particular message.

Also, the other issues I thought, there's a lot of peripheral processing obviously in a lot of markets. How do we switch then the central processing? How do we switch these people from thinking about execution, et cetera, into clearly the benefits and risks and other important information?

Also, there's a lot studied about correct placement of the warnings. I just mentioned the primacy and recency effects. In print ads, you know, exactly where are people looking for the warnings, and especially if you have deficiencies maybe with the elderly population.

Children, more based on what we know is how to promote learning cues and other sort of educational efforts to enhance their perception of risks and benefits and the development of skepticism as I said before.

And then finally, ethnic and racial

minorities based on the scant research. There are certainly issues on matching maybe ad spokespeople who are already consumers, but then you have the issue also. Again, that's more of a peripheral effect. So you want to try to switch them in a way from that maybe to get them more involved, to switch them more into central processing, and obviously you have some opportunity to process limitations that I think that are very real.

So that's about it.

CHAIRMAN FISCHHOFF: thank you very much.

DR. ANDREWS: I don't know if there are quick questions.

CHAIRMAN FISCHHOFF: No, I think we'll do the two talks back to back and then we'll have time for questions together.

DR. ANDREWS: Okay.

CHAIRMAN FISCHHOFF: I want to make certain that Cheryl gets to speak.

DR. HOLT: Good morning. Thank you

for the opportunity to be here with you today to talk about some health communication research issues.

Again, I'm Cheryl Holt, and I'm in the Division of Preventive Medicine at the University of Alabama at Birmingham. I'm a social psychologist by training, and I've been doing health communication research for roughly 11 years, seven of those independently. Most of my research funding comes from places like CDC and NIH.

So probably a contrast with regard to the previous presentation, which is outstanding, is that my talk will be a little bit less marketing focused and maybe also a little indicative of public health background or public health milieu that I'm kind of immersed in.

But there are a lot of similarities as well. I was really glad to see Dr. Andrews bringing up discussions about elaboration likelihood model which I've also worked with,

and also the work of William McGuire, which is a couple of cornerstone models in terms of theoretical models.

So a lot of overlap which I think reflects the multi-disciplinary nature of our group today, as well as this issue.

So what I hope to address or begin to address, rather -- I don't think one little talk can address it -- but is that chasm that was brought up earlier by Dr. Paling, I believe, is that chasm of where do we stand with regard to best practices in communication research, communication approaches for this type of advertisement that we're talking about today.

So I want to start broadly by talking about some basic communication components and then move a little bit more into some what I feel are best practices for health communication based on our research experience.

So in terms of basic communication

components, as was kind of, I think, touched on in the previous presentation, we tend to think of it -- and I'm going to break it down real simple -- we tend to think of it as source, message, channel, and receiver, as one way to think about developing and investigating a communication.

And so you have source factors like source credibility, source similarity to the receiver, and by source I mean the person or whoever is sending the message, and so working with some of the groups that we're talking about today, source is very important, particularly with under served communities, you know, any community, but the source of the message is important.

There are often trust and credibility issues, particularly under served communities that have been taken advantage of historically, and so source credibility is very important, a source that you can trust, that you can believe, and the university and

the medical community is not always the most trusted source, you know, in the community.

An example, too, is if we had a -- I think I saw a study reporting that cigarettes are not bad for you, and then, of course, my immediate reaction was who sponsored the study. So we've been talking about some of these issues here today. So that is a little bit on source. What is the agenda of the source? Okay? And I think that's very important with this DTC issue.

Message factors, what is said? What's in the message? How much information is it, the type of appeal? Is it an emotional appeal? Is it an informational appeal? The amount of information, and that relates directly to what Dr. Andrews was talking about with regard to processing. So these things kind of dovetail in together.

The channel, the channel being how is the -- in what way does the message get to the person? What kind of media is used? Is

it a print media? Is it Internet? Is it television? Is it an in-person talk with a community health advisor or something of that nature?

And I'll talk more about this in a minute, but different channels are going to be, of course -- and you know, you think you don't even have to say something like this -- but it's always good to remember that different channels are going to be appropriate or more or less appropriate for different audiences.

And then the final component is is the audience or the receiver or the person getting in the information, and that person or persons are going to have demographic characteristics that are going to affect their ability to process, to affect their processing of the message, to affect their behavior and all of the outcomes that we've been talking about.

So source, message, channel and

receiver factors are, I think, important foundational things to consider in developing a health communication strategy.

Okay. With regard to direct-to-consumer advertising and the ability to communicate to subsets of the general population, the subsets that we've been talking about, elderly, racial and ethnic minorities, children, they're very different, and again, basic, but we have to remember that, very different, and so different communication strategies are going to be more or less appropriate for each of these groups. Okay?

So we're going to talk about different sources. Different sources will be credible for different populations, different types of messages, and different channels.

So is the Internet the best channel for the elderly population? I don't know that, but I don't know that it is and I don't know that it isn't, but we do have issues such

as the digital divide that was mentioned earlier, and so you know, we just have to be considerate of the type of channel as well.

And so what I'm getting at is the targeted approach, and so I want to make this distinction between targeting and tailoring. I've done some work when I was at St. Louis with regard to tailored communications that are individualized for each individual person, and that would be based on an individual assessment. So I fill out a survey. My responses are read into a computerized program that's going to pull out the message for me, okay, based on me being who I am, based on you being who you are, and yours is going to be different than mine.

A targeted intervention approach alternatively is, I think more what we're talking about here today, and it's developing the health message for the senior population, developing the message for the parents of children with ADD. The targeted approach is

going to target more of the groups.

With regard to DTC effect on access to information, I think we need to focus that. One way to focus that conversation, I think, would be on the communication effectiveness of that DTC ad, and that's going to depend, I think, on a number of factors, including those relating to source, message, channel, and receiver.

And then the other kind of area that I wanted to talk about today are some what I think are bet practices with regard to health communication research and putting together a communication strategy, whether that be a DTC or some other kind of communication strategy.

But there are particular strategies, and this, I think relates to the impact of DTC on health disparities. There are particular strategies that we use to target under served populations or to target any population, relating back to the comment

made earlier, the different strategies and the extent to which we can do a good job in developing a targeted strategy, then we may have an impact on health disparities.

Of course, that's a very simplified explanation, but the development of the targeted strategy for under served population I think may involve things that are including but not limited to involvement of the community at every step of the process.

So I think it's very important to involve the I hate to use the word "target community" or the "priority community" who is going to be receiving the message. Those people should be involved in the development of that message for it to be, I think, relevant and effective.

So targeted strategies, again, a good fitting approach for a particular population. Research has tended to show that one size does not fit all.

There's a lot with regard to

culturally appropriate communication, and there are different levels by which a communication may be considered to be culturally appropriate. For example, it may be that a standard brochure has pictures of one type of people, and let's say women. To adapt it to men, you take out the women pictures and put in the men pictures. I mean, that's not really culturally appropriate as we think about it, but I think that's the most shallow, if you will, level of cultural appropriateness.

A deeper and perhaps more effective approach is to address the cultural beliefs and the things that are culturally relevant to the population in the context of that behavior that you're looking at, and so that may involve things looking at the particular population, looking at things like faith, like family, like whatever kind of cultural factors are going to be appropriate for that population.

Moving on, the importance of pre-testing, I think, cannot be understated. Pretesting the message using an iterative and systematic process of doing, you know, whether it's focus groups and see that the package is put together appropriately or if it's individual interviews, something also to determine message understanding. We've been talking a lot about message understanding today and do folks understand the message, and I think rather than kind of guessing on that that we need to see with some folks from the population and have them read the message back to us in their own words to see if they understand it is one way to approach it.

And then the notion of the evidence based message or evidence based approaches, and that is just basically something that you collected data on and it's shown to be effective or shown to have an effect.

So what effect does this message have? If it's a colorectal cancer screening

campaign that we're putting together and it increases screening rates, then that may be said to be an effective or evidence based approach rather than developing an approach and hoping that it works, knowing that it works, and the evidence based approaches are the ones that we really want to disseminate.

Targeted strategies might also be based -- I think we've been hinting a lot today at our audience segmentation, audience segmentation in which particular characteristics, characteristics that vary in the population and that relate to the outcome behavior are identified and messages are developed based on these characteristics or sets of characteristics.

So at a very basic level, demographic segmentation, you know, for senior white women, for young African American men, you know, what have you. So an example, but demographics are not the only audience segmentation. Variable, it's possible that

there are some others, more psycho-social variables that may even be more effective for the development of unsegmented messages.

And then we've talked also about health literacy and literacy concerns overall, but specifically health literacy, and it seems as though if literacy is potentially problematic, health literacy is maybe going to even be more problematic because of all the terminology and things that a person may or may not have been exposed to, and so use of plain language, short sentences, pre-testing, again just cannot be overstated.

So in conclusion, I offer this contextual information from the field of communication and health communication to ask us to consider the role of source message channel and receiver factors, as well as offering what I consider to be some health communication best practices.

CHAIRMAN FISCHHOFF: Thank you very much.

DR. HOLT: Thank you.

CHAIRMAN FISCHHOFF: Let's open it for discussion. Actually let me make a comment because I had an interjection I've been feeling bad about for a while about why I don't trust things that are in the gray literature, and I think it sort of supports the -- maybe it follows naturally from what you have here.

So why do social scientists not trust survey results that are in the gray literature? Basically for the same reasons that pharmacologists wouldn't trust results in their respective gray literature., that there are questions of disclosure. Well, first of all, there are questions of human subjects that we don't have a guarantee for things that don't go through institutional review.

You have questions of archiving. Can you get access to the data? And questions of disclosure: so are the data archived so that somebody else could check with what

they're saying?

And then is there full disclosure? Has somebody just cherry-picked the results that support a particular conclusion? You just don't have that quality control.

You know, as conscientious as people want to be, you've just got to trust them.

Third is you have the quality control on the research. So you've gone through four or five years of graduate training. You've trained graduate students. You've been in the field, and yet you still need the pier review and you do the pre-testing and you still need the peer review for somebody to say, you know, you can't support that claim with that question. You know, that's biased in a way that you didn't really understand.

So by the time that the thing has gotten through peer review, somebody has -- my papers have gotten through peer review.

Somebody has beaten up on me so that I'm not making claims that I can't support,a nd that's on the quality of the data. That's on the statistics that I used, and I look even on the subscriber to the former employer's publication. They had a survey on this that showed up in my door this week, you know, and as much as I trust them, I don't know what to make of their results.

And then finally, there's this question of cumulative knowledge which came up in these last two talks. So you show me one result in which it looks like or you claim that eight year olds have some kind of critical capacity, and I don't know whether to trust you on that or not.

But then if I know as in any science that the research is a kind of cumulative meta analysis on the theories that underlie it, if you've gotten through peer review, then you've cited the people who found it and who haven't found it, and I know things

about the robustness is fine, and that I don't have the kind of consultants peer review, consultants stand-alone project.

If there's an anomalous result there, then maybe it's a fantastic breakthrough in science or maybe there's something wrong and the reviewers will have beaten them up.

And just as an example, in one of the submissions that came across our desk -- I don't want to identify anything in particular -- all the citations were to gray literature or occasional government reports or I don't know what the review process for them is.

There was one published study. I went to the study and found that the summary picked data that supported a particular position, but had data that contradicted that position.

I have no way of doing that if the study were in the gray literature. So as scientists, you know, we study gray literature

is probably better than raw opinion, but it's a whole lot worse than peer reviewed study.

So let me put that out there so that people have a chance to discuss agree with me and get it off my chest.

Please.

MS. GREENBERG: I think in a perfect world it would be great if every what are you calling it, gray literature? Gray polling data, et cetera? If there were -- if everything was peer reviewed, but I think you can make some distinctions and there is a hierarchy of the non-peer reviewed literature. For example, it's absolutely appropriate to ask where the funding comes from for various studies.

But I happen to know that consumer reports, for example, doesn't take any money from anyone basically. They don't take money from companies. They don't take money from trial lawyers. They don't take money from labor unions, and so they sort of stand closer

to the ideal, the platonic ideal that you might be looking for in terms of peer reviewed literature.

But it is just, I think unrealistic to imagine that everything is going to go through that very rigorous process as we look at all of the data that are coming before us.

But I think we should know where the money is coming from to fund the various studies. That's a very legitimate and important question for us.

CHAIRMAN FISCHHOFF: Jacob.

DR. DeLaROSA: I agree with both comments thus far, but I think it's important to understand that old data, be it the double blind prospective, randomized, all data is biased, and you read the data. You look who's written it. You make your decisions, but all data.

Being part of these studies that are landmark studies in JAMA and New England Journal, I know who is doing the study for

what reasons and what's going to come out of it.

So I agree there's a hierarchy. We hope for the best, but all data, you have to read it almost as you read the Bible, with proof mentality, et cetera.

DR. NEUHAUSER: To the same point, it's just striking how woefully inadequate the data are that we have about such an important topic as increasing consumers' access to both the health benefit information and risk information about all of the products that FDA regulates.

And what's striking to me is if you compare this with what we've done in this country about looking at other issues, about looking at diseases, billions and billions and billions of dollars spent every year by NIH and CDC on minutia of studying diseases.

So I think that what I would recommend for the record is somehow that we develop a research agenda of the most

important things that we would like to know. A lot of them have been brought out. We have a literature that we could debate its validity here, but at least there's something to start an agenda.

And then we think of creative ways to find a way to fund that. Maybe that means go to Congress. I would suggest that HRQ would be a likely agency to provide funding, and that with a research agenda, some of these questions could be answered. I mean, I can think right now of sources of funding, for example, the NIH health literacy grants. I have not seen any of them go towards looking at these issues, but that could be proposed somehow.

So I would welcome any of your thoughts about where funding might be found and a research agenda set so that we wouldn't be here a couple of years from now just saying, "Are there any studies on this, any studies in what we want to know?"

So, again, I would welcome suggestions.

CHAIRMAN FISCHHOFF: We have time for one more comment from John, and then we'll break for lunch. We have an open public hearing at one o'clock, and we'll reconvene promptly then, but first John.

DR. PALING: Thank you, Mr. Chairman.

I didn't identify at the outset that I used to be a wildlife film maker and producer for 20 years. Among my films were such oddities as the mating behavior of fleas and predation in alligators, and that of itself is not relevant, but what is, is an experience with otters that changed my life.

We from England used to struggle to get money for films unless we found an American net work to sponsor us. This is not my experience, but that of a close colleague. Otters are great because they're entertaining. They put their heads up like

little people. They do slides in the snow, and they make great entertainment.

So a margarine company sponsored it. When the film was made, it was beautiful. The otters put their head up, went down slides, and swam through the weeds as otters do, and a great film was produced, except that it did not meet the acceptability of the sponsor. Why? Because the visual message of an otter in the weeds was in conflict with what they wanted to show themselves to be.

We protested thinking, oh, that's ecology. The truth was they taught me this lesson. You're not making wildlife films from your old professorial background. You're making product, and you need to recognize that when you communicate, the picture greatly overrides any words put anywhere, let along in the displacement position.

For this reason I am acutely aware that there is a huge oddity in the way that our country, my country tries to communicate

risks. The drug companies do great on the benefits and poorly on the risks. In my submission, FDA tends to do rather badly on the benefits because that's not what it's there to do, but is great on putting out the risk and regulating, approving products.

So if you're a member of the public, you struggle with this dilemma, and the least I would ask of Kristin and her colleagues is when you do look through story boards, the bigger message, and since we are the risk, guess what. Communication Advisory Board, please be aware that the greater communication is going with the images.

We ask the editors of film what does the picture say, and you'd be in my submission derelict not to recognize what's really going on there. There's far too little attention given to that. That's one dissatisfaction.

So, Mr. Chairman, getting back to the big issue of how does the public hear when

benefits come beautifully from the drug companies that, in essence, have a huge problem because we give far more emphasis to the negative than we do to the positive,a nd we can worry you off doing what's best for your good.

The whole world of risk communication to me is sadly disappointing, less good than it could be, and yet the way in these groups we have to address it is to deal with what the regulators ask us to do, and that's how it should be.

I asked to speak just before lunch because I have all sorts of what seem like reaction reports, like I almost need to drop my voice and whisper here, like, you know, the emperor has no clothes. I even question whether the mantra of the FDA and all of the drug companies of safe and effective is not actually the editor's clothes, namely, it's not totally safe. It might be the highest level of safety we can reasonably obtain, and

it's not effective always, meaning the number needed to treat, all of this stuff.

And I'm even questioning in my own mind what would be good practices of effective communication. Without anyone here knowing it in my committee, I have spoken to Lee and to Nancy, who have been super at trying to answer my millions of questions that go on behind the scene just between here, and I realize that I am really very inefficient. I am very ignorant. I've actually had the ability to talk to FDA officers who have interests in what I'm interested in. I've learned a huge amount.

And basically what I find myself doing is to be learning all the while how ignorant I am. You remember when I started I said, well, I am also an American citizen. What comes with this is the ability to act sometimes independently.

And just as a matter of information, I tell you that I have set up on

our Website something called constructive suggestions for the FDA where I pose to the world key questions that are not regulation driven, and there's nothing wrong in that. It's just I feel so inept. I don't know enough.

There are people out there, many of you sitting there, who can tell me things that I can learn from you, but what I'm trying to do is to filter this site so that no one is abusive upon it, but for my own personal educational to learn for myself, and the first question is the one that was posed two years ago and has never been answered, and I've referred to several times already, which is what constitutes good risk communication practices for industry and also for the FDA.

I'm just going to invite ideas. I want in announcing this to make clear in public I am in no way dissatisfied with what Lee, Nancy and their colleagues have done. They have bent over backwards to a storm of

letters that I've been sending for six months, always trying to help with dockets and information.

It is not a criticism. It is not a revolution. It is me trying to improve my own knowledge, and I tell you that in public in case it gets another agenda in some other place. The Website, if you need it, is risckcomm, r-i-s-c-k-com, c-o-m-m like "communication," dot, com, forward slash, FDA, and this is purely personal to me. I will give the Chairman and all of my colleagues all of the help I can in the particular topic of the day, but I sit here thinking we're not really addressing the biggest questions, and this is my way to do so.

Mr. Chairman, thank you.

Sorry. Forever I'm being asked to make sure it is my site and not the Committee's site. If you go there, you will find innumerable references in red and white, not in blue yet, saying that very fact. This

is personal to me, and the questions are not those we're always being asked to address here, and I don't want it to be seen as critical, but it most surely will improve my personal education.

thank you.

CHAIRMAN FISCHHOFF: Let me ask the Committee members aMay 30, 2008 and the consultants to see Karen or Ann outside about lunch and then ask everyone to be back here at one for our open public hearing.

Thank you.

(Whereupon, at 12:06 p.m., the meeting was recessed for lunch, to reconvene at 1:00 p.m., the same day.)

AFTERNOON SESSION

(1:05 p.m.)

CHAIRMAN FISCHHOFF: Okay. Let me now call us to order again for the afternoon

session.

This session will be the open public hearing. We have four people who are listed as speaker. We'll first hear from Ellen Liversidge and then from Peter Pitts. There are two other people who have signed up to speak, and Lee Zwanziger would like you to consult briefly with her. These are Jenelle Mayo Duncan and Mario Majette, if I pronounce those correctly. So if either Jenelle May Duncan and Mario Majette are here, please talk briefly to Lee.

By the procedures of the Federal Advisory Committee Act under which we're operating, the speakers are in line, or at least the first two where we know where they are, are in alphabetical order. Everyone has five to seven minutes to speak, and then we'll have an opportunity for question and answer between members of the Committee and the members of the public on the matters that were in your public testimony.

And I'm now going to read something into the record, which -- right? Do I read this?

DR. ZWANZIGER: Please.

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

For this reason FDA encourages you, the open public hearing speaker, at the beginning of your written or oral statement to advise the Committee of any financial 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 financial relationships. If you choose not to address the issue of financial relationships at the beginning of your context, it will not preclude you from speaking.

So let me ask first Ellen Liversidge to join us.

MS. LIVERSIDGE: My name is Ellen Liversidge, and I have no financial anything to report.

Thank you for allowing me the opportunity to speak to the Risk Advisory Committee. I don't believe I ever have before. I am a consumer board member of the Alliance for Human Research Protection, which is a not for profit national network of lay people and professionals dedicated to

advancing responsible and ethical medical research and full disclosure of drug safety information.

Of particular concern are vulnerable populations, especially children, the elderly, and people with disabilities. I have attached for your interest a submission the organization made on May 8th focusing on a typical antipsychotic use in children in foster care to the hearing on the utilization of psychotropic medication for children in foster care. The hearing was held by the House Committee on Ways and Means, Subcommittee on Income Security and Family Support.

In addition to this testimony today, I've presented at previous FDA hearings, the last one in June 2007 regarding the MedGuide Program, in which I pointed out there are no MedGuides for atypical antipsychotics at all.

I've presented in the public media,

in private publications, and even to France to television. The majority of my presentations have focused on psychotropic drugs, particularly antipsychotics.

My only son Rob was killed by the antipsychotic Zyprexa over five years ago and would have been 45 years old today. At the time he died, there was no warning about the drug by the FDA, even though they were aware that Japan had required its maker, Eli Lilly, to place a warning for diabetes, hyperglycemia, and death. My son died of profound hyperglycemia, and I have worked to warn of the dangers of this and other atypical antipsychotics ever since.

Speaking out has been a memorial to him and an act that represents the many parents I know across the country who have lost their children to antipsychotics and other psychotic drugs, but don't live in the Washington area and thus can't get here.

The direct-to-consumer advertising

as it impacts children is, in my opinion, out of control. Children of all ages are exposed to advertising about erectile dysfunction, intimate body issues such as incontinence and the like, but the worst exposure to both children and parents is to psychotropic drugs.

There is now a group called Campaign for a Commercial Free Childhood, which is targeting the flood of commercials now appearing that is attempting to get young children to want to attend PG-13 movies. I quote, "Especially for kids. They'll see the toys which are movie linked before they'll see the movie ads. If they want the toy, they usually want to see the movie."

The UN Rights of the Child ratified by all countries except for the United States and Somalia states under Article 17, Subset E, "Encourage the development of appropriate guidelines for the protection of the child from information and material injurious to his or her well-being."

But the FDA is not protecting children either from atypical antipsychotics or their use or other psychotropic or sexual or inappropriate advertising on television. There had been talk of the pharmaceutical companies keep erectile dysfunction and other such ads contained to post-child bedtime hours, say, 10:00 p.m. to 6:00 a.m., but this has not happened.

The FDA may need statutory authority to place such limits from Congress, and if so, it should get it. But the agency also needs to require strong black box warning on atypical antipsychotics for children in the first place. Currently, the only such warning of these drugs is for the off-label use for seniors with dementia who are dying in droves from these drugs of heart attacks.

Among children, off-label use and even now some approved use of atypicals has skyrocketed partially due to the dubious labeling of children as bipolar. Many doctors

describe aggressive behavior, not bipolar behavior among children so labeled, and states are beginning to do their own monitoring of use in the absence of firm protection of children by the FDA.

Dr. John Holttum, a child psychiatrist in the State of Washington, a state planning a system-wide review and control of atypical antipsychotic use in children, says, "We absolutely need some oversight of atypical antipsychotic use in children. Some of the children who walk in my office have been grossly mismanaged."

The serious adverse events of these drugs, including gynecomastia or the growing of breasts in adolescent boys given risperdal, all the way to the death of little Rebecca Riley, need to be given aggressive attention by the FDA as soon as possible. Until all of the risks are clear and clearly stated with warnings, these drugs, along with all other psychotropic drugs now aired as DTC

commercials should be contained to late night hours.

And finally, any psychotropic drug now appearing in ads should receive extraordinary attention and scrutiny by the FDA. As Dr. Ruth Day, Director of the Medical Cognition Laboratory at Duke stated last week in Representative Stupak's hearing entitled "DTC Advertising, Marketing, Education or Deception," studies across drugs and pharmaceutical companies show that the benefit is understood by the vast majority of ad watchers, while the risk is understood by very few.

Thank you for your attention, and feel free to ask me any questions if you have them.

CHAIRMAN FISCHHOFF: Thank you very much.

Let's have our next speaker, who is Peter Pitts.

MR. PITTS: Good afternoon. My

name is Peter Pitts. I am President of the Center for Medicine in the Public Interest and Global Health Affairs Director at Manning, Selvage & Lee.

I have previously been an Associate Commissioner at the Food and Drug Administration, where I helped to draft the current draft guidance on brief summary in print advertising, and I am at present a special consultant to this Committee, but I do not appear as a consultant to the Committee today.

Samuel Johnson said that the future is purchased by the present, and that's as good a place to start, I think, in a discussion of direct-to-consumer advertising on the elderly as any.

According to recent polls, older Americans are more distrustful of the PhRMA industry and the FDA than the general population, and even more so in the wake of the current debate over drug safety. Seniors

want safe drugs and rightfully so, but why are they more negative than other groups of Americans? I believe it is because throughout the significant majority of their lives, their only information about the medicines they took came from a single source, their doctors, and the only information offered was how to imbibe the pill, with water, with food, minus alcohol, and the occasional caveat against operating heavy machinery.

There was no doctor-patient discussion, and there was certainly no public conversation. That was the environment in which today's senior citizens were born, grew into adulthood, married, raised children, and grew grayer. It was an environment where doctors were gatekeepers and the gate was kept tightly padlocked, and second opinions when they were offered at all were considered an affront to Marcus Welby, M.D.

Juvenal said, "All wish to possess knowledge, but few comparatively speaking are

willing to pay the price." Today we must face up to that dilemma. Like it or not, America's senior citizens are 21st Century empowered health care consumers.

Today the learned intermediary has been replaced by the Internet. The patient is a purchaser, and Dr. Welby is a vendor. Managed care directs. Serious and life threatening diseases have morphed from polio and diphtheria to AIDS and Alzheimer's disease. There really shouldn't be any wonder why older Americans, indeed, most Americans, are frightened. The entire health care paradigm has changed.

Woody Allen said, "Change is inevitable, except from vending machines."

(Laughter.)

MR. PITTS: Management guru W. Edwards Deming said, "Change is not required. Survival is not mandatory."

Change is frightening, and in the 21st Century, we must all be "pharmascenti,"

and that includes older Americans. The good news is that an informed health care consumer is a healthier citizen, and while information comes from many sources outside of the physician's office, one of the most pervasive channels is through direct-to-consumer advertising.

Consider the metrics. According to FDA's own research, between three and five percent of all doctor visits scheduled are scheduled specifically because a patient, otherwise known as a person, saw a DTC ad.

Now, we can debate whether or not three to five percent is a lot or a little, but I think that we can all agree that it is a significant number.

Again, according to FDA research, of patients who have visited their doctors because of an ad they saw and asked about a prescription drug by brand name, 87 percent actually had the condition the drug treats, and in six percent of those DTC generated

visits, a previously undiagnosed condition was diagnosed.

Again, according to the FDA's own research, 18 percent of those recalling ads said DTC had caused them to talk to their doctor about a specific medical condition for the first time. This is a remarkable result suggesting that approximately one-sixth of the adult population who have seen doctors in the past three months have been motivated by advertising to discuss a new health related topic.

And this is particularly germane when it comes to older Americans. The CDC's national health and nutrition examination survey found that nearly one-third of people over age 65 or older whom the survey found to have high cholesterol measurements said they had not before been told by a physician or other health professional that they had high cholesterol.

Evidence is emerging that large

numbers of elderly patients underuse needed medical care. According to a 2004 health affairs study that examined the growing philosophical conflict over the abundance and inequities that characterize the U.S. health care system -- that's their quote -- there is evidence of significant underuse of prescription drugs.

The preponderance of published medical literature and clinical guidelines according to the article compels the expansion of pharmaceutical use among Americans, a tool, again, of direct-to-consumer advertising.

A 2007 study in the peer reviewed Drug Information Journal discussed the FDA's theory of less is more when it comes to risk information in print ads. I've added this document into the docket. I'd be glad to send it to the Committee as required.

And I should point out that the protocol was vetted inside the FDA, both at the Office of the Commissioner level, as well

as with representations from CDER and within CDER from DDMAC.

In closing, I urge this Committee to ponder the question posed by T.S. Eliot who asked, "Where is the information we have lost in knowledge? Where is the knowledge we have lost in information?"

Thank you.

CHAIRMAN FISCHHOFF: Thank you very much.

For those who are unfamiliar with this process, the docket is a wealthy place to go to find information from members of the public, including those who are not speaking here, I strongly recommend people looking at it.

We have a few minutes for direct questions, for clarification. Is Mario Majette here?

(No response.)

CHAIRMAN FISCHHOFF: Okay. I understood wrongly, but I was right.

So we have a few minutes for direct questions of clarification from members of the Committee for either of our two speakers, and if somebody has something to ask by way of clarification.

(No response.)

CHAIRMAN FISCHHOFF: Okay. Well, let me thank you for coming in and joining us.

We have a little bit of time now before our next panel, and I thought that it might be good to spend, with Lee's forbearance --

DR. ZWANZIGER: Yes, go ahead.

CHAIRMAN FISCHHOFF: Yes, I thought it might be good for us to spend a little bit of time talking -- actually, I'd like to wait until Lee is free. So I'll just wait for a second.

Okay. I thought it would be worthwhile, our spending a little time thinking about how we as a Committee can work most effectively in our role as advising to

FDA. That is, that's our charge, is to be useful to FDA. And in some sense that's FDA's commitment and my commitment as Chair to the Committee, that everybody have a feeling that their time is being used well.

And so with Lee's forbearance I said, let me tell you what I understand to be how the system works, and then Lee will correct me if I'm wrong.

So this is an Advisory Committee. That is, we don't make explicit recommendations. We don't set the law in any way for FDA. We just provide advice, and some of the advice is in the form of what at EPA they call consultation. So this would be an EPA -- at EPA they call it consultations and reviews. EPA has a formal status where somebody gives you a document that is actually reviewed and it goes through formal.

To the best of my understanding we don't have any formal reviews. There are no documents that officially summarize the

opinion of this Committee. Everything we do is in the form of a consultation, and in a sense we prove our worth by saying things that FDA finds useful.

And so how does FDA -- please stay with me if you can. Are you here? Okay. I just want to make certain I'm not getting off line. Trying to stay within the Federal Advisory Committee Act.

So one way we provide advice is that at the end of the meeting Lee, as the Designated Federal Official, writes up a summary. There's a quick summary that she develops in consultation with me and perhaps with Nancy Ostrove that then goes up as high as the Commissioner's Office to get what the sense of the meeting was.

And there was such a summary. It's unofficial, and there was such a summary that went up from our last meeting, and then there's an official summary of the meeting that members of the Committee get that's

developed in conjunction with Nancy, Lee and myself, and everybody gets an opinion, and then it goes out and becomes an official document.

The transcripts of our meeting then become available for anybody who is interested in this topic. The representations to the Committee, that our meeting serves as a catalyst for producing testimony like we've just heard and all of the submissions to the docket. So if someone is concerned with this specific aspect of direct-to-consumer advertising, then this is a place where they can find the information, which is distinguished from all of the work that's out there about direct-to-consumer and that we're looking at this particular topic.

In addition to that, there are members of industry, of NGOs and of the FDA staff who are in the audience, some addressing us and some just in the audience, hoping that we'll say useful things, and if we say useful

things, then there's some chance that they'll go off and if in industry, find out a way to make a buck out of it, and if they're in Government, find out a way to improve processes, or if they're in NGOs, find out a way to improve the operations of their work.

So there's a sense in which some of our impact is intangible because we're not saying, "Thou shalt do X," and waiting to see when that comes through.

I'd hate to have this be a situation in which we're hiding behind the intangibility to feel that we're doing a great job and not really doing it.

So John just before lunch had an intervention that he felt somehow or other the way things were being framed were not producing the kind of input that he was looking for and set up an independent operation that as he carefully said has nothing to do with FDA that will, he hopes, help him to be a more effective member of this

Committee and then help FDA additionally.

On the topic that we have now in front of us, FDA has a requirement to produce a study within 24 hours and report to the Congress with a requirement to consult with this Committee. I hope that we're making ourselves useful to the FDA working group that I guess Kristin described, and if we made ourselves very helpful, maybe you'll come back at our next meeting or the meeting afterwards for even more pointed questions.

So that's my understanding about how we're advising FDA. I'd like Lee or Nancy or Kristin to correct me if I'm wrong and perhaps to hear from members of the Committee on how they see the process as working, and then we'll go on to our next panel.

DR. ZWANZIGER: Thank you, Chairman Fischhoff.

I think you've captured both the advisory aspects of the Advisory Committee as well as the public transparency and public

interaction components quite well.

Do you want to say anything further?

DR. OSTROVE: No. I mean, I agree with you. I would make two small, minor kind of clarifications, which is that the transcripts can go up before the official minutes are made available to the public. So they are available, I believe, within two weeks approximately.

DR. ZWANZIGER: Two weeks is about what we contract to get from them. So it's usually a little longer than that.

DR. OSTROVE: Okay.

DR. ZWANZIGER: But as soon as we can get them up.

DR. OSTROVE: As soon as we can get them up.

And I have to say, Dr. Fischhoff, that if we had to do the report in 24 hours for this particular report, that would be problematic. So they did give us 24 months to

do it.

(Laughter.)

CHAIRMAN FISCHHOFF: Twenty-four hours, did I say -- there's a 24-hour report from the meeting.

DR. OSTROVE: From the meeting.

DR. GOLDSTEIN: Okay, yes.

DR. OSTROVE: Okay. So that was it. Thank you.

CHAIRMAN FISCHHOFF: So let me ask if any member of the Committee either has input or on these questions of process things that they'd like to direct to the people. For those who weren't here, the first meeting we had one day in which we got a general background. It was just very general. I found it a very interesting discussion, and the second day was a topic that was brought to us by the FDA staff that was in the FDA Amendments Act where we provided advice on recall notices.

And now we've had topics that have

been brought to us again from the staff, and they're on their agenda. They're ready to run with them. If you read the FDA Amendments Act, there are a few other things that are probably heading our way in the same sense.

That does not prevent us from saying, "Here's something that we'd like to talk about. Can we squeeze that in in addition to the things that Congress has required you to look at?"

So if anybody has any comments on this or a chance to ask our staff, I'd like to take this as an opportunity.

Marielos.

MS. VEGA: I just wanted to make a comment regarding some of the documents that we got in terms of what is available in the Website. I was mainly looking at the information that is available in Spanish.

And at the end of all, either the brochures or the pamphlets or all the other type of documents for the Spanish speaking

population, there's a number that you can call if you require more information or you need more clarification about something.

And I actually wanted to see how it worked. So I did pick up the phone and made the phone call, and I expected a message in English first and then in Spanish, but no, everything was in English, and there was no way for me as a non-English speaking person to know what to do after that.

So I think it would be very important to look at that because I'm not sure how many people will use it for information, but I think there should be a message where we'll direct the Spanish speaking population.

I don't know if the FDA has at any point done an evaluation or looked at what is the impact of all this information within the Website. Are people really accessing the information? Is it being cost effective to put all of this out there?

And I think it goes back to a lot

of the things that we were discussing this morning, the benefits of advertisement, the benefits of labeling. It's really getting to the outcomes that we want to see.

So my main point was concerning the number, but also I found that some of the language materials, there is a disclaimer. Then the documents are undergoing review by Spanish speaking reviewers, but they have not been edited. The English version of the document is considered the official guide on the topic.

So I'm curious to know if even when it comes to the advertisement aimed for example in Spanish, the Spanish language, if the FDA reviewed any of those other Spanish language materials or it's just the English version is official because what I have found is that many times when people take the English versions, they just do a translation word to word of the information and really the message at the end is many times the wrong

message.

So I don't know if anybody from the FDA can.

MS. DAVIS: Sure. When we receive materials that are in a foreign language and, in particular, in Spanish, if there's an audio component we do try to get a native speaker to listen to that for the pacing, the articulation and all of that.

To be honest, for some of the print pieces that come in, they do have to come in with an official translation, a certified official translation, and for most of our staff that would be what we look at if we do not ourselves have the ability to read the other language, whatever it may be.

And as far as the broadcast ads where we do listen, whether it's radio or television, you know, we find someone within FDA that can help us with that. The only language I'm aware of though is Spanish. I don't think I've ever seen -- this doesn't

mean it doesn't exist -- a broadcast in a different foreign language. So just to let you know that.

DR. OSTROVE: And in terms of the questions about the Web and our brochures for which we provide translations, and I believe some of your questions were concerning that, I think there's more than one person you would have to ask that question in order to get a complete answer.

Now, one of those people, Ellen Frank, is on the panel this afternoon, and we can ask her about how at least the Center for Drug Evaluation and Research deals with the brochures that it translates into Spanish.

The other group that does a lot of work that we heard from at our first meeting in this particular arena in terms of providing translations of brochures into different languages is the Office of Women's Health. I don't know if we have anyone here from that group, but I do know that they do a fair

amount. Well, all of their communications are at least focus tested.

Now, I don't know how they do that. I'm assuming that they do that for other languages as well, but I could not swear to that.

So that is something that we could get further information for you and then transmit that information to you at another time when we've kind of checked up on it because I don't want to give incorrect information today.

MS. VEGA: One of the reasons why I asked that is because in a lot of the things that I review that were sent to us in terms of like consumer education about generic drugs, in the Spanish version, a lot of the words that were used, they were "drogas genericas," is generic drugs, but for a lot of people the word "drogas" in Spanish is a term that they will associate with actual drugs like marijuana, cocaine.

I did find a PowerPoint presentation at the FDA Website that used the word "medications genericas," which is more appropriate for the Latino community. So that's why I was interested in knowing how the materials are tested.

DR. OSTROVE: And you bring up a very important point that we really are cognizant of. I mean, your point especially which I need to follow up on concerning the number, and I'm not sure what the number is to. So I would have to do some more research on that at the end of brochures that we put out that are in Spanish, and then you made a call and you really didn't even get the option of hearing any information or talking to someone in Spanish. That's certainly something that we need to think more carefully about because you do set up certain expectations by having the brochure out there, and those are expectations that we need to consider in what we then kind of have on the

back end of that process.

With regard to the Web, that's a project in evolution, and we are moving toward trying to do a better job of determining what the impact is. It is really undergoing a lot of change. It's being done incrementally, but it is happening. I think we had a short presentation about that the last time, about how our consumer Website home page has changed.

So we're working on that one, and that's as far as we can go at this particular point, but we expect to make progress in the near and far future.

DR. DeLaROSA: I have a comment in regards to this Committee, and this Committee is different or unique from other committees, such as Biologics and Devices, et cetera, in that when you were one of those committees and you advise, you know the next week if your advisement -- what happened with the device or what happened with the biologic, if it was

approved or disapproved by FDA, et cetera.

But I see that we advise and we might not necessarily get back that feedback. For example, as the last meeting that we did have, we advised on sort of a central type of communicator from the FDA to consumers, and again, I don't know how far that's gotten or not, but I think it would be nice to at least get a feedback back to the Committee on every meeting that we have on our last previous meeting and where it has gone, how high it has gotten. Is it being discussed or the Office of the Director decided, no, we don't want to do that, but at least get some feedback because that is where we're different than other committees. We don't know that our product is now being used or FDA approved.

CHAIRMAN FISCHHOFF: Yes, and maybe that suggestion, among others, was in the report that went up and maybe the staff could tell us, you know, put your heads together and see what you could tell us by the end of the

day.

I don't want to put you on the spot right now, but I want yo to think about what you can tell us without internal secrets.

DR. OSTROVE: That's fair. We will put our heads together and we'll absolutely do that.

CHAIRMAN FISCHHOFF: Okay. Madeline and then Linda.

MS. LAWSON: I just had a couple of questions, well, one question and a comment from the panel this morning since we have time. Dr. Andrews' presentation, under the ad research findings on minorities you had stated that for African American consumers the product evaluations were more favorable for African American versus white models, but only for African Americans who identified strongly with the African American culture.

And I'm just curious how it was determined those who identify more favorably with their culture than others. That was very

curious to me.

The other was basically a comment to Dr. Holt. You had a very good presentation from what I could hear. I couldn't hear it all, and I just wondered if you could make your presentation available to the Committee.

DR. HOLT: Sure.

DR. ANDREWS: To answer your question, that's a great question. I wondered about that as well. Tony Whittler was the author on that, and it was a scale item. He had a measure to measure this, and this was given to all of the people in this experiment, and I can find that for you later on.

MS. LAWSON: Okay.

DR. NEUHAUSER: I had a comment about Ms. Vega's comments earlier when she was talking about issues with Spanish language adaptations or translations. I have seen this as a cross-Federal agency major issue that has been poorly addressed. I don't know of a model agency, but there might be one.

And one thing I could suggest is that the National Library of Medicine in 2006 held a workshop on Hispanic outreach for health communication, talked about a lot of the issues that you just brought up and more. It would be very relevant to the issues that are being discussed by this Committee and beyond, and I would recommend getting a copy of the proceedings and recommendations. I can help make those available, but Rob Logan at the National Library of Medicine would be one person to contact. He might be here. So that was one thing.

The other is that in terms of process, I think a lot of the issues that we're asked to discuss here relate as we have seen in the last meeting and this meeting to -- they have research implications. So anything that this Committee is asked to think about and put forth advice, for example, on the template that we talked about at the last meeting and issues on this meeting relating to

television advertising, et cetera, should be evaluated for their impact.

And this brings up the issue of how do you find the resources to do that. Are they within the agency or elsewhere? So I would recommend that as a process issue we always have some focus on the research implications, including the funding needed to get that work done and perhaps think a little more creatively as I suggested this morning about how we might do this within the Federal Government system.

DR. PETERS: I actually had two questions for Craig Andrews, if you don't mind. My first question had to do with the statement you said, that older adults use more peripheral than central processing in these advertisements, and I was wondering whether those were actually done on prescription drug ads.

And the reason that I ask is that there is some literature from Tom Hess and

some of his colleagues suggesting that when information is less meaningful and relevant then older adults do sort of use this peripheral kinds of processing, but if it's more relevant and more meaningful to them, that they actually engage more in central kinds of processing more similar to younger adults.

And I would suspect that if I was an older adult and I had a condition and/or a drug I was already taking, that would be pretty meaningful to me.

DR. ANDREWS: No, I totally agree with you, and a lot of these studies were not specific to DTCA. However -- to advertising in general. So I totally agree, and I think that's the ultimate question in how you get them to switch, to make sure that they're fully processing in a central fashion.

DR. PETERS: Yes. My second question was also around that same point. There's one way that drug ads differ from any

other kind of advertising. Most ads present a happy picture of a product and talk about all of the benefits of that product for you or your family or whoever.

Drug ads have two aspects to it though. They do talk about the happy picture and they talk about the benefits, but they also have to include negative information. They have to talk about the risks.

And there are actually two possibilities from the theoretical literature that would have implications that might predict how older adults would respond. One actually goes back to one of the public comments, and I'm afraid I forget the gentleman's name, but having that tradeoff between positive and negative may actually lead to increased upset and a desire to delegate and avoid kinds of decisions. That's one possibility.

A second possibility is, okay, you have positive and negative information there,

and it may be that, again, according to the theoretical literature, that older adults may focus relatively more on the benefits than the risks, a kind of positivity effect from Laura Carstensen's work and some other work from her lab and related labs.

Is there anything that you know of that would relate to either of those?

DR. ANDREWS: I immediately thought of prospect theory with a focal attention to more of the negative than the positive.

DR. PETERS: Shown mostly with younger adults, by the way.

DR. ANDREWS: So I would think that that might be weighed a little more, but again, I can't generalize here, especially to DTCA situation, but that just comes to mind.

DR. PETERS: Yes, the evidence for prospect theory comes mostly from younger adults and not from the elderly. There's very few studies with elderly adults that I know of at least.

DR. ANDREWS: I think that would be definitely worthy of some research.

DR. PETERS: Yes, thanks.

DR. MORRATO: I had a comment on Dr. Holt's presentation that I thought would be good to share in which she was talking or discussing about the value of pre-testing. And when one thinks about advertising development, you know, there's pre-testing that's going on in qualitative focus groups. It's followed by quantitative testing and such.

We were having some discussion about the FTC as a model in which they actually have guidance around standards for concept testing and expectations of how those kinds of studies should be done. It's something I think the FDA may want to consider as you're writing guidance documents for DTC advertising, whether or not some of those same principles could be adopted here so that you get the notion of any of the pre-testing is

more transparently presented, and it's not all behind the scenes, just done by the manufacturer and people don't know about it.

And oftentimes in the pre-testing is where the rubber hits the road, and you understand how things are perceived and are you really communicating and what are you communicating, and I think there would be value in making that a more transparent process.

CHAIRMAN FISCHHOFF: Could you say a little bit more? Who does the work for the FTC?

DR. ANDREWS: At least when I was there a few years ago, they have in-house copy test experts to do this. Of course, if it would go beyond a consent agreement to trial, there's outside experts that get involved in copy test work, but there are some standards that are out there for copy testing guidelines.

CHAIRMAN FISCHHOFF: And just from

what you know about them, how applicable would those be to pharmaceuticals?

DR. ANDREWS: I think that's worth exploring, I think. There are other issues as mentioned before as far as the communication of fair balance of risks and benefits, certainly, but I think you've got a communication aspect with consumers to know what exactly the take-away would be, the net impression of the entire ad.

However, it's different. You've got credence claims where they might not fully understand all the aspects, let's say, of the particular content.

CHAIRMAN FISCHHOFF: Thank you.

MS. MAYER: Just a question for either Dr. Andrews or Dr. Holt. You know we haven't talked much about the perception of benefits, except in rather vague terms, and I think that's likely because especially television ads really don't make very specific or quantifiable claims. They don't say, for

example, you know, X percent of patients with this condition benefitted from taking this disease.

Yet there is research from Dr. Schwartz and Woloshin to suggest that actually comprehension may be better with benefit, quantified as well as harm is quantified.

So I think I'm just sensing I'm putting myself in the position of a patient trying to weigh risks and benefits, and I understand that the physician is the intermediary here and hopefully will be giving a patient a clearer sense of benefit, but I know that in the real world that often doesn't happen. There's just simply a recommendation in the ten minutes or so that the patient has to spend with her physician.

So I'm wondering what the research suggests and what you think about quantifying both harms and benefits from drugs.

DR. ANDREWS: I can't comment specifically on DTCA, but from what I

presented, we were really concerned about this idea of competing modality where you've got benefits being portrayed visually in terms of peripheral executions. I don't know. There was an untitled letter years ago, I think, on somebody doing cartwheels, I think, on a beach or something where the risks are presented in an audio fashion at the same time.

I think, you know, the research shows that obviously the picture, the visuals are very powerful, and so that does concern me. As far as specific research on DTCA, I'm not aware of that. I'd love to see something in that fashion.

The other thing that can be done is certainly on a copy test you can look for specific beliefs that might be a fact in different populations.

DR. HOLT: I don't have anything significant to add. My area specifically is more in the area of health communication than risk communication. There are probably others

in the room more qualified to comment on this, but quantifiable is probably better, it would seem, than not, but I think we have to be very careful because the literature seems to indicate that there's a great deal of potential for a problem in understanding, even when a quantified risk is presented. Does the patient really understand what that means for them?

That's my limited two cents worth.

DR. HUNTLEY-FENNER: Again, a question for both Drs. Andrews and Holt, and this relates to the issue of persuasion and credibility. My question has to do with how the message and the source interact. I'm thinking of an occasion. I'm a school board member in my local community, and one of our students commented on health education, particularly with regard to sort of safe sex.

And he found one source to be incredible in part because of their avowed sexual non-history as sort of telling him

something that was relevant to his experience as a high school student.

I know that individuals have very sophisticated filters that they apply to messages. It is possible that in some cases you might look for benefits, let's say, from the manufacturer and risk information from the FDA, and even though both sources have both types of information, you filter out one type of information when it comes from one source and filter in that type of information when it comes through another source based on your understanding of the source and your credibility.

Is there any evidence bearing on that hypothesis?

DR. ANDREWS: I think there's a rational assumption on prior expectations you'd have to know the expectations and levels of involvement. I know back in my dissertation we worked with source of facts versus the message and the traditional

hypothesis via ELM would be under low involvement, that people would focus more on source of facts rather than a message and vice versa on high involvement.

So it really depends, I think on the audience and what they're involved in. Sometimes it doesn't always work, but you have to look at the context. I would say the prior expectations and involvement or motivation levels would be important.

I don't know. Did that help answer a little bit?

DR. HUNTLEY-FENNER: So then what are the implications if you're going to design a communications system that's going to provide both risks and benefits? It seems like multiple sources would be relevant and you couldn't assume that a single source would provide everything that every type of individual would need in order to make a rational choice.

DR. ANDREWS: I guess back to my

days at the FTC, I think copy testing would be important to understand their expectations about these sources or in a true experimental design you'd want manipulation checks to find out how the sources differ, and if you knew that, then you would know maybe the interaction with the message.

DR. HOLT: And you mentioned one source, and again, that kind of goes back to the one source is probably not going to fit all, if you will, for the most credible, most effective communication.

CHAIRMAN FISCHHOFF: Okay. Well, then let's move on to our next panel, which will be people from FDA. These are all slide presentations.

MS. FRANK: Good afternoon. My name is Ellen Frank. I'm the Director of the Division of Public Affairs in OTCOM, which is the Office of Communications and Training in CDER, and what I'd like to do this afternoon is give you a little bit of a background of

what we do in my division and then show you some examples of some of the education materials that we're putting out and talk about some of the vehicles we're using and some of the things that we think we've been effective in doing and some of the areas that we need to work harder at.

First, I'd like to tell you about our division. We've been going now for about ten years, and when I first came to FDA about 12 years ago, there wasn't even a communications office. We didn't even have a way of getting messages out to the public, and then there was talk about we're FDA. We've got a great name. The consumer has a lot of confidence in us. Why aren't we doing more to take messages about using medicine safely and getting that out to the consumer with FDA's name on it?

So we started to come up with education campaigns. Now, we couldn't compete with private industry because we didn't have

funds. I mean, literally I operate on, you know, in a good year $40,000 a year, and you know, one ad is $80,000 in one magazine. So we couldn't depend on a budget to actually go out and educate consumers on certain issues. We had to be creative.

And I'm going to show you a lot of examples of how we've worked with partners, national organizations and in some cases with industry to get messages out.

Now, our messages have to be general. We can't talk about a specific drug. We don't want to promote or say anything negative or positive about one drug. So we have to come up with messages that had a broad audience and what I'm going to focus on today is not all of our messages. I'm going to focus on messages we've developed for the elderly, for children, and minority groups because I know that's the focus of this meeting.

First of all, in our division we

usually decide on what campaign we're going to do in a variety of ways. Sometimes Congress says to us, "Go and do education on generic drugs," for example. Other times the national organization will come and say, "There's an important issue here. Can you do an education campaign on this?"

And other times we within FDA think, well, this is an issue that needs to get out in a long term basis, beyond just a press release or a public health advisory. We need to take this message and have it go out even further.

And what we've learned about our education campaigns is there isn't a one prong approach. It's a multi-channel approach and people receive information in a lot of different ways. Some people like the radio, some TV, some magazines. Some like to pick up a brochure. Some like to hear it from their doctor.

So the way we've decided to go

since we don't have a budget is get to as many different people as we can through as many different vehicles with as creative a way we can without a lot of funding, and that's what I'm going to show you some examples of what we've done.

I am always open for new partnerships. Any ideas, because every time I speak at a meeting if I can come up with one or two new ideas on who to partner with or what messages we should be talking about, that's a success.

So first I want to focus on the elderly. We've developed several products that have been specific to the elder population. Now, you can look at all of our products and say they reach the elderly and that's our audience because the highest users of medications are the older generation. So really everything we do is used for the elderly.

But there are some specific pieces.

We partnered with the Council on Family Health on this brochure, and what's specific about this material is that it focuses on what's unique about what happens to your bodies when you're growing older and why you should be looking and taking and asking about medications differently because you're aging.

We've worked with the Substance Abuse and Mental Health Services Administration. They are focused on alcohol. We were focused on medicines. We've joined in a partnership to educate the aging on how medicines and alcohol affect each other and what the elderly could do to reduce adverse events caused by the interaction of both.

We've come up with public service announcements. Now, public service is just that. We go and we send them out to magazines, and then we kind of cross our fingers and beg and hope that they're used. Sometimes yes, sometimes no, but when we get a hit, that could be a $100,000 full page in a

magazine. That's a success. So we don't give up.

We meet with magazine editors and advertisers and try to convince them that messages are worthy of them putting in.

These are some other ads we worked on for the elderly. These talk to them about making sure that when they're using their medicines that they're reading the label. They're not taking too much of the same active ingredient, and they're taking the right dose.

We worked on a campaign about aspirin. We realized that a lot of people were taking aspirin incorrectly. They thought they had heard in the media, hey, aspirin prevents me from having a heart attack. I'll just go and take a Bayer or take an aspirin every day.

Well, wrong. That could cause damage. That could cause adverse events. So we wanted to educate the public about how to take aspirin safely, and most importantly,

that they should talk to their doctor first before they go off and take aspirin on their own.

We did an education campaign with the Department of Transportation on driving and taking medications, and this was kind of tricky because we had to stick with what the label says, and the label basically says make sure that if you're taking a medication it might cause drowsiness. Maybe you shouldn't drive a vehicle. So this was just an awareness campaign to get those using medications to read the label and see if it gives you a warning about driving, especially the elderly under medications. Maybe they shouldn't.

Oh, and I want to go back. This is an example where we would creatively figure out how do we get this message out. So one member of my staff contacted Mapquest, and Mapquest went ahead and for free put that little tag line on top of every Mapquest.

Every time somebody clicked on Mapquest, they would get that driving, click the medicine label, make sure you're -- you know, check on the medicine label to make sure you're able.

That was the message, that if the reader clicked on that, it would take him to the FDA Website where they would get more information about the hazards of driving while using medications.

So that's the kind of example of where we're always thinking of creative and inventive ways to get out messages out.

We worked with the National Consumers League on this campaign, and it was about mixing medications. Make sure that you read the label so that you're not taking a medication that has an active ingredient that shouldn't mix with another active ingredient.

The misuse of acetaminophen and ibuprofen is a big issue in FDA and outside of FDA, and this was a hard PSA to get into magazines because for some reason they didn't

want that next to their ads that the drug companies were paying for. We understand that.

So what we're trying to do is get the message out from FDA that if you're taking a medication, check to see if it has acetaminophen in it. If it does or if it has an active ingredient in it and you're taking another medication over the counter or prescription, make sure it doesn't have the same active ingredient or that you talk to your doctor before you take too much.

And we really believe that people just aren't aware of this, and this is just a good awareness campaign because there are a lot of incidences coming into FDA where acetaminophen is taken too much over too long a period of time and there's adverse events.

We did a campaign on buying drugs outside the country, and FDA's message on this, I believe it still stands, is don't do it. We know that the older generation, the

general population is trying to reduce cost and buying their medications from outside the country. We want them to know that this is risky. They don't know what they're getting. They might get a counterfeit. They might get a fake drug, a drug that has no ingredient at all, and that they just shouldn't do it.

We worked with the United Health Foundation Insurance Company, and we came up with a message that we both felt passionate about, and this was that exceeding the recommended dose can do more than wipe out your pain. Just ask your major organs.

Originally that said, "Just ask your liver," but we didn't want to be specific. So we had to compromise. That's okay. That's still a good message, and it gets the point across that if you take too much of the same active ingredient, it can do your internal organs harm.

Now, this was a success because we wanted to get this message out. So did United

Health Foundation. We worked on it together. It was a real partnership, and fortunately they had the funding to get this into all of those magazines on the left-hand side, full page ads over a six-month period. That's a real success when we can get a message out to that large an audience.

Our resources in terms of time went in, but we didn't have the funding to do it. So it was a great partnership.

There are public service ads that we developed for the consumer, and this is about making sure the consumer plays a role in their health care, that they need to balance the benefits and risks of taking medications, and that they need to talk to their doctor, know what questions to ask, look at what the side effects might be and make the decision that's best for them.

These are some more of our risk management education public service announcements, and these have had some pretty

good play. In the little booklet that you pick up at CVS and RiteAid, that little booklet that a company called Medizine puts out, they often put our one-page full color ads in those when they have remnant space, and that's a great partnership that we have with them.

Generic drugs was and still is a big campaign that we're running, and we have done this, the generic drug campaign, and a lot of the pieces I've shown you and I'll show you will be in both English and Spanish, and this was a campaign that was funded by Congress, and it is still going on, and the goal of this campaign is not to have consumers switch from generic to brand name, but to give them the confidence in generics that they may not have so that when they take a generic or are given a generic they understand that it is equivalent.

We came up with a brochure that is in consumer language that they can understand,

and this brochure we've done in several languages, and it's one of our most popular pieces with the drug stores. We meet regularly with the top person at the major chains, the people who can make the decision as to what of our materials will go in the drug stores nationwide, and this is one that they are interested in.

Some of the problem is that we don't have a printing budget to supply, for example, 4,000 Walgreen stores, but Walgreen's took our generic education brochure, and they went and printed it and put it in all of their 4,000 Walgreen stores. So that's another successful example of a partnership.

We developed this on-line My Medicines Record, and what's unique about this and great about this is the consumer can go on line, type in the medications, all the information there, print it out, take it to their doctor, their pharmacist, their health care provider, and they can go in and update

it.

So it's a great interactive tool because we know medications are always changing, and we want them to have the most updated list of what they're taking with them at all times.

We have done quite a bit for children in our division, and these are some examples of the materials we're doing to educate consumers about children. This is Kids Aren't Just Small Adults, and it's a brochure we did in English and Spanish in partnership with the Consumer Health Care Products Association. It's a really good brochure for parents to learn how to give medicines to children. It touches upon all of the areas, dosing, the weight of their child, the dosing mechanism to use. It's a great brochure, and we're always running out of it, and it was a partnership where Consumer Health Care Products did a massive printing, and they get a lot of requests for this.

We did several public service ads within our division. We wanted the consumer or the parent to know how important it is to know the weight of your child when you're giving medications, and we have sent this out to a variety of magazines like parent magazines in hopes that they'll run this.

Antibiotics resistance, we've targeted a lot of different audiences. We have messages in Spanish. We have these messages for parents about giving antibiotics to children, and the message here is make sure if you're giving an antibiotic to your child that thy really need it. Ask the doctor if what they have requires an antibiotic because of the misuse and the overuse of antibiotics and the potential for resistance.

Medicines in my Home Program started out to be initially a program aimed at sixth graders for teachers -- well, that really shows the slide up well. This program was geared for sixth graders, and it was aimed

for teachers to use in their curriculum to teach young children about the importance of medicines at a young age, and that they should also be aware of how to use over-the-counter medicines, and it's never too soon to start educating.

And Karen Feibus, Dr. Karen Feibus is going to talk about all of the intricacies and how this program has expanded and how important it is in her presentation.

Well, we went to a little higher age group of children. This is aimed toward teenagers, and the goal of this is to -- what we realized is that there is an increase in teens using prescription pain relievers, for example, like OxyContin and Vicodin, misusing those, taking them to parties, putting them in these big bowls, having kids just pop them, and the kids, if they knew that they could die from doing that just once, maybe they wouldn't do it, and this is what the message is for those kids, it's to tell them, you know, just

because they're approved drugs doesn't mean it can't kill you if you misuse it.

Now, these drugs if they're used properly, they are safe and effective, but if they're abused in a way for kids just having fun, they could be deadly, and that's such an important message to get out.

We sent this out to hundreds, to thousands of colleges to put this ad in their newspapers.

Now, we send stuff out, but we don't always know if they're using it, but that's okay. We're hoping they do, and every once in a while we get feedback. So what we think is what we hear back of the use of our materials is just the tip of the iceberg. We know that a lot of our materials are being used and people aren't just informing us or showing us how they're using it.

We did for the Native American community a brochure in cooperation with CDC on educating them about the misuse of

antibiotics. So we're reaching out to a large variety of different audiences.

The Hispanic population is able to learn about OTC medicines with this brochure, English on one side; you flip it over and it's Spanish on the other. This was in cooperation with Consumer Health Care Products Association.

We took our generic drug brochure, and we had the field public affairs specialist through a small grant that we gave them translate these into a variety of different languages. So when anybody ever asks us, you know, are you doing anything in other languages, we have this as an example to say that we have.

I want to mention now some of the things that we're doing to disseminate our messages. One of the ways we disseminate is we try to get it into the retail stores at the point of purchase in pharmacies and supermarkets where they have in-store

pharmacies and the in-store clinics that are starting to open up, urgent care centers. And this is an example of where Walgreen's took our poster and reprinted it and put it in all 4,000 of their stores.

And I know this because I went to Florida to visit my mom and I went into the Walgreen's store down there, and there it was. You know, then I went to another state and there it was. It was like this is great. It was in every Walgreen's store around the country.

Fry's, for example, took our Spanish brochure and put it in certain stores where the Spanish population was greater and sent me a photo.

So like I said, these are the tip of the iceberg stories that I hear, but when I meet with these folks from the retails once a year, they come to me and say, "Thanks for your materials. I've been using them all year. What else have you got for me?"

And that's the biggest feedback, and that's powerful feedback knowing that they are using our materials.

We also work with the company that puts the little flyers on the bags when you pick up your prescription. They're giving us remnant space to let us put messages on those little flyers that are attached to the prescription bags. Fifty million people since 2003 have received our messages this way. K-Mart and CVS have used our messages on their bags.

This is newspaper articles. We have some funding. We send it out to 10,000 newspapers. We have magazines, as I mentioned, that are putting our PSAs in. We've spent a little bit of money through a company called Viacom to put ads at malls and trains, and we even worked with Blue Cross/Blue Shield, and they did a billboard in Michigan with our public service message on it.