one of the Committee members talk about translations. We are very cognizant of the need to be culturally competent in terms of the materials and how we communicate, and also in our hires, that people who work for the Food and Drug Administration are in the middle of a hiring surge of about 1,300 people. We're going to be very conscious of the diversity, that we pick and choose and talk about the talents we need to make us culturally competent because you see the diversity of the population of the United States is shifting, and we must also be

flexible in that.

Health literacy is also important. Forty-eight percent of the population of the United States is health literate. The balance, I think we need to have a lot of work to do. Health literacy is to be able to understand a prescription medication, how to read a drug label, and then in taking the medication and also to be compliant.

Also, in communications with the physician, after telling the doctor what is exactly wrong with them so that the doctor can give them the right kinds of treatment.

Limited English proficiency, again, goes hand in hand with cultural competency. If the community member did call that number and did not get a Spanish speaking person to be responsive, that is an issue that we should look into, but we use the National Alliance for Hispanic Health to help us to bridge the shortcomings in our English proficiencies, and I said some of the other organizations within

FDA, we don't have a standard way of translating materials, and we should have some sort of standard way of looking at how we translate and communicate to racial, ethnic, and under served populations to make sure that they are also subjected to access, openness, and transparency of the agency.

I believe that concludes. I hope I didn't race too much, but I'm happy to entertain any questions that may have.

CHAIRMAN FISCHHOFF: Sorry that I caused you to race. Thank you very much. We just have this very full schedule. So we'll have a chance to ask questions after.

Just one of the things that just occurred to me is just, you know, what's the relationship between the communication model that FDA has which you showed us and Ellen Frank had and how that compares with the communication model underlying direct-to-consumer communication, and by triangulating between the two, we might have some

understanding of both of them.

But I won't give you time to answer.

MS. HITCH: Okay. Thank you.

CHAIRMAN FISCHHOFF: Thank you very much.

And our next speaker is Cathy McDermott.

MS. McDERMOTT: Good afternoon. My name is Cathy McDermott. I am the Director of the Public Affairs Branch in the Division of Federal-State Relations under the Office of Regulatory Affairs at the FDA, in its very long title, and I thank you for this opportunity to day to talk to you about FDA's field public affairs specialist or PASes, as they are commonly known, another government acronym. So we refer to them as the PASes, and their role in communicating the agency's message. They provide yet another vehicle to the FDA in getting the word out around the country.

Today's discussion, my topic will touch on a number of things: FDA's communication goals; the Office of Regulatory Affairs, which is commonly referred to as ORA at the agency; and the field public affairs specialist.

The Office of Regulatory Affairs is the lead office of all field activities under the FDA, and since the public affairs specialists are stationed in the various states around the country, they naturally fall under the umbrella of ORA, and administratively, the public affairs specialist program in a headquarters unit falls under my office, the Division of Federal-State Relations in ORA.

I'll also talk about the role of the public affairs specialist, how they reach their communities. We'll give a quick sample of some of the outreach that they have done and some of their challenges that they have in communicating the messages.

A couple of the FDA communication goals is to facilitate internal and external information exchange. As a matter of course information is constantly being provided to the public affairs specialists out in the region, especially when the FDA is in the midst of a major agency recall. They can reach their audience better than we can at headquarters in the Parklawn Building. So it's imperative that they have the right information very quickly to communicate to their communities.

In turn, the PASes can also provide us what is happening in their respective communities, say, if they get any consumer complaints or any reports of adverse events so that we can filter that information in headquarters and see what we can do with it.

Another goal is to give consumers timely, understandable, useful, and actionable information. As I said, especially in the matter of a recall that is imperative, and to

foster and maintain public trust.

A quick snapshot of the Office of Regulatory Affairs, public affairs specialist. There are currently 30 public affairs specialists stationed around the country. They are spread across ORA's five regions, which we'll see in the next slide, and the five regions are broken up into 20 districts.

The PASes are key links between FDA and our constituents throughout the U.S. and Puerto Rico. They serve as our community based educators because they are out in the field. They know their communities, and they are the best people to reach the grassroots level audience. They serve absolutely as the face of the FDA out in the various states.

And also there are currently approximately six PASes who are bilingual and who speak Spanish.

And here's a quick snapshot of the five regions of the Office of Regulatory Affairs: the Pacific region, the southwest

region, the central region, southeast, and the northeast. And if you need to see the various states that comprise the regions, that is on the FDA Website.

What are the roles of the public affairs specialists? A number of roles. They respond to consumer, health professionals, academia, health educator, media, industry, and federal, state, and local official requests regarding FDA regulated products. That is their foremost role.

Their primary focus of outreach has always been consumers. I know now they are also addressing industry, but for years their primary focus had been consumers, and they are the best people to do so.

And they also serve the general public and also traditionally under served populations, such as women, seniors, and ethnic communities.

And how do the PASes reach their communities? A number of ways. They plan,

develop and conduct presentations, workshops and seminars. Each of the PASes have extensive networks, well established networks, I might say, within their communities, and they are always looking to expand those.

They design and staff local exhibits and assist with national exhibit programs. Our Office of Women's Health and our Center for Foods work very closely with the PASes around the country to help them get the word out on their programs by actually funding them to attend various conferences or staff exhibits and distribute their material. So they really depend on them.

For example, as Mary and Ellen had alluded to, the Office of Women's Health's Take Time to Care campaign about diabetes has been very, very successful, and the PASes have played a great role in that.

They also work with federal, state, and local governments and organizations. Again, they have a wide network within the

territory they cover. They conduct outreach programs for minority populations. They facilitate and implement special national and local educational programs, and they work with the local media. Especially this is the case when there is a recall. They are, again, the best people to reach everyone on the local level.

Here's just a quick snapshot, a small sample of some of the outreach that the public affairs specialists have done. Conference and training for women in Dallas, Texas, our public affairs specialist in Dallas has partnered with the Texas Health and Human Service's Commission on Border Health to present information and to train Spanish speaking women in El Paso, Texas. These women, sometimes referred to as "promotoras," are recruited to share educational and medical information with other women in the poorest of neighborhoods.

These women travel to "colonias,"

which I'm sure you all know are unincorporated developments without public services, say, no water, no sewage, no electricity, and these women actually carry the messages that the FDA public affairs specialist has given to them. Such topics as she has carry the message on, include the dangers of raw milk, lead in candy, and methylmercury in fish, topics that this particular audience need to know about and are very interested in knowing about.

Senior citizens in Alameda, California, our PAS in Alameda has presented information to the Marin County Commission on Aging. Her topics of presentation have included senior food safety, how to read a food label and safe medication usage.

Multicultural audience in central Florida, our public affairs specialist in Maitland has spoken to the Center for Multi-cultural Wellness and Prevention, which serves the local Haitian population there. Her topic, again, was food labeling and food

nutrition. As you can see, food safety and nutrition is very important and very popular.

The elderly and people with disabilities in Massachusetts, our public affairs specialist out of the New England District has an established relationship with the Hallmark Health Visiting Nurses Association which provides her an opportunity to participate in many community health affairs around her state all year long. This group's work mostly centers upon the elderly and people with disabilities. Her topics have included the safe use of medications and food safety.

And lastly, an ethnic community in Southern California, we have a fabulous public affairs specialist in Southern California. She regularly meets with the Orange County Asian Pacific Community Alliance for meetings and to distribute FDA materials. The audience is community members in Orange County, mainly Vietnamese, Cambodian, and Pacific Islander.

A couple of the communication challenges that public affairs specialists have. Some of them are accountable for up to six states. So some of them have a heavier work load than others. It's just the very fact of the way they are divvied up across the states.

They need to reach a variety of audiences and expectations, as you may imagine. It goes the range, all kinds of population, all age groups, and of course, every audience has a different expectation on what they need to know and how it needs to be relayed to them.

FDA's issues are scientific and regulatory. I think we all understand that can be very confusing, very convoluted at times. So the PASes need to tailor that message, and we know that they know their audience so well, and tailor that to the specific people and the communities they are addressing.

And FDA issues may be emotional. We have found, for example, that any topic dealing with children is emotional. For instance, if there was a recall, say, on infant formula or baby food, that elicits many emotions from parents, doctors, and any caregivers of children.

And those of us who have to relay this information have to be sensitive to that issue and at the same time focused on conveying the correct information and actionable information that they can take home and use immediately.

Conclusions. Communication is the responsibility and top priority for the FDA, and I know it always will be. The agency has a real will and desire to keep the public informed, take it very seriously. ORA's public affairs specialists are innovative and dedicated towards reaching their individual communities. As I said before, they have a host of networks, a host of organizations they

deal with, and they're always looking for new ways to reach their communities.

And most importantly, I think, we need to know how we're doing. That's the only way we're going to do our job better. We need feedback, good or bad. We need to hear it.

And lastly, the most important, how do you contact an ORA public affairs specialist? First and foremost, you can look in your phone book. In the nearest largest city, you look for the FDA under the Department of Health and Human Services saying the pages of the U.S. government section, and you'll be able to find your nearest FDA district office, and we also have a current listing of the public affairs specialists on the FDA Website under the office I work in, the Division of Federal-State Relations.

Thank you.

CHAIRMAN FISCHHOFF: Thank you very much.

And our final speaker before the

break will be Karen Feibus from the Office of New Drugs.

DR. FEIBUS: Good afternoon. My name is Karen Feibus, and I'm here to speak to you about the medicines in my home educational program, and I am the medical team leader on the maternal health team in the Office of New Drugs, which is a consult team that serves the review divisions in the Office of New Drugs.

And I'm attached to this program because I spent the first three years at the Food and Drug Administration in the Office of Non-prescription Products, and while I don't have any official background in health education or in risk communications, as a physician I thought one of my primary responsibilities day to day and seeing patients was to communicate risk and benefit to them and to have very individualized conversations with them.

So in coming to FDA instead of having individual patients, I have the entire

American public as my patients and am trying very hard to be an unofficial student of health education and risk communications.

I want to tell you a little bit about the background and program development of Medicines in my Home, and we'll go through some slides. Because I couldn't get an Internet connection, I actually have sort of a mock version of the Website on CD, and so we'll try to take a little bit of a tour, but hopefully most of you through your electronic background package, have had a chance to explore some of the information about the program, if not the Website itself.

So why do we need to teach Americans about the safe use of medicine? I mean, isn't it just common sense? Unfortunately it's not, and misuse of medications is common. And Ellen Frank talked earlier about the problems with acetaminophen overdose and liver failure, and I was intimately involved in looking at that issue

when I was in the Office of Non-prescription Products, and it's really kind of scary.

Focused testing that FDA did do on this issue captured somebody talking about chugging a bottle of cough and cold medicine, not measuring it, you know, just going through it a bottle a day, taking swigs every now and then when they weren't feeling very well.

And then there are certainly published examples of adults giving their children adult formulations of medicines or getting confused between different children's formulations, between children's formulations using different medicine tools, and ultimately giving their child either a small dose that's not effective or too much, which can cause adverse effects, some of which are irreversible and rather severe like liver failure.

Abuse of legal medicines is common. I was working with a group that was pulled together by DARE America, which helped them

develop a lesson plan on the misuse and abuse of medications, and the Partnership for a Drug-free America now considers legal medicine a gateway drug into abuse for teenagers just like they consider marijuana a gateway drug.

And so in 2007, Medicines in my Home did partner with DARE America and other federal agencies to help them develop a lesson plan on this topic, and they actually used the Medicines in my Home Program on which to base their fifth grade lesson, which focused on correct use because we made that point that if you don't give kids a base in what correct use is, how can they possibly appreciate what misuse and abuse is when they don't know what the right thing is to do.

And sometimes there is really too much of a focus on telling kids what they do wrong and forgetting to tell them the way to do it right or to tell them what they are doing right.

So why help education? Why did he

look to the schools for this program? And this is a big quote from the United Nations educational and scientific and cultural organization, and it's a very sophisticated way of saying health education works, and I certainly remember this as being a child, that health education had a huge impact when I was growing up. It's why I went into medicine.

So the concept and rationale for Medicines in my Home was born about four years ago. I had been at FTA about four and a half, five months and heard a British regulator come and talk about what Great Britain was doing and the measures that they were taking to deal with misuse and over use of acetaminophen and the liver failure that they were seeing.

And she made an offhand comment about, "Well, I don't know if you're doing anything in the schools," and I rushed up to my Deputy Division Director afterwards and said, "We have to go into the schools and teach people."

And he said, "Whoa, you can't do that."

And so four years later to be standing here in front of an advisory committee all about risk communication for FDA and talking about this program just shows me how far FDA has come in this direction in the four years, and I'm just thrilled to be here.

And so here we are in the present day with FDA's focus on drug safety and risk communication.

So at the time that I was developing the concept for this program, I tried to look for information on self-medication in children, and there was an incredibly small amount of information. No matter what I tried to pull up in PubMed, this is all I could find, and I probably wasn't looking at all the right places, but I found a survey of junior high school students in Nova Scotia and a study on what medicines children have packed away in their camp trunks when

they go away to summer camp, and they both suggested that self-medication starts at about age 12 or so, and so we thought that this was about the right time to target an educational program where children would start to build awareness and become more self-involved in their medication use.

And then on top of that, many of us probably use babysitters that aren't all that much older than 12 to 13 to babysit for our children sometimes, and sometimes children need to have medications administered while they're having a babysitter over.

So these young people who are starting to grow in knowledge need to know this information.

On a broader scale, FDA is concerned about unintentional or purposeful misuse of OTC medicines. Education on the safe use of medicines may positively impact public health and safety, and we have seen this through other campaigns about smoking,

alcohol, drug abuse, wearing safety belts when you're driving, and reproductive education. And these campaigns have had significant impact, and school health education lessons can indirectly educate entire families. It's very empowering for an 11 or 12 year old to go home and say, "Guess what I learned in class today. We're doing this all wrong. Let me teach you about the right way to do it."

So we formed a working group in October 2004. We partnered with the Maryland Montgomery County Public Schools, went to talk to their health curriculum coordinator. We were partnered with three health education teachers in three different middle schools and went on to develop the program with the county and also with the National Council for Patient Information and Education, and actually piloted the program in the schools during the 2005-2006 year.

Then at the end of that year we actually launched the Website and then updated

it in May of 2007 when we developed the Consumer Room, which was more designed towards an adult audience.

And we learned a lot through the pilot program. Unfortunately, because we don't have employees that are dedicated to doing this kind of education building and we have no funding dedicated to this kind of education building, this is really being done through a lot of just hard sweat and labor, and the best feedback we had was getting in front of these students and seeing what held their interest and what made them fall asleep or become distracted, and that is really how we finally settled on a formula that worked.

Currently we're trying to develop some new web materials including a checklist that parents can use at the store while they're standing in front of those rows and rows of medicines to try to choose an over-the-counter medicine for their child, to sort of walk them through the steps and to give

them a place to put the information they need to have with them, such as the child's weight and the allergies that child may have, any recommendations they may have gotten from their doctor.

We're trying to develop information, basic information about the drug development and approval process so that American consumers can have some idea about what an approved versus an unapproved drug is and what that means to them.

We're developing a senior's corner within the Consumer Room so that we can develop materials that may be easier for seniors to access and read things that are in larger type size, materials that hopefully through partnerships we can get in printed form since some seniors are not going to be comfortable exploring the Internet, and as well as materials that may address specific senior issues, such as there's decline in kidney function in older people. What kind of

special concerns does that raise with using medicines, especially seniors who are using multiple medicines that may have interactions.

And it's proved very challenging to try to figure out what to say about misuse and abuse of medicines. We've discovered that across the wide range of federal agencies and other organizations the use of the terms is not standard, and it makes it very difficult to talk about this topic.

And then there's also an online interactive program that we're developing, and we're hoping to have it put out for contract. Two of my colleagues who have been my right and left arm on this program who are in Ellen Frank's division, the Division of Public Affairs, Cynthia Fitzpatrick and Manday Eisemann, sat down and actually developed a script for an online interactive program, and it's really wonderful and we can't wait to have an interactive program to bring online to make learning more fun.

So these are the key concepts, and some of you may have had a chance to read this in your background package. We want to teach people that the drug fact label tells you what a medicine treats, how to use the medicine, and if the medicine is right for you and your problem.

We also want to teach them that when you use an over-the-counter medicine, read the label, the whole label. Follow the label directions carefully and correctly. Medicines should only be used with permission from a parent or guardian.

Now, these are the key concepts that really form the basis of the student program. That particular key concept goes away for adults.

Two medicines that have the same active ingredient should not be used at the same time. Measure your medicines correctly with a measuring tool made for medicines, and if you or your parent has questions about your

medicine, ask your doctor or pharmacist.

Now, we could take a tour right now. That's one of our options. There are some other slides that follow, and you did not get these ahead of time, and for that I apologize, but I'll make sure that there are copies left here so that it will go up with the materials for the Advisory Committee long term, and you will find there, again, some of the learning objectives that were in your background, some information about the teacher's kit which I'm going to show you online.

I did want to show this slide. What we did is we created in order to have something for students to look at while we were going through our slide show lesson in the classroom, we created a fake drug, children's feel better cold and fever suspension. We made it look lots of fun. We made it great flavored, and the information that's in the drug facts label is the real

information that comes off of, that is a real drug facts label from a product that would contain ibuprofen and pseudoephedrine.

We've had huge debates about whether pseudoephedrine should be on the label with everything going on with it now being behind the counter. So that's been another debate.

But we happened to use this as an interactive tool to find information and actually practice using the drug facts label during the course of the lesson.

This is the booklet you have before you, and I'm going to go to my little CD right now so that we can actually take a little unofficial tour. I'm going to close everybody's slides. I don't know how helpful that's going to be to Lee. Let's just minimize this. That might be smarter. Hopefully this is going to decide to boot up. There we go.

So I have to give thanks to the

CDER Web team who has both been very important in putting together our Website, but also in putting together this CD today so that we could take a tour. This makes it somewhat live.

I guess this is as big as it's going to get. Okay. I apologize for that.

So this is what the home page looks like, and the core of our educational program for this school is in the teacher's room. We had a house as our symbol. So we created rooms as the different places to go visit. There's a teacher's room. There's a student room. The consumer room is not on here because we don't have active links to it right this second.

So the teacher's room contains the opportunity -- it describes the program. You can go to course descriptions and objectives here, but you don't have to, and there's also extra resources that provide links to various government sites and non-government sites

where teachers might find additional health education related information that they can use to supplement their lessons either about safe medicine use or on other things.

In the teacher's kit are all of the materials that we've developed, and one of these materials is the actual booklet, the information for students on using over-the-counter medicine. There's the feel better drug facts label, which I just showed you, which was the front primary display panel in the drug facts label.

There's an in-class work sheet that teachers could choose to use to make kids pay attention and actually fill in answers as they go, but I think they found it was more effective to use it afterwards to see what they learned, and you'll see that this pulls in some of the major lessons from the slide show.

The teachers also helped us develop a pre-test and a post test, and originally the

goal was to actually use those as ways to assess the effectiveness of our lesson, and unfortunately we really never got to use that to the full extent that we wanted.

I'm about to run over. Okay. I'm going to take you on a quick view of the PowerPoint presentation.

It's very hard to hold kids' attentions for a long time, and so this was a bit of a challenge, and honestly in the first few renditions we would lose their attention after about 15 or 20 minutes. We'd hit the warning section of the label and they were just out in la-la land.

So we really worked on making this very interactive, and we started with a very basic lesson. We gave them a definition of a medicine or a drug and what it does because we certainly got some questions about how vitamins relate to medicines, and it's a hard thing to explain to kids who are 11 or 12, the difference between a medicine and a dietary

supplement, and so this sort of formed a basis to be able to handle those questions.

And then we started asking them, well, who used medicines. Who used an over-the-counter medicine? And there was so much participation. We heard all sorts of things, and it usually led them to talking about the differences between prescription and over-the-counter medicines, which is how this progression developed.

And so we talked about the similarities and the differences, and while this program really focuses on over-the-counter medicine, we did want children to understand how they're the same and different and whether you can buy a medicine off the shelf in the store or whether you need an order from your doctor, all medicines can be harmful if they're not taken carefully and not taken in the right way, and so we wanted to show them that.

The other thing that we found very

helpful, we basically would go through the different parts of the drug fact label -- yes. The other thing we found effective which I think is good to remember is we used scenarios. We started to try to create scenarios with real people that kids could relate to that maybe they'd see a little bit of themselves or their older sibling in one of these kids.

So we had a young lady here who gets sick and mom goes away and she needs to take her medicine. We had a child playing soccer who was in a lot of pain before his game. No, actually he wasn't in pain. He had allergies, and he was playing a big soccer game.

And so these were things that we found effective, and so that's a brief tour, and I want to thank you for your time and thank you once again for letting me be here with you today.

CHAIRMAN FISCHHOFF: Let me thank

you, too, on behalf of the Committee.

Actually let me thank all four of the speakers for the really interesting presentations and even more so for all of the work that went into what you were able to concentrate or were asked to concentrate into 15 minutes.

Our speakers will be here during the break, and let me suggest that people approach them individually and ask clarifying questions, and we'll meet back here in 15 minutes and then we'll pick up and try to provide advice to FDA on direct-to-consumer advertising to special populations.

(Whereupon, the foregoing matter went off the record at 3:04 p.m. and went back on the record at 3:26 p.m.)

CHAIRMAN FISCHHOFF: Okay. Let's start now.

Let me thank again the last four speakers both for their presentations and, again, for the work that went into it.

And so we have time now for a general discussion reflecting on everything that we've heard today and everything we've learned in our lives and, in particular, a chance to think about what the implications are of FDA's communications are for the direct-to-consumer communications that are our topic here. What do they tell us about the informational environment within which DTC is going? What do they tell us about different patterns of communication, and so on?

So now is our chance to give advice and let me just reread our charge, which is, "Please provide suggestions or points to consider for FDA to keep in mind as we prepare a report regarding the relation of DTC advertising to increasing access to health information and decreasing health disparities for subsets of the general population, including elderly populations, children, and racial and ethnic minority communities."

In your response, please try to

address those groups. This would include -- these would be suggestions about how FDA should do it, suggestions about how it should regulate this, suggestions about the kind of research that it needs to do.

At this point in the proceedings sentences beginning "FDA shall" are welcome, and I throw the floor open. And towards the end of the day, in concluding Nancy Ostrove will be giving us some concluding remarks along with some feedback on what has happened since our last meeting.

So Marielos.

MS. VEGA: For me exposure does not necessarily mean understanding or equals understanding. We saw a presentation where we were provided with the many different campaigns, and the FDA is doing now with different organizations, and I would like to see a movement toward the better evaluation of how these campaigns are really impacting the public because I don't think by just putting

information out there that necessarily means the people are understanding that information.

When it comes from me to the Hispanic community, it's very important. One of the most successful ways that I have in my community of working Newark, New Jersey, and we are very successful reaching the Hispanic community, because we go to the churches. We go to the community-based organizations where they come.

I feel like these campaigns with organizations are too big at the national level to reach those communities. So I would think that working at the grassroot levels will be a good thing to do.

It doesn't surprise me to see some of the data that was presented to us in terms of only 14 percent of Hispanics rely on the mainstream media for information. Only ten percent of Hispanics visit ethnic Websites. Seventy-six percent of Hispanics, they have low or no use of the Internet.

So we should consider that. I mean, to me that's a red flag when it comes to advertisement and risk communication to a group that in this country is now a majority minority.

Hispanics tend to be very interpersonal, and that is why they like when the information comes from the churches, from the community-based organizations that they visit, and one of my dreams and I think it's a feasible dream, it will be to see that FDA has at each state level. Like I could tell you in New Jersey what organizations work very well with the Hispanic community, and all of us represent different states around this table and in the public. I think there should be some type of I don't know -- database or something of this organization, the grassroot organizations, that when it comes time to a public advisory or something the FDA can directly give that information to this organization.

So that will be my dream, but I think it's very feasible.

CHAIRMAN FISCHHOFF: Christine.

DR. BRUHN: These really were excellent presentations, and I echo the thank you.

I have two general comments. The first relates to the public affairs officers who are really very, very good. I know the one in my region quite well. I feel that the effectiveness of this program is hindered by some of FDA's policies regarding reimbursement, that is, travel expenses. The public affairs officer can only attend a program if they travel on their own dollar. I know educational institutions, such as mine and I'm sure others across the country, are often putting together conferences, programs where we partner with other health professionals. Our public affairs officer is an integral, valuable contributor to this program, and the officer's information is

multiplied many times through using these partners.

But the public affairs officer can only come to a program if she still has money left in her travel budget. We are not permitted to cover her expenses.

I understand that there could be conflict of interest if a for profit industry is asking her to come and speak, but truly for an educational program, the benefit is for the public. The educational institution is also a public institution. We are employs of our state, and we serve our citizens.

And so I would, first of all, request that the FDA consider reevaluating their program on the travel activities of their very valuable and competent public affairs officers so that we can have them more frequently in more of our programs, and I believe that would help the outreach. So that's number one.

Secondly, and along the same line,

involves who one should go to for research or for educational materials. There was some discussion earlier about who was the project funded by, where did the money come form, suggesting that the source of the money is going to influence and bias and make no longer valid a research project.

I think it's appropriate to ask where the money comes from, but I don't think there should be a barrier that indicates no money can come from a source that might have a vested interest. The critical thing is if a research project or an educational program is delivered in a valuable, unbiased, science-based manner and for a research project I think clearly presenting the details and going through the peer review process helps to validate that; it doesn't make sure that it's going to be absolutely perfect. All things can and should be questioned.

But it's the group that has the financial interest that is likely to fund the

research. So we have a number of issues here where the area is ripe for research, like how prescription drug medication is viewed, how the advertisements are viewed, and how there are differences by ethnicity or by age and so forth.

And I would encourage the FDA to consider partnering with organizations perhaps that are funded by the pharmaceutical industry, you know, not a company itself, but a parent company or an organization, a trade group, whatever. You know, pharmaceuticals is not my area. It's food safety, but whatever umbrella group that might be, to gather some information.

I do believe our economy works better when the consumers know their choices and the industry knows what the consumer wants, and this can be in the area of pharmaceuticals as well.

So I consider that it's acceptable to get money from that source even though the

source has a vested interest. That's why they're putting down the bucks. You can still have a good research project.

And the educational material that we were presented here on the Medicines in our Home, what an exciting program, and the idea of delivering this to kids and having a CD and putting it in schools, great, wonderful idea.

It takes money also. So perhaps again an industry consortium type of group, not a single company might be able -- I consider that an appropriate partner for FDA under the very, very careful scrutiny that FDA provides, and if not, research funded exactly. The researchers don't have to be FDA researchers. They can provide money that others, maybe academics, can go to to help deliver this type of program, deliver it in the schools and then validate to see what difference it makes.

We did something like this in the area of calcium and nutrition. Our funding in

this case was a health organization. It wasn't any commodity group that was related to the particular topic, but we had videos made, games for the kids, and we looked at ethnic differences. We looked at Asians and Hispanics, as well as Caucasians at a specific age group, a very expensive project, but it was validated as well.

So I would say open the doors. Keep the standards on the validity and the quality of the research, but open the doors to other funding agencies so this work can be done.

CHAIRMAN FISCHHOFF: Thank you.

It sounds like so perhaps the argument is that if health literacy were increased across the board, particularly in the groups that we have here, the challenges faced by legitimate direct-to-consumer advertising would go down because you have better informed consumers. So there would be incentive compatible for industry to support

this being done in a hands off way.

An institutional example that FDA might want to look at is that there's something -- I think it still exists at the Harvard School of Public Health called the Health Effects Institute, which was founded, I think, in the late 1970s, funded by the automotive industry in order to study in a hands off way the effects of air pollution on health. Not everybody agrees with what it is, but there are some institutional experiences that FDA might look at.

Jacob.

DR. DeLaROSA: I also want to thank all of the presenters today. They were excellent presentations.

It was interesting to find out about the commercials are reviewed because I wasn't aware if they were or were not reviewed.

I recommend that, you know, as you do review new launches and look at their story

boards that I think that all new launches for all new drugs biologics, again, all devices that should be reviewed as well as the actual final product before it goes to market or before it gets out. It should be reviewed. I don't know. You could comment. There is maybe 200 or something of new presentations that go out, but they should be reviewed before they go out to the general public.

In regards to the presentations, the last ones we had from Ms. Frank, in regards to what you're doing and with your budget, I was given, you know, as a heart program in Idaho a $150,000 budget for the year, for marketing, et cetera, for awareness, and when you tell me that you do all that you do with $40,000 it's very impressive. And I do salute you and I hope that others understand that at FDA because that is a lot what you do with a budget of $40,000, and it's pretty incredible.

You know one of the comments that I

have is it would be nice to see if all magazines, and I think this was done in the past, but if all magazines allowed a space for something from a public affairs message, et cetera, on these magazines, on O, on Elle magazine, et cetera, and one of those pages could be reserved for us from FDA, from something to awareness that's to be made. It's not necessarily an advertisement, but just an ad that can be there.

I think it would be very important, and it could be very crucial as far as health disparities in the United States.

But as I say, I thought it was excellent presentations today. Thank you.

DR. KHANNA: I also want to echo the thanks for the presentations and the folks from the public who spoke up.

It seems to me I'm looking at this and hearing everyone's comments and thinking we're really talking about three things. We're talking about the information and to

preserve the accuracy and the validity of the information. That's why we're talking a little bit about who's funding the information that we're getting, but I do agree that despite who's funding it, the information can be accurate, very helpful whether it's a study or whether it's some kind of communications campaign.

Secondly, I do appreciate the lack of resources, and my hat's off to you for doing what you do for $40,000 because it's fabulous.

And I think one way perhaps to get around diminishing resources, particularly in the government, is to continue to build alliances, working with, for example, health information web sites to get the information out that way, working to put public service announcements on radio and television and the equivalent of whatever that is in newspapers, and then build alliances and networks with existing organizations, such as the

Alzheimer's Foundation, the Parkinson's Foundation. I mean whatever issue it is that we are going to be addressing in these target groups, i.e., the elderly for that particular example, let's build upon the organizations that are already out there and develop those networks because I can't imagine, say, for example, something like the Parkinson's organization which helps preserve the health of folks that have that particular illness would not be interested in making sure that their constituents take medication appropriately and that type of thing, worry about drug interactions, et cetera.

And the last is tangentially the vehicle in which we get this information across. Organizations are not only important, but I also was thinking as we're sitting here about the value of having celebrity endorsements. I just visited last week with Dr. Koop. Do you remember our former Surgeon General, C. Everett Koop? He's 92 years old.

Wow, he'd be a great person to talk about medications and so forth for the elderly, and I know he would do it. I mean, he's very public health oriented.

We see Robert Wagner on TV talking about life insurance and health insurance. I know those guys get paid, but I can't imagine we can't find some equally appropriate, age/ethnic group representatives to help us out with these public service announcements.

Dora, big kids' cartoon character for the Spanish language population. Maybe we could even get Hannah Montana, again, looking after the kids.

So I think we -- and there's athletes and actors in all kinds of different demographic groups. So I think we should look towards all of these things and really the overriding theme here is with lack of resources if we develop alliances with some of these established networks, organizations, vehicles, and people who can get the message

across in a credible way, I think we would be able to go very far as opposed to the FDA itself reinventing the wheel and expending large amounts of dollars which essentially it doesn't really have at this point.

MS. LAWSON: I, too, would like to thank all of the panelists. I really thought it was a tremendous presentation from each of you.

This last panel I was making so many notes over here because there was so much going on in each department, but the question and I guess the recommendation for me would be that, one, there are a lot of activities and initiatives that seem to be addressing the effective ways of communicating with the public.

And I think it would be even more effective if you looked at how you could have a central focal point for getting your messages out. I know that in many of the agencies within HHS there is an Office of

Minority Health, and I guess I'm really looking at this from the concerns that we all have about health disparities, and within HHS there are many -- within the agencies there are many Offices of Minority Health which has a primary responsibility for looking for ways to address disparities and health and health care.

And so I would hope that FDA will look at, although I don't know if you consider that, will look at the possibility of establishing that office so that all of these offices that we heard from this afternoon would certainly have a major role in getting the messages that will have a positive influence on access to quality care and addressing health disparities.

But I do think that there's a lot that you're doing, but perhaps it could be even more effective if it was more centralized through an office that had a primary focus on addressing health disparities.

CHAIRMAN FISCHHOFF: Thank you.

I'm sorry. Ted and then John. I just was talking with Lee that there is an Office of Women's Health within FDA, and your suggestion is that there should be an Office of Minority Health that would somehow -- kind of a matrix organization that people who are working with these problems have a systematic way of getting this kind of input to the table.

Madeline, Ted, John, Ellen, and Mike. Oh, we had Madeline. Ted.

DR. REISS: Okay. I'm next?

CHAIRMAN FISCHHOFF: Yes.

DR. REISS: I just have a couple of comments, I guess. One of the themes that I'm hearing amongst all of the presentations is that to achieve the objectives for today's meeting to reach a lot of the under served groups, even with sort of traditional direct-to-consumer advertising, that sort of collaboration and outreach is going to be

necessary with a lot of different groups.

So I think that's probably something that from an industry perspective that the industry will have to think about and sort of deal with to get the message out effectively across a number of different groups.

I also wanted to touch on the data issue and then the scientific collaboration part, which is near and dear to my heart because I agree with the comments that you were making. I think good science should come from wherever it is, you know, whoever sort of sponsored the initiatives as long as there's effective peer review and open discussion and transparency around those data issues.

And in the same vein as we were talking about collaboration, especially around science. I just wanted to throw another model on the table. In Europe, in the European Union, there's an initiative called the IMI, the Innovative Medicines Initiative, which

really has to do from a science perspective with things that are in the so-called pre-competitive space. It's a public-private partnership to look at a number of scientific issues, and I think it's really an excellent model moving forward that the European Union is putting forward to move some of the problems or some of the issues with developing new agents and doing it effectively from a public health perspective, and I think a similar thinking process could be brought here in this particular space as well.

CHAIRMAN FISCHHOFF: Could I ask you to expand on what you see as sort of the industry equivalent of this kind of networking that we heard in these programs here?

Because sometimes organizations that get in league, get in bed with industry end up feeling as though they've been burned, the Heart Association or whatever. So how does that get done?

DR. REISS: That depends on --

excuse me. I'm not an expert in this area, but I'll just give my sorts of opinions.

You know, I think that any interaction can be done effectively as long as it's clear and transparent. So, you know, we've been talking about general health, direct to consumer sort of stuff through some of the conversation here. There is certainly the more traditional direct to consumer advertising, and in order for individual companies, I think, to reach different groups, they're going to have to work collaboratively with certain local groups to do that.

You know, the only thing I can add is that if it's done as clear, transparent and effective, and whether those are done through a consortium of companies or other sorts of ways around individual disease areas, I think that's something that people should just think about for the future.

CHAIRMAN FISCHHOFF: Let's see. John and then almost everybody else.

DR. PALING: I'd just like to suggest some other alternatives for partnerships. You might already have thought of these. Mona's suggestion that you try and incorporate a celebrity. She dropped a word in there that I know a good deal about, which is cartoons. I used to work with Disney, and I know all of these organizations need programs to train their more junior members. You will not get access, as I'm sure you know, to the main characters, but if I were you, I'd start in two different ways, and somewhere I think you might get a hit of great financial value.

Starting with Disney, explaining that this is a great public service thing, it actually has tax benefits for them to train their people in part by working with you. Hanna-Barbera and then the other cartoon companies, that's one way, because they have characters. They cross the linguistic barriers, and they're appealing.

Now, starting from the bottom up, I would dearly suggest to you working with students and school kids to do their own claymation and you giving great publicity to the result. Think of the win-win situation. The kids are doing something creative and in the same way as kids will relate to other kids' work more readily, I am of the view that you may be able to get five or six different little projects, each of which is a joy, and for $100 or $200 or some publicity or bring them to Washington and give them a Haagen-Dazs ice cream; if it's approved by health reasons, in some way to reinforce their value, the children, the students themselves are learning, and you will have the sort of visuals that speak to those that are so difficult to reach.

CHAIRMAN FISCHHOFF: Thank you.

Ellen, Mike, Musa, Linda, David and AnnaMaria. Okay, Ellen.

DR. PETERS: So let me talk about

this on a slightly different level in terms of how information is processed within advertising. Just in general, and I think I might have said this before, it's not only about what content is presented and verbalized, but it's how it's understood and it's how it's used, its impact as it's called in the provision of 503(b) that someone kindly presented earlier.

One think I think that the FDA should do is to better understand what is the strength of evidence in terms of whether direct-to-consumer advertisements are presenting benefit information more than risk information, and I don't mean that in terms of the actual information, but in terms of people's perception of that information.

That's important for several reasons. It's important because there's supposed to be this fair balance of risk and benefit information, but it's also important for some other reasons. In the real world

there is a positive relationship between risks and benefits. Things that are high risk tend to be high in benefit or they just don't exist out in the marketplace.

But in perception it's different. In general, things that are perceived as high in risk tend to be perceived as lower in benefit. Things that are perceived as higher in benefit tend to be perceived as lower in risk.

So having a change in how risk information is presented doesn't adjust the perception of risk but may also change the perception of benefit. The same thing goes with presentation of benefit information. If you change it, you may also change the perception of how the risks themselves are perceived overall.

In addition to that and specific to one of the populations that we're talking about today, there tends to be -- again, this is according to the theoretical literature. I

haven't seen anything in direct-to-consumer advertising -- but there's a positivity effect that older adults tend to show. So compared to younger adults, older adults will tend to weigh positive information relatively more than negative information, and that may have an impact in how they perceive direct-to-consumer advertisements.

They also seem to show a larger truth effect with repetition, and I believe in direct-to-consumer advertisements the benefits are repeated throughout the ad more often than the risks are. So that also may have a particular impact on one of our special populations.

Let's see. What was I going to say next?

So, again, it's not just about what the content is, but how it's understood and used.

Also, given a fixed time to process information, there seems to be somewhat of a

tradeoff between the completeness of information that's provided and how well it's understood so that less information, but the most critical information can sometimes be understood more.

That comes out clearly in the 2004 FDA draft guidance about print ads. But in addition to that, and I'm not sure if you know this or not, that matters more for people who have less skills, people who are less numerate and people who are less literate. The idea that less is more makes a bigger difference to them.

So people that have different expertise, who have expertise about what is most important, and that might be physicians. That's in some cases the patients themselves because they know what's important to them, combined together with empirical work about what ends up being understood and what ends up being used is critical here.

One just very specific comment, and

this came out of some of the work that was presented earlier and some examples that were given us on some of the educational tools that are being used. One of the gentlemen -- and I'm sorry I'm forgetting your name in the last second -- talked about some work that Ian Skurnik and others had done, and the idea that telling consumers that a claim is false can sometimes make them misremember it as true, and that's especially true for older adults after a delay.

In some of the materials that I've seen coming out of the FDA there's a series of do this, a series of do's and don't's. The do's are great, but don't use the don't's because the don't's may be misremembered over time. The don't word may be dropped and forgotten over time, and the false statement itself may be remembered as true.

And I think that was everything. Thank you.

DR. GOLDSTEIN: I, too, want to

thank all of the presenters, and I especially want to thank those that presented the specific new programs that have been developed and I, too, recognize that a lot of the work was done with a limited budget, with limited resources, and so I applaud all of those efforts as well.

I want to go back to something that many of us have said before about the importance of the research base and the really woefully inadequate evidence that we have about what the impact of direct-to-consumer advertising is actually doing to both clinician behavior as well as consumer behavior, and I think that's going to make it hard for FDA in the report to be clear about what should and should not be done next.

And so I think there really does need to be a research agenda that FDA puts forward for consideration perhaps not alone, in partnership with some of the other organizations that have been mentioned around

the table, particularly the Agency for Health Care Research an Quality, which has as one of its main mission driven objectives to improve safety in the health care setting, and I can see this as being the mission of FDA and the mission of AHRQ are so much in line with each other that there's a need for a collaborative research agenda.

And to give a couple of specific suggestions about that, I think the outcomes and the impacts that are referred to in the directive need to be specified. So we need to look at understandability for sure, perceptions of consumers, perceptions of providers. Some of that research was presented today, but we also need to look at other kinds of outcomes. We need to look at behaviors, particularly adherence behaviors. To what degree are not only people talking about prescriptions, getting prescriptions. To what degree are they suing the medicines appropriately? To what degree are they

continuing to use the drugs appropriately?

What is the quality of the decision making that's taking place between the patient and hopefully the clinician that's working with them? And there are other research efforts that are looking at the quality of decision making. Specifically the Foundation for Informed Medical Decision Making has developed some very specific criteria that's used in their studies that look at the quality of decisions that are made after an intervention is delivered to enhance the decision making capability of people.

I think we also have to look at other kinds of outcomes, not only the use of the medications themselves, but also as I mentioned earlier in a comment, the use of other kinds of health information. To what degree is there overuse of medication to address health problems as opposed to using other forms of interventions, whether it's changing health risk behaviors, following

through with medical care guidelines, following through with self-management and self-care guidelines?

To what degree has direct-to-consumer advertising shifted the balance away from some of the other important behaviors that are now known to be related to the health disparities within these special populations?

So I think we need to be looking at outcomes in a broad way, and there needs to be a research agenda that reflects those needs, and from a resource point of view, I realize FDA doesn't have funds to do this. There has to be some obviously deeper partnerships with the organizations that the government supports to do research, NIH, CDC, HRQ, and perhaps other agencies that I haven't mentioned.

So that would be my number one recommendation. I do think the efforts that have been presented today for helping to inform the public are really, really valuable and important. Those should be evaluated in

ways that I'm suggesting, and in addition there's opportunities there to look at ways to evaluate even in a less rigorous way the impact of those interventions on the awareness, the beliefs, the behavior of the populations.

CHAIRMAN FISCHHOFF: Thank you.

To amplify on that, perhaps in the spirit of what Madeline was saying, there's probably a limit to how far FDA can outsource this work, that if you don't have internally people who understand issues of minority health, you can't evaluate the product that you're getting elsewhere. If you don't have people who understand adolescent psychology, you're not going to be able to handle that part of it because everybody has misconceptions about other groups.

So there has to be some kind of staffing up in those areas. I mean, FDA is remarkable in the amount of social science expertise it has, the Department of Homeland

Security, Environmental Protection Agency. They've got nothing or almost nothing, but I think my point the last time we met, that FDA has to admit that it can't do the job in order to get the resources in order to be able to do the job, and we're dealing with, you know, my impression from the outside; we're dealing with public health people who really like to produce an entire program out of $40,000, and there's a limit to how far you can go without making -- and if you can't ask for the money, we'll ask for it in your behalf.

MS. MAYER: I want to echo what other Committee have said, to thank particularly this afternoon's panel for their excellent presentations.

I have to say that I found these presentations a little poignant because the efforts were incredibly skilled and well directed. So much was being done with so little that I found myself reflecting, I guess, as an advocate about what we really

value as a society when we're seeing billions of dollars spent annually for direct-to-consumer marketing and only thousands at least reported to us here being spent for public service announcements and other initiatives to provide more balanced information.

You know, all of the indicators are that as a result of this upsurge of direct-to-consumer marketing over the last ten years or so, we're using more drugs by magnitude of I think it's two or three than any other developed country in the world, and yet I don't believe that we are healthier by any measure that I've seen, and I don't accept as a given, I guess, that marketing is inherently educational in nature. And that seems to have been something we haven't discussed directly.

Perhaps we should. Perhaps that's going beyond the reach of what we're here to do today, but given the tremendous disproportion in spending, I think that we really have to do everything we can and FDA

has to do everything it can to insure completely balanced and clear and transparent communications of benefits and risk in all direct-to-consumer marketing and, for that matter, all marketing to health care professionals as well.

And I think we've had really excellent suggestions from the panel, from the Committee, and from many, many of the presenters today about the things that could be more fairly balance and more clear.

And as far as this relates to the special communities that we're here to talk about today, with the exception of Hispanic communities or other communities that are non-English speaking, I think it's pretty clear that whatever will move us in the direction of clearer direct-to-consumer advertising, that is done in such a way that is transparent to all, that it's clear to all that these special communities will also benefit proportionally.

I think if we think of the most

vulnerable and, you know, the elderly communities, adolescent communities, minority communities, people who are disadvantaged in a number of ways and think about how to reach them clearly, we will reach everyone clearly. I don't think that specific targeting with the exception of the language issue is what we should focus on.

I guess I'll stop there.

CHAIRMAN FISCHHOFF: You're saying that it's really the outreach that's the critical missing piece more than the content, other than the language?

MS. MAYER: I'm not really talking about outreach. I'm talking about making sure that those billions of dollars are sending a message that is genuinely helpful to people, and that gives the necessary information for people to make a decision about their health care and their products.

What I'm hearing is that in the face of that expenditure, the small amount of

dollars that our society is prepared to spend on public health initiatives to correct misimpressions, over use, over treatment, and so on, I don't think we have a prayer of intervening in that regard. So I think we need to intervene in regard to making sure those messages that are being sent through advertising are as accurate and clear and accessible as possible.

CHAIRMAN FISCHHOFF: And your final point about the special communities, that was the part that I didn't understand.

MS. MAYER: Yes, I guess I wasn't explaining it very clearly. I think that by doing that, by keeping the most vulnerable among us in mind, we will reach everyone. We have the potential of reaching everyone.

CHAIRMAN FISCHHOFF: Sort of trickle down from the vulnerable.

DR. NEUHAUSER: I, too, want to say how much I appreciated the very impressive work that you're doing, and it would be

wonderful, as Dr. Goldstein said, if we could have some documentation, something peer reviewed about the value of that work. Perhaps that would increase your budget from 40,000 to maybe a whopping 80,000.

And one suggestion besides making that more of, let's say, a priority of the FDA would be to think about some clever ways to work with local schools of public health and graduate students to do some work on something. Just pick one thing that you think is really important, and for not a lot of money you can get a good research design which could even look at behaviors and other outcomes of interest and publish that in a peer reviewed journal.

So that's not a huge goal. It's not an overwhelming goal, but it would be something important.

To Musa's point about keeping the most vulnerable in mind, I, too, agree that except for language if you work with the most

vulnerable, that will be better communication for everyone. I'd like to suggest that a unifying principle among the vulnerable groups we've looked at, except for language, is the issue of health literacy.

I noted that in the presentations about the literature to date, there is almost nothing on health literacy. I think there might have been one study and perhaps it was qualitative and not peer reviewed. I don't know.

But NIH and CDC have done have done massive amounts of research on this, disease related. I think we need something here.

There's a possibility I would recommend that Congress find a way to fund the FDA so that the FDA could put out a program announcement, such as NIH and CDC do, looking at health communication issues related to health literacy, and the other would be to piggyback on some of the existing ones.

CDC has a health marketing program

announcement that would be just absolutely perfect to look at issues of the impact of FDA related issues for these populations and also there is the NIH health literacy annual program announcement. It's another good one, too.

Ms. Hitch in her presentation said that she wished there was a standardized way to do translations, and I would suggest that there is. There's a literature on this. There are a lot of examples of guidance that could be turned into guidelines for how to do translations, how to do it right the first time, and I don't think that would take a lot of resources to do, pull together the literature or pull together some of the organizations.

Georgetown University has a cultural competence group, a lot of very good guidance about doing translations that are more like adaptations. So that's a doable goal also.

One further thing. This came up at the last meeting, but in listening to the presentation about the public affairs specialist, there's only 30. It's hard to, you know, stretch those people around, even though I'm sure they're doing very innovative work. One systematic change that the FDA could consider is to take the existing public information officer system around the country and leverage that, the public information officers in each state are charged with taking health information and getting that out in a very timely way, immediately, if necessary, to all of the counties and cities, and FDA's type of information is just as important as emergency information that those public information officers are used to giving out.

You could leverage in a day the resources of tens of thousands of people around the country without probably spending anything much. It might take one person at FDA to interface to begin with the National

Association of Public Information Officers and take it from there, but you would get a lot for not much spent.

MS. DeSALVA: I've been sitting here today listening and thinking and enjoying the discussion very much, but as we get ready to wind down I also can't help but think about how difficult it is to actually deliver on the objective of today's meeting in certain respects, which is to provide advice that can help inform what is fed back for this report and how the Secretary ultimately reports to Congress in a way that ultimately impacts the way that the industry is regulated so that we have a better outcome.

And that's for all of the reasons that many of us have already discussed, because the research so far is directional. Dr. Lord said that, you know, it required still quite a bit of substantiation, and so the empiric evidence isn't terrific.

I also think that we're missing the

opportunity for more real world experience because I think that the experiences that have been presented this afternoon by various communications officers from the agency are, in fact, excellent for all of the reasons that have been described.

And it would be good, as Dr. Goldstein has said, to evaluate that experience and then to pull best practices from that evaluation.

The same can be said for the work that the industry has done, you know, and I know that there are many reasons to be skeptical of the industry's direct-to-consumer advertising, but I can tell you that there has been some very thoughtful work done in terms of multi-cultural work, and I think that if we had heard from some industry experiences we would have heard things about partnership at the community level, and I think we would have certainly heard that the most effective of those campaigns, the multi-cultural campaigns

that actually improve public health outcomes don't treat DTC advertising as a singular event. It's part of a system of communication that also relies on social networks and much more thoughtful types of education.

You know, so I think that when we think about best practices, you know, we do need that research agenda, and we need it to be rigorous. We can't just keep iterating, you know, the ambiguity. We have to figure out what are the important questions that really have to be asked to help us have a breakthrough in terms of reaching some conclusions about DTC advertising.

And then how do we mine the real world experience? And from there, you know, how do we form some hypotheses about what best practices are?

And you know, I would even go so far as to say how do we put together an industry consortium who will actually test these hypotheses and who will embrace them and

who will work in a public-private sector type of partnership to say if these are the potential methods to really create a better outcome, let's use our resources to see if that is, in fact, the case or, you know, how do we advance knowledge and practice and evaluate and share that knowledge much more broadly.

So I think all of that is possible, and I think that, you know, if we were able to somehow effect that, that would just be a giant step forward.

DR. MORRATO: I would echo what you said about thinking of this really as a campaign and not just singular ads in that context.

I thought it was incredibly commendable dedication that is going on to communicate safe use of medicines to the public, and I think there should be more recognition publicly for getting this information out. I don't think it's well

appreciated what the FDA really is doing.

I think what is heard in the news is more the negatives as opposed to all of the positives, and maybe getting things in the literature and all of that will help towards that.

But I had just a couple of comments as it related to sort of the nuts and bolts of putting together a report and some specific recommendations just to add.

With regard to the ability to communicate to these special populations, one is I found it very exciting that there's now provision for a pre-review of DTC ads, but as you had mentioned, I think it would be useful for the FDA to see that in context of a campaign, and how does this one ad fit into the larger whole?

Not just a script, but to be able to see the final product that has been mentioned by several here today in terms of the visuals, the sounds, et cetera, as I

mentioned earlier, I think that would be a time where it would be useful to have data on copy testing or comprehension of the ads.

And we mentioned the FTC is one model. We had some follow-up that it's not so much that the specific questions from the FTC current copy testing can be used exactly here, but that the framework of what they're doing would be a good model.

I think also the Rx to OTC switching studies are done and required, which has also a framework for label comprehension testing could be looked at as precedent to consider, and not just looking at the content of the ad. I would recommend that the FDA consider that there would be a discussion of the placement of the ads. What are the channels? What are the media being used? And through that you could have some thoughtful consideration of the special subpopulations, and are they really being reached in what the ad campaign is? And that you can include some

of these special subpopulations as part of the copy testing as well in terms of over sampling there.

But I don't know how much can be accomplished in a review of 45 days, but at least it's moving in the direction towards it being in a context as opposed to just reviewing a single ad.

The other point I wanted to raise which has not really been discussed is sort of the integration of the delivery of the direct-to-consumer advertising with the delivery of emerging drug warnings. We didn't get the opportunity to hear MedWatch talk today in terms of what they are doing to push out drug safety messages earlier.

We know that there's an increased number of drug warnings that are coming out and drug alerts; that those alerts are coming at a time of the safety signal emerging, whether it be the first report in medical literature or whether the FDA is undertaking

an analysis. It's not just at the end when we say here's the warning.

So how does the timing of those warning messages integrate with direct-to-consumer advertising? Are they going to be considered integrated? Are they really two separate messages, you know, going out?

And I think there has been some discussion around some specific drug examples recently in which there's a lag between the time of you know there's a warning and then you actually make changes to the advertising, and I think that should be addressed perhaps in the report of how those would be integrated.

And as it relates to special subpopulations, we've heard today that they're accessing different media channels, and so they may not be the same media channels that are picking up the drug safety alert warnings. They tend to go very mass media, and those may not be the TV. They may not be the radio

that some of these special subpopulations. So they might just increase the disparity between hearing the warning and then what they're hearing on an ad.

So those are just two points that maybe could be considered in the report, and then I would appreciate maybe an update about the Reagan-Udall Foundation. I know part of its mission is to be looking at this, you know, methods and means to improve drug safety, drug development. I'm not sure where it stands now in terms of its scope and role as it relates to drug risk communication and whether or not it really is going to have funding to help support research in that area, but I would appreciate an update on that.

Thank you.

CHAIRMAN FISCHHOFF: Thank you very much.

Betsy.

DR. SLEATH: I have a few different comments based on everything heard today, and