UNITED STATES OF AMERICA

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FOOD AND DRUG ADMINISTRATION

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PUBLIC HEARING

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TUESDAY,

NOVEMBER 1, 2005

The Public Hearing was held in the Lower Level Boardroom of the National Transportation Safety Board at 429 L'Enfant Plaza, Southwest, Washington, D.C. at 9:00 a.m., Tom Abrams, presiding.

PRESENT:

TOM ABRAMS, Chair
KATHRYN AIKIN
RACHEL BEHRMAN
GLENN BYRD
KRISTIN DAVIS
SCOTT GOTTLIEB
MARTINE HARTOGENSIS
MELISSA MONCAVAGE
NANCY OSTROVE
ROBERT TEMPLE
DEBORAH WOLF

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ALSO PRESENT:

ROSE CUNNINGHAM
JANET WOODCOCK, Deputy Commissioner of Operations, FDA
SHARON ALLISON-OTTEY
RUTH DAY
LEWIS GLINERT
JOHN KAMP
ANDREW KLEIT
J. PATRICK KELLY
ABBY MEHTA
MICHELE SPENCE
CHRISTINE WINNICKI
JAMES GARDNER
GAIL JAVITT
WILLIAM PERSON
CAROLE ROGIN
MARLENE TANDY
REBECCA BURKHOLDER
LEE HAMMOND
GARY STEIN
LISA VAN SYCKEL
DIANA ZUCKERMAN

I N D E X

P R O C E E D I N G S

9:01 A.M.

MS. CUNNINGHAM: Good morning, everyone. Anyone still out in the lobby, please come forward. We had over 500 people signed up. It doesn't look like we have 500 people here yet, but they'll be dribbling in and out and in part today and then tomorrow, different people.

If you are one of our panel members on Panel 2, please see me as soon as possible. I want to make sure you're all here, because you'll be coming up as soon as we have a break.

We're going to begin. I've been asked to remind people to please turn off your blackberries. It interferes with the audio. We have wireless mikes that are going to be used and it picks up static.

So with that the restrooms are out front. There are restaurants in the complex. Everybody is given 12 minutes. Please stick to the time because we have a very ambitious schedule and lots of people talking.

With that, I'm turning it over to Tom Abrams who is the Director of our DDMAC.

MR. ABRAMS: Good morning and welcome to FDA's public hearing on consumer-directed promotion of

regulated medical products or direct-to-consumer promotion, also known as DTC.

I am Tom Abrams, Director of DDMAC, the Division of Drug Marketing, Advertising and Communications in CDER, the Center for Drug Evaluation and Research. And I will serve as the presiding officer for this hearing.

It would be an understatement to say that much has happened in consumer-directed promotions since the first DTC ads appeared in the early 1980s. There's also much interest in this area, illustrated by we have a full registration and we will have a full attendees today. I know people are coming in later from the Metro.

The Agency, the industry and other members of the public have gained much experience with consumer-directed promotion, so we believe it's a good time at this point to take a step back and to evaluate what regulatory issues should be addressed in FDA's activities.

This hearing today is intended to provide an opportunity for broad public comment concerning consumer-directed promotion of medical products, including human and animal prescription drugs, vaccines, blood products and medical devices.

I would like to introduce the FDA Panel at this point. Starting from my left is Kathryn Aikin, Social Science Analyst in DDMAC. To my immediate left is Robert Temple, the Director of the Office of Medical Policy in CDER. To my right is Rachel Behrman, Deputy Director of Office of Medical Policy. And Scott Gottlieb, the Deputy Commissioner for Policy for the Food and Drug Administration.

Going down to the Panel on the floor, closet to the front of the room is Deborah Wolf, Regulatory Counsel in the Office of Compliance for the Center of Devices and Radiology Health. Next to Deborah is Nancy Ostrove. Nancy is Senior Advisor for Risk Communication in the Office of Planning of the Office of the Commissioner. Melissa Moncavage is the leader of the DTC Review Group in DDMAC. Martine Hartogensis is Promotion and Advertising Liaison in the Center for Veterinarian Medicine. Glenn Byrd is the Chief of the Advertising and Promotional Labeling Review Branch in the Center for Biologics Evaluation and Research. And finally, Kristin Davis who is Acting Deputy Director in DDMAC.

We have 38 speakers in this hearing, so to provide a most productive meeting, let me just go over some of the ground rules. First, this meeting is

informal. The rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only FDA panel members will be allowed to question any person during the presentation or at the end of the presentation.

If time permits after the FDA Panel has completed its questioning of each panel session, public comments will be taken from the floor. We will open it to the floor at that point.

Public hearings under part 15 are subject to FDA policy and procedure for electronic media coverage of FDA public administrative proceeding. Representatives of the electronic media may be permitted, subject to certain limitations to videotape, film or otherwise record FDA's public administrative proceeding, including the presentations of the speakers today.

This meeting will be transcribed and copies of the transcript may be ordered through the dockets or accessed on the internet.

Each speaker will be given 12 minutes to present their information and the FDA Panel Members will have up to 8 minutes to ask questions, so we'll have the speaker for 12 minutes or under and then FDA will open up with questions. After all the speakers

are done on the panel, we will open it up to the floor for comments, if time permits.

Given the full agenda today, we request that each speaker keep their presentations to 12 minutes, so we will have time to hear from all the speakers. We thank you for your interest and participation today. We look forward to a very productive meeting.

Now I would like to introduce Janet Woodcock, the Deputy Commissioner for Operations of the Food and Drug Administration.

Dr. Woodcock?

MS. WOODCOCK: Thanks, Tom. And good morning to all of you and thank you for participating in this hearing. As you're aware, the subject of consumer-directed advertisement of prescription products also called consumer-directed promotion or DTC, generates great interest from diverse groups and I expect we will have a lively set of presentations over the next several days.

Before we get started hearing the testimony it may be useful to review some basics about the DTC and how it evolved to where we are today with this form of promotion.

First, there are no laws or regulations

that prohibit promotion directly to the consumer. FDA often gets questions about this and this basic fact. Second, the regulations focus on the content and not the extent of promotion. Therefore, as a result, it's legal for companies to promote directly to consumers, and additionally, of course, there is no legal limit on the amount of money a company can choose to spend on direct-to-consumer advertising.

FDA regulates the content of the promotion to ensure it's truthful, balanced and not misleading. Regulation of promotion in this manner is important because of the impact of prescription drugs and restricted devices may be different from other products because of their potential risks inherent in their use or misuse.

Therefore, it is critical from a public health standpoint that ads are truthful, balanced and not misleading. Balanced, in this context, means having a candid representation of the risks associated with the use of the product presented in the advertisement, along with the representations of the benefits, the potential benefit.

Prior to the early 1980s, prescription products were not promoted to consumers and patients. In fact, as we've discussed before in this setting, a

long time ago, it was viewed that it was not very helpful for patients or consumers to actually know what was wrong with them. However, that changed in society and in the early 1980s, a few companies began advertising two products to consumers. One was an arthritis drug and the other was a pneumonia vaccine. Because there was no experience with direct consumer promotion, up to this point many parties expressed concerns about the possible impact on the public health.

To allow time to evaluate and make this assessment, FDA issued a policy statement on September 2, 1983, asking industry for a voluntary moratorium on direct-to-consumer. The industry complied with this request, giving the Agency time needed to study whether current regulations which had been developed in the 1960s for promotion directed to health care professionals provided sufficient safeguards to protect consumers when applied to DTC.

This also gave the Agency time for a dialogue among the affected stakeholders, consumers, health care professionals, industry and for interested parties to conduct research on DTC. After meetings, research and discussion, FDA lifted its request for the voluntary moratorium in 1985, stating that the

regulations provide sufficient safeguards to protect consumers.

Since that time, FDA has held several meetings and issued a number of guidances. However, as Tom said, a lot has changed, especially in the past decade in DTC and we believe it's time to obtain additional input to guide our overall policy development.

We also want to note that DTC promotion for medical devices has not received as much attention previously because until recently there's not been a significant amount of DTC device promotion, except in very limited areas. However, this situation may be changing and we seek input on this topic as well.

Today, we will hear thoughts of the panelists concerning current DTC regulations and how it might be improved or changed. Today, the FDA is here to listen. We will be reviewing everything that is presented during these proceedings and to the docket to determine our next steps.

Once, again, we want to thank you for taking the time to come today to assist us in this endeavor and we also look forward to the written comments that might be submitted to the docket. Thank you very much.

MR. ABRAMS: Thank you, Dr. Woodcock. Let's review the agenda and then we'll begin. We will have four panels today and four panels tomorrow. We will have two panels this morning with a break in between those and then break for lunch, come back and have two additional panels with a break between the two panels.

So we will begin with the first panel. Each panel member will come up and present and then FDA's Panel will pose some questions. The next panel member will come up and present and FDA will have an option to pose questions to that panel member. And then, as I mentioned, if time permits, after the panel has completed its presentations and FDA panel has completed its questioning, we will open it up to comments from the floor.

I'd like to begin with the first speaker, Sharon Allison-Ottey.

MS. ALLISON-OTTEY: Good morning. First, I want to thank the FDA and DDMAC, Mr. Abrams, and the entire Panel for number one, having the hearing and opening up an opportunity to present this data, but also for having the interest of Americans at heart.

I'm going to present some brief summary research that was actually commissioned by Pfizer,

they commissioned Ipsos, which is an international market research firm and in a few slides you'll understand why I'm presenting on behalf of the key opinion leaders and experts in health literacy and some consumer advocacy groups that were asked to participate with guidance on this.

This project's research objectives were to determine if alternative versions of the brief summary do a better job at conveying additional information than the current brief summary, to communicate key risks and benefits, to motivate and not necessarily demotivate appropriate discussion with a position, and to recommend potential alternatives to the current brief summary with a huge focus on health literacy in making sure that patients understand risks and benefits.

The project kickoff and I think it has to be noted that prior to any of the data, prior to any of the research being done, Pfizer engaged public health thought leaders such as members from the National Consumers League, American Academy of Family Physicians, COSHAR, which I represent, the National Council on Aging, all of us whom have an inherent interest in patient safety and in making sure that communication is effective.

Then the formats, the qualitative research was completed and we moved forward with quantitative research which I'll discuss.

The qualitative research was conducted in September of 2004 and really the focus was to better understand consumers' and physicians' reactions to eight innovative or new alternatives to the current brief summary. Interviews were conducted, about 60 minutes, with 27 consumers and 14 physicians. Based on that study and that data, four innovative options that were developed that may be able to help provide consumers with more user-friendly information were recommended.

One, empowerment, and you will see these in a few minutes, the empowerment module which provided information that was important about the information on the two disease processes that were the target of this data were high cholesterol and migraine. So empowerment was to not only talk about the disease process, but to talk about medication, lifestyle changes that can empower the patient and thus the term, to improve their own outcome.

"Fast Facts" which provided the pertinent information in an easy-to-follow format allowing the reader to do what most of us do and that is to quickly

scan and read the sections that are most important.

The "Questions" format provided, again, a Q and A approach as another way of getting information to the patient or consumer. And then finally, the "Safety Guide" which seemed to be actually highly user-friendly. There were the blocks and different things in the format that drew the eye to the safety guidelines, risk and benefits.

These were combined with the existing brief summary versions and prototypes of those referenced by the 2004 FDA brief summary guidance to create the quantitative tests matrix.

And you will see, I've talked about these. These are just kind of an overview of the nine that were utilized.

The methodology for the quantitative research, a survey instrument was administered to at-risk and diagnosed populations, patients or consumers self-identified. There were 2100 actual participants in the survey. Each alternative version of the brief summary, including one version that was an ad only with no brief summary, was tested. A fictitious product name and that was at the name of the recommendation of the FDA and I think it should be noted, as it was noted here, that the FDA's input was

requested and incorporated at several levels and development of this research project.

The front page was the same for each of the ads and each sale had 200 respondents with the current brief summary having 300 respondents.

The interview process was somewhat simple. The respondents were asked to read and review an ad, i.e., that was a forced exposure. And then the respondent was administered and interviewed, the survey instrument.

Respondents were asked with aided recall, i.e., is this product useful for high cholesterol, high blood pressure, etcetera, etcetera, asked aided recall of specific communication points. They were questioned on their recall, again, of who the product was for and who the product was not for, other things you can see on the slide, what the side effects of the medication are and how severe they are. They were also asked about their reaction to the ad and in the upcoming slides you will see affect. Affect descriptors are were the ads useful? Was it informative? Did it appear cluttered? Was it easy to read? Was it hard to understand?

They were also asked about actions they may or may not take as a result of seeing the ad.

Would you speak to your physician? Would you look for more information? Would you call a 1-800 number?

There were additional questions about health as well as demographics. And you can see, again, the N for this is 2100. The respondents of the study were balanced to match the sufferer/at risk universe and the demographics are similar to what we see in this country.

Many of you know, before I was here in 2004 presenting data for minority communities, and it is interesting to note that there is a good representation across the board for this study.

Analysis. Each version of the back page has been analyzed based on the following dimensions: one, aided recall; two, prompt discussion; and three, the affect, which I discussed. The analysis that determines the degree of effectiveness on the back page version by dimension or component of dimension is based on a two step test, one, which alternative version is better than the control. And remember, the control is the current brief summary. And two, if the alternative version passes that step and it's better than the control, among those that move forward which is best?

I talked about affect and I briefly just

wanted to go over this when we look at the scoring. The question items that comprise the affect scale you can see on the left. The desired answer is the next column and the sample respond, the actual answer. If the respondent answered or gave the desired answer they received a one on a scale of seven factors and this was extrapolated out to a scale of 100. And those are the data that you will see now.

Key learnings. Before looking at the final slides are one, the added self is an integral part of risk communication. Consumers do receive information about side effects and other important information from the ad alone which was demonstrated by the ad sale only. But two, the brief summary, as we all know, matters. And ad with a brief summary is much more effective at conveying side effect information compared to having an ad only with no brief summary at all. Three, the brief summary can definitely be improved. The current brief summary is clearly inferior at communicating information, compared to all of the other alternative measures that were tested. Four, there are several appealing alternatives to the current brief summary. On the crucial dimension of recall and severity of side effects and thus patient safety, three of the

alternative versions proved superior to other versions tested within both therapeutic areas and remember that the therapeutic areas are migraine and high cholesterol.

And importantly, risk communication and motivation are not incompatible. Each of the versions as motivation scores that are no worse than an ad paired with the current brief summary.

This is a performance survey and you will be able to see better for the essence of time. Here, look at the yellow portions which indicate -- the following table indicates the shaded cell, those versions perform significantly better than control on the dimensions tested. You will see that the yellow indicates the cholesterol module, the migraine module is the hatch marks and you can see the ones that perform better for both migraine and cholesterol. Clearly, the brief summary has room for improvement.

And finally, the performance funnel. Number one, the ad only and this is who is the winner? So you start with the ad only which performed the most poorly. I don't think that's a word, but performed poorly. It does not do better than control on side effect communication although, as I said before, some side effect communication was -- some

side effect information was conveyed, based on this study. Then you move down and you see that the next ads do better than control on side effect communication for one indication, but not for both. And then finally, the winners are fast facts, questions and the safety guide. These three prototypes all do better than control on side effect communication for both indications.

The most exciting phrase to hear in science is the one that heralds new discovery -- it is not "Eureka", but "that's funny." In that light, I believe that this data shows that. If we keep it simple, but effective with an eye on safety, but the ability to effectively communicate in a way that patients/consumers can understand, we can achieve our goals of making sure that side effects, risks, indications and all of the information is communicated. But we must speak the language of the patient.

Thank you.

MR. ABRAMS: Thank you, Dr. Allison-Ottey. We will open it up to questions at this point from the FDA Panel.

Dr. Aikin?

MS. AIKIN: Thank you for your

presentation. It was very interesting. I do have a question for you. You mentioned that the new versions of the ads scored no worse in terms of motivation than the control ad, whereas I would have expected an ad or rather a brief summary that's more accessible to score better in terms of motivation.

Do you have any insight as to why it didn't score any better?

MS. ALLISON-OTTEY: Well, in some areas, it actually did score better. But I think -- remember, the front of the ad stays the same. And is it that the front of the ad is the motivator? And then on the back you have information that talks about side effects and risks and those things and I think there's a balance in that.

MS. AIKIN: So were you simply -- were they simply measuring motivation in terms of motivation to read the front of the ad?

MS. ALLISON-OTTEY: It was motivation to speak to the physician; motivation to not speak to the physician; motivation to dial a 1-800 number. So it was the motivation to take action.

MS. AIKIN: Okay, thank you.

MR. ABRAMS: Dr. Temple?

DR. TEMPLE: One of your formats, if I can

remember the name, is empowerment?

MS. ALLISON-OTTEY: Yes.

DR. TEMPLE: If I understand you, that didn't make any special effort to communicate side effects. It really, to some extent, has a different purpose. It's about why you might want to use the drug. So I take it you don't think that its failure to communicate side effects is either here nor there, as to whether that might be a useful thing to do. It seems to have a different function.

MS. ALLISON-OTTEY: It does have a different function, but side effects were noted. And so it actually did not fare any worse than the current brief summary on communicating those side effects.

DR. TEMPLE: So telling people about the disease didn't help them understand side effects, particularly, but one might not have expected it to. Okay.

DR. TEMPLE: Dr. Ostrove?

MS. OSTROVE: And if you don't have the information with you, I certainly understand. You said that one of the affects that you asked about according to this was whether the ad or the information was scary or frightening. Can you say anything about the results of those?

MS. ALLISON-OTTEY: I think because of the ambiguity, we took out some of that information because how is that interpreted? And so I'd rather send you something on that. I'm not prepared to really comment.

MS. OSTROVE: That would be great, thank you.

MR. ABRAMS: Dr. Behrman.

MS. BEHRMAN: This may be along the lines of what Nancy was asking about, but when you say risk communication and motivation are not incompatible, are you essentially trying to address the question of whether the risk information in the ad discourages people from seeking -- seeing a physician or seeking help from addressing the matter. Was that what that point was trying to get at?

MS. ALLISON-OTTEY: Yes, exactly.

MR. ABRAMS: A question. Will you be submitting to the docket this detailed information? I know you were only given a short time.

MS. ALLISON-OTTEY: We certainly can.

MR. ABRAMS: We would appreciate that. Okay, Dr. Allison-Ottey, we appreciate that. Dr. Allison-Ottey is from the COSHAR Foundation.

Our next speaker is Ruth Day from Duke

University.

MS. DAY: Good morning. The topic is comprehension of benefits versus risks, is their fair balance in DTC? First question, how do people understand risk information? The answer is with great difficulty. There are a lot of reasons for this, including heavy information load, complex technical information and so forth, but today we're going to focus on cognitive inaccessibility. Cognitive accessibility is the ease with which people can find, understand, remember and use drug information and hopefully in a safe and effective manner. Cognitive inaccessibility occurs when people have trouble with any of these processes.

In our research lab, we study a wide variety of types of information about drugs. Today, I'll be focusing on TV ads for prescription drugs and their implications for print ads as well.

The basic approach in our research is to perform cognitive analyses on the materials first. We obtain quantitative measures. We calculate cognitive accessibility and compare it for both benefits versus risks. Then we develop enhanced displays of the same information based on cognitive principles and then perform cognitive experiments in the laboratory to

test the effects on attention, comprehension, memory, problem solving, decision making behavior and ultimately health outcomes.

All of this is based on a variety of cognitive principles, some of which I'll discuss today. So let's consider some TV ads.

This research spans a wide range from the Year 2000 to 2005 and let's see what a typical experiment is like. People will see an ad or three ads and then we will test them on benefits versus risks and one type of question is what is it for, the indication. And as you can see, people typically do quite well on this type of question. Generally, about 80 percent correct across a variety of different ads. However, when you ask what are the side effects, they have great difficulty, only about 20 percent overall. So those are the averages over various drugs. About 80 percent for things in the benefits category; about 20 percent in the risks category, especially the side effects.

So we might ask why is this so hard? And there are many answers and let's start by looking at an actual script of what is said during an ad. One factor is readability. Now readability is not the same thing as comprehensibility. However, it's easy

to measure and has predicted value and therefore we use it as a quick proxy for comprehensibility. In the 2001 sample, here were the ads that we looked at. And we plotted what grade level people would need in order to understand the benefits versus the side effects. For benefits, it was slightly over the sixth grade level. Side effects, ninth grade level. And as you can see, this is a good three grade levels higher.

In 2005, has anything changed? Here are the ads we looked at most recently. And readability still is showing the same pattern, but now there's only a two grade level difference involved here. And by the way, side effects are comparable to all risks in general when you combine them together. So these are averages across many different drug ads. Let's now look at each individual drug ad. In order to do this, we're going to compute a different score. The readability level for benefits minus side effects. If there's no difference, the results will be around this red line. And then we're going to plot grade levels in addition that would be needed if benefits are harder or side effects would be harder to understand and there are the results. As you can see, most of them are towards the side effects harder range.

Is this fair balance? I think we'd have

to say no and what can we do about this? Well, we can set some criteria. For example, we can decide that plus or minus two grade levels is not very good or one grade level, etcetera, but at least we have a quantitative way to measure benefits versus risks.

Let's consider the location of the information. Here's a speaker time line for the drug ad for Allegra. You'll see yellow blocks here indicating that someone was speaking and the straight lines means that nobody was. So the first block says" it's allergy season or Allegra season." The next, "enjoy your world with nondrowsy Allegra for people 12 and older" and then a longer block.

Notice that the principle of chunking is observed for the first two blocks, that is to say put together what goes together and separate it from everything else. But once the side effects are uttered, there is no chunking after it. More information just keeps coming which makes it hard to mentally digest that information.

Another cognitive principle is called the Serial Position Effect. When we see or hear a list of items and then have to report them, we do better at the beginning and the end of the last and have trouble in the middle. So performance is best in the middle

of the list and a little bit to the right.

What about the location of side effects? And the 30 second ads they were in the middle and a little bit to the right. Forty-five second ads, 60 seconds in the middle and a little bit to the right. That was in 2001. Clearly, unfavorable location was being used to place the side effects. What that was then, this is now. Let's take a look. Now we're plotting the same information, but now we put the different durations of ads all into the same metric and look at the percent of elapsed time, of total time, when the side effects occur and there you can see where they are. They're between 60 to 85 percent of elapsed time and all risks between 50 and 85, generally speaking, of total elapsed time. Again, still unfavorable location today.

But you might say what does -- what effect does location have on cognition? We need to have some evidence. So therefore, we've produced a new TV ad for a hypothetical drug called FluAide and the structure and content is like that of typical ads. The purpose is to vary specific factors and observe the effects on cognition. So let's look at the first experiment in this series, just the part where we ask what were the side effects. There were many other

experiments we do within this.

On a random basis, half the people heard the side effects in a more favorable location versus the unfavorable location. Its exact same visual and auditory displays, they differ only in the location of the side effects. We plot percent correct and we get the typical results for the unfavorable location and a nice increase for the favorable location, about 100 percent increase in people's knowledge of the side effects.

There is still some people unable to report any side effects at all, but as you can see, nearly all of them are in the unfavorable condition and this is an 800 percent difference.

Speed is important as well. We can plot speed by the number of syllables per second, as different portions of the ad are presented. Now let's compare benefits versus side effects for two drugs for the same indication. For Ambian, you can see that the side effects went much faster than the benefits. And for Lunesta about the same. Focusing just on the side effects, there is a big difference between these two ads and you might say so what? So the question is does speed affect accuracy? And the answer is you bet.

So fast talk leads to lower knowledge. Slower or normal talking speed leads to higher knowledge. Another principle is about divided attention and for this I will ask for some help from the Nasonex bee, a very charming character. And in these drug ads, the bee flies around. For the side effects, he's flying most of the time around this window. Watch his wings. I don't have time to show you the video, so I'm going to simulate just a portion. Fix your eyes on the wings and let's see what happens. All right, his wings are moving around quite a bit during the side effects. During the benefits, at the end of the ad, his wings are not going and in fact, he doesn't have any wings at all. So we can now plot number of wing flaps per second for benefits versus side effects and that's what we get, clearly more during the side effects.

There is also an effect we can only describe as wing flashes, where there may be flashes from other parts of the body, but definitely when the bee faces forward, there's some flashing effect here. Now this may be a graphic artifact which I can describe during the discussion, if you're interested, but clearly more of it goes on during the side effects than the benefits. So the effect of all these wing

flaps and wing flashes and all these sparkly things happening is to divide the viewers' attention, watching these things rather than diverting attention to the processing of the -- all of the different side effects. This leads to decreased knowledge and their comments that people say where they tell us there weren't any side effects. And people actually argue with us, there weren't any side effects and we have to show it to them again in order to convince them that there were.

There are a variety of speaker effects in the typical ads. The side effects are spoken by a narrator, a voice offscreen, but there are some new approaches. For example, in this ad, the wife begins talking about the side effects. The husband chimes in and they talk back and forth about it. So we have chunking, personalization and positive affect, feeling positive about this by the way they look. This does lead to increased knowledge, acceptance and comments that well, these people seem okay with the side effects. They must not be too bad.

Another example from Ortho Evra where a doctor will mention there are risks. The patient says "oh, how do I know I'm one of the people involved?" And then the doctor answers. So again, there's

chunking, personalization and notice how the appearance of the patient changes from being very attentive to having been afterwards being satisfied with positive affect. Again, this leads to increased knowledge, attentiveness and acceptance.

So why is it hard to get the risks? There are many, many factors involved. I've just shown a few. Let's move to conclusions.

There is currently a clear unfair balance in cognitive accessibility of benefits versus risks in these ads, weighted towards the benefits side. So risk information is there. It's physically present, but it's functionally absent. Physically present, but functionally absent.

Before we have a rush to judgment, however, we must beware and compare. We get similar results from the ones I've showed you today, in various other types of drug information, for medication guides to the professional label. Risk information is less accurate than benefit information, excuse me, less accessible. Risk performance is worse, but most importantly, risk performance increases with enhanced cognitive accessibility.

Recommendations. To regulate or not to regulate, that is the question on many minds today.

Whether 'tis nobler in the mind to suffer the slings and arrows of inaccessible risks or to take arms against the sea of troubles and by opposing in them and with apologies to William Shakespeare. Should there be an end to DTC? There are many pros and many cons and this research clearly shows that there's an unfair balance of benefits versus risks, but it can be improved. Better balance leads to improved performance in perception, comprehension and memory for risks. So I'm arguing for an evidence-based approach for industry and regulatory sectors.

Sure, it's great to have a positive treatment for benefits, but let's do that for risks as well, so we'll be in fair balance.

In conclusion, risks generally go like this, up over the head. We can get them into people's heads so they understand and the way to do that is to increase cognitive accessibility.

Thank you very much.

MR. ABRAMS: Thank you. You talked about a concept of chunking and that seemed to be quite beneficial as far as more effectively communicating information that you want to convey. But it's not being done often with certain information.

Any downside into chunking that you can

think of, or more generally, any obstacles for people not being able to do this or wanting to do it?

MS. DAY: I see no obstacles for doing it. First of all, don't use speech compression. There are sampling techniques where you can acoustically take out parts of an utterance and you can still understand what it says, but it goes very fast and so on. I see no downsides to chunking. I suppose industry might think well, when you chunk and pause, put pauses in, that takes away from time from the total ad, but I think there's ample time in a 60-second ad to get everything in that's appropriate.

MR. ABRAMS: Dr. Temple?

DR. TEMPLE: Could you explain chunking?

MS. DAY: Chunking is the following: if I give you a long list of information, let's take something very simple, like a list of digits and I say 8, 5, 3, 4, 3, 2, 6, 1, 9, 7. These are typical laboratory experiments and ask people what were those numbers, people have difficulty remembering them. However, if I presented them in this way, 8, 5, 4 -- 3, 2, 6 -- 1, 9, 7, performance goes up dramatically. So chunking is partly the clustering of like information, not sprinkling it around in different places, putting it together and then separating it

from the surrounding information. This can be done in time, when it is spoken. It can be done in space when it is written and this principle got started in the 1950s by George Miller and it's been replicated and found hundreds of times in the research literature with various types of material.

DR. TEMPLE: One other question. I understand why speeding up would give you adverse effects. One of the most important features though was location and I guess I ask we have some sense that telling why you take a drug, so it automatically comes first and you can't do anything unless you do that. So is there some problem in this that you always are going to hear somebody say I should take it first and what do you do about it?

MS. DAY: Well, I did go into detail about where we placed the side effects with a favorable condition, but there is ample time to either give the indication and/or say what the product name is before going into the side effects. So you don't just start out with side effects or adverse effects, that would be ridiculous. Why would people listen to the rest of it? But there is ample time within the time course of a 60-second ad and even in briefer ads as well.

Dr. Gottlieb?

MR. GOTTLIEB: Thank you. I enjoyed your presentation. You mentioned the difference between the grade level, the comprehension needed to understand the risks versus the benefits of the medication. Can you explain a little bit why -- is there something inherent in the risk versus the side effect information itself?

MS. DAY: Yes and no. If what you do is put the side effects in a really long sentence, and if any words in it are technical, then you will get a boost in your readability score. Readability scores have pros and cons. They're easy to calculate. There are a variety of different measures. They really only take into account the frequency of the words in the language, whether they're high or low frequency or high or low commonality and overall length.

However, there are people, when they write, say medication guides or other kinds of things, struggle to get the readability level in the sixth to eighth grade range. You can do that, but you can still have the information hard to understand. There's ways to kind of cheat around it. And so if you say for the side effects, one big long sentence is automatically going to come up as a higher readability, but there are ways to even make the

sentence shorter and still have it difficult to understand as well.

So in other presentations I've talked about what the real measures of comprehensibility should be, like the number of prepositions per sentence, cohesion, syntactic complexity and so forth. So there are ways to present all risk information and have the readability and hence, comprehensibility be comparable to benefits. That's used typically for benefits.

MR. ABRAMS: Dr. Ostrove?

MS. OSTROVE: You've apparently done a lot of studies. Typically, can you give us a sense of how long it takes to do one of these cognitive studies that you're reporting on?

MS. DAY: Yes. It depends on if you test one on one or in a group situation. These are carefully controlled studies where study time is fixed, based on pilot study or we let people take as long as they want and then we time how long that is and so forth.

But one of the studies I presented today was completed, it took time to design, prepare the materials and so forth, but it was collected in two days. And that was because we had small groups of

people or medium sized people in a room at the same time where they can't see what each other is doing and an experimenter and an experienced experimenter administers the test and the testing phase and there's much more than I showed here today. There's a perception and attention and comprehension and memory components, but everything can be collected within a half an hour, including instructions and the briefing, telling them what it's about and getting their feedback.

MR. ABRAMS: Dr. Aikin.

MS. AIKIN: I think you've made a really good attempt to quantify fair balance which is something that we struggle with a lot.

Have you asked your subjects or your participants whether they think the ads are fairly balanced? Not just in terms of benefits and risks, separately, but overall?

MS. DAY: Not in a formal way. I don't think they understand the concept. I have asked it informally sometimes. So do you think this is a balanced ad and they get this kind of deer in the headlights look and say what do you mean? And then I'll say, well, did you get the benefits and the risks equally well? And you get a wide variety of responses

and I don't have enough formally collected to comment thoroughly, but some people have the attitude, well, those side effects, they just have to throw those in as if there's just some requirement and they don't need to pay much attention to them.

Sometimes they say oh, there were side effects? Or they talk about other things. I don't think they quite get that concept and that's why I like some of these newer ads where they're directly -- the adverse events are directly shown by the patients interacting with each other or with a physician or somebody else, or speaking them. Have a patient talk about the side effects and look like he or she is accepting them and knowing about it anyway, I think is quite remarkable. But I will follow up on that, Dr. Aikin.

MR. ABRAMS: To FDA sitting on a panel, it doesn't seem to be a real difficult concept to understand your need to have balance, risk information is real, real important.

Do you have any suggestion for FDA how we can better convey this concept so people can understand it?

MS. DAY: Well, of course, this would be in some guidance to be developed, I guess. I would

show what the consequences are of having an unfair balance in the cognitive accessibility of the information. I think generally most of us when we hear fair balance, we mean what is the information in the ad? Are there the benefits and are there the risks? And then what I would do is say hey, the risks can be there, but they can be functionally absent. That is to say, you could put them in the least favorable location. You can put other sparkly things going on so people won't listen to them. You can do X, Y and Z and so forth, and they're going to functionally absent.

So whatever you're doing to enhance the benefits, do that also to enhance the risks so we will then have good, cognitive accessibility and be in fair balance on that.

MR. ABRAMS: Dr. Day, thank you.

MS. DAY: Thank you.

MR. ABRAMS: I have a request for all the speakers and anybody else who has done research in this area, to submit to the docket, to make it publicly available if you're comfortable doing so. FDA is a data-driven agency, obviously, and we like data. We use data to drive our policy development. So any data you have, please submit if you're

comfortable doing so, to the docket to all parties, so public and the Agency can have access to it.

Our next speaker is Lewis Glinert from Dartmouth College.

MR. GLINERT: My submission today is a response in a spirit of linguistics and communication science to the FDA's repeated calls for hard research on the communicative workings of televised drug advertising.

Among the public's main -- many concerns about televised drug advertising, the provision of risk information stands out, as we know. How do we get people to act on risk information is, of course, a communications according to the Holy Grail. But when people don't even believe they're being adequately warned as FDA research of 2002 and Prevention Magazine's 1998 survey brought out so clearly, you have a problem of an entire different order.

Research of Louis Morris and others in the 1980s on the formatting of ads whether the position of risk information, whether it should be visual or audio or both, how much of it there should be was used by FDA, rightly or wrongly, to justify the type of ads we watch today. However, the fair balance between benefit and risk information enshrined in FDA guidance

has neither been rigorously operationalized nor empirically demonstrated. No practical procedure exists for easily judging fair balance, nor for proving it holistically although they have made many strides towards this goal. As a result, FDA has found itself reacting to events rather than guiding them.

My submission today relies in part on collaboration with John Schommer, Professor of Pharmaceutical Care and Health Systems at the University of Minnesota, who unfortunately cannot be here today. We are engaged in revisiting the key issue of the formatting of TV ads and its communicative effect which leads us to question some of the working assumptions in common drug advertising regulations.

In a recent paper, advertisement format and the provision of risk information about prescription drug products, we examined ways to include the required risk messages in TV prescription drug ads. We took two ads, one for lower-risk and one for higher-risk medication and using male and female voice over artists, we produced two alternative male and female versions of the ads with the risk information shifted to the end and supplemented by a risk messaging caption.

For the higher-risk medication, we found that placing the risk information at the end of the ad, with captions, had the following effects: (1) it significantly improved the students' short-term memory of general and specific side effect information, but without the medication appearing to be more risky. Two, it created the perception that the advertisement was more informative. Three, it produced feelings of distraction. Four, it produced feelings of information overload such as bewilderment and finding it hard to follow. However, little effect was found with the advertisement for the lower risk medication and medication being taken by many of the students, perhaps because they simply didn't care to pay much attention to the risk message.

On the other hand, the female voice over had considerably more effect than the male voice over which intrigued us. At the moment, we cannot be sure why.

While our experiment was restricted to a group of first-year pharmacy students, most of them female, we believe that it points the ways of improving risk information in drug advertising. We hope to extend our work to a broader population.

In addition, and in our view of great

importance, there is an urgent need to study the response of the elderly, the semi-literate and other vulnerable groups. The elderly, for example, have been shown to have difficulty with rapid or disorganized text and with elaborate inferencing. And even at the best of times, TV ads, like any spoken message, cannot offer the viewer the same opportunity for scrutiny as the printed ad can.

In clinical studies of communication, whether they're surveys or focus groups or experimental manipulations, are notoriously difficult and expensive to construct. Often the setting is artificial. Nor do they easily robust or general conclusions. If we are to conduct the kind of case by case studies that Morris pinpointed in the major review published in 1998, one of the most promising and practical avenues is linguistics and discourse analysis.

Linguistics studies linguistic structures, sounds, words, syntax and the meaning they create. Discourage analysis opens the lens still further to look for patterns in whole specters of text and to see how they relate to the situation through the speakers and addressees, how they relate socially, what they are doing culturally and what other systems of

communication are being used, visuals, body language and so on. Discourse analysis, in other words, is holistic.

Linguistics and discourse analysis are not in and of themselves a way of empirically predicting quite how readers or listeners will understand the text. But they can call upon massive databases of verbal behavior and on the analyst's own well-honed intuitions, in order to anticipate what a text might mean.

Equally important, however, discourage analysis alerts us to a complex and often daunting web of meaning. Behind the disembodied semantics of a sentence is what is called pragmatics. The use we make of the sentence in context, the associations in a phrase like "ask your doctor" -- ask has more than one meaning. The tone of voice, the suggestivities, the strategic ambiguities including all kinds of innuendoes for which we would not be wished to be held strictly accountable.

All of this is part of language and so when a trial (9:58:21) assesses what something means to the ordinary man or woman, something of this web of meaning and pragmatics will generally be taken into account, but not enough. It takes trained analysts to

disentangle such meanings and then to point the way to empirical investigation of key phenomena.

The two most challenging and sophisticated types of text for analysis of meaning are the poem and the advertisement. Few of us often portray advertising as being either informational or persuasive. However, discourage analysis sees advertising based differently. Consumers should not expect to find any logic in an ad. Guy Cook, in his book, The Discourse of Advertising, has argued that an intrinsic playfulness and creativity in advertising is inherently playing with words. And extraordinary creativity constantly seeking to surprise and to reinvent the rules of the game.

We now face this in a particularly potent form. The post-modern ironic or retro advertising where the words are becoming less and less important and the image is saying it all, the consumer will try to play along to various degrees.

What then of literalism, the popular belief that a sentence has a literal meaning, quite independent from its implied meaning? This belief in literalism is inconsonant with the way ordinary people actually understand language. With far reaching implications of a study of advertising, in the words

of Dwight Ollinger, the president of the Language Society of America, the most insidious of all concepts of truth is that in literalness. Advertising capitalizes on the legal protection that it affords.

I'm sorry, I'm having a little problem here. I'm a Mac person, not a PC.

(Laughter.)

An example of what linguistic and discourse analysis can bring to the evaluation of drug ads, I micro-analyzed the text and visuals of several ads using linguistic and discourage analytic procedures. My research questioned what the ad was seeking to do, how the wording and visual patterns related, and what messages a viewer was likely to derive.

Here are the main findings. One, functionally, the advertisements were a bewildering blend of promotion, information and aesthetics or entertainment with many touches of post-modernist irony. One celebrated campaign made a point of mixing science with science fiction in its ads. Or again, what does the viewer make of a finale, delivering a final punch, but distorting some of the key medical information delivered elsewhere in the ad. Is the outcome a cognitive dissonance or will viewers perhaps

draw upon the entire message in reaching that conclusion and take this finale as merely a total flourish. And this is the kind of finale in breach of FDA guidance of fair balance.

Two, risk messages frequently competed with upbeat music and visuals and with these words of course, having to process the warning caption "your results may vary" together with an image of a beaming woman and a quick line of string of superlatives, the average viewer may well not consider the possibility that for many people the effect may be less than a complete cure.

Three, we found intense switching and fusing of styles and here, the cognitive and persuasive effect of this on people of a non-American cultural background needs to be investigated urgently.

Four, strategic and linguistic ambivalence was frequently used and thus running through testimonials for an asthma medication was a tension between absolute and relative claims of efficacy. Three of the testimonials were cautiously couched, gets out more, fewer symptoms. Doesn't have to use his reserve inhaler as often. More nights of restful sleep. Fewer asthma symptoms. However, the fourth testimonial and the epilogue had an absolute ring, for

day and for night, control of asthma symptoms. This can be construed as a very small claim, toned down, maybe by helps control, helps control asthma symptoms, but it ends all day and all night. Again, sweeping connotations.

Fifth, there was much variation and ambivalence after the source of authority and the identity of the addressee. For example, the traditional advertising distinction between personal and impersonal was sometimes ostentatiously flouted. These results point to textual features that preserve experimental or other empirical studies. I would stress that one of the central issues in analyzing a text in the communications terms is the relative impact of its component elements.

Are we to consider the whole text in toto? It is the nature of this kind of qualitative micro-analysis to focus on the limited group of texts and study them as organic wholes. Undoubtedly, large scale studies are needed, using teams of analysts and the results could then be compared with survey and focus group responses.

Complex as it is, discourse analysis holds out promise of providing a useful rapid evaluation of advertising requiring either prior or post-factual

approval. More generally, it can contribute to our general understanding of how TV advertisements convey meaning with respect to drug benefits and risks with implications that advertisers, regulators and patient education.

Thank you.

MR. ABRAMS: Thank you for your presentation. Questions form the panel?

Dr. Behrman.

MS. BEHRMAN: Thank you. You touched on two things that we struggle with a lot internally and maybe you could help us think about how to approach them or whether there are more data that will help us. The first thing was cognitive dissonance which, if I understand what you're saying, is distinct from or broader than simply distraction.

And the second, you didn't use quite these words, had to do with whether disclaimers can ever correct a mis-impression or a strong impression. And in both cases, we struggle with how to quantify the impact and how to balance those.

Do you have any comments on those two subjects? I think they're somewhat related.

MR. GLINERT: As I've said, linguistics is a companion to empirical and quantitative studies of

cognition. They're all within linguistics. Many very sophisticated quantitative and qualitative techniques, for example, in cognitive semantics and in the study of gigantic databases.

In general, I would say that countless thinking in linguistics is that language acts as a cue for meaning. We can't find meaning located intrinsically in text. It depends crucially on what the reader chooses to focus on and therefore the job of the linguist is to analyze the actual structures and to point to where the public dissonance is like to arise and should be examined.

Ultimately though I'd say that there is a phenomenal variance between different speakers, different listeners, different social settings, different genres. The very question of whether a viewer things they are being entertained or being informed is critical and I guess they got many people from non-American culture backgrounds might be more liable to listen and pay attention to a text that is written actually in a very academic and let's say less comprehensible style because then the mark of an authority is to speak in difficult terms. This does raise a whole slew of questions.

MR. ABRAMS: Dr. Temple?

DR. TEMPLE: Two things. At the beginning of your talk, you noted one thing and I want to see whether this is (inaudible- speaking from un-miked location). He had done a time course of comprehensibility that (inaudible- SFUL) material at the end. Do you think that's what your initial finding was? (inaudible- SFUL)

So it's the middle that's the worse. The end and the beginning might be better.

MR. GLINERT: I don't see any incompatibility between Dr. Day's findings. We were looking specifically of what happens if you take the materials and show them at the end. And one thing in the back of our mind which still requires a lot of study is whether it's part of the cognitive schema of someone seeking information to look for it, put let's say soberly and in a very organized fashion at the end.

In other words, what are different types of viewers really expecting when they watch a TV ad? So we have some great fundamental questions and clearly a whole range of different studies need to be performed.

DR. TEMPLE: My second question is you've noted a wide variety of linguistic tricks and

properties and so on. Have you gotten yet to the point of trying to study variations on these things and how they actually communicate particular information or is that sort of the next step?

MR. GLINERT: That is one of our goals. There will be a fair amount of information about the particular need area of ergonomics and human factors. For example, Michael Vogelsberg at the University of, I think it's South Carolina, has found that many studies looking at the effect of particular description terms. So, for example, he found that a product, a food product, that says "no fat" was understood as having less fat than a food product that claimed "fat free". That's the kind of stuff that can sen regulators into a tailspin. But, as I say, a substantial amount of study of these individual items has been conducted, and it does lead to very serious concerns.

DR. TEMPLE: It would, in the end, though be of interest to take an ad that has many of these properties, you know, witticisms that get into the way and all that stuff and see if you could amend the ad in a series of steps to make it function better.

MR. GLINERT: Yes, yes. I would start with that beautiful expression "ask your doctor".

DR. TEMPLE: That's right. So we need an alternative to that --

MR. GLINERT: Maybe.

DR. TEMPLE: So, we'll think about it.

MR. ABRAMS: Dr. Gottlieb?

MR. GOTTLIEB: Thanks a lot. You talk about doing linguistic testing to see if cognitive dissonance arises while, when people are viewing the ads. What's the extent of that kind of testing, how long does it take, how many people do you need to survey to see a reliable answer from that?

MR. GLINERT: In a sense, it really is a question of what kind of social populations we want to examine. It's a fairly simple matter to take a set of students, put them in front of a TV ad and then administer a questionnaire or whatever. But if you're looking to explore how things work in a natural context, then you've got some very difficult work to do. Again, if you're looking to, as we hope, to see how the semi-literate and other vulnerable populations respond to these things, I think we, one could replicate these experiments fairly quickly. But I think the question is how much of a range of experiments we want to do.

MR. ABRAMS: Okay, and final question is

from Ms. Davis.

MS. DAVIS: When you were studying the format in the provision of risk information and you were moving that to the end, did that also alter such things like the competition from background music and the visuals in your test ad, or where what people were seeing otherwise the same -- it was just the location in the voice-over and there was text?

MR. GLINERT: We went to great lengths to keep absolutely everything the same. We had to go out and find the right music to put it back in, and, yes, we did everything was the same.

MR. ABRAMS: Doctor Glinert, thank you very much for your presentation and responses.

Our next speaker is John Kamp, from Coalition for Health Care Communications.

MR. KAMP: Good morning. Thank you very much.

On behalf of the Coalition for Health Care Communication we thank you for the opportunity to present our views. I'm going to try to save a lot of time here by summarizing our longer material which we're going to put in the record. So, I'm just going to outline a few points that we think are very important, and then end with a major question.

First, we want to know that the advantages and the perceived disadvantages of DTC, despite all that, we're convinced that DTC is here to stay. There's no scary Halloween scenario around DTC. DTC research demonstrates that DTC helps patients become aware of new drug options. It stimulates conversations with doctors. It leads to better prescribing. And it improves patient compliance with their drug regimen. FDA itself has been on the leading edge of much of this research, and we're pleased that several witnesses today are talking more about new research in this area. New research needs to continue to be done.

We note, however, that some of the most important issues around consumer communication -- namely, the best way to improve health literacy, to increase patient compliance, and to communicate the safety information -- all of these are still not really well understood. And we must be very careful as we change regulation not to create a problem.

Our current scheme of DTC advertising is not broken, so let's be very careful as we tinker with it not to fix it in ways that move us backwards. Some proposed fixes that we're hearing about DTC would do just that. Here's one. Because some drugs are not

completely safe, and some might have hidden safety issues, DTC must go. It's a non sequitur. Cars, like drugs, are sometimes recalled for safety reasons. Cars, like drugs, can kill if not used as directed. And even when used as directed, cars, like drugs, have latent unknown and sometimes deadly safety issues.

It makes no more sense to ban advertising in response to drug recalls than it would to ban car advertising in response to brake recalls.

And let's not fall into the seemingly sensible cause for a rigid 1-, 2- or 3-year moratorium on drug ads, somewhat like a phase IV clinical trial.

Such schemes undermine the very integrity of the drug approval process by the FDA and they need to be rejected outright.

At the same time, we applaud the PhRMA principles on DTC. For example, we think it was appropriate for PhRMA to give caregivers much more time to be educated about the drugs before the launch of DTC. These flexible programs enable companies to balance the needs of professionals and consumers, but still speed innovative drugs to patients. But a rigid rule here could inhibit the public health. We all contemplate -- as we all contemplate the possible horrors from an avian flu pandemic, neither the FDA

nor the industry should face a well-meaning moratorium that would prohibit consumer information on a new vaccine that was urgently needed throughout the population.

Moving on, the FDA staff are becoming increasingly sophisticated about consumer behavior and consumer understanding the messages. Then-Commissioner McClellan stated it most succinctly last year when announcing the brief summary proposals. He said "we have learned that often, more is less in consumer advertising." Consumers can only really take away one, maybe two, at the most three, ideas from an ad.

But while not fundamentally broken, it's time for the FDA to do a systematic review of its consumer advertising policies. DTC is the most regulated form of advertising in America and the replete and the very complicated requirements often serve to confuse more than enlighten. Wayne Pines, well known to all of you, may have said it best in a recent FDLI update: "It's time for the FDA to recognize, and to incorporate into its regulatory approach, the view that DTC advertising is not just a derivative of physician advertising. Simply put, what a physician needs to know in deciding whether to

prescribe a drug and how to advise the patient when it's prescribed is different from what a consumer needs to know in an ad."

That's a problem.

We also recognize and praise the FDA for the recent strides that it's made on the brief summary and the risk information material that enable us to make those messages more consumer-friendly. But the FDA should eliminate the immense subjectivity of FDA advertising policy. For, as Wayne Pines also said in that article, "there's no way for any company or advertising agency to anticipate all the issues that a collective DDMAC review might identify.

It's a problem, especially for the FDA itself in these days when more and more DTC ads are going to be submitted for pre-review. An advertising agency and its clients must fully be able to understand the rules and confidently develop ads that are correct before they're submitted.

Ron Pintello, CEO of Euro RSCG Health and head of the AAAA Medical Advertising Committee, may have said it best when he noted that it's really a problem also now of consumer understanding, quote, because it's impossible to predict how the FDA staff will react to certain creative executions, even those

that are only slight variations of previously-approved ads, our advertising, our drug company clients are responding by becoming increasingly more conservative. As a result, it's almost impossible to create a compelling advertising message that a consumer can understand.

The FDA also has to rethink its advertising approach for another reason. It's no secret that the FDA's reputation and jurisdiction is under attack. As we've discussed with the General Counsel, one of the drug advertising regulators are seeking to whittle away the FDA's primacy in this area through a multiple Federal and state pieces of legislation and state enforcement actions under all types of consumer protection and false claims actions.

Meanwhile, private class-action attorneys are getting into the fray by using marketing theories in their high-profile product liability cases. The FDA must develop clear, effective policies that demonstrate their policy understanding and leadership in this area, and demand legislative and judicial deference.

American citizens simply do not need multiple sets of drug marketing regulations. They need one that makes sense, that works and is

vigorously enforced by the FDA and only by the FDA.

Especially noteworthy -- oh, one final point, it to express our concern about the so-called voluntary constraints on DTC and other marketing that are increasingly part of the drug-approval process. Especially noteworthy is the FDA's approval this last summer of the drug Symlin, by Amylin. Similar, but less extensive limits, have been imposed on other drugs and more are expected.

Our question: how do the Coalition and the public appropriately participate in these very important decisions? We have asked to participate in the December hearings on communicating drug safety issues, but we worry that these vital decisions will continually be made out of the public view. Importantly, we recognize that the marketing conditions on drug approval are only nominally voluntary. Much like I volunteered to go to Vietnam once the draft notice was in the mail.

Decisions to ban DTC, to ban professional advertising for two years, and to ban marketing only to a limited number of physicians are not private decisions. They are profound public policy decisions and they are matters subject to judicial review under the Administrative Procedures Act and the first

amendment. These mandates require good evidence, public transparency, critical reasoning, tough and objective standards and good common sense. And the burden of proof on all of these is on the FDA. Limits on Symilin marketing may or may not be appropriate. We don't know. The public was not there.

On a personal note, I'm a diabetic, and a possible candidate for Symilin. Perhaps it's the most important breakthrough in the treatment of diabetes since the development of insulin in the last century. I'm startled that FDA accepted as a condition of approval the idea that not only I must not know about this drug, neither must my primary care physician. My doctor disagrees with the FDA.

Indeed, without a clear public record on these restrictions, they reflect a kind of paternalism that I think is unsuited in our culture and contrary to the basic idea that educated physicians and educated consumers make better healthcare decisions.

So, again, our closing question, how does the coalition and the public participate in these vital decisions about healthcare communications.

Thank you for the opportunity. I am delighted at the new research that we're hearing about today at this meeting.

MR. ABRAMS: Doctor Aikin?

MS. AIKIN: Thank you. You brought up the Wayne Pines quote that DTC is not a derivative of position advertising. In fact, the requirements are different. Do you view this as an argument for separate DTC regulation?

MR. KAMP: Yes, I think so. I think you've cleared up exactly as Wayne said it. It's not a derivative of professional advertising. And what a professional needs to know to make a prescribing decision and what he or she needs to know to tell the patient about the side effects are simply not the same things that a patient usually needs to know.

MR. ABRAMS: Doctor Temple?

DR. TEMPLE: One of your pleas was for less subjectivity in reviewing ads. The alternative to subjectivity is usually rules, guidance that approaches rules but isn't a rule. Is that really what you'd like to see?

MR. KAMP: Yes. You raise a very good question. In fact, if this were an easy thing to do we wouldn't have to be here today, right? I don't think so. I worked both at the FTC and the FDA and I watched the FTC engage in many of these same activities. I fear in some way that the FDA as the

drug-approval process organization takes too much of the drug-approval process into the ad-approval process. And therefore, oftentimes it tells the advertiser exactly how to do it.

Instead, the FTC does it a different way. It essentially tells the advertiser that it's their problem to make sure that the ad is fully understood by consumers in the way it should be. So, instead of telling them exactly how to do it, and then advertising agencies are going to be very clever to follow those rules, but still get the message across in their own way.

The FTC does it another way, by essentially telling you you must know how consumers perceive this ad and it must not be in a false and misleading way.

DR. TEMPLE: So, that would mean, essentially, every ad would have to be comprehension-tested before it was put out. Is that --

MR. KAMP: It doesn't have to be, according to the FTC rules. But the advertiser is responsible for how consumers understand the ad, not the agency. So it keeps the agency out of sort of this little, sort of making all these little tiny decisions, telling for example, I mean, some of the

kinds of things and, you know, this in some ways is urban legend, so you know, whether it's true or not. One of the advertising agencies I work for has shown me two copies of an ad that used time clocks for it to demonstrate the passage of time. In one case, they used an analog clock, and the FDA said you can't do it that way, you have to reshoot it, we want a digital clock. And, so the agency said, okay, if that's what you want, that's what you get.

Whether or not that really made a difference to consumers we don't know.

MR. ABRAMS: Doctor Gottlieb?

MR. GOTTLIEB: You raise an interesting point, and I'm just curious how you would contemplate such a regime short of requiring companies to come in with copy testing on the advertising itself. Would you rely on competitive forces; maybe competitors would copy-test their other ads of other firms and bring it to the FDA for violation. How would you contemplate that regime working?

MR. KAMP: Well, as we all know, the FTC doesn't require or even encourage -- in fact, absolutely refuses to do prior approval. It doesn't absolutely require that everything be copy tested. But it relies on the fact that sophisticated marketers

and sophisticated advertising agencies know what they're doing and if a question arises later, it puts the responsibility on the advertiser that it did it right.

MR. ABRAMS: Doctor Behrman?

MS. BEHRMAN: I want to follow up on two thing you've said. One was your dismay, if you will, over some information about a new drug was not being rapidly made available through the DTC avenue, and I'm a little curious about what you think is the primary purpose of DTC advertising and then, if you could link that to what you think our primary role is. I gather it's to ensure that the advertisement not be false and misleading, but do you view DTC primarily as an informational tool, a promotional tool, I mean, how do you link those two?

MR. KAMP: Yes. Advertising for the most part is best used as an informational tool in this context to perhaps begin a conversation. To begin a conversation that a caregiver might have with a patient. To begin a conversation that a patient might have with a doctor. If you try to do much more than that, it gets very, very complicated and the messages get mixed.

The kinds of discussions that we've had

here this morning demonstrate to us that the more you try to do in the ad, sometimes, the less that can be learned. I think that we all in this society know even more than maybe we knew a year ago, but not drugs are not safe in all circumstances. They have to be done carefully. I think we're getting that message. I also think that the drug companies over the last year, especially the last six months, are doing a much better job than some of the ads that Ruth talked about today, about putting that safety information forward. And as she said, using patients to talk about the safety and side-effect information. I think that the industry now gets it much better than it did before, and I'm very pleased to see the kinds of changes in advertising we're seeing.

I'll also tell you from the front, from the advertising agency people that I'm talking to, that the companies are demanding different things from their advertising agency that they sometimes ask, demanded as few as six months ago. They now want ads that don't push the envelope on the benefit side, but are pushing the envelope on the full information side. But, again, to go back to your question. You can't ask for much. You can really only begin a conversation, get an idea in the head of the viewer

and reader and then begin what we hope is a conversation that leads to appropriate healthcare outcomes.

MR. ABRAMS: As a follow-up to that side conversation, you can't get too much risk information, so you should not try to put too much benefit information too? And, what's too much? Where would you kind of quantify that?

MR. KAMP: Well, it's sort of a one-level, one of the very question is one of the things that I think might be better for the FDA to avoid -- sort of that is to micro manage what has to be in and what's enough? How much is too much? If I knew how much was too much I wouldn't have an extra ten pounds on my body right now. I'd stop eating sooner. Those are very difficult, subjective and many times cases questions that I think you have to deal very carefully and I think sort of getting into some of the minutiae on here has actually caused the agency to get itself into some trouble.

MR. ABRAMS: Okay. Thank you Doctor Kamp. Our next speaker is Andrew Kleit from Pennsylvania State University.

MR. KLEIT: Good morning. I am Andrew Kleit, Professor of Energy and Environmental Economics

at the Pennsylvania State University. On behalf of my co-authors David Bradford, Paul Mietert and Steven Ornstein at the Medical University of South Carolina, I want to thank you for the opportunity to present some results from several of our recent research studies this morning. I note that we have a continuing research program on the issues of DTC advertising. Before we begin, I would like to take a moment to thank to Agency for Healthcare Research and Quality and the National Heart, Lung and Blood Institute, who supported our research. Of course, the views I'm going to express this morning are our own, and do not reflect those agencies' positions.

In August 1997, the FDA changed the rules surrounding broadcast DTC. Today, there's a clear divide among policy circles about the consequences of this change. Many groups assert that DTC advertising puts physicians under pressure to prescribe drugs unnecessarily. Other groups assert that DTC advertising can inform people about conditions they might not know they had, or about treatments they might not be aware existed, which would tend to improve healthcare. Obviously, it is important to evaluate these claims of each group to implement effective public policy.

There's now a growing body of research that's becoming available on DTC. Much of it assesses the opinions of the public or providers. My co-authors and I believe, however, that to more completely understand the effects of DTC advertising, we need to examine detailed patient-level data. The limited research that does exist of this sort is non-conclusive about the effects of advertising on economic efficiency. This research we want, the research we wish to discuss this morning is, we believe, precisely the sort that is required. Evaluations of detailed patient-level information using cases that allow us to say something directly about the effects of DTC ads on patient well-being.

There are certainly reasons to expect both positive and negative implications of DTC. Economists have discussed the potential for both. For example, researchers have asserted that DTC might move patients who are currently untreated to go see their physician and so become treated. Early work on this issue also suggests that there might be some positive impacts in terms of getting new drugs to penetrate markets more easily, which would promote innovation and better care.

On the negative side, economists have also

pointed out the potential of DTC for having anti-competitive effects by making patients less responsive to price changes or by helping incumbents maintain market share.

As mentioned above, we believe that our research can directly address some of the key issues raised and currently unanswered in research debates about the role of DTC. We have examined an important patient population, people with osteoarthritis. This is a widespread and debilitating disease. Drug therapy is one of the main approaches to alleviating pain and suffering.

Cox-2 inhibitors, one of the drug classes used for treating arthritis pain, has also been at the center of much of the public debate about DTC advertising lately. The two main Cox-2 inhibitors were Vioxx and Celebrex. And both of them were heavily advertised. As you well know, these drugs were also controversial because of the increased risk for serious cardiovascular side effects that are apparently associated with their use. Vioxx was withdrawn from the market in 2004 for this reason.

We believe that these drugs present an ideal opportunity to study the impact of DTC. They were heavily promoted. They were believed to have

potentially serious side-effects. But these side-effects were only widely discussed after the drugs were on the market and advertised. So, it we are able to see any positive welfare effects from DTC ads for this drug class, then that would suggest that policymakers would want to take greater care in broadly restricting this practice, at least without further careful study.

To conduct our study, we obtained data on patients from nearly 90 primary-care practices scattered across the United States. This data contains all the information one would normally find in clinical charts, including details of diagnoses, vital statistics and detailed prescription histories.

We pulled all the osteoarthritis patients out of this data, and examined how their prescribing patterns were correlated with national and local DTC ads spending over the 2000 to 2002 time period.

We also collected information on television advertising spending for Vioxx and Celebrex for each month in 75 media markets. Patients and physicians were linked to the closes media markets that were relevant to their location.

Our analysis consists of regression models which we used to explain three different dependent

variables. The first is the number of osteoarthritis patients who come into each physician practice each month. This is designed to tell us whether DTC advertising prompts patients to seek, whether the hypothesis that DTC advertising prompts patients to seek care is correct or not.

The second regression model explains the number of prescriptions for Vioxx and Celebrex the physician practices wrote each month. This tells us whether there is any change in prescribing overall once patients come to see their physicians.

Finally, the third regression model explains how long patients wait after they've been diagnosed with osteoarthritis before they start using either Vioxx or Celebrex. This last model is the most direct test of whether DTC ads improve or harm social welfare.

I will discuss this in detail in a moment.

Our first set of models, you had clear answers to questions of if patients responded to DTC ads by going to their doctor's office. We find that advertising promotes Vioxx and Celebrex increases the number of patients with osteoarthritis to get office visits each month. This effect is consistent across many ways of specifying our model, or measuring DTC

advertising level locally.

The second set of models indicates some interesting dynamics at the market level and are somewhat less easy to interpret. We find that the number of Vioxx prescriptions rose in communities in months where there was more advertising for Vioxx or Celebrex. In that sense, the ads had what we might call class-level effects. Advertising for any brand tended to increase the use of Vioxx. However, the results for Celebrex prescribing are different. Neither Vioxx nor Celebrex DTC spending seems to have had an effect on Celebrex prescribing. Again, these results are stable across our models.

However, there are other ways that DTC can be expected to affect prescribing use other than raw counts of the numbers of prescriptions written by each practices each month.

These two practice-based studies indicate that DTC advertising has an effect at the micro level. However, this leaves open the issue of whether these DTC-induced changes are good for patients or not. For that, we need a different level of analysis, and we need to conduct and analysis of patient decisions rather than practice-level change.

To explore this question, we collected

micro-patient level data and asked how long patients delayed before they started using Vioxx or Celebrex as daily therapy for their osteoarthritis symptoms. This is an important question because clinical guidelines suggest a number of steps that should be taken before patients start daily Cox-2 inhibitor therapy. For example, patients that try changes to their exercise and diet or should try less powerful, over-the-counter pain medicines. So, some delay in taking these drugs is optimal.

However, we also know that some patients were better candidates for using Vioxx or Celebrex. In particular, patients who have gastrointestinal side-effects from some pain medications are more likely to benefit from the special nature of Cox-2 inhibitors. If DTC ads provide real information, they would encourage these patients to adopt Vioxx and Celebrex sooner. We can identify which patients fall into this class.

In contrast, there are some patients who are clearly poor candidates for Vioxx or Celebrex. In this case, we now know that patients with cardiovascular disease or hypertension were at higher risk for cardiovascular adverse events and should try many other options before resorting to Vioxx or

Celebrex for their symptoms. But this information was really only widely discussed after the publication of a key article in the clinical literature in August of 2001. So, our second test of whether DTC ads provide real information will be to see whether or not they encourage patients with cardiovascular risk to adopt Vioxx or Celebrex later. However, as an added wrinkle, if it is a DTC information effect, this delay should occur only after August 2001.

So, if DTC spending is moving patients in the right direction, we should see that patients and communities or time periods with more DTC spending and who have gastrointestinal difficulties should adopt Vioxx or Celebrex more rapidly. We should also see patients and communities or time periods with more DTC spending and who have cardiovascular problems adopting Vioxx or Celebrex less rapidly, but only after August of 2001.

Note that we have a fairly specific test here. In fact, when we estimated our models, this is exactly the pattern we observed. Greater amounts of any Cox-2 inhibitor advertising encourages gastro patients to adopt sooner for all time periods. On the other hand, greater amounts of any Cox-2 inhibitor DTC advertising before our cutoff date of August 2001

encouraged CVD patients to adopt sooner and after 2001, August 2001, encouraged CVD patients to adopt later.

It's hard to imagine another mechanism, other than the provision of real information through advertisements, that would account for this pattern.

Our patient level analyses are remarkably consistent and clear. DTC advertising for Vioxx and Celebrex did affect prescribing behavior and did so in exactly the direction you might want. Good candidates for the drug got the drug sooner; poor candidates got the drug later. Thus, our results imply that Vioxx and Celebrex television ads actually improved the matching of therapy to patients.

In summary, we are able to state the following. DTC advertising for Vioxx and Celebrex had the effect of encouraging patients to see their physicians. At an aggregate level, DTC adds affected the rate of prescribing for at least one of our study drugs, and for the average patient DTC television ads in this time period seemed to act to improve matching patients to treatment.

In conclusion, we would like to leave with the following message. DTC advertising has become an important feature of the U.S. healthcare system.

There are a number of reasons to expect that DTC ads can improve the flow of information to patients. We have studies the impact of DTC advertising on a drug class, Cox-2 inhibitors, that has been one of the most controversial over the past two decades. Even for these drugs, we find that the net impact of DTCA is to get patients in front of their physicians and to improve the matching of patients to treatment. Thus, DTC advertising has at least some positive effects on social welfare.

We view our results, however, as a little light in a very dark place. Much more research at the patient level is needed to understand the impacts of DTC advertising.

Thank you very much for the opportunity to speak today. I'll be happy to try to answer any questions you might have.

MR. ABRAMS: Ms. Davis?

MS. DAVIS: Did you look at all whether or not the physicians that were prescribing to these patients were being, I guess, detailed or promoted to at a similar rate, or what effect that might have. And I guess that the second question that relates to that, did you see if when, this data came out about cardiovascular effects, you talked about patient

adoption of prescription. But do you have any insights into why physicians were prescribing for these patients who might be called inappropriate for the drugs?

MR. KLEIT: With respect to the detailing, our conversation with industry folks indicates that detailing for these two drugs which, as you know, were very popular, was constant over this period, basically that, every representative at every opportunity was trying to promote these drugs in meetings with physicians. Now, with respect to the second question, what we observed, and I know you are going to ask to follow up on that, we observed that a switch in prescribing patterns after the August 2001. We don't have direct data on how physicians got their information, but we infer that, excuse me, how physicians got their information, but we infer that physicians kept up with the clinical literature in this area.

MR. ABRAMS: Dr. Aikin?

MS. AIKIN: Thank you for a very interesting presentation. I was fascinated to see that advertising for both Vioxx and Celebrex just increased Vioxx prescribing.

Did you happen to look at another

indication in tracking these data, perhaps one that wasn't specifically indicated by labeling? To sort of get at the issue of perhaps of inappropriate prescribing.

MR. KLEIT: We did not have the, we did not look at other indications although of course we'd be open to suggestion.

MR. ABRAMS: Okay, Doctor Kleit, thank you very much for your presentation. We have just about 10 minutes until our break, so we are going to open up the discussion for comments from the floor. So I invite anybody to come up to comment. If you do, please identify yourself with your name and your affiliation.

Okay, I'd like to thank the panel for very good presentations, great interactives, discussion from our questions. Thank you.

(Applause.)

We will begin -- I'll turn it over to Rose.

MS. CUNNINGHAM: I'd like to let people know there is a sign-up sheet out in the front if you would like to speak, you know, later on, when we have an opportunity such as happened just now. And the next panel, please be sure to be back on time. Tom?

MR. ABRAMS: Okay. And we will break and we'll start promptly at 11:15.

(Off the record.)

MR. ABRAMS: Good morning. If everyone could take their seats. We have an action-packed agenda, so we really need to keep this moving.

Okay. We had an outstanding panel of speakers earlier this morning, and I am very pleased that we are starting the second panel another panel of outstanding speakers. We will begin with our first speaker, Patrick Kelly, from Pfizer.

MR. KELLY: Okay. Good morning. I'm Pat Kelly, the president of Pfizer U.S. pharmaceuticals. Thank you for inviting me to participate on this panel. And we will also be submitting written comments to the hearing docket.

As a representative of Pfizer and the pharmaceutical industry more broadly, I believe that informed dialogue between patients and healthcare providers is the single most important element of healthcare communications. We also believe that information from any source is central to any definition of dialogue. And, as we've stated before, we believe that under the free speech clause of the first Amendment of the U.S. Constitution, patients

have a right to receive information in DTC advertising and our companies have a right to impart it.

That said, today I'll focus on the personal and public health benefits of DTC advertising. Let me start by saying that one of Pfizer's greatest responsibilities to our customers and our business is to communicate information about medical conditions and our products in ways that enable the best health outcomes possible. We believe, and research supports, that direct communication with consumers and, more specifically, DTC advertising, is an important and effective channel for this information.

Further, we believe that DTC advertising helps patients work with their healthcare providers to make more informed decisions about their health, which in turn, leads to needed diagnoses, appropriate treatment and ultimately better health outcomes, for Americans and our nation.

This last point is especially important because there are tens of millions of Americans who are undiagnosed, untreated or under treated for medical conditions that could be treated if they were aware of these conditions or motivated to seek help. These include such serious conditions as high

cholesterol, diabetes, depression, high blood pressure and asthma. For example, today some 35 million Americans don't know they suffer from high cholesterol. And 19 million do know they have this condition, but aren't being treated for it. Here you can all see the numbers of those untreated for high blood pressure and diabetes.

Under any analysis, the costs to the healthcare system of these untreated people are and will be substantial. Research has shown that DTC advertising raises awareness of medical conditions and motivates people to seek information, diagnosis and treatment. It encourages consumers to talk to their healthcare providers about benefits and risks, and helps them stay engaged in caring for their own health. In fact, study after study has shown that DTC advertising delivers important information to patients. As patients themselves report, DTC advertising motivates people to seek additional health information. The information that people receive through DTC advertising motivates them to speak to their physicians, to finally advertising-driven conversations result in new diagnoses of important conditions.

According to the 2004 Prevention Magazine

survey, more than 65 million patients have talked with their physicians after seeing a DTC advertisement, and 29 million of these patients mentioned a condition to their doctor for the first time.

DTC advertising has helped one in four patients who have asked about a DTC-advertised product during a doctor visit, received a diagnosis for a previously unknown medical condition. And more than 40 percent of these new diagnoses were for such high-priority conditions as diabetes, high blood pressure and asthma.

This impact extends to other medical conditions that can have a major impact on consumer health and consumer quality of life. Often, these are conditions such as overactive bladder and erectile dysfunction, which itself is often a surrogate marker for cardiovascular disease, that consumers have been reluctant to discuss even with a healthcare provider, and aren't necessarily uncovered during a routine physical or check-up.

These public health and quality of life benefits notwithstanding, we fully understand that critics have serious concerns about how pharmaceutical companies communicate with consumers. They questions whether promotional messages can accurately provide

product information. They also question the appropriateness of the medication utilization that may result.

Before tackling these concerns, though, I'd like to note that through our own research conducted over the nearly eight years we have communicated directly with consumers, we've learned much about their health information needs, on how DTC advertising can have a greater impact on healthy behavior. Specifically, we've learned that one, ads need to provide information that motivates consumers to overcome the significant barriers that continue to prevent millions of Americans from seeking information, or starting that all-important conversation with their doctor to get the medical help they need. These barriers range from a lack of awareness to denial and misinformation to low health literacy, perceived stigma and lack of insurance coverage. As this is true across all disease areas.

Second, DTC advertising is and should remain a catalyst that drives consumers to get the full depth of information about prescription medicines, something they pursue through a variety of sources, including their healthcare providers. We know that consumers use a variety of health

information sources, including DTC advertising, at various points to become motivated, engaged and committed to better health. Our research shows that the average patient consults four to five different information sources to understand his or her condition.

DTC advertising is not, and should not, be viewed as a comprehensive health information source that leads consumers to think that they don't need any more information. Health information needs to be accessible and understandable. Our experience has shown that patients and potential patients often lack basic knowledge of medical conditions, treatments and medications. While we know that 87 percent of patients are aware that prescription medications come with risks that must be discussed with their physicians, they often lack basic knowledge about a medication's specific indications and specific risks.

And our research has shown that consumers cannot easily understand medical information. To address consumers' need for easier to read and easier to understand health information, we have developed and applied to all of our consumer print communications, including our ads, clear health communications principles, that insure that all of

these materials are written and understandable at the 6th-grade reading level.

Four, DTC ads are communicating important risk information. According to the Prevention survey on DTC advertising, completed in January of 2005, 79 percent of those surveyed recalled that risk information was included in prescription drug TV advertisements. At the same time, 75 percent recalled that benefit information was included. Both numbers are up, as you can see, from the prior years' levels.

In more controlled settings, TV and print ads have been shown to significantly increase risk perceptions, based on comparisons of people who viewed specific ads versus control groups of people who did not. Testing has repeatedly shown significant increases among those who viewed an ad in the perceptions of the overall seriousness of side-effects, recognition of specific side-effects, and recognition of who should not take the advertised medicine.

Five, we must reinforce the importance of a good patient/provider partnership and the role of this partnership plays in appropriate diagnosis, treatment and outcome. Good healthcare decisions, including decisions about prescription medicines, can

only be made when consumers consult a healthcare provider, engage in a productive conversation and mutually determine what the best course of treatment is.

Let us also remember that one health care decisions, the decision to prescribe medicine, ultimately rests with only one person, the healthcare professional, the doctor. As to the appropriateness of that decision and the utilization of medicines that result, research shows that when consumers visit a doctor as a result of seeing an ad, they usually have the condition the advertised product treats. According to the FDA's own survey, that was 88 percent of the time.

Number six, having said all of that, we can do more to increase the proven health benefits of DTC advertising. Despite the many benefits that it has provided, Pfizer has heard the concerns expressed about DTC advertising. And we recognize that more can be done to encourage valuable dialogue between patients and healthcare providers. To help consumers better understand the risks and benefits of prescription medicines, and to continue to motivate people to overcome potential barriers to better health. It was in this context that PhRMA developed

guidelines.

At Pfizer, we've taken those guideline steps even a step further. From our media budget we've diverted the rough equivalent of financial support for one major medicine to address general public health as a stand alone brand, if you will. By doing so, we hope to communicate information that supports prevention, compliance and constructive doctor/patient dialogue, without mentioning any medicine.

We're also, as it's been seen, postponing advertising any new medicine until physicians have at least six months to become familiar with them.

In addition, our branded TV and print ads and product websites now include language informing patients that their doctor may recommend alternative treatments, such as diet, exercise or other non-Pfizer medications, and that only the doctor knows what is right for you.

We are no longer running ads that do not include the indication, benefits and risks associated with the advertising medicine, our so-called reminder ads. We'll begin using a new consumer-friendly and consumer-tested print brief summary with FDA's approval. We're running an ad campaign that is

devoted to our comprehensive prescription assistance programs, Pfizer Helpful Answers. And we'll fund further research to help further improve risk communication in DTC TV advertising. We're seeking input on this research from the FDA and third parties, and we'll adjust Pfizer's communications based on the results.

As the FDA considers how to maximize the benefits of DTC advertising, we urge consideration of these important factors:

One, the record show that DTC advertising benefits consumers and healthcare more broadly.

Two, it's critical to provide information about prescription medicines to consumers in a way that is clear, understandable and accurate.

Three, we must do all we can to help consumers work with their healthcare providers toward the best healthcare outcomes possible.

Four, the current health information universe is broad and deep. This enables consumers to take advantage both of the information they seek out and the information that is delivered to them through mass communications. Let's continue to expand information options, not limit them.

And, finally, we need to understand the

barriers that people face engaging in health behavior and create communications that address those barriers. We must focus on assuring that consumers continue to benefit from accessible, understandable and motivating health information.

On behalf of Pfizer, thank you again for the opportunity to participate.

MR. ABRAMS: Thank you, Mr. Kelly, for a great presentation.

And your research, when your science indicated that there's increased awareness of risk perception in DTC advertising, yet much of the data from the research that we're seeing indicates that patients and physicians are feeling that patients are not getting enough risk information. Whether it's not there, enough it not there or not taking away, can you elaborate on that?

MR. KELLY: Well, it's a fair question and it's an important question. I think it is, as is being discussed here, a determination of how is enough to reach whatever the level is we expect. Is it that we will accept that a consumer understands that there is risk inherent in any medication, and that there are risks inherent in this specific medication, or do we need them to be able to recite the specific side-

effects that might occur with that medication. So, I think it comes down to, in this case, a matter of determining what we think is an effective standard, or the approximation of understanding of risk in the consumer population.

MR. ABRAMS: And, have you done research as far as drilling that down, what the consumer should have or we believe would be optimal?

MR. KELLY: Well, I think that we continue to pursue research that is that specific in determining if there is some point at which the risk information becomes so overwhelming that it actually deters the patient from seeking or seeking health or seeking help in that case. And that's the boundary that we seek to define. We don't know, yet. Again, we have, like other companies, been testing a variety of new approaches that are intended to see where we can provide what is presumed to be adequate provision of risk information and still motivate patients to take action with that information.

MR. ABRAMS: Doctor Behrman?

MS. BEHRMAN: What have you thought about internally. We can now talk a little about balancing risks and benefits. And to a certain extent while that's hard, at least count them and recommends what

they are, but one issue that came up in the last panel that we struggled with internally, have you thought internally within your company about the entire message of the ad and how do you ensure that one part of it doesn't dilute or obscure the other part. Have you talked about that or thought about that?

MR. KELLY: Absolutely. And I think that starts though with an understanding and appreciation of what is accomplishable in sixty seconds or thirty seconds, if you're talking about TV advertisement, or a page or two if you're talking about print advertising.

Within that context, then, it is at least our interpretation that the regulations are quite clear, that you need to be able to adequately communicate what the product is for, you're allowed to communicate what the product might provide in the way of benefits, as long as you balance that with some approximation of that description of the benefit with the description of risk. Accomplishing those three things would seem to be the core recognition of what the regulations envision and, in fact, command.

Then the question is, can we accomplish that in a way that still accomplishes what the ad is intended to do, which is to motivate action. That

action can be in two forms. Either it is to seek out further information in the area is being discussed, or to consult with their healthcare provider.

Accomplishing all of that is a rather complex matter within the context of these short bursts of --

MS. BEHRMAN: Yes.

MR. KELLY: -- information. So I think we need to kind of step back and establish what it is we think is reasonable to be accomplished within that context, and then ensure that we are accomplishing it as effectively as we can.

MR. ABRAMS: Ms. Wolf?

MS. WOLF: Do you have any information on the differences between what we call health seeking or disease awareness ads that you talked about at the end of your presentation? How differently those might bring people to their doctors as opposed to health product ads --

MR. KELLY: Yes.

MS. WOLF: -- bringing people in.

MR. KELLY: Yes, we do. And, in fact, that's one of the findings that is not necessarily well understood is that general health awareness and health seeking ads do not drive patients to the doctor

to anywhere near the degree that information about a solution or a potential solution will. Again, one of the things we face in the patient populations that we're talking about is there may be some built-in inertia, either associated with perceived barriers to them seeking health and seeking treatment for their disease or medical condition, as well as just a general inertia about this problem isn't serious enough for me to worry.

What we have found is that if you express that just you should be aware that there is a medical condition or a disease that you should worry about, it doesn't generate as much action as if you then say and there might be potential solutions that you should consult with your provider about. So it is the other connection that's important towards a motivating action.

MS. WOLF: And is there any difference within that distinction whether patients or consumers do or do not have insurance?

MR. KELLY: Again, we don't have a lot of research in that particular last point. But we do know through the research we've done more broadly, that the lack of insurance coverage is a barrier to taking action in many disease states.

MR. ABRAMS: Doctor Temple?

DR. TEMPLE: Let me see if I have my mike on, is that on?

You answered Ms. Wolf's question about health-seeking ads, but you were referring to an ad that's only a health-seeking ad. But, product ads can have health-seeking components. Some of the early statin ads were quite good that way. Do you have any insight into whether those elements contribute to better understanding and what I'm focusing on particularly is the need for a long-term use of these agents and compliance. I mean it's really a public health disaster that people, with all the things you've shown, that people with elevated blood pressure and abnormal lipids don't treat them long-term. So, that question about the health-seeking component, whether that contributes, then I have another question.

MR. KELLY: Sure. So, I think that there is a contribution that is oriented towards seeking health, or even better I think, seeking help as a way to understand what the objective is here. And I would not suppose that because I was answering that question on health seeking only, as opposed to health seeking as a component within product messages.

I think that the other part of your question though, there is a very important component towards these ads, in these ads, relative to trying to continue treatment in those patients that have received that particular treatment. The ads do serve as a reminder to that. Now, the research has been conflicting as to how much of a degree that reminder helps. Again, it was cited in one of the earlier presentations, there's some research that has seen that it is a modest, to almost insignificant, effect on compliance.

We've seen other studies and done other studies and shown it is a more significant effect. So I think there is value to health-seeking as well as reminding to continue on your medication or treatment that the doctor has prescribed that should be a component of this kind of advertising.

DR. TEMPLE: I was going to ask you about the possibility, I mean, the difficulty with a national ad is that it is hard to know what effect you've had on compliance. I mean, you sort of have to move national compliance and that's a tall order.

There might be more localized environments in which, an HMO or something might let you in to try to promote maintenance of lipid therapy, say. I mean,

there are all sort of interested in that in some ways even though it costs money. Are you contemplating any things like that? It would be an enormous step if somebody could show that there are communication devices that could actually do that.

MR. KELLY: Absolutely. We're engaged in that. The most successful venue for that that we have found in our experience is the pharmacy. It is not the health plan level but at the pharmacy level where patients are interacting with pharmacists on the prescription or the refilling of the prescription of the medication. And we've been able to show anywhere from 30 to 50 percent increase in compliance rates using pharmacy-based interventions.

MR. ABRAMS: And are these good studies with, you know, randomization to pharmacies --

MR. KELLY: They are absolutely.

MR. ABRAMS: -- and stuff like that?

MR. KELLY: They are absolutely.

MR. ABRAMS: Okay. Well, I hope you'll let us know about that.

Mr. Kelly, thank you very much. Our next speaker is Abby Mehta from Gallup & Robinson Incorporated.

MS. MEHTA: Good morning. It's a pleasure

to be here and I'd like to commend the FDA for the opportunity to speak today. I hope you'll find this presentation interesting and helpful in reference to your questions about the use of certain standard advertising practices. I'll be presenting research findings regarding celebrities and advertising. Thank you.

I have some experience on celebrity advertising effects across various consumer products, and it was also the topic of my doctoral dissertation. Currently, I'm the Director of Research at Gallup & Robinson, a marketing and advertising research company which has been conducting advertising research for over 50 years.

We have undertaken masses of data analysis from our data base to understand better how celebrities work, as well as conducted specific studies on the subject. Last year, Gallup & Robinson was commissioned by Pfizer to design a study to evaluate and understand the impact of celebrities in the DTC area. The results of this study I hope will be of value and in answering FDA's questions about celebrity advertising.

So, the important question is, does celebrity advertising perform differently from non-

celebrity advertising? More specifically, is celebrity advertising better able to break through the clutter, gain attention and be memorable as compared to non-celebrity advertising? How is celebrity spokespersons in advertising perceived? How is the ad itself with the celebrity perceived? Does celebrity advertising persuade more than non-celebrity advertising? And what impact does celebrity advertising have on the advertised brand?

First, I'm going to briefly present some research about general consumer products and brands and then discuss the DTC advertising study.

There is research evidence that celebrity advertising can deliver a premium in terms of breaking through the clutter and obtaining higher awareness levels for the ad and the brand. Based on an analysis from Gallup & Robinson's database of consumer products, on average day-after recall of celebrity magazine ads is about 34 percent higher than that of general ads. There is, however, a wide range of results and celebrities don't guarantee break through. While over half of the celebrity ads showed above average recall levels, roughly one in three were at parity and about one in six celebrity ads was found to be below average.

In terms of celebrity perceptions, ratings for celebrity spokepersons are significantly higher than ratings for non-celebrity and non-celebrity spokespeople or non-celebrity actors in identical or similar advertising for attributes such as likeability, credibility, physical attractiveness, although there are some exception seen for particular celebrities in particular contexts. Additionally, celebrity advertising in general is also more liked than non-celebrity advertising.

In terms of persuasion, though, celebrity advertising results are more mixed. Celebrity ads may or may not motivate purchase interest. Buying interest for print ads amongst recallers of the ad on average was only four percent higher than that of non-celebrity or general other ads. And again, in our database of massive data analysis.

We see a wide range of results, roughly one in three celebrity print ads shows above-average persuasion levels. Half are at parity and about one in five falls below average.

So, those were the general findings. We looked more specifically at the DTC category. Two health conditions were studied: migraines, a symptomatic condition; and high cholesterol, an

asymptomatic condition. An experimental research design was used. Identical celebrity and non-celebrity ads were created, and the performance of these ads were compared.

Two celebrities and one non-celebrity was used per condition for a total of four celebrities and two non-celebrities. Celebrities were selected after appropriate research. We used fictitious brands, so the results would be clean and not -- prior knowledge of the brand would not be coming into the ad.

The ads were tested by Gallup & Robinson's established magazine ad testing methodology, MIRS, which has been in use for over five decades. It is an in-contest, in-magazine, at-home exposure design which involves and I can explain that. It involves recruiting target respondents for a magazine readership test. Test ads, either celebrity or non-celebrity ad, is tipped into the magazine and this magazine is placed with a qualified respondent. A telephone interview is conducted with the respondents the day after they've read the magazine. And data is collected during this interview.

First, recall is taken for the ads based on a brand Q, after which respondents are asked to open their magazine, look at the ad again and

recallers and non-recallers are then force-exposed to the ad and further questioning is taken. A total of about 1,050 sufferers of migraines or high cholesterol from 15 different geographically-dispersed national markets, participated in the study these such findings.

On average, recall levels for the celebrity ads was significantly higher than for non-celebrity ads. Perceptions, after cost exposure, were also significantly higher for the celebrity ad for being more attention getting and eye catching.

Celebrity spokespersons in ads were consistently rated significantly more favorably than non-celebrity spokespersons for a variety of attributes such as likeability and credibility, among others.

Celebrity ads were also more liked and seemed to be more impressive overall than the non-celebrity ads, but they were not perceived as providing more important messages or being more informative or even more believable overall.

In terms of persuasion as measured, as interest in the product among those that recall the ad the day after reading the magazine, there were no differences across all celebrity and non-celebrity

ads.

After forced exposure, motivation to consult doctors shows celebrities were more effective in one of the two conditions only. In the migraine conditions, celebrities had higher levels of doctor consultation intent than the non -- whereas the high cholesterol condition, there were no differences between celebrities and non-celebrities.

In terms of brand reactions, overall a few global image attributes for celebrity ads showed higher results. The brand was seen as more unique and sometimes likely to improve the quality of life. But none of the specific brand efficacy and performance measures shows any consistent differences across celebrity and non-celebrity ads. I've listed a few attributes here to show you the results across the two conditions. There were no differences for the celebrity and non-celebrity ads in migraine or the high cholesterol condition.

In conclusion then, results of the study showed that on average celebrity DTC ads can and do show higher break through clutter, gaining attention and memorability on a day after basis. Celebrity spokespersons are rated more favorably than non-celebrities in the DTC ads and the celebrity ad itself

is perceived more positively on an overall liking basis and a few other measures like that. But celebrity ads are not seen to be providing more important messages or being more informative and believable.

Celebrity ads may or may not motivate doctor consultation. Various factors, including health conditions seem to influence celebrity effectiveness. And while a celebrity-endorsed brand is seen as unique and sometimes is seen to be improving the quality of life, its efficacy and performance is not expected to be different than that of a non-celebrity ad.

Thank you.

MR. GOTTLIEB: Thanks a lot.

MR. ABRAMS: Dr. Gottlieb.

MR. GOTTLIEB: Sorry. Two quick questions. Have you looked at breaking down what the celebrities are being asked to do in the advertising and whether having them talk about the benefit information and having risk information presented in a different format is creating more difficulty interpreting both sets of information? And you talked about health condition influencing the impact of the celebrity. Are you speaking to the fact that have you

gleaned form your data that having celebrities talk about disease conditions in sort of a first person way has a higher impact? Is that what you were referring to there?

MS. MEHTA: Yes and no. The first question, did we look at risk benefits differently by celebrity, is that what you --

MR. GOTTLIEB: My question is you talked about cognitive dissonance and I'm just asking whether -- what the celebrity is being asked to do in the advertisement, if you've looked at that in terms of what their role is in the ad and whether that's creating more of an inability to recognize the risks relative to the benefits in this advertising?

MS. MEHTA: In this study, we created very identical ads, whether it was a celebrity or a non-celebrity and we just compared the results of these two. We did not manipulate how or what the celebrity was doing and in other areas we've seen that the celebrity is well involved with the product, they can be more effective, but in this case we just studied the one format.

Your second question was about --

MR. GOTTLIEB: I think you answered that as well. It was about you said something to the

effect of health condition --

MS. MEHTA: Yes, we studied migraines and high cholesterol and we saw that in the migraine condition the doctor, the motivating doctor consultation was affected by celebrities, but in the high cholesterol it was not.

MR. ABRAMS: Dr. Ostrove.

MS. OSTROVE: Well, thank you very much. It was very interesting. And as you've -- I'm sure you've heard earlier today, we're very interested in the risks, the communication of risks as well as the benefits. Has there been any attempt to look either in terms of the day after recall or in terms of a forced exposure what consumers, what your research participants got in terms of the risks of the products?

MS. MEHTA: We did not ask any questions about the risks in our research. The questions are general. The day after recall of the -- do you remember an advertising for XYZ? Do you remember that? And then respondents are asked four open-ended questions. What did the ad show you and what did it tell you and what did you learn about it. And so we don't -- we didn't ask specifically about the risk messages.

MS. OSTROVE: Do you think that your methodology would allow you to do that?

MS. MEHTA: Yes, of course, we could. This is, like I say, standard questions that have been used, but it could be adapted.

MS. OSTROVE: And for most consumer commodities, the interest is in the benefits and whether the benefits are coming across, but clearly in our particular situation, it's a little bit different. We're also interested in whether the risks are coming across and it seems as if, especially looking at it in this -- you have the potential here for a much less artificial kind of research environment than some of the others than we've been hearing where it's very clearly a forced exposure. So it seems to me that there's -- there is some real potential.

MS. MEHTA: Yes, I'm sure we could construct some appropriate questions to get at that if that was the objective of the study.

MS. OSTROVE: Thank you.

MR. ABRAMS: Dr. Aikin?

MS. AIKIN: Dr. Ostrove covered my question.

MR. ABRAMS: Thank you, Dr. Mehta, thank you very much for a very informative presentation.

MS. MEHTA: Thank you.

MR. ABRAMS: Our next speaker is Michele Spence from Kaiser Permanente.

MS. SPENCE: Thank you and good morning. I'm Michele Spence from Kaiser Permanente and today I'm going to talk to you about a study which looks at direct-to-consumer advertising of Cox-2 inhibitors, the impact of appropriateness of treatment.

We conducted this study with the UCLA Department of Public Health and it was funded by the California Health Care Foundation.

Our research aim was to determine whether patients who have seen Cox-2 ads and asked their doctor were more or less likely to receive a prescription for a Cox-2, according to clinical guidelines.

We decided to study Cox-2 inhibitors because at the time of this study in 2001, Cox-2s were heavily advertised. $78.3 million was spent on advertising Celebrex and $160.8 million was spent on advertising Vioxx.

These drugs are high cost. They are generally 10 to 15 times the cost of traditional NSAIDs and they are widely used. And we also decided to study the Cox-2s because we had a clear definition

of appropriateness. So we looked at some clinical guidelines that reserved the Cox-2s for patients at increased risk of GI bleeding.

We took our data from two sources, from a mail survey of 3,000 Kaiser Permanente patients in Southern California and also from our administrative prescription databases. This was a stratified random sample. Half of the patients received a new prescription for a Cox-2 and half of them received a new prescription for a traditional NSAID. And then these were the patients that we surveyed about DTC ads.

The surveys included questions like have you seen ads for Celebrex? And after you saw the ads, did you ask your doctor about Celebrex? And we included a set of questions about Vioxx as well. And to measure appropriateness, we asked questions which gauged the level of GI risk for the patient. And this was based on a score tool. This is a standardized tool that was developed by Gurkirpal Singh at Stanford and it's used to identify patients at highest risk of serious GI events that are treated with traditional NSAIDs.

The surveys were mailed in February 2001 and they were available both in English and in

Spanish.

Okay, we looked at three different clinical guidelines for GI risk and we decided to look at three guidelines because we wanted to allow for variations in what is seen as appropriate and also we didn't want to be criticized for just using the Kaiser guideline. So our Kaiser guideline stipulated that patients who are at highest risk that measure score, score number four on the score tool, they're at highest risk and therefore the most appropriate candidates for a Cox-2 inhibitor.

We then looked at the modified Kaiser guideline for patients who scored three or four were the most appropriate candidates for Cox-2. And finally, we used a set of criteria developed by Loren Laine. And this is a much broader definition of GI risk. For example, any patient who is over the age of 65 would be considered high risk for a GI bleed and therefore an appropriate candidate for a Cox-2.

Our dependent variable had three levels. First, those treated with a Cox-2 when the guideline would recommend a traditional NSAID. Second, those treated with an NSAID when the guideline would recommend a Cox-2 and third, those appropriately treated with either a Cox-2 or an NSAID.

Our independent variable was the patient saw the Cox-2 ads and then asked their physician and then we compared those patients with all other patients, so those are either they didn't see the ads or they said they saw the ads, but they didn't ask their physician about Cox-2s.

We controlled for a variety of patient covariates, including demographics as well as their duration and location of enrollment in Kaiser. We also controlled for physician characteristics, including age, gender, specialty, their location and how long they've worked at Kaiser.

We received a 47 percent response rate. Twenty percent of the respondents said that they saw the ads and asked their physician about a Cox-2. And 80 percent of them reported that they either didn't see the ads or they saw the ads and didn't ask.

Okay, in this slide, this tells you, sort of breaks down the levels of appropriateness. So it shows you the number of patients prescribed either a Cox-2 or an NSAID using the three different guidelines. And the shaded boxes indicate appropriate treatment. So if you look at the top two lines, this uses the Kaiser guideline. So patients classified as low risk, who got a Cox-2, they would have been

inappropriately treated. Fifty percent of our respondents fell into that category.

Patients who were high risk and got a Cox-2 would have been appropriately treated, 9 percent. Patients who were classified as low risk and got an NSAID were also appropriately treated. That was 39 percent of our respondents. And finally, a small number of patients who were high risk and got an NSAID, it was only 1 percent.

Then we used these same patients and classified them according to the modified Kaiser guidelines, so this is a more generous definition of risk. You'll see that the boxes of appropriateness go up 31 percent in each group. Those that are treated with a Cox-2 and the recommendation would have been an NSAID, went down to 29 percent and those that were high risk and got an NSAID also that went up to 9 percent. And the same kind of patterns happen when we use the Laine criteria. We have more people being treated appropriately, classified as being treated appropriately.

Okay, our next slide, this is where we used a multivariate regression analysis and the impact of the ads on appropriate prescribing. So using the Kaiser guideline, patients who saw the ads and asked

were four times more likely to be prescribed a Cox-2 when the guideline would have recommended an NSAID. And that was statistically significant.

Using the other two guidelines, the odds ratios were about three. Patients who saw the ads and asked were three times more likely to be prescribed a Cox-2, to be over-prescribed a Cox-2.

We looked at the -- the impact on NSAID treatment. The Kaiser guideline wasn't significant, but if we look at the modified Kaiser guideline, patients who saw the ads and asked were significantly less likely to be under treated with an NSAID. And we also found the same impact with the Laine criteria.

In conclusion, patients who saw Cox-2 ads and asked their doctor were significantly more likely to be prescribed a Cox-2 instead of a traditional NSAID according to guidelines. This finding was very robust. It was consistent across three different guidelines and it suggests that DTC advertising leads to inappropriate prescribing of costly medications.

We also found that patients who saw the ads and asked were less likely to be prescribed an NSAID when a guideline recommends a Cox-2. This finding occurred in just two of the guidelines and those were guidelines with very broad definitions of

GI risk and it suggests that some patients for whom the drugs are truly appropriate may benefit from DTC advertising.

So on balance, we find a simultaneous small benefit in the large costs associated with DTC advertising of Cox-2s. It may avert some under use, but it's offset by increased prescribing for conditions for which the net therapeutic effect is negligible or in the case of Vioxx, even negative.

The limitations of the study, we had low overall Cox-2 use in KP, so it probably underestimates the impact of DTC ads. We didn't include a measurement of physician exposure to drug promotion. We only looked at one class of drugs and there could have been potential recall bias among our survey respondents.

Finally, the demise of Vioxx should make us reconsider our attitudes toward DTC advertising. This advertising promotes over use of newer drugs without a track record of safety and effectiveness. Consumers need credible, balanced drug information. And finally, there's a need for increased consumer and physician vigilance toward DTC advertising.

Thank you.

MR. ABRAMS: Dr. Temple?

DR. TEMPLE: This was all done before Vigor was published, is that correct?

MS. SPENCE: Vigor was published in 2001.

DR. TEMPLE: Maybe 2000.

MS. SPENCE: Yes.

DR. TEMPLE: Actually, I'm not sure. The guidelines that you're referring to at Kaiser Permanente, they were cost guidelines principally, would that be correct?

MS. SPENCE: Cost effective.

DR. TEMPLE: I mean before Vigor, there wouldn't have been any particular reason not to use Vioxx or Celebrex. It's just that they're expensive and wouldn't seem to have an advantage. I guess that's the idea.

So the advertising interfered with the attempt of Kaiser to carry out what it considered to be rational cost control.

MS. SPENCE: We were concerned about the impact of the ads on the appropriate prescribing of Cox-2.

DR. TEMPLE: Okay, probably there's a longer discussion, but the idea of the Cox-2 selective ones and the studies that were done were not done on high risk people. They showed decreased bleeding in

general populations and that was the idea of Cox-2. But it is perfectly reasonable that Kaiser would make the judgment that it's worth it for people at higher risk. So this was really about undermining cost containment policy.

MS. SPENCE: Yes.

DR. TEMPLE: It seems at least possible that could agree with the cost containment policy, wanted less GI bleeding even for people who weren't at high risk. That could explain some of it.

MR. ABRAMS: Dr. Spence, thank you very much for a good presentation. We appreciate that.

Our final speaker for this panel is Christine Winnicki from Time, Inc.

MS. WINNICKI: Thank you and good morning. I'm here today on behalf of Time, Inc. to present some findings from our latest DTC study. It's a consumer study.

Time, Inc. has conducted six waves of research on DTC advertising in the past eight years. Part of our latest wave focuses on recent sufferers and the information sources they use and the actions they take from the time when they think they have a problem to doctor diagnosis.

Seven conditions were identified as key

conditions for this year's study. They were selected on the basis of the fact that they're gender neutral and that a lot of advertising weight has been placed against them. They included symptomatic conditions, allergies, arthritis, chronic heartburn and depression and asymptomatic conditions, cholesterol, diabetes and hypertension.

Our study was conducted on line with Harris Interactive. We used the Harris poll on line study for the U.S. population, first to find our sufferers and also in order to collect some general attitudes towards DTC advertising among the population.

We also needed to over sample to find sufferers of our seven key conditions and we did so using the Harris Interactive Chronic Illness Panel.

Our final group sizes are large and we compensated for the fact that we both conducted the study on line and that we over sampled for our seven key conditions by weighting the data.

We surveyed a total of 3,570 people and we found 1,417 recent sufferers of our seven key conditions. Our field period was about a year ago. It was the end of September through mid-October of 2004. We focused on our recent sufferers, meaning

adults who had been diagnosed by a doctor with one of our seven key conditions in the past two years. We wanted them to have the ability to recall what they did and where they turned to for information before formal diagnosis by a doctor, what happened when they were at the doctor's office, as well as what they were now doing.

Early on in the survey when we had established that someone was a recent sufferer, we asked them to think back to the period before there were guidelines and tell us if they had either experienced symptoms or aware that they might have a condition.

We then explored what information sources they use, if any, to find out what was wrong with them and which they used in order to treat or to learn about treating their condition.

It's primarily patients with symptomatic conditions that we spoke to in our pre-diagnosis stage, but at and after diagnosis we had equal representation of symptomatic and asymptomatic condition sufferers.

At diagnosis, we wanted to what the doctor recommended to patients and if and where they look for information about their condition or ways to treat it.

After diagnosis, we wanted to know what patients are currently doing and how they continue to learn about their condition and treatments for it.

So overall what we found was whether it's pre or post-diagnosis, we find that the recent sufferer turns to the health care provider first, for information about their condition or ways to treat it. That was 71 percent. And that number is largely populated by doctors. They account for 64 percent. Pharmacists and nurses are also included in that.

Four out of 10 patients turn to the internet and friends and relatives. By the internet, we mean health-related websites and internet advertising with that number largely being driven by health-related websites.

Between 25 and 30 percent turn to magazines, TV, pamphlets or brochures or TV programs in doctor's offices or pharmacies. The magazine and TV numbers you see are a combination of both the content and the advertising. One out of four turn to medical books and journals and one out of five turn to pharmaceutical company websites for their information.

Between 6 and 16 percent turn to newspapers, radio or say that letters or pamphlets in the mail are a source of information for them. The

none means none of the particular line items that we presented to them which were 19.

Overall, when we look at our five main media sources which are TV, magazines, internet, radio and newspapers, we find that 58 percent of our recent sufferers turn to the media content sources for information about their condition or ways to treat it. And 27 percent turn to the advertising sources.

Ad recall and the use of advertising varies greatly by condition. With allergy sufferers and depression sufferers being much more amenable to advertising as a source of information for their condition.

We presented various benefits of prescription drug advertising to our general population, as well as our recent sufferers and asked them to tell us whether they agreed or disagreed that prescription drug advertising provided these benefits to them.

Over half of adults said that prescription drug advertising made them more confident in talking to a doctor about their condition, provided information about who should or should not take the medication as well as to help them remember the brand or the company name.

Our recent sufferers in particular were significantly more likely to feel that prescription drug advertising provided information on who should or should not take the medication. Over half also felt that it provided clear information on the drug's benefits and supplemented the information provided by a doctor.

Our recent sufferers were also significantly more likely to feel that prescription drug advertising helps people evaluate which drugs are best for them.

Among our recent sufferers, the majority of our sample had indicated that they had indeed seen prescription drug advertising for at least one of our seven conditions. We focused in on those who said they had seen that advertising both on television and in magazines. We then asked them to tell us which type of advertising was better at providing certain benefits. Overall, we find that both magazines and TV are effective in encouraging people to take medications or to refill their prescriptions. Both say people are more confident in talking to a doctor about their condition and both also help people to remember a brand or a company name.

Magazines, in particular, were seen as

more effective at providing sufficient information about a drug's side effects and risks. Magazines are also seen as being either equal to or better than television and providing clear information on a drug's benefits and effective dosages and duration of treatment and directing people to a website for more information.

TV ads were seen as equal or more effective than magazines when it comes to brand or company recall.

Now let's look at what patients are doing prior -- or recent sufferers, in particular, prior to diagnosis by a doctor. We found that over 60 percent of recent sufferers that we spoke to said that they either had symptoms or were aware that they might have a condition prior to being diagnosed by a doctor. Two out of three of these sufferers tried to address their condition in some way. Forty-one percent took over-the-counter medications. Thirty percent made lifestyle changes like stopping smoking. Twenty-six percent either changed their diet or exercised more regularly. And 24 percent tried some type of self-treatment with home remedy such as an ice pack, which was one of the examples we gave, or alternative medications like St. John's Wort or echinacea which

were specific examples that we gave. And four percent began some kind of therapy. Remember, we looked at a variety of conditions.

Now let's see what happens when they're at the doctor's office. Seventy-three percent of our recent sufferers said that the doctor gave them a prescription medication. Nearly half said that the doctor also recommended diet and lifestyle changes to them. Thirty-eight percent said that the doctor gave them a sample and we found that varied greatly by condition with, for instance, half of chronic heartburn sufferers receiving samples from doctors.

Even though 38 percent were given samples, only 26 percent said that the doctor gave them literature about the condition and only 13 percent said that the doctor gave them literature about the medication itself. Nine percent said that the doctor recommended an over-the-counter medication for them.

Now what are our patients doing on an on-going basis. Well, we see on an on-going basis that our recent sufferers generally say that they are indeed taking prescription medications, but an almost equal number are saying that they elect to make lifestyle changes also in order to treat their condition. Those at diagnosis, 73 percent said that

their doctor gave them a prescription medication or a prescription for a medication and only 70 percent are taking medications on an on-going basis.

We found the greatest resistance to be among arthritis and diabetes sufferers. Twenty-nine percent of the patients use alternative medications to treat their condition on an on-going basis and 17 percent are taking over-the-counter medications.

So what is the summary of what we found in our research that may be relevant today? Health care providers are playing a key role. Advertising is an important information source. It encourages patient and doctor dialogue. It helps patients understand who should and should not take prescription medications, especially those recently diagnosed sufferers and for them in particular, it supplements the information provided by the doctor.

We find that magazines and TV work together. Magazines seem to be better at communicating side effects and risks and TV is better at helping patients remember a brand or a company name. Patients choose to address their conditions in an on-going way two ways. They do take prescription medications, but they also make lifestyle changes.

And we found a need for more patient

communication. Doctors are giving out samples but not enough are giving out literature about conditions or medication information.

Thank you.

MR. ABRAMS: Dr. Gottlieb.

MR. GOTTLIEB: Thank you, Christine. As a physician, I was heartened to see I'm a better information tool than the internet.

(Laughter.)

Two questions. One, do you have any information on why the magazine advertising was more effective risk communication tool than the television and when you looked at people who had turned to the internet for information, do you have any sense of what they did on the internet, whether they went to search engines where they might be more apt to first encounter something that was sponsored versus going to trusted health care sites or what their behavior was on the internet?

MS. WINNICKI: We unfortunately didn't delve further into either of those questions, so it would be speculative on my part to say anything further about that.

MR. ABRAMS: Any other questions from the FDA Panel?

Okay, Ms. Winnicki, thank you very much for your presentation.

I want to thank the second panel for their excellent presentations. Also, I'm going to make a request of the second panel as I did for our first panel and everyone in the audience to submit the data that you present summaries for if you're willing to make it publicly available. This helps the Agency develop its policy.

Thank you very much.

(Applause.)

Now we're going to -- we have 10 minutes. We're going to open the floor for questions. We have a sign up sheet. So I would for ask the first person, Brad Bernard from Life Med Media Company.

MR. BERNARD: I will try to speak up. Brad Bernard. We have created a community of diabetic patients. (inaudible- SFUL)

For example, on our website and television program along this area and this has just recently occurred in the last several months we've seen this increase.

(Inaudible- SFUL) DTC ads (inaudible-SFUL) better dialogue and interaction (inaudible-SFUL).

Thank you very much.

MR. ABRAMS: Thank you, Mr. Bernard. We have no other members of the public signed up on the sign up sheets. I invite anybody who wishes to make a public comment, if they wish to at this point, come to a microphone.

Okay, I remind folks to, if you wish to submit comments to the docket, you can do that as well and we look at all comments. We appreciate those.

We're going to break for lunch now. We'll return here at 1:35 and we'll start our other two panels promptly at 1:35.

Thank you.

(Whereupon, at 12:27 p.m., the meeting was recessed, to reconvene at 1:35 p.m.)

MR. ABRAMS: Good afternoon. We are going to start our afternoon session. Our afternoon session will consist of two panels. We will have a break in between the two panels.

Okay. So we'll begin with the first panel. And our first speaker will be James Gardner from One to One Interactive.

PANEL 3

MR. GARDNER: Hello. Good afternoon. I'm James Gardner with One to One Interactive. For those

of you who don't know us, we're a mid-sized Boston-based interactive marketing services firm. We have a fair amount of experience in interactive marketing, specifically with direct consumer promotion of regulated medical products. So there's a lot of both knowledge and a lot of interest in the topic on our part.

What I'm going to be doing in the next 12 minutes is sharing some of our perspectives on the role of the interactive channel in direct consumer marketing and perhaps enlightening the panel on some of the best practices we have seen, both with clients and on clients, and some thoughts on how the FDA might move to promote it, too, which is something we would strongly advocate.

Before I begin, I wanted to just thank the panel for the privilege of being here today. It is an honor to be part of the process. And we certainly appreciate the opportunity to join you today.

Just stepping back and reflecting a little bit on what we heard this morning, one of the things that struck me personally was just the fact someone obviously I guess in hindsight said the interactive channel is somewhat of an oversight or an afterthought in the grand scheme of direct consumer marketing.

It's completely understandable, though it does somewhat pain me as an interactive marketer to hear that. But I understand completely that the traditional channels of television, print, radio are, just by their nature, a lot higher profile, where a lot more money is being spent. And, frankly, it's where a lot more of the controversy is being generated.

That being said, in the spirit of sharing some of our experiences in using the interactive channel, what I thought I might do today is share some of our beliefs as an agency -- Obviously these are our beliefs, not the beliefs of our clients, I'll just stress that -- about what we have seen as best practices and some thoughts that the FDA might take away from today.

The first and somewhat obvious, although sometimes it forgets forgotten in the discussions, is that for millions and millions of Americans, the interactive channel is an indispensable part of how they manage their health. It certainly doesn't pretend to take the role of the interaction with the physician, but as a first line of defense, it's where by many counts, up to 100 million Americans are turning for health information today, more so than a

lot of the other channels that seem to attract attention.

What we would also postulate is that used responsibly -- and I would stress that because the interactive channel is only a tool. It can be misused. It can be used improperly. But when it's used responsibly, it can really play a valuable role as a public health education channel a swell as making good sense for the pharmaceutical marketers. That's important. They're not charities, obviously. It needs to work both in the public's interest and in the interest of the pharmaceutical marketers.

What I would also point out is that relative to some of the other communication channels that are being used, I would point out that the interactive channel has some pretty unique advantages that might cast this in a somewhat different light than some of the conventional channels that have been used, specifically as a relationship-building vehicle as well as an outreach and education channel.

And then, lastly, the FDA in my opinion can certainly play a really instrumental role here in driving its usage and driving its adoption going forward.

So let's step back and just share some of

the data about the interactive channel's usage as a health education vehicle. What we know from research that was released about two weeks ago by the Pew Internet Project is that 68 percent of U.S. adults now have online access. So it's no longer just a niche communication vehicle. That's approaching the level of the adoption of cable and some of the other so-called mass channels.

What we also know is that in terms of its usage by different demographic segments, there is widespread usage. Specifically, 79 percent of U.S. adults have researched health information in the past year. Eighty-two percent of women have researched health information, which is slightly higher than men. Again, given the propensity of women to manage health information for their families, that is not surprising.

What is somewhat in cycle is that usage tends to increase with age, which, again, correlates in our experience to a greater preponderance of health management issues, the onset of different conditions that warrant adults going online and researching different medical conditions.

What we also see is that usage tends to increase with experience online, which forebodes well

for the use of the channel going forward as people develop more experience with using the internet. And as broadband adoption increases, we'll certainly see more and more adults going online to manage their health.

In terms of what they are doing online, there is a lot of condition information being researched, a lot of drug information being researched. What we would call it here beyond the obvious is that condition information is at the top of this list.

There are a lot of sensitive topics or complex topics being researched, again something that doesn't necessarily lend itself to the more traditional channels. And I would call it things like sexual health information or mental health issues, where for many people there is not a comfortable place to find that information, but in the privacy of their home, they can certainly access a Web site and find high-quality information.

In terms of the beneficial impact that consumers are playing back when asked, -- this was some research done by the Boston Consulting Group two years ago -- a couple of key things jumped out in terms of the benefits that people were seeing as they

used the online channel to manage their health.

Ninety percent of them claimed that it enhanced their understanding of a health problem, which is quite significant. Eighty percent commented it affected how they managed their overall health.

Seventy-five percent changed how they communicated with their doctor. They didn't specify if that was for the positive or for the negative, but I've got to assume in almost every case, they were going with more information and having a more informed dialogue that led hopefully to a better diagnosis and more effective treatment.

And then, importantly, 65 percent of these respondents commented that it improved their compliance with drug treatments. Again, that's a particular strength of the interactive channel and how it's being used today by pharmaceutical marketers. In many cases, it's a significant compliance tool via the use of e-mail and desktop applications.

What I want to do now is just share some of what I would call best practice success stories. These are not work done by our agency. So there's hopefully some objectivity that I would call these best practices.

The first is a promotion that is actually

live right now done by GlaxoSmithKline in partnership with the American Lung Association using a number of vehicles, including TV and online promotion. They hope to reach asthmatics who are not adequately controlling their condition, which is a serious, serious health issue. They may be using inappropriate devices or not treating their condition at all.

What it asked people to do was take the asthma control test and measure in a pretty quantitative fashion with five questions how well they were controlling their asthma. This was all done online.

Then the call to action was after you have taken the test, if you are scoring in the red zone, go talk to your doctor about how you should be controlling your asthma more effectively. So I think that is a pretty effective educational example of how the online channel can really reach out and drive people into their doctor's offices for an informed conversation.

Another example by Pfizer is there was a Pfizer for Living Web site addressing the need expressed by a lot of physicians and by a lot of consumers for objective, credible information and engaging tools that they can use to manage their

health and improve their knowledge of conditions.

Pfizer developed this Web site unbranded to their drugs, obviously, to provide a lot of tools and a lot of resources beyond just straight content, I would stress. There are encyclopedias. There are quizzes, self-assessment surveys, and a lot of really rich tools that will help people learn about a condition and then ultimately, as the Web site suggests, go speak with their health care professional with an informed point of view.

Then the last one is a project done by Roche. Obviously Tamiflu doesn't really need extra promotional support at this point. But they were addressing the unique effects of this drug, which is that it's most effective when taken immediately after exposure to the influenza virus.

So you have a somewhat unique compliance problem right there because if the flu virus is sweeping into your geography, traditionally there has been a real challenge in educating people that they need to go to their doctor and discuss whether or not they need to get a flu shot.

This desktop application is downloaded onto your computer. So it's not a traditional Web site. You enter your Zip Code. And then on a

periodic basis, it downloads data from a flu-tracking source of data. And it will alert you if the flu virus is within two days of your geography and obviously suggest that you go seek professional help because you are at risk of being exposed.

So these are some unique examples of how the channel is being used to drive people into their doctors' offices, to drive compliance, to drive just general education, all things that traditionally offline channels have struggled with.

I wanted to, lastly, just call out some of the unique qualities of the online channel. Obviously the most interesting one is the fact that every experience online is a voluntary user-initiated one.

Traditionally the complaint, if you will, about some of the mass channels is that they are intrusive, in many cases providing irrelevant information at the wrong time, on the wrong condition, and in a way that you're not comfortable seeing it. This is especially irritating in the case of sensitive drugs or sensitive conditions. When you are online, you are choosing to go to a Web site or you are choosing to use a search engine. So there is a lot more user control.

I would also point out the fact that it's

a lot more balanced. Again, that was a concern that was discussed this morning. I think the online channel is somewhat unique in that it gives users the opportunity, both to view the safety information, the fair balance information, potentially to print it but certainly to digest it at their leisure, as well as to use that as the jumping off point for additional research online, perhaps at the FDA Web site, perhaps at the National Institutes of Health, but it's a great jumping off point in a way that a lot of the other channels don't provide.

The fact that it is dynamic and engaging is also something unique. We know that consumers learn most effectively when they're given an opportunity to actually engage with content via quiz, via survey, via some type of tool. The online channel is very effective at doing that.

And, lastly, there is this idea of a modest investment, which, again, is not necessarily a concern of the FDA but certainly goes to the issue of the amount of money that is being spent on traditional mass advertising. For a much more modest investment, you are able to reach a similar sized audience and publicly provide a lot richer experience in terms of the education that you are disseminating.

So how can the FDA help? This is what I wanted to leave you with as just some final thoughts. For those of you who are not familiar and comfortable with the online channel and using it to manage your health, give it a try.

You know, go to WEBMD. Go to Yahoo! Health. Go to some of the other high-quality sites that are out there. See what is being done by some of the pharmaceutical marketers. Do some searches on Google or Yahoo! using condition terms or drug terms and be exposed to some of the best practices that are out there.

Compare and contrast that while you're doing it with some of the mass channels. I think you'll see that the interactive channel is very unique. And certainly as you contemplate potential regulation of direct consumer promotion, I would encourage you to think through whether or not the rules that apply to other channels are most suitable here.

Lastly, encourage its responsible use, again responsible use. I think, as we have seen with some of these examples today, when it is used in an education and compliance mode, it can be very, very effective. And that is certainly something that I

would personally like to see expanded going forward.

And then, lastly, support innovative applications, like the desktop application that we saw from Roche. That is very unconventional. And I applaud them for doing something so innovative and distinctive to solve a compliance problem in a way that I think is going to be quite effective.

That is the end of my comments. I again thank everyone for giving us the opportunity to participate in the process and would certainly field any questions.

MR. ABRAMS: Thank you.

Dr. Gottlieb?

DR. GOTTLIEB: Thanks for that. I appreciate the comments, although I might quibble with your comment that it's a voluntary experience here, either that or I want to get a copy of your pop-up blocker.

I wanted to just ask you quickly. You know, I think most people, their interaction with the internet is to go to the search engines and type in some search terms. Is there any evidence that the search engines are steering people towards more credible outlets of information or that consumers online are paying attention to things like accrediting

bodies that accredit good information versus stuff that might not be as reliable?

MR. GARDNER: Yes. That's a great question. Our experience is that if a consumer actually has a prescription in hand, their usual reaction is to go to a search engine and usually use the drug name to get to the drug site or directly enter it.

And we are seeing evidence of people becoming more savvy in their searching, which I think was part of your question as well, using multiple terms to refine their searching. So they're getting more and more relevant results.

Certainly Google and some of the other higher-quality search engines are consciously trying to push the great quality content to the top of that, like the National Institutes of Health or the CDC or FDA Web site, which are known to be very, very credible.

DR. GOTTLIEB: That is actually built into their algorithms how they rank stuff?

MR. GARDNER: Yes. Although their algorithms are proprietary, there is evidence that they tend to have a bias towards .gov sites or .edu sites, which tend to be objective and not commercial.

That's correct.

MR. ABRAMS: Thank you, Mr. Gardner.

Kristin, do you have a question?

MS. DAVIS: Yes. Thank you for your presentation. I just had a quick question.

You were talking about some of the benefits of this medium versus some of the others. I was wondering if you have any information that might be relevant to the agency's objectives of making sure that risk and benefit are both presented and how this medium does as far as what people take away from it. Have you researched that at all?

MR. GARDNER: We don't have specific researchers in the agency. Certainly in working with pharmaceutical companies we follow the FDA's guidelines on fair balance, disclosure of safety and prescribing information scrupulously.

MS. DAVIS: Okay. Thank you.

MR. ABRAMS: Okay. Thank you, Mr. Gardner.

Our next speaker is Gail Javitt from the Genetics and Public Policy Center from Johns Hopkins University.

MS. JAVITT: Good afternoon. My name is Gail Javitt. And I am a policy analyst with the

Genetics and Public Policy Center at Johns Hopkins University.

The center was founded in 2002 with the mission to create the environment and tools needed by key decision-makers in both the private and public sectors to carefully consider and respond to the challenges and opportunities that arise from scientific advances in genetics. I appreciate the opportunity to speak to you today and to raise a serious problem related to direct-to-consumer advertising of genetic tests.

Genetic testing is becoming an increasingly important part of health care. Genetic tests can help diagnose genetic conditions and guide treatment decisions, help predict risk of future disease, inform reproductive decision-making, and assist in medication choices for a variety of diseases, including several types of cancer.

While the number of tests available is exploding, genetic tests are subject to far less scrutiny than other medical products. And FDA oversight, in particular, has been quite limited.

In recent months, several news reports have discussed a genetic test called the Baby Gender Mentor. The test, which is advertised and sold over

the internet, claims to diagnose the sex of a fetus as early as five weeks of pregnancy, with more than 99.9 percent accuracy.

According to news reports, the test has been sold to thousands of women, many of whom have received false reports. In other words, the test predicted a baby of one sex, a baby of the other sex was born.

The Baby Gender Mentor is sold to consumers as a kit over the internet. It claims to diagnose fetal sex, which while merely a matter of curiosity for some expectant parents also can correlate with sex-linked genetic disease.

The Baby Gender Mentor is, therefore, a diagnostic device. But to date, FDA has taken no action regarding the claims being made for this product or regarding the test itself.

This one genetic test is just the tip of the iceberg. The past few years have seen a proliferation of genetic tests advertised and sold directly to consumers. These tests run the gamut from the mainstream to the truly alarming.

One Web site advertised and sells a test that it claims can diagnose genetic predisposition to addiction and other behavior disorders, such as ADHD.

The Web site also advertises and sells a variety of so-called nutriceuticals to treat conditions such as alcoholism, cocaine addiction, tobacco addiction, ADHD, and PMS. Again, FDA has taken no action to date, to our knowledge, against these claims or these products.

Another Web site advertises genetic testing for the purpose of predicting and avoiding adverse reactions to drugs, to prescription drugs. The company claims such testing can improve the safety and effectiveness of more than one-third of the most commonly prescribed drugs, such as antidepressants, heart medicines, and painkillers.

The test claims to predict based on an individual's genetic makeup how he or she will metabolize a particular drug and, thus, whether and in what dose the drug will be harmful or helpful.

In other words, the Web site claims the results of these tests can improve the responses of an FDA-approved drug or, conversely, tell that the drug is contraindicated.

Yet, to our knowledge, FDA has not reviewed these claims or the tests themselves. While FDA has approved one kit for drug reaction testing, laboratories are not required to use that kit. So

that there is a lack of regulatory parity for this kind of increasingly prevalent genetic testing.

These are only a few examples of tests that are currently available DTC, predominantly over the internet. The unregulated advertising of genetic tests for a myriad of conditions, some of which are highly dubious, leaves consumers vulnerable.

According to a 2004 survey conducted by the Genetics and Public Policy Center, the public widely believes that the government already regulates genetic tests and, moreover, widely supports such regulation.

However, contrary to this widespread belief, little has been done to ensure that the claims made about genetic tests are truthful or that the tests are safe and accurate. Of the more than 800 genetic tests currently clinically available, FDA has approved only about a dozen.

While there may be independent jurisdictional limits to the agency's activities regarding some genetic tests, FDA can and should do far more. Moreover, FDA can and should collaborate with its sister agencies within independent jurisdictions, such as the FTC and CMS, to create a seamless web of safety to protect consumers from the

harmful consequences of bad information and bad tests. Public health and the public expectations demand such protection from the federal government.

In July 2005, the Genetics and Public Policy Center launched a genetic testing quality initiative. The goals of this initiative are to foster a framework of oversight in which the validity of tests is accorded by the science before they are offered to consumers and which uses of outcomes of tests can be evaluated over time, in which laboratories demonstrate their ability to get the right answer reliably, in which health care providers are educated about tests and able to provide them to patients with adequate context and counseling, and in which patients have confidence in the claims made about the tests and about the tests themselves.

I realize that much of this hearing is devoted to DTC advertising of drugs. Nevertheless, FDA has a critical role to play here as well to ensure that accurate and sufficient information is available about genetic tests, particularly when these tests inform drug prescribing.

Over the coming months, we hope to work with the agency to discuss ways that FDA can ensure that the information directed to consumers regarding

genetic tests is truthful and adequate and that the tests being advertised are accurate and reliable.

Thanks very much for your time.

MR. ABRAMS: Ms. Wolf?

MS. WOLF: I just want to clarify a couple of things. FDA's jurisdiction in terms of these genetic tests is not entirely straightforward or clear. And I think that we are currently working with the department in terms of looking at how we might more or better regulate the kinds of claims that are being made.

Unless the reagent is part of the kit, there is a disconnect between FDA's regulation of the reagent and the lab's use of the agent to do testing. And it's important. You know, it would be useful to have input on how we would be able to work with the labs. We work with the centers for Medicare services in terms of their regulation.

MR. ABRAMS: We need to just clarify the question for the speaker. This background is useful, but we're limited as far as time. So if you have a clarifying question, that would be great.

MS. WOLF: I just sort of would like to know if you have any specific ideas on the kinds of things you would like to see FDA be able to do given

the framework.

MS. JAVITT: Sure. We have to some extent more than probably we can discuss right now. But I do want to respond to the jurisdictional point. Obviously the agency has a governing statute. And we're sensitive to that.

But at the same time, in various points in history, the agency has taken a position it can regulate all of these tests. And as far as I know, the last public statement about FDA's jurisdiction is that it can. In recent years, there may have been differences of opinion about that, but I think it's not entirely clear.

And the fact that the agency has been unclear about what it is willing and what it feels it can do is somewhat frustrating and leaves advocates for the quality of genetic testing at a little bit of a loss into how to proceed. So clear signals from the agency in either direction would at a minimum be helpful.

And to the extent that the agency has more jurisdiction than it is currently exercising, which I think is a very defensible position, we believe more could be done around the areas of clinical validity, at a minimum, to prevent the obviously false claims

that are allowed to proliferate.

MR. ABRAMS: Does the panel have any more clarifying questions?

(No response.)

MS. JAVITT: Thank you.

MR. ABRAMS: Okay. Ms. Javitt, thank you very much for your presentation.

Our next speaker is William Person from 50 Plus WEBHealth.

MR. PERSON: Thank you very much. Good afternoon. My name is Bill Person. I'm President of the 50 Plus WEBHealth.

A little bit of background on my company and myself. We spent three years designing the medical information Web site. I guess we're the third group here talking about the internet. Specifically for adults over 50, we have conducted marketing research on adult health issues, including what information adults are looking for and how to communicate health issues to adults.

The site basically provides the best Web site links by disease and health issues. We cover 23 diseases and 17 health issues, including prescription drugs, flu vaccines, links to the VA, Social Security, and the warning sites from the FDA.

For those of you who haven't visited the site, just briefly we have health issues on the left and then topics on the right that you can basically go into and get information on.

My presentation is going to focus on adults over 50, which comprised 46 percent of the health care market. Health care and its costs play a very intimate role in the lives of this market segment. The presentation will focus on prescription drugs only. The presentation will also focus on the internet as a communication vehicle for adults over 50.

The first recommendation, any communication agreement that is decided on must have a distinct market segment strategy to consider the message is delivered, received, and understood. From the prospectus that came out on this conference, they discussed age, language, and others. I would like to just highlight under the age area vision, reading, memory retention, are all different for the age groups.

So if you put together a policy that you're communicating to the public, it must understand these market differentiate and how people will receive it differently. I know recent announcements indicate

the pharmaceutical industry recognizes this need for market segmentation.

Main overall recommendation is the truth. Honesty is essential. One of the topics that has been continually mentioned here today is about information cannot be misleading. Display risks along with benefits.

The people I have worked with, consumers I have worked with, I believe can manage the risks. They are well-aware with any health care solution there are risks, and they are aware of it. The people I work with, adults over 50 with Medicaid and significant health care issues, the benefits -- many of the patients are living -- significantly outweigh the risks. So the benefit-risk ratio is extremely high for the people I work with.

One thing the group would like to see is just the history of success for particular health care solutions. The FDA and the health care industry must continually build credibility. That has to be an underlying criterion in everything that goes forward.

And, lastly, the public needs to be educated in their responsibility to be aware of and understand the benefits of drug risks. You are going to see a little later on how the public is becoming

more and more involved in managing their health care. They need to be more and more aware of the risks.

Communication requirements should have effective monitoring system to assure it's effective. We're talking about how we communicate to adults. We need to make sure that we're monitoring it, ensure that it's working, and if it's not working, change it. And I'll give you some recommendations on this at the end.

Consumer-directed communication methods are historically magazines, TVs, and almost up until the late '90s the doctor-patient relationship was the key area.

I just pulled this out as an example of a back page of a magazine ad where it basically puts in the health risk. This one happens to be on Lamisil, actually, very easy to read for an adult over 50, vision problems. It has the risks on the right side, the side effects on the right side, so very easy for somebody to look at and understand. Many of them, unfortunately, are a little more challenging. The table on the top right does a very job of listing at first the facts but very difficult and challenging for somebody to read.

Adults are seeking health information on

their own. And we'll get into some statistics on that. One of the reasons is they're continually reading in a variety of publications that 200,000 patients, a little under that, are dying each year in hospitals.

There was a quote in Time magazine about two years ago. When you try to explain how you're feeling, chances are your doctor will interrupt you 23 seconds in the recital. And that is out of the Journal of the American Medical Association.

I continually in my work see topics like the bottom two there, where studies show Americans get only have the recommended medical care. This is why the adults who have the ability to go to the internet are going to the internet and looking for health care information.

So as far as the status of adults with communication and health care issues, the public will not accept the policy of health care information only from the public. The public will not accept the policy of limited or rationed information on products, including new products.

The key reason now is the public has the option of finding the information elsewhere on the internet. They no longer have to rely on going to the

doctor's office and finding health care information. They can dial up, do a search, go to a Web site, and get information.

The first speaker talked a lot about the Pew reports. So I'll go through this very, very briefly. I know we're under some time constraints here.

Basically, the Pew report came out and lists half the adults, Americans, are searching online for health information with prescription drugs near the top of the list. Wall Street Journal just early this year talked about internet chapters searching online, exercise fitness, prescription drugs. People are going to the internet and looking for information, and they're finding it.

Again, some Pew information, again discussed earlier, 93 Americans using the internet for health topics, media audit report. Internet usage growth is driven by the older age groups. You heard about that, actually, from the first speaker this afternoon.

Some conclusions from the Pew report. Disabled or chronically ill users are avid online communicators. So we can talk about some statistics about adults. The people that have health care

problems, who we are really talking about today, are avid users.

Fifty-seven percent are looking for others. So it's just not somebody going and looking for their issue. They're doing it for a friend, neighbor, or whatever. Chronically stable and dually diagnosed are more frequent users.

I underline this last one because I think it is very key to my whole presentation. Seventy-three percent of health seekers say the internet has improved the health and medical information services they receive. The public is viewing this avenue of information as successful.

You heard from Pfizer this morning about the fact that there are a number of people out there that aren't diagnosed. They have health issues. More importantly, there are solutions out there, and they are not being diagnosed.

These are just some statistics from Rand in the Wall Street Journal about a year or so ago. Another article in the Wall Street Journal talked about doctor awareness being low.

Diagnosis advertising on media, TV, magazines is very prevalent. And hopefully you are all aware of that. I consider it a distinct segment

of direct and consumer advertising, but I think it's very critical.

A massive number of health issues go undiagnosed. And this fact raises overall health care to the factor of quality of life. And, frankly, for Pfizer and others, it's an opportunity for solution providers.

There are too many people out there today where we have solutions that aren't aware of it. And currently there are a number of professional online diagnostic options. You heard the first speaker talk about some online options, people going in, doing little checklists, and then taking it into their doctor's office.

And, by the way, I think doctors, physicians are key to this health care program used on the internet. In everything I'm talking about today, the doctor still plays a very vital role.

Just a comment here on the new drug promotion, the consumer policy. And I have read where drug companies and the FDA are discussing limiting the advertising on new products until doctors are familiar with it. I think it's a great policy. The doctor absolutely needs to be a key element.

With the availability of health care

information via the internet, it's going to be days or weeks before patients walk in to the doctor and say, "Doctor, what about this? Is this the right thing for me?"

The point I'm making right here is that, you know, whether FDA and the drug companies agree to delay things, the consumer is going to find out about it and be asking for it.

Second key comment there. If a solution to a health issue has passed all tests by the health care provider, the pharmaceutical company, and the FDA, we have a right to make sure that the people who can benefit from it know about it right away.

Some brief statistics on internet use. And I need to move along here. You look at the center column there. You can look at internet use by people 50 to 60, 63 percent; 65 and up, 30 percent. Five years, these are going to be in the 90s. So if you look at the growth rate of people using the internet, it's growing significantly.

Again, moving quickly, Bell South, SBC, Verizon are putting in internet service around the country. I guess the City of Philadelphia is talking about going across the board. FCC has some statistics in Business Week about homes of broadband.

Internet content options. There's unlimited data access, global access. There are over a billion people now with internet access.

Sharing options. You can take a report off the internet and send it to your sister, brother, wherever. Print out options. You can go in and print out something and bring it in to your doctor's office.

The number of health care information resources -- and this is why the internet is so valuable and has a lot of information -- Reuters covers more health care conferences, press releases, and journals. AARP for adults over 50, great health care Web sites, numerous government-backed Web sites.

The Wall Street Journal has health issues because they're basically financial news. Clinical trials are now online. The New England Journal of Medicine basically paid to get their service, but after six months, everything is free.

These are just a couple of articles from the Wall Street Journal. What they do, they've got a couple of great authors here. They take very complex medical issues and put them in a form that the consumer can understand.

Internet search options. It's not all things to all people. You go in and do a Google or

Yahoo! search. You're going to get more information than what you can deal with.

A comment from Woman's Day a year or so ago, "What makes the internet useful for health care information, you can find everything. It also makes it maddening how to sort through it."

Communications from consumers. Presently there are limited requests for feedback until you come back to the doctor. The internet offers a very efficient method to check on a patient's progress. You can identify health reaction problems sooner. I'm sure the patient is following up on recommendations.

Also communications from consumers, the FDA's adverse reaction program should even be more effective by broader promotion of its availability and use via the internet. Last year 422,500 responses came into that service. And I would recommend the FDA look at expanding that.

Conclusion? The public needs to play an active role in our health care. The public is already demanding and pursuing an active role in our health care. Consumers are aware of the trade-offs with health care solutions. Doctors and others in the medical system need to continue to have a strong role.

I believe the 73 percent rating of those

who say they are benefiting from the internet for health reasons will grow as information becomes easier to access. The internet changes the health care communication rules.

Recommendation? The safety of the consumer must be maintained. FDA policy should take into account consumer market segmentation, continue to allow advertising while requiring effective notification of risk and historical success rates along with benefits, and share truthfulness and integrity of all communications monitored, key word under there.

And I think that the FDA can do that, the effectiveness of cautionary advertising, educate the consumer on their need to manage their risks, and allow direct-to-consumer advertising promptly after new product is approved.

Thank you.

MR. ABRAMS: Dr. Aikin?

DR. AIKIN: You propose a monitoring system for the effectiveness of cautionary advertising. What sort of system do you propose? And what sort of variables would you measure in such a system?

MR. PERSON: What you need to do is work

with people who are taking certain drugs, make sure they understand the health risks of the different measures so they know what they're doing, really measure it by the people who are using it to measure whether they got the word or wherever, just what they're trying to do.

DR. AIKIN: So you propose to talk to people who are actually taking the drug after they have been exposed to the advertising?

MR. PERSON: Yes. People who are taking the drug, were they aware of the risks when they were taking it? Did they go into it with their eyes open?

DR. AIKIN: Okay.

MR. ABRAMS: Dr. Ostrove?

DR. OSTROVE: Just a quick clarification. I'm not sure if I understand your position with regard to limiting advertising on new products until doctors are familiarized because at one point, it seems as if you felt that was a good idea. But you also believe that direct-to-consumer advertising should be allowed promptly after a new product is approved.

MR. PERSON: Basically the bottom line is you've got days or weeks before that doctor needs to know. You've got days or weeks to educate the doctor

because people are going to come in and be asking him.

Whether or not the pharmaceutical company or other solution provider educates him, he's going to hear about it. A consumer is going to hear about it from Reuters, Wall Street Journal, or whatever, about a health care solution. And they're going to be in asking the doctor about it.

The industry does not have months or a year to educate that doctor on a new product that's out on the marketplace. The consumer will begin talking to him right away. He has other sources to find out about that new product.

DR. AIKIN: So your sense is that there should not be any kind of a delay in educating the health care professionals right from the get-go.

MR. PERSON: You are not going to be able to do that. This group in this room and the health care providers do not have the liberty to go do that.

People in the Wall Street Journal will pick up that information on a new product at work with results of a clinical trial. And they will make that available to the public the next day. And literally they do. And the day after that, somebody will be walking into a doctor's office.

The reality is that what we're seeing with

the internet is that health care information or people who get that information, there's another vehicle, major vehicle, providing that to the consumer and the consumers looking at it, looking for it.

MR. ABRAMS: Dr. Temple?

DR. TEMPLE: That wasn't quite the question. We understand that you believe that people will become aware of novel drugs, probably related to how important they are, and that doctors need to be able to deal with that. Nobody disputes that.

The industry has said we are going to wait before we do DTC promotion, which is another source of stimulating attention, until we have had a chance to notify doctors. That is what Nancy was asking about.

You seemed to say that that seemed like a good idea before you sort of launched the DTC promotion, but then it wasn't clear at the end of your talk whether you actually did think it was a good idea.

It isn't about whether you inform doctors because they do need to know.

MR. PERSON: But they don't have a lot of time to do it.

DR. TEMPLE: Because the dam is going to break and there will be a lot of people. Okay?

MR. ABRAMS: Okay. Mr. Person, thank you very much for your presentation. Our next speaker is Carole Rogin from the Hearing Industries Association.

MS. ROGIN: Good afternoon. I am Carole Rogin. And I appreciate the opportunity on behalf of the Hearing Industries Association to talk with you and be part of this very important hearing today.

By way of introduction, the Hearing Industries Association is the trade association of the manufacturers of hearing aids, hearing aid components, and hearing aid-related products, such as batteries. And collectively our members manufacture most of the hearing aids that are sold in the United States on an annual basis.

We are here today to reinforce how very, very important direct-to-consumer advertising is for hearing health care in America. Our products, hearing aids, have a neat regulatory profile.

Hearing aids, unlike many of the drugs -- and I guess I am the first person talking about devices today, but many of the devices that FDA regulates have a virtually unblemished safety record. They are just not the type of product that poses a health risk, especially in context of the full array of drugs and devices that the agency regulates.

Further -- and I think this is very important to the advertising component -- hearing aids are dispensed directly to the consumer without the need for a prescription from a physician.

Despite the safety record of hearing aids, the FDA for many years has paid special attention to how hearing aids are promoted to the public while our members respectfully disagree with the level of the need for such scrutiny. We have always thought to work cooperatively with the agency and to assure that all of our customers receive accurate and balanced information.

The importance of direct-to-consumer advertising to our companies and to our users cannot be overstated. Very, very importantly, consumers self-initiate hearing examinations, either because they have a concern themselves, not often enough, at the recommendation of their primary care physician, but mostly at the urging and begging of friends, family, and significant others.

The goal of our advertising has been not only to promote our product but, very importantly, to educate consumers about the symptoms of hearing loss and to help them understand that for the vast majority of hearing losses, hearing aids are not only the

treatment of choice but the sole treatment available for hearing loss.

Additionally, hearing aid advertising differentiates today's hearing aids from those less technologically advanced instruments of just a few years ago. Indeed, direct-to-consumer advertising of hearing aids not only reminds consumers that there are effective devices to assist with their hearing problems, but it also enables them to learn about new innovative products and features that can further assist with their hearing problem.

Despite our efforts, the percentage of people with hearing loss who use hearing aids remains inexplicably low. Our surveys have been tracking these numbers for decades. And they remain remarkably and depressingly consistent.

Of the 32 and a half million Americans with some degree of hearing loss that interferes with their daily lives, only about 23 percent of them currently use hearing aids.

This is unfortunate because today's hearing aids are very effective. While there is an array of advances in miniaturization, multiple microphone technology, and other features, it is the incorporation of digital technology that has

revolutionized our products.

We all know someone, grandparent, parent, aunt, or uncle, who bought hearing aids years ago and did not use them because they did not provide the assistance in an array of listening environments or provided inconsistent performance. Today many of these problems have been addressed. And, frankly, satisfaction with contemporary hearing aids is at an all-time high.

Hearing aid advertising also addresses another key element. And that is stigma. While in the United States we don't view glasses as any kind of a stigmatizing device and we don't worry about having vision loss, there is still stigma associated with hearing loss or wearing a hearing aid, this despite the fact that untreated hearing loss can be much more visible, if you will, than a hearing aid when people don't understand or respond inappropriately.

As Dr. William Slattery of the esteemed House Ear Institute in Los Angeles noted in a Newsweek cover story just a few months ago, "People with hearing losses who don't use hearing aids" -- and I quote Dr. Slattery -- "are afraid to look old but don't mind looking dumb."

Direct-to-consumer hearing aid advertising

addresses the problem in two important ways: first, by making clear that hearing loss is nothing to be ashamed of. It is often age-related but, in fact, also a result of living in an age when we listen to rock bands and hold hand-held hair dryers at ear level every day of our lives.

Secondly, the advertising highlights today's hearing aids, which differs substantially from the memories that many people have. Today's hearing aids are now so small and fit either entirely in the user's ear or behind the ear that they are virtually invisible.

The hearing aid industry has truly had a silent revolution in technology. And we use our advertising and promotion to encourage people with hearing losses to seek help.

For people with hearing losses, hearing aids can truly reconnect them with their lives. And, very interestingly, in a study that was just completed by the Better Hearing Institute, hearing aids can increase individual income substantially.

Better Hearing Institute, BHI, conducted a study which confirmed that there is a difference of between one and 12 thousand dollars annually in the income of individuals with hearing loss who use

hearing aids and those who don't. This obviously translates into billions of dollars of lose income.

I want to assure you that the hearing aid industry takes advertising responsibility seriously. More than a decade has passed since the FDA took enforcement action against bad advertising. And to augment the cooperative actions that we undertook with the agency at that time, HIA developed its own voluntary guidelines for hearing aid manufacturers, for substantiation of performance claims, when the agency in 2002 sunsetted its own guidance document.

Additionally, in order to assure that our advertising standards are maintained, the following year HIA developed a voluntary review system that is a process that all of our members agree to employ if advertising complaints or disputes arise.

In summary, HIA and, indeed, all of the hearing aid industry believe that direct-to-consumer hearing aid advertising serves a critically important public health function by helping people understand that hearing loss is nothing to be ashamed of; by helping them understand that that loss can be corrected with hearing aids; and realizing that, in the words of Dr. James Fuhrman, who is President and CEO of the National Council on the Aging, untreated

hearing loss is not a benign condition.

HIA believes that the advertising by our members is being done pretty uniformly in a responsible way and that we have systems that assure that this sense of responsibility is maintained.

We appreciate the opportunity to be here today to reinforce how very important direct-to-consumer advertising is for our industry and the people that we serve. And I would be happy to answer any questions.

Thank you.

MR. ABRAMS: Ms. Davis?

MS. DAVIS: Hi. Thank you for your presentation.

It sounds like you haven't had a lot of or you haven't had, really, an increase in treating hearing loss, even though there is branded DTC advertising going on. And I was just wondering if there has been any testing within this market of either other types of promotion, maybe unbranded campaigns or of the use of specific mediums of promotion to see if they would have an impact on getting patients treated for this

MS. ROGIN: There has not been a great deal of scientific research on the part of the

companies that advertise. We have done a great deal of work with the medical community looking at the impact of messages to primary care physicians about hearing health care. And through one initiative, for instance, we were able to increase the percentage of general physical exams that include any kind of a hearing test, including just the question, "How is your hearing?" from 16 to 21 percent of those physical exams through advertising to physicians. But there has not been a really scientific review of messages to consumers.

MR. ABRAMS: Thank you, Ms. Rogin, for your presentation.

MS. ROGIN: Thank you very much.

MR. ABRAMS: Our next speaker is Marlene Tandy from Advanced Medical Technology Association.

MS. TANDY: Hi. Good afternoon. I'm Marlene Tandy. I'm with the Law Department at Johnson and Johnson. I'm here today as the co-chair of AdvaMed's advertising and promotion working group.

AdvaMed, as people in the device industry know, is the national trade association for medical device manufacturers. We have been involved with supporting direct-to-consumer advertising for a couple of years now. We support the concept of

direct-to-consumer advertising.

I think, as Dr. Woodcock noted this morning, you know, devices, we're thrilled to be here because we don't really have as much of a presence yet in direct-to-consumer advertising of restricted devices on broadcast media, particularly TV. More so in print we have done, but less so on TV. But we're getting there.

And so we started to be a player, I guess is our message. And as a player, we see that we are probably going to as an industry have increased use of direct-to-consumer advertising. We watch what goes on in Rx pharm because, you know, that's important to us as a harbinger of future developments for the device area. And we have also been cognizant of the benefits that people have been talking about, direct-to-consumer advertising.

I think it's clear, although we haven't done any studies or research ourselves as the trade association or, you know, our companies by and large, we do have to recognize that there are benefits that have been established by the available research.

And in the device area, it was thought of for so long that devices, particularly like implanted products, would be way too complicated to try to

explain to consumers. And we're all consumers. But it was thought that it would just be too difficult to explain a hip implant or a stent or a pacemaker. How do you explain that on TV? And so there was that reticence to kind of get into the area compared to I think the Rx pharm industry.

But now we have seen with all of the other DTC ads that have gone on that, in reality, we can make ads in print and in broadcast that do explain surgical procedures, particular products, particular implant, other particular products.

And we can inform patients, and we can tell patients that there are options available. We can make people aware. We can make the advocacy groups that are here today and others out there aware of devices so that people generally have an increased opportunity to talk with their doctor in the 23 seconds that they get to explain to their doctor to explain what is going on with them.

I think that that particular message is a very important one that we have heard, and we have all experienced it, that our time with our doctors has been drastically reduced for a number of different reasons.

And so if a patient, if we ourselves are

more informed about something that might be available to us that we have seen on TV or the internet or in print and we write it down on a little list or we print it out from the internet and we're ready to go when we talk to our doctors and we just ask, "What about this? What about that? Could this be right for me? Is it time for me to have an implant?" possibly. So to engage in that dialogue, that's where we see the benefit of DTC.

Because I'm a lawyer, I have to talk about like legal things. So those of you who are lawyers will maybe wake up now, you know, at this point where we are talking about legal authority.

Restricted devices. What is that? If you are a device person, you know that FDA has authority in the Federal Food, Drug, and Cosmetic Act to restrict the sale or the distribution or the use of a device product.

And they can do it basically in two ways. FDA can do it by issuing a formal regulation, a final rule, the proposed rule first, then the final rule to restrict the device or FDA can do it as a condition of approval under the pre-market approval regulations.

So for drug people, the PMA is like an NDA and a PMA for a class III device, which it's a

risk-based classification system. So the class III device is the higher risk device category. FDA has conditions of approval when you get that PMA approval. And those conditions can be to restrict the sale of the device or its use in a certain way.

What is really important for us today about restricted devices is that is the category of devices for which FDA has jurisdiction over their device advertising. So I'm going to probably say "restricted devices" a lot, but I wanted to explain it since, you know, again, I think this is primarily an Rx pharm audience.

Now, we have different statutory requirements in one respect for DTC advertising of restricted devices in the statue, in the Federal Food, Drug, and Cosmetic Act.

We have the same requirement as everybody else that the device ad has to not be false or misleading. That is what the statute actually says. What it really means is that it has got to be accurate. You can't mislead by omission or by commission. So you have got to provide accurate information about your product.

But then we have this special -- the second bullet here is special to restricted devices.

We in devices -- if you're going to advertise a restricted device, you have to include in that advertising this brief statement. And it actually says in the statute what is written here. So if you look at that, that really looks like it's pretty heavily weighted towards the risk side.

You know, we were talking about like fair balance and, you know, benefit versus risk. Well, we've got to talk about the relevant warnings, precautions, side effects, and contraindications. We have got to mention the device's intended use. Great. And we can certainly mention the benefits.

But that is a whole lot of information on the risk side that has to be presented in order for this to be a compliant ad. And that is different. Again, this is different. This is a device requirement, not a drug requirement.

So because we have that requirement that is in the statute and we already are heavily weighted towards the risk side from that, I'm going to go back up from that brief statement that we have to put in. That's why we think that FDA doesn't need to have some sort of separate regulation. There is no separate FDA regulation right now just focused on DTC advertising for restricted devices.

And we would say that that is okay because that brief statement requirement is pretty clear. It's pretty simple, pretty concise, and we think we have been meeting it. We think we have been mindful of it in our limited experience with our broadcast advertising and our print advertising.

We would be happy with a guidance document because we could flesh out some more details. I think it was February in '04 the device center issued a draft guidance document on restricted device advertising.

AdvaMED commented on it in August. And, actually, one of the things we commented and we said in our comments was that we would really like to have a public hearing at which device people could present what is relevant to us in terms of our DTC advertising because I think this is one of the first times we have been able to do that. So we thank FDA for listening to us in those comments.

We are also going to resubmit those comments to this docket because in those comments, we had a lot of very specific detailed comments on what we thought would be appropriate for a guidance document for how to implement the brief statement, various options to communicate the side effects and

the warnings and the precautions. So I'm not going to get into those specifics here right now because we think we have done that in writing and we are going to resubmit it.

We did want to go through the questions at least a little bit that FDA specifically asked for today's hearing. And, again, we're going to put in a new submission to this docket that is going to answer these questions in more depth. But we just wanted to cover them briefly here.

As I said, we think that by following our existing statutory requirement that is heavily weighted towards the risk side, that we will be able as a device industry to adequately communicate to consumers the relevant risks of the device that is being advertised.

We didn't answer question 2, by the way, because that is an Rx pharm question. So we're not involved with that. So I'm skipping to question 3.

In question 3, we have a little bit more specific recommendations. We think that when we have a device-specific ad for a restricted device, that, of course, we have that relevant safety information, the brief statement that has to go in there. And, again, we think we have been doing, by and large, pretty good

on getting that into our TV ads and our print ads.

Then sometimes we have in the device industry ads that talk about a surgical procedure or a type of surgery. And they don't necessarily mention a device, but they may mention a device. And so we think when we have that kind of ad, that it's appropriate to present more general risk information about the surgical procedure. And in our comments, we actually submitted some ideas for how that statement would look when you have a general surgical kind of procedure ad.

We also think that all of these ads, product-specific or surgical procedure ought to recommend that the consumer speak with his or her physician.

We do think that that guidance would be useful. We think that FDA has had a number of helpful guidances on how to speak to the lay people. There's right write. There's device guidance for patient labeling. So we think that the guidance should talk about a variety of options and keep encouraging us to develop that consumer-friendly language. I think I just said that. Okay.

Last question. We really think that FDA has adequate statutory authority, a whole range of

enforcement options to deal with what the agency might think is a violative ad. So we don't think that the agency needs more authority. We think that on a case by case basis, the agency can choose whatever existing authority to use that they have.

Now, this pre-review of device ads, we don't really do a whole lot of this, you know, maybe compared to pharm. And it's an option. We don't think it should be mandatory. Again, people spoke about the First Amendment. But we think it should be an option.

But if it's going to be a realistic option, then CDRH is going to have to get some more resources to do this because they just don't have enough. And they don't really have a process for it.

Thank you. And I would be open to answering questions.

MR. ABRAMS: Dr. Gottlieb?

DR. GOTTLIEB: Notwithstanding the fact that there are different statute and different jurisdictional requirements on the device side of the house versus the drug side of the house, you seem to be advocating a consistent approach across all of the advertising, which I guess presupposes that you think there are times in which we have been inconsistent.

You don't need to answer that.

My question then becomes, what do you think we should be doing? Is it additional guidances? And are there specific things we should be issuing? Are there operational things we should do internally to take a more consistent approach?

MS. TANDY: I wouldn't say that you have been inconsistent. I guess what AdvaMed had said -- and, you know, we said it in our comments, so I might as well repeat it here -- is that we have had the feeling over time that the agency just takes the drug rules and slaps them onto devices. So it's not inconsistent. It's that it's not perhaps what should be happening mindful of the statute and mindful of the differences between devices and drugs. So I don't think you have been inconsistent.

We do think that the guidance document on restricted device advertising should issue. We recommended a whole lot of revamping towards it, you know. So we thought that we put in a lot of good ideas.

And we do think it would be helpful because we don't have a regulation. And so even with just the brief statement requirements, it's still helpful to flesh out a little bit more, you know, how

to do that and various ways in which we could do that. So we would like to see that revised guidance document issued. We think that would be incredibly helpful.

You know, we follow this area. We look at any enforcement action that happens. We look at the enforcement actions in Rx pharm. And we try to kind of glean things from there. But, you know, again, that's not as good as having a nice guidance document.

I guess I could say if we thought that anything else would really help, we're like the biggest advocate for having more resources in CDRH devoted to the DTC area because we think there's not enough.

MR. ABRAMS: Dr. Behrman?

DR. BEHRMAN: You had a bullet about technical information.

MS. TANDY: That one?

DR. BEHRMAN: No.

MS. TANDY: No?

DR. BEHRMAN: Maybe it's 4? No. Keep going. Maybe 5 or 6.

MS. TANDY: This, technical information in consumer-friendly language?

DR. BEHRMAN: Yes. Thank you.

So are you saying that should not be a requirement, it should be a recommendation or you feel that impact is already required and we should just emphasize it? What was your point?

MS. TANDY: The thinking about there is that, I mean, we would love to hear how you think we should do it.

DR. BEHRMAN: Okay.

MS. TANDY: We don't want you to tell us that you have to do it this way, this way, this way, but some of the things that FDA has learned through experience that would be really helpful on like when we look at our IFUs, instructions for use, -- that's what we call our labeling in devices -- when you look at the IFU and we're trying to craft our brief statements and so we have all of this technical unbelievable only like a, you know, health care professional person can understand it and then we've got to make it into consumer language for TV, we spend a lot of hours doing that.

So we gave some ideas in our comments, but, you know, we would like the guidance to incorporate those ideas and any other ideas.

MR. ABRAMS: Dr. Temple?

DR. TEMPLE: Okay. Yes. It's probably

because I've just read stories about coded stents in the New England Journal. We have problems with comparative kinds of claims appearing in advertising and what kind of support they should have.

It strikes me, although I don't really know device advertising, that the temptation to make claims there must be, if anything, even greater because it's such a big deal.

Do you have any particular thoughts on standards and criteria for making comparative claims?

MS. TANDY: That's a great question. I guess I would say that what I have seen, where I have seen comparative claims for the device ads is in the professional ads. I haven't really seen it -- I mean, again, we do limit it to DTC broadcast and print, but I haven't really seen it there. And maybe it's because we have limited time, limited space; whereas, like we have a four-page brochure that we could hand a surgeon. And so I have seen it more there.

So I think it's more the professional sector, not that we couldn't talk about it, because, again, we try to follow some of the principles that have been laid down in 21 CFR 202 on drug advertising for comparative ads for having the support.

Now, in devices, you know it's different

because most of our products are 510(k) products, which means we don't always have to have comparative clinical trials or even any clinical trial data. So we couldn't have that as the standard for making a comparative claim because the product review wouldn't support that and we wouldn't have that data in the product review.

DR. TEMPLE: That is sort of why I am asking. In the particular case I am talking about, there were two controlled trials comparing two kinds of coded stents. So you, arguably, have the sort of data you usually have, but in a lot of cases, you have engineering data or something like that.

So I just wondered if you had any thoughts about how in that setting without the clinical data you would deal with this or whether it is just too complicated to expect a patient to cope with or what.

MS. TANDY: You know, I guess I would say to say on the professional side, when we do it on the professional ads, the way we try to do it, again, is you have got to have valid data to support that comparison.

And like if it's a mechanical claim or a performance claim, then we have to have when we do it in the professional brochure a reference. We have to

show maybe the data is on file, you know, that type of level, but we have to have that support.

In a consumer-directed ad, I think we would have to have the same thing if we did it. And we would have to figure out a way that we could adequately explain to the consumer what these two devices are, how they were tested, and what the results show.

So I think it would be a lot harder. I'm not going to say we couldn't do it because we'd never say we couldn't do it. But I think it's a lot harder in devices because we've got data that we usually don't have.

MR. ABRAMS: Ms. Tandy, you mentioned before that the previous thought in industry was it would be too difficult to explain these complex devices to consumers so it's understandable, but then industry apparently took steps to do that.

I guess I have a couple of questions. What steps have you taken to do that so we can learn to translate these terms? And then how do you know you're really effective in conveying these complex concepts to the consumer?

MS. TANDY: Also great questions. I think we thought as an industry that we would scare people

if we put on TV and we put in print about surgery and implants and stents and have your hip surgery.

And we thought, honestly, that it would frighten consumers, you know that nobody really wants to think about these horrible surgeries and awful things that can happen to you that, you know, you need to have surgery. So I think that's why we stayed away from it for a long period of time.

Then I think as we saw the Rx pharm, all of a sudden, people seemed to get a lot more comfortable with -- I mean, there are a lot of awful diseases out there. And, all of a sudden, there's a lot of Rx pharm ads for, you know, very distressing diseases. And they're on TV all the time.

And then you've got the internet that people are talking. I think that was the hugest explosion that people are actually researching things on the internet and, instead of a mentality like "Oh, no. I want to kind of not hear about these things," you know, like in the old days, doctors sometimes felt that it wasn't necessary to even tell patients about their own illness because we wanted to try to keep things from them. We were a little more in that vain.

But I think that has turned full circle. So we began to realize that if you talked to consumers

about surgeries and implants and if you actually showed an implant, like a consumer wouldn't like react with shock and dismay.

So I think that was a turning point. And I think that started us thinking we really could do this, you know. So how do we do it? What are our legal constraints in order to do it?

And then I think our biggest challenge so far has been how do we turn that information about what the product is used for and how do we turn that information from our professional-level explanations into the brief statement?

And we do. We spend a long time looking at the risks, the side effects, the warnings, contraindications. How do we explain that in a way that a consumer is going to understand in 30 seconds or 60 seconds on TV?

And I would be remiss if I didn't mention we also have the help-seeking ads. You know, we run ads where we talk about disease states. And we don't ever mention a device. We may mention that a treatment is available, but, again, it's an education that there are certain diseases out there that people may never have heard of and there is treatment for that, like normal pressure or hydrocephalus.

We ran an ad by Codman, one of the Johnson and Johnson companies, to educate consumers about what are the signs of normal pressure, hydrocephalus, and they should see their doctors if they have those signs.

I hope that answered your question.

MR. ABRAMS: Yes, it did. So one technique, just to distill this down a little bit, would be to show the consumer the procedure and things like that. Other techniques that you have tried have been successful/have not been successful?

MS. TANDY: You know, I probably wouldn't want to talk about the unsuccessful ones, but I will think about that. But the successful ones certainly we actually do have, not on TV but on our Web site -- you know, most of the device companies have Web sites that go to the consumer. And we do have a procedure you can watch on some of these Web site, a procedure from start to finish.

So if you're going to have your implants, you could go on there. And you could do that. The idea is maybe you could see it on your computer or you see it on like a CD-ROM or a DVD. Maybe it's less scary when you actually get there, you know? So a lot of that seems to have worked well.

I know that the people in our company do measure the responses. And it's very interesting because when most of our ads on TV say, you know, have a Web site that patients can also log into for further information, what I have heard from our people who measure this is that within a short period of time after that ad airs, that there's like this big spike in people coming, hits they call it, hits onto that Web site. And that amazes me because I'm not so computer-friendly yet. And I can't believe that that happens.

But it seems to be that the internet combined with the TV message seems to be very effective. Those have been our most effective methods.

MR. ABRAMS: I have a request. Any research that you have done for industry that companies are willing to share -- I understand there are obviously concerns about particular products but things that would make this useful complex information more useful for consumers, anything that you could share with us we would really appreciate having submitted to the agency.

MS. TANDY: We will look. You know, to be honest, I mean, the research presented today already

was so interesting to me because I know we haven't done any of that as a device industry association, but we will see what we have got.

Thank you.

MR. ABRAMS: Ms. Tandy, thank you very much for your presentation.

Nobody has signed up for providing public comments from the floor. So I invite anybody who wishes to. There are open mikes. We have about ten minutes at this point. If you could identify yourself, name and affiliation, that would be useful.

DR. DAY: Ruth Day, Duke University.

I appreciate the information about the internet. I am a strong and enthusiastic supporter of health information on the internet. However, there are some things to be concerned about.

I believe Mr. Gardner said that the online channel is more balanced because there is more place to show the benefits and the risks. We have done studies and others have as well looking at drug product Web sites. And we have found that the number of points and clicks that it takes to find the side effects is greater than to find the benefits.

So this is very much in line with my comments this morning about the cognitive

accessibility of the information. Certainly the internet has more space for more stuff. But what is the ease with which people can find it? That's point number one.

Point number two is about these wonderful take-the-test Web sites. They are fun. They are interactive and so on. However, there are some interesting issues. What happens when a person enters his or her information? You have to hit the "SUBMIT" button. Where does that go to?

So we have done some studies where we have Jane Does and John Does take the tests. And then we wait for three months to see what happens. And sometimes there has been advertising and promotional material that has been sent to that individual.

So where does the information go when someone takes a test? And how is privacy preserved? Of course, you can have some initials or funny name for your e-mail address and so on, but there are IP addresses. And so I think there are some privacy issues.

The final point on that is that sometimes a test taker has concerns about privacy and so clicks on the privacy statement. And the privacy statement they think is there to make sure that their data are

private. Privacy statements are mostly about protecting the company. And so people don't understand the privacy statements.

So I think there is a range of issues that are in common with DTC in other arenas and ones that are specific to the internet.

MR. ABRAMS: Dr. Day, we appreciate your comments. And I hate to be redundant, but just take this because data is important to the agency. It's how much we value data. Dr. Day, if you have data that you would be willing to submit to the agency, we would appreciate it. Thank you.

Yes?

MR. CAVALLINI: My name is Mario Cavallini. I am with Simstar. It's an interactive marketing agency for the pharmaceutical industry. My position with Simstar is that of manager of competitive intelligence, a little spooky title, but I mention it because my job is consuming and dispersing information. And I am speaking as a consumer of one particular source, which is Manhattan Research.

Dr. Gottlieb, earlier you asked the question about people using search engines and whether they are able to find reliable information. What came to mind for me is data that Manhattan Research has.

Manhattan Research has been doing surveys of both patients and health care providers over the past five or six years. In their most recent round of physician survey, what they have been finding is an increasing use of Google and other general search engines by physicians for clinical information. Almost exactly half of the responding physicians in the current round said that they use Google and similar search engines daily for clinical information.

One of the things that is interesting in that fact is that they are finding enough there there to keep coming back and using it again. Now, they also have certain advantages in being able to sniff out reliable information. If you take a look at the professional literature in PLOS Medicine, BMJ, and other journals, you will see more articles providing advice on how to use search engines, how to use Google Scholar and Google Image, for instance. So that is an indicator that there should be more emphasis on raising health literacy among consumers on how they can better use search engines.

If you look at credibility of research, a lot of it is done by Fogg out at Stanford. His initial studies tended to deal with how professionals use search engines and how they evaluate Web sites.

And a lot of it dealt with credibility markers. But then when he started talking with consumers, their response was "Well, it looks professional."

Now, that could be interpreted as judging a book by its cover, but I'm going to make the intuitive leap and say that people are getting more experienced with finding information on the Web and looking up health information in various sources. And so while they may not be fluent in just identifying what those markers are, they're getting more of a sense of what is responsible and reasonable.

The other items that comes to mind -- and I thank the previous speaker for her comment because it does dovetail on this -- if you talk with any webmaster of a product dot-com, they will tell you that the most frequently accessed pages tend to be the pages on side effects. People go to Web sites, and they look for side effect info.

There is a myth that is connected with that, though. There is a fear that people get spooked by the side effects and then go screaming off into the night.

At Simstar, we submitted a query to Manhattan Research, which does collect a lot of information on how people use medical information

sites, how they use product sites, what they do afterwards, what they do at the sites.

We asked them to run a cross-correlation on people who identify as looking at the side effect information at a product site and people who use product information sites but don't look up side effect information.

What we found across the board is that the people who look up side effect information also are more likely to look up other information. They are much more likely to use the tests and quizzes on the sites. They are much more likely to use the talk to your doctor tools, much more likely to use Telefriend and other functionality.

Afterwards, the people that look up side effect information are much more likely to talk to their friends. They're much more likely to go to the doctor. They're much more likely to be confined with their drugs. It's really amazing to see the connection.

MR. ABRAMS: Thank you for your comments.

That concludes this panel. I thank the panel for their excellent presentations.

(Applause.)

MR. ABRAMS: We will take a 15-minute

break and start promptly at 3:15. Thank you.

(Whereupon, the foregoing matter went off the record at 3:00 p.m. and went back on the record at 3:19 p.m.)

MR. ABRAMS: Welcome back. We are having our final panel of the day. And we will begin with Rebecca Burkholder with the National Consumers League.

MS. BURKHOLDER: Thank you.

PANEL 4

MS. BURKHOLDER: The National Consumers League, the nation's oldest consumer organization, is pleased to be here today to comment on direct-to-consumer promotion of prescription medication.

Founded in 1899, NCL is a private, nonprofit advocacy group representing consumers and workers on marketplace and workplace issues. Our mission is to protect and promote economic justice for consumers and workers in the United States and abroad.

NCL has long been interested in ensuring that consumers receive accurate and helpful information about their health care, including information about prescription medication.

Direct-to-consumer advertising prescription drugs, DTC, is part of a long-term

systematic shift towards patient-centered care. With this shift, it is critical that consumers are able to assess risks and benefits of health care treatments, including prescription medication.

Today I would like to focus my remarks on the following. First, I will talk about the presentation of risks and benefits in current DTC promotion; second, some suggested improvements for DTC; third, other communications regarding prescription medication, including in pharmacy communications; and, fourth, a bit about FDA oversight.

First, I would like to talk a little bit about the risks and benefits information in current DTC ads. DTC can be a useful tool for initiating and complementing patient health care professional communication.

Armed with balanced clear information, consumers can initiate dialogue with their physicians about the risks and benefits of and alternatives to prescription drugs as well as talk about medical issues they may not otherwise.

A 2002 NCL survey of over 1,000 adults showed that more than half of those who saw a DTC ad were motivated to take action. Thirty-one percent

decided to talk with their doctor about the medication of their next appointment and 26 percent, over a quarter, sought more information about the drug from various sources.

Those who sought more information from pharmacists, medical or drug reference books, or a health Web site wanted to know if the drug was right for them or a family member.

In addition, the survey showed that consumers are wary of DTC advertising and cynical about the motives of pharmaceutical companies. More than half agreed that the ads just help pharmaceutical companies sell their drugs and nearly half think the ads are largely responsible for the increased cost of prescription drugs and that they encourage people to ask for drugs they don't need or cannot take.

As we know, DTC needs to do a better job of presenting balanced risks and benefit information and not create unreasonable expectation or promote inappropriate use.

We know that consumers are failing to take away important health information after seeing, hearing, or reading a DTC ad. While risk information is present in these ads, it may be hard to comprehend due to the technical vocabulary and formats used, such

as small type.

In broadcast ads, risks may be missed by consumers when they are listed very quickly in one continuous segment and while contradictory visual images are shown.

Confusion of risk information can affect consumers' perception of risk. We encourage you in a continuing study of the most effective way to present risk and benefit information to consumers.

Given what we know about current DTC ads, we would like to suggest some improvements. FDA's current requirements and policies for prescription drug advertising and promotional labeling are really ill suited to communicating information to consumers.

FDA should revise its regulations and policies to allow for more consumer-friendly information about the safe and effective use of prescription drugs that is clear and understandable to the average consumer.

NCL supports FDA's 2004 draft guidance recommending alternatives to the current brief summary common in most print ads. Because the brief summary is an accompanying advertisement and a consumer must still obtain a prescription before receiving the medication, which when dispensed will be accompanied

by more information on safe use and risks and benefits, NCL believes certain information can be deleted from the brief summary, including exhaustive risk information, dosage, and administration. In this context, less is really more. The emphasis in DTC ads should be on the most serious and common side effects.

NCL further believes that a standardized information panel, such as an Rx facts box, much like the successful format that is now being used for nutrition facts, supplemental facts, and OTC drug facts, would be a better way to communicate risks and benefits to consumers. Coupled with user-friendly language and adequate provision for the consumer to obtain additional information from other sources, this approach would be helpful to consumers.

We are encouraged that FDA seems to consider this type of standardized information panel as one option in the 2004 guidance. NCL is also pleased to see that some pharmaceutical companies are seeking consumer input to reformat the risk and benefit information in creative formats, such as question and answer and fast facts formats.

For DTC ads to truly educate or benefit consumers, they should not only contain understandable risk information but also information on the drug's

benefits. Many ads use vague qualitative terms to describe the benefits; for example, lower your number for cholesterol drugs. The ads' actual benefit data may lead consumers to believe that a drug works better than it actually did.

A benefit box with published data on the chance of various outcomes with or without the drug should be considered for inclusion in DTC ads. Consumer perception of drug effectiveness could be improved with this type of information.

NCL would also welcome more educational content about disease and conditions in DTC ads. If consumers understand the role of drug therapy in treating their disease or condition, they will have reasonable expectations of the drug's benefits. In addition, we would encourage more disease awareness communication without the promotion of a specific drug.

If we really want to improve public health, we should spend some of the billions of dollars spent on DTC on messages about disease awareness, health conditions, diet, exercise, and drug compliance that is not product-specific.

For certain under-diagnosed diseases and untreated conditions, such messages are conversation

starters between patients and health care professionals. These communications should include evidence-based information and direct consumers to other sources for more information.

Third, I would like to talk about other communications consumers receive about prescription medications. We know that consumers obtain information about prescription drugs that they take from many sources: from physicians, pharmacists, drug package inserts, health plans, internet, magazines, newspapers, family, and friends. Given this, FDA should consider how its policies can foster, rather than hinder, the flow of communication from these alternative channels.

Restrictions and disclosures that are necessary for sponsored DTC ads may not be appropriate for communications from health care professionals and pharmacists and may even consider with consumers. Amount and type of information required to accompany prescription drug communications should depend upon the particular type of message.

A one size fits all requirement is not appropriate. For example, sponsored messages that encourage patients to continue to take the drug therapy that has already been prescribed and dispensed

are different from ads in the mass media and should not be treated the same way. These compliance messages should not be considered promotional in this context.

In addition, customized messages delivered by a pharmacy with a drug should also not be treated in the same way. These messages are part of the practice of pharmacy. And the pharmacist is readily available to talk about the drug dispensed and adjunctive or alternative treatments with the patient.

FDA we believe should follow the Department of Health and Human Services' final privacy rule, which deems refill reminders and pharmacy-initiated communications be part of a health care professional's treatment of a patient, not marketing. NCL would welcome further guidance from the FDA on in pharmacy communications.

Finally, a few comments on FDA overnight. NCL believes FDA should be able to review all DTC ads before deployment. This would enable agency staff to revise material if needed so misleading information does not reach consumers.

In order to effectively and efficiently review ads in a timely manner, FDA will, of course, need the resources to provide sufficient review staff.

If FDA is not able to review these ads before they are deployed and ads are later found to be misleading, the sponsors should be required to engage in corrective action to remedy the misrepresentation.

We would also like to see consideration by the FDA of prolonging the period between drug approval and initiation of product promotion; in other words, a moratorium on advertising for certain drugs when there is the need to gather more safety information, educate physicians and health care professionals.

It has been suggested that FDA should even consider adding a provisional status for some drugs. Such a status would allow time for limited exposure of the product to appropriate patients while there is additional post-approval safety data collection.

In conclusion, I would like to thank the FDA for allowing us to comment on this important issue. Thank you.

MR. ABRAMS: Thank you for your presentation.

Your presentation included many interesting concepts, a whole lot of concepts, and suggestions of what FDA should do. What would your advice be to the agency as far as if we were going to incorporate these? Should we do it by guidance

development, changing regulations, some other mechanism?

MS. BURKHOLDER: We would see that there needs to be a change in regulation, that those regulations were not written incorporating the lay comprehension evaluative criteria, but that's an important starting point to redo the regulations so that the idea that understandable consumer information needs to be part of the DTC promotion in advertising.

MR. ABRAMS: Thank you.

Dr. Temple?

DR. TEMPLE: I was particularly intrigued by your thought that there should be more detailed effectiveness information. We think about that, too, but how to do that is considered challenging.

I mean, you have heard all of this, I am sure, but you give the percent reduction in heart attacks. And that sort of overstates it. You should actually give the actual percent difference between the populations.

Do you think it is realistic to think that, at least on more complicated things, that can be done well without sort of making more trouble?

MS. BURKHOLDER: Is it realistic? We would like to see more study on this issue. And I

think what we have seen is that it is possible for certain drugs to do that.

I agree with you that it is a tricky issue. I think we really need to look more carefully about how we can do that. We know consumers generally think the drug is more effective. And when they are presented with this benefit information, they generally have a lower view of effectiveness but have found it to be very helpful.

DR. TEMPLE: When we first approved over-the-counter H-2 blockers, there was a package insert that showed that the difference between treatment for one and treatment with placebo is about 50 percent.

But we wanted it in there so people knew how modest the effect was. But we were never satisfied that we had actually succeeded in communicating anything to people.

MS. BURKHOLDER: Right. And I think part of it is that consumers need to be continually presented with some of this information. I think when they are presented with it, they will become more savvy and perhaps become more detailed.

Thank you.

MR. ABRAMS: Dr. Ostrove?

DR. OSTROVE: Interested in just hearing a little bit more about your belief concerning wanting to see more in the way of disease-oriented promoted.

This morning Pat Kelly kind of talked about that and talked about how it doesn't seem to be, I guess the way it has been done doesn't seem to be as effective, in getting patients in to see the doctor.

Well, you know the question I guess in my mind is, is that the right dependent measure? You know, is that the right thing that we should be looking at? Is there something else that you all would have in mind, for instance, as an assessment of the value of the disease-specific promotion, disease-oriented promotion, as opposed to product-oriented?

MS. BURKHOLDER: That's a very interesting question. I would think that it would be very hard to assess the impact of those. But, in addition to just talking to your physician or going to see your physician, some of it, as we know, consumers are turning to the internet, to other sources to gather more information. So after seeing ads such as that, they may be seeking out other sources of information that still may be helpful to them.

I would also say that perhaps we can do

better with those disease awareness ads. We do know that DTC is prompting people to talk to their doctor about a drug. It seems like if we could do those ads right, we could prompt more people to talk to their doctor about a condition or disease.

DR. OSTROVE: Thank you.

MR. ABRAMS: Ms. Burkholder, thank you. And we thank you for your patience with the technical difficulties distraction.

Our next speaker is Lee Hammond with the AARP.

MR. HAMMOND: Good afternoon, ladies and gentlemen. My name is Lee Hammond. I am a member of AARP's Board of Directors.

On behalf of our over 35 million members, we would like to thank you for convening this public hearing and for including AARP in your discussions about direct-to-consumer advertising of prescription drugs.

In two weeks, millions of older and disabled Americans will have the opportunity to choose prescription drug coverage as a part of their 2006 Medicare benefit options.

The new Medicare benefit prescription drug program will help millions of beneficiaries afford

needed medications. We now need to take the next step to make prescription drugs affordable for Americans of all ages.

One of the places to start is by changing some of the direct-to-consumer advertising practices that lead to unnecessary increases in drug spending. Direct-to-consumer advertising of prescription drugs can be helpful to consumers. If done well, ads can provide general information about a specific disease or condition, particularly one that is historically under-diagnosed and/or treated. These ads also cause increased and often unnecessary health care spending.

In recent years, the amount of money spent on prescription drug direct-to-consumer advertising has skyrocketed. Between 1997, when the FDA relaxed its guidelines for broadcast advertising, and 2004, spending on direct-to-consumer advertising increased by $3 billion. In 1999, just 25 top-selling medicines promoted directly to consumers accounted for about 41 percent of the nearly 18 billion increase in retail drug spending from the previous year.

The link between increased direct-to-consumer advertising and the overall increase in health care costs is real. For instance, patients are prescribed often unnecessarily, new

heavily advertised pharmaceuticals as the first-line therapy, rather than the older, equally effective but often less expensive, medications.

Providers often feel pressure to prescribe the advertised prescription drug, perhaps forfeiting a meaningful dialogue with the patient about other appropriate courses of treatment, including non-drug treatment alternatives.

A recent study in the Journal of the American Medical Association found that doctors were five times more likely to write a prescription about a specific drug requested by their patients compared to those who did not mention a specific drug.

AARP believes that the FDA should be given the resources and the authority to require review of advertisements, both print and TV, before the ads are disseminated to the public.

Some broadcast DTC ads now include more direct communication of risk information. We do not know if or how this will translate into more cautious prescribing for new drugs.

Unfortunately, the risk information printed in DTC ads is neither useful nor informative for consumers. In most cases, it's nothing more than a microtype reprint of a so-called brief prescribing

summary.

The search suggests a direct relationship between risk statement completeness and consumers' perception of drug safety and appeal. We support the FDA's current research plan to develop more consumer-friendly risk communication strategies for print advertisements.

Earlier this year the Pharmaceutical Research and Manufacturers of America's Board of Directors approved voluntary guidelines on direct-to-consumer advertising of prescription drugs. These guidelines are welcome, but, rather than relying on the industry to police itself, we believe that the Food and Drug Administration must play a bigger role, starting with the revising of its 1997 guidance for industry, consumer-directed broadcast advertisements.

We urge the FDA to work in consultation with other interest groups, including consumers and providers, to ensure that direct-to-consumer advertisements inform the consumer and provide clear accurate information and that the ads encourage the consumer to have a productive dialogue with their provider about treatment options, including prescription and non-prescription medicines, lifestyle

changes, if applicable.

Finally, we believe that the U.S. health care system can also benefit from a more serious investment in the research of comparative clinical effectiveness of prescription drugs.

Unlike other countries, the U.S. does not require that drugs coming onto the market demonstrate enhanced effectiveness and safety profiles in head-to-head trials with drugs already available in the marketplace.

Congress as a part of the Medicare Modernization Act of 2003 authorized $50 million in funding in F.Y. 2004 and "such other sums as may be necessary" in subsequent years for comparative effectiveness research.

To date, Congress has only appropriated 15 million for this valuable research. This amount is $2 million less than Merck spent advertising Vioxx in 1999, its first year on the market.

With Medicare footing the bill for many prescription drugs starting in 2006, this is a perfect opportunity for Congress to boost funding for comparative clinical effectiveness studies that will provide scientifically based information on the relative clinical effectiveness of different

prescription drugs within the therapeutic class.

In some cases, the newer drug may be the best treatment option. In other cases, the best treatment option may be an existing brand name or generic drug. Broad dissemination of the results to both the public and health care professionals may help to reduce the influence of direct-to-consumer advertising.

Direct-to-consumer advertising is just one way to inform consumers about newly approved medicines. While AARP will continue to examine how DTC can best educate and inform consumers, we will also pursue other ways to promote appropriate and cost-effective prescribing to help consumers make wise choices about their medicines.

Thank you.

MR. ABRAMS: Dr. Temple?

DR. TEMPLE: I just want to say one thing. To my best knowledge, at least none of the European countries require the drug be better than what is available. They do ask for comparative data.

MR. HAMMOND: They do ask for comparative data.

DR. TEMPLE: That's true. And it can affect their price, but it's not a requirement. One

of the points you made earlier -- and it's certainly true -- is that the things that are promoted in DTC advertising are the new branded ones. That's certainly true.

Do you have a thought about what the remedy is? I mean, I don't think anybody is going to promote generics or older drugs that have generic competition very much. And, in fact, they don't. What are your thoughts on what one could do about that?

MR. HAMMOND: I think there are two things that could be done. And one goes back to the cost-effectiveness studies with the drugs that are already on the market.

The second is the encouragement of the consumer to actually create a dialogue with their health care professional concerning these things. The health care professional generally knows what is available, both in the pharmaceutical name brand market and in the generic market. I found in my case, for example, in many instances my health care provider has said there is a generic drug which will do just the same thing.

So I think encouraging that dialogue is certainly one of the major ways that we can actually

reduce the cost I think of some of our prescription drugs for people.

DR. TEMPLE: So the doctor would have to say that there is a generic drug that is different. I mean, in fact, advertising of drug stops once there is a generic pretty much. But they may continue to promote a different molecule that is more or less the same.

So the doctor would have to say you don't have to use this ace inhibitor. You can use that ace inhibitor because there is a generic available for that.

MR. HAMMOND: That is a possibility, yes.

MR. ABRAMS: Dr. Ostrove?

DR. OSTROVE: It's really just a request. You mentioned that patients are often prescribed products that are inappropriate, prescribers feel pressured. And I'm assuming that as part of your testimony that you will be submitting to the docket that -- I mean, it would be very helpful for us to have those references.

MR. HAMMOND: I think staff could make sure that that is involved in the written testimony.

DR. OSTROVE: Fantastic. Thank you.

MR. HAMMOND: Thank you.

MR. ABRAMS: Mr. Hammond, thank you very much for your presentation.

Our next speaker is Gary Stein from the American Society of Health-System Pharmacists.

DR. STEIN: Thank you.

ASHP is a 30,000-member national professional association that represents pharmacists who practice in hospitals and other components of health care systems. For more than 60 years, ASHP has helped pharmacists improve medication use and enhance patient safety.

Luckily, we had our policy-making council's meeting in Bethesda in mid September, just after the notice of this meeting came out. And we were able to poll some of our members regarding the questions the FDA asked in that announcement.

We will be submitting more extensive comments in a written submission by the February deadline, but I would like to present our initial views on the questions and our members' initial views on the questions that FDA asked in its announcement of the meeting.

Our members believe that certain ads, such as for drugs for erectile dysfunction, are shown all day long. And children are exposed to these ads. One

of our members said the parents, of course, to discuss the issue, which is certainly not the intention of the direct-to-consumer advertising but may confuse the parents of smaller children.

In terms of the presentation of risk information, our members feel that the language should be at a low-grade level. Print ads are written in order to ensure that lay people understand the advertisements.

The discussion of risk should not be presented with positive backdrop images. Coupons and money-back guarantees, which will hold the specific questions that FDA asks, should not be allowed because they convey the idea that the medication always works and that there are no risks.

The expression of benefits in percentages, such as works in 70 percent of patients, we feel that this tends to induce consumers to overlook or to minimize risks.

It's uncommon for drug companies to do comparative studies. They often take two separate studies and compare efficacy, even though both drugs were not included in the respective studies. This is very misleading. And the FDA should prohibit such comparisons.

In terms of whether changes in certain required prescription drug disclosures might improve the usefulness of the information for consumers, the language in the package insert is difficult to navigate for consumers, of course, and it's written for a health care professional to interpret and not for a lay person.

We recommend that it be presented at a lower grade level, as we often do, our members often do, for their patients when using print materials. Also, the fact that the package insert is printed in is not conducive to reading. Often seniors are looking for this information and cannot read those documents as printed. And the font size should be sufficiently large to be readable.

As far as the question of whether changes in the requirements for disclosure of certain information in broadcast advertising could improve the usefulness of the information for consumers, the disclosure is usually at the end of the advertisement and it's said very quickly, not allowing consumers to comprehend it.

We recommend that it be spoken and at the same time appear on the screen so that the consumer can follow along. And also the visual background and

the context should reinforce the information that's presented.

In terms of new communication technologies, our members believe that the FDA needs to regulate Web-based promotions. Direct mailings to consumers, such as CDs that are sent to consumers, also need to be regulated.

The Federal Register notice of the meeting also asks what action FDA should take when companies disseminate violative promotional materials to consumers.

And one of our members said that there should be a graduated fine structure culminating in a six-month moratorium for a company's entire product line for direct-to-consumer ads after a third offense. This would give companies pause before trying t push beyond the regulations.

In terms of whether current DTC ads present benefits and risks in an accurate and non-misleading balanced and understandable way, currently the FDA requires a fair balance between benefits and risks, but there is no definition of fair. Is this 50/50? Some of our members believe so?

The risks are usually discussed toward the end of the advertisement and discussed in a rapid-fire

manner. The terms are often in what one member called medical speak and not in layman's terms.

We have been discussing the idea of direct-to-consumer advertisements. We had a policy developed in 1997, when these ads first became prominent. And when our policy-making council met in September, we addressed direct-to-consumer advertising. And this is not a fully ratified policy yet, but this is the direction I think that we're going is to support direct-to-consumer advertising that is educational in nature about prescription drug therapies for certain medical conditions that appropriately include pharmacists as a source of information and, further, to support direct-to-consumer advertising specific prescription drug products with the following requirements. Such advertising should be delayed until post-marketing surveillance data are collected and assessed. The risks and benefits of therapy are presented in a comprehensible format that allows informed decisions on both the part of the consumer and the health care provider and that there is a clear relationship between the medication and the disease state.

Like I said, since 1997, ASHP policy has opposed consumer advertising of specific prescription

medications. In September, our council acknowledged the current state of direct-to-consumer advertising and the possibility that some consumers may be induced to seek treatment as a result of such marketing.

And we strongly believe that specific product advertising should be delayed for newly approved products until post-marketing data can be annualized to determine the ongoing safety of a product. The increasing demand for such products before such an analysis would present a possible premature risk to the public health.

We also believe that such advertising needs to be more forthright and comprehensible about the disease state to be treated and the risks and benefits of treatment.

And I will be happy to answer any questions that you might have.

MR. ABRAMS: Ms. Davis?

MS. DAVIS: I thank you for your presentation.

I have a clarifying question. You talked about the emerging technologies and that FDA should regulate these. Do you have any specific recommendations for regulations that might address these technologies or were you just speaking as a

general matter?

DR. STEIN: We think this is as a general matter. I think that when we submit our written comments, we'll try to come up with something more specific.

MS. DAVIS: Thank you.

MR. ABRAMS: Dr. Temple?

DR. TEMPLE: I assume the thought that there should be a delay in this kind of advertising until surveillance has had a chance to go forward is based on recent issues, like antidepressants and COx-2.

DR. STEIN: Absolutely.

DR. TEMPLE: Surveillance did not reveal either of those results. They were revealed through randomized trials in children, which were then pulled together to get the data, and by several very large comparative trials and subsequently some placebo-controlled trials with the various COx-2 inhibitors. That makes it a little unclear what you mean about surveillance.

If those are the models, I guess I would like to hear more about what you are looking for in terms of actual surveillance. Some adverse reactions are seen that way.

DR. STEIN: Right. That is what we were considering: adverse reaction reports and public prevention.

MR. ABRAMS: Dr. Gottlieb?

DR. GOTTLIEB: You mentioned that you think the advertising should be written at a fourth grade level. Is that based on observation from ASHP or other kinds of benchmark to other types of consumer --

DR. STEIN: That's based on observations of our members who are dealing with patients.

MR. ABRAMS: Mr. Byrd?

MR. BYRD: You mentioned something about, if I remember correctly, comparative claims. Could you clarify a little bit about comparative claims regarding other products?

DR. STEIN: Clinical effectiveness trials is what we were talking about.

MR. BYRD: Not head-to-head trials but --

DR. STEIN: Right.

MR. BYRD: -- separate trials --

DR. STEIN: Right.

MR. BYRD: -- being used together?

DR. STEIN: Yes.

MR. ABRAMS: Dr. Stein, we thank you for

your presentation.

Our next speaker is Lisa Van Syckel with Drugawareness.org.

(Whereupon, a tape was played.)

MS. VAN SYCKEL: My name is Lisa Van Syckel. I am also Michelle's and Christopher's mother. When Michelle was given Paxil, it turned out she actually had Lyme disease. She has been treated for Lyme disease. She is now in her third year of college majoring in criminal justice and doing just fine.

My concern is with the drug advertising. These drugs are being prescribed off label. And we were promised the black box warnings. I don't see black box warnings on television. I don't see them in the print. I don't see them in magazines. And, you know, when you look at the article, it says "may have increased thoughts of suicide."

Ladies and gentlemen, you heard a 911 tape of a child attempting suicide. When you look at the black box warning in the ad, which is on the second page behind, where parents don't see it. Does that really put out the full effect of a suicide in a child due to a drug?

I want you to look over here on the side.

This is from GlaxoSmithKline from 1997, their sales representatives. Look at it. It says, "Discontinuation." Why this is an issue, one billion dollars.

My daughter attempted suicide on day two of Paxil withdrawal. Had I seen that, had doctors been given that, would my daughter have gotten Paxil? Probably not. Would he have told me about withdrawal? Absolutely.

Why didn't GlaxoSmithKline warn us in their advertising? Withdrawal doesn't happen, they say. But they knew about it. They were more concerned about their billion dollars than they were about the life of a child.

Now we have in the schools promoting materials for medications off label. And I'll read it to you. It says, "Mental illness has never been more treatable, but there is a deafening silence about it in all classrooms. So begins the brochure on break the silence through education.

This program is a new curriculum that will be introduced in the classroom for this school year. It is specifically designed to reduce the stigma of mental illness and provide information on all aspects of this illness, signs of mental illness, coping

skills, needed support from family, and the availability of therapies and medications.

Materials are designed for specific age groups: preschool, school age, teenagers. The materials are packaged with instructions, worksheets, and lesson plans that will encourage student participation. Poster games, follow-up activities, definitions, a book, and recommended sources give the teacher the broad range of approaches appropriate to the class level and abilities.

Comparing mental illness to physical illness helps the child understand that mental illness is like high blood pressure. Both are helped by treatment and drugs.

These drugs are not effective in children. They don't work. That's been proven. That's why they have been banned in the United Kingdom. And the other thing that I would have liked to have known, which the FDA was aware of, is that a Dr. Palazzo, who was a clinical investigator for Paxil in the OCD trials of Paxil for OCD -- they knew that she was changing records. She has been charged 15 counts of fraud.

Why did the FDA keep that silent during the hearings? Why didn't they say one of their

doctors, one of the clinical investigators, was charged 15 times with fraud? Isn't that something the public should know about? Shouldn't the public know that if our child becomes violent on a medication, that Pfizer has got a prosecutor's manual on how to prosecute our kids? Lovely, isn't it?

We're trying to take care of our children. As parents, if a child is going to suffer a side effect, we need to know about it. We need to know how to prevent it, take care of it. But, my God, if we can't control it and that child commits a violent act, we have got Pfizer going into the courtroom with our prosecutor.

Pfizer should be wanting to help our children, not prosecute them. It makes no sense. And then, you know, the FDA says that there was no homicide, suicide in the clinical trials. That's wrong.

It was detected on July 19th or July 17th, 1983, but Pfizer submitted a document to the FDA and said the reason why the 43-year-old man was discontinued from the trial was because of nausea and agitation. Agitation in the context of a clinical trial is homicide. And it's right there. I've got the document if you would like to see it.

I would like to know why Pfizer filed a document with the FDA and didn't tell them the truth. So we want them to put direct-to-consumer marketing ads out there that are false?

I would like to see a complete ban until you at the FDA can take control of these people and make sure that our children are safe because, ladies and gentlemen, when you go home tonight and you place your head on your pillow, think about the children in the stories. Think about the 911 tape that you heard of my children. My daughter was misdiagnosed. Think about that.

If they're willing to place our children in harm's way, if they're willing to kill our children for the sake of the almighty dollar, can you imagine what they would do for the whole public? They can't be trusted.

You know, I would like to know from the FDA. I mean, you have meetings of drug safety. You have meeting after meeting after meeting. And nobody has done anything. Aren't you adults? Don't you have courage to do something about this, stand up and say, "We're going to protect our kids, And we're going to make sure that they don't promote off-label prescribing to children"?

Thank you. Emotion got away with me. I apologize.

MR. ABRAMS: This is a part 15 hearing. So FDA doesn't comment on questions posed to it. I just want to clarify that.

Do we have any questions from the FDA panel?

(No response.)

MR. ABRAMS: Ms. Van Syckel, thank you for sharing your thoughts and your presentation with us.

Okay. Our final speaker is Diana Zuckerman from the National Research Center for Women and Families. We thank you for hanging in there to be our final presenter today.

DR. ZUCKERMAN: Thanks very much.

Well, I'm last, and I will show some pictures. I hope that will help in being last.

I'm Dr. Diana Zuckerman. I'm President of the National Research Center for Women and Families. Ours is a nonprofit organization dedicated to improving the health and safety of women, children, and families.

There are a lot of different ways to do that, but it ends up that direct-to-consumer advertising has a lot more impact on the health and

safety of women, children, and families than I think any of us imagined would be possible.

So what I would like to talk about today, having heard some wonderful examples of why it is important to regulated direct-to-consumer advertising and wonderful examples of ideas of what could be done to make advertising much more informative and helpful to consumer, but today I'm going to really focus on what is, not what could be. I think you have heard some wonderful things about what could be, but I am going to focus a little bit more on what is and what the problems are that we have currently.

Next, please, or do I do it? Oh, I'm sorry. There we go. Okay. I'm going to just show some ads from magazines. And obviously this one for Vioxx is a few years old.

What I really want to talk about is the power of this ad. We can talk about the specifics of the language and exactly what wording is here, but the power of the ad is the image.

This is a beautiful image. And I congratulate Merck for this wonderful photograph. It really reminds me of a Norman Rockwell painting of what we wish our lives were like.

When I first looked at this, I thought it

was a mom. And then I realized, of course, no, she's a grandmother. Look at her. She looks fabulous. And she's bending on her knees. And she has no pain. And that is the power of the image that they are selling an idea that if you buy this product, your life can be like this. And that is, in fact, what advertising is all about.

My training is in psychology and epidemiology. The epidemiology comes in handy when I am looking at the risk data, but the psychology really comes in handy when I think about how you sell products and how you change people's attitudes and behavior.

If you want to change people's attitudes and if you want to change people's behavior, you don't just talk to them about facts. You give them an image. And this is a very powerful one.

The wording is great, too, "What if how your body feels wasn't always the first thing on your mind?" But it is the image that is so powerful.

And here is another one from Vioxx. These were both in women's magazines a few years ago. The wording actually on the right side is the same for both of the ads, but, again, that's just a beautiful image. This time it's a little bit more obvious that

the woman is not 30 years old but, again, this great image of how great your life could be without pain. And that is what Vioxx is all about in these ads. It's not about the specifics of the wording.

Both of these ads did have information on the back side of the ad that did talk a little bit about what the risks are, but, really, the power is in the image.

This ad is for hormone replacement therapy, again a couple of years old. So there are no warnings about everything that we now know should be warned about for hormone therapy, but this is, again, just a great image, all of these happy mid-life women looking fabulous, being inspirational.

And on the one side of the ad, you can't probably read it, but the language is all about "If you are one of the over 11 million women who take Premerin or Prempro, we want to hear from you." And it's all about telling your story.

The other side is very important because that is where all of the risk information is. That was on the back side of the ad, of course. And assuming that you can't read it from the PowerPoint, let me just tell you the very top part, which has risks, just in a few sentences.

We can talk about should this be at the fourth grade level or should this be at the sixth grade level or should this be at the eighth grade level. And when our center did a booklet for breast cancer patients, for example, we decided on, NCI actually decided on, the sixth grade level as being really important so that most patients would be able to understand it.

This is the wording of just a few sentences at the very beginning, words like "close clinical surveillance," "endometrial sampling," and "undiagnosed persistent or recurring abnormal vaginal bleeding." I mean, that is all just a few words in the first couple of sentences of risks if anybody were to actually ever read it. And that font size is really, really small. So that would make it difficult.

The next ad is Zoloft. And this was I think in Glamour magazine, yes, Glamour magazine, a couple of years ago, again a fabulous image, "This is what your life could be like." On the right side, which is actually the back side of the ad, they don't even have paragraphs on this stuff.

So these are the warnings that patients are getting. And instead of having even paragraphs,

let alone any white space, they have just done wording right across the page. It's actually quite impossible to read, even if you're young enough to read Glamour magazine.

This next one is from Newsweek, very recently, an ad for Aderal. This is a product that has been reported to be associated with sudden deaths in pediatric patients. But there is nothing like that in this ad, again just a great image of a very happy mom, very happy child, and how happy they're going to be if he's taking this particular medication.

I did look on the Aderal Web site to see what kind of warnings they have for their product because, of course, they are supposed to have warnings on their Web site. The main part of their Web site, where it talks about it, basically says thing like "This product was evaluated for safety in over 20 studies." I'm sure that's true, but it doesn't say what the findings were. It only says it was studied in over 20 studies.

This is my personal favorite. This is Newsweek last week. This is supposed to be an informative ad. All it is is you can get a free sample of Ambien, which, as I'm sure you all know, is for sleeping. That's all it is. That's the

information it has. Bring this in. Get your free sample, nothing about risk, not even about what it's for, just you can get some freebies. Again, this was Newsweek just last week.

Here is another ad, also from Newsweek, two weeks ago. There have been some complaints about this ad because it is kind of creepy. You know, it's funny. Most of these images are beautiful and compelling. This is compelling in a different way.

It sort of makes you a little bit sick. And the idea is if your toenails are brittle, you have these little disgusting creatures causing that problem.

Again, it's a little hard to talk about this as an informative ad that's helping patients make important health decisions. This is a product that is effective, but it has some very, very substantial side effects. And you wouldn't know it from this ad.

You know, I don't know how effective it is to get people to want to buy the product, but it sure is effective to make you not want to have this particular problem, I'm sure.

So, just in summary, I just wanted to say that when we're talking about what we need to do about direct-to-consumer advertising, there are enough

studies that tell us how powerful these ads are, but looking at them I think helps us to think about where we are right now. Where we are right now is that medical products are being sold just like any other product, just like the toys that my children want or the other products that people want to buy.

And, instead of really giving us information about risks and benefits, really, all the goal is to make us want to get them. And they're effective, but they're not educating us. And it is the reason why prescription drugs have been going up about 28 percent per year during this time where there is so much advertising and we're just surrounded by it.

Thank you.

MR. ABRAMS: Dr. Zuckerman, thank you for your presentation.

You showed a couple of advertisements and you made a point of the image that you're selling what you can be, promotion. How would you advise the agency to regulate something like that? Where do we draw the line? And what factors should we consider?

DR. ZUCKERMAN: Well, I think, at the minimum, you would want risk information to be put in a font that's as large as the benefit information. It

shouldn't be on the back. I mean, I'll talk about magazine ads because those were my examples right now. Obviously TV is a different issue.

If you look at magazine ads and all of it is imaging in large lettering about the benefits and most of the risk information is in tiny fonts on the back that many people never even look at, even if they do, it's actually impossible to read.

I think of all of the people who are -- I mean, most drugs are being sold to aging people, whose eyesight is not so great. And, yet, these fonts are like a size eight or nine font that most of us really can't read, even when there is white space.

There are some ads that are better now. I mean, I have seen risk information that's better. There are some that actually you can read. It looks more like a 10-point font or maybe even 11. And there's some white space around it so you can read it.

But I think the absolute minimum is that the risk information be understandable and really obvious. And we have never had that. That has just not happened yet. So there might be some little bit of risk information on the front side of an ad, for example, but most of the real risk information is on the back, where people don't know it.

And I can tell you that I asked my daughter, my teenage daughter, who gets a lot of magazines. And, of course, they sell a lot of prescription acne medication and other things on the magazines. I said, "Have you ever looked on the back side of an ad?"

And she said, "What are you talking about?" She actually had no idea what I was talking about. It had never occurred to her to flip over an ad and that there was information on the other side. Just for the many magazines she reads and has read for years, she never knew what that stuff was and just never even looked at it.

MR. ABRAMS: So how can we get people to look at that information? Suggestions? Put it on a different page? Incorporate it? As you said, there is more white space in some of these ads. Some suggestions as far as those?

DR. ZUCKERMAN: Well, it shouldn't be on the back. It should be next to it, and it should be incorporated in the ad. I mean, I'm not a lawyer. And I'm not going to try to get into the legal issues. I think that advertising for medical products should be very different than advertising for cars or toys. And I think that there should be different rules for

that.

And there are some rules about providing risk information, and I think we should take it seriously so that we can actually understand it and that it's part, I mean, incorporated as part of the ad.

If I went back to this image, at the very least, it should be on that. Oh, I'm sorry. It's online, but I guess it's not on there. It should, at the very least, be next to that beautiful image of the happy woman in her garden. The information about risk should be right there, not on the back.

MR. ABRAMS: Dr. Behrman?

DR. BEHRMAN: Following up on Mr. Abrams' question, can we go to the Aderal ad?

DR. ZUCKERMAN: Sure.

DR. BEHRMAN: So there you have, as you pointed out, a mother and a son and her life has been made complete. So one problem that you're bringing up in the presentation is the risk information, but could you give us some insight on how would you advise us that the message that just the image is sending? What are your thoughts about that in terms of what this is promising to this --

DR. ZUCKERMAN: Well, I personally think

that the image is so powerful that it should be regulated. As I said, I'm not a lawyer. So I don't know what the limitations are on that.

But when you have an image that is powerful, I mean, who are we kidding when we say this is an educational ad? You know, I do think that it's possible that people don't know about depression or ADHD and that it can be educational to let people know that there are other kids like theirs and other parents with problems like theirs and other people who feel depressed the way they do. You know, that can be educational, but that just isn't what is going on in these ads.

So I guess my question is, you know, at the very least, you want the information incorporated into the ads. But I think there should be limits on how powerful these images can be. I don't pretend to know how one goes about doing that, but all I know is that the law was interpreted differently than it used to be.

DR. BEHRMAN: Can I ask a follow-up? So what you are saying is that there is a message in the image --

DR. ZUCKERMAN: Yes.

DR. BEHRMAN: -- apart from what is in the

words. Do you believe -- I guess you said you basically have a psychology background, epidemiology background -- that you could inform or correctly expand on that message with additional words or do you think that is impossible?

DR. ZUCKERMAN: Well, I mean, anything is better than what we have got now. I mean, I can tell you there is a whole research, for example, on smoking which shows that kids know that smoking is unhealthy, but when they see advertising images showing people smoking, looking sexy, and living exciting lives, those images are more powerful. And they have done research that shows that the kids will say it's more important to them to look a certain way than to know what the truth is.

So you could do, you know, FDA could, study an impact of an ad to see what is the message that is going. And if the requirement is that the message be educational about the risks and benefits of the ad, it could be studied. It has been studied on other things.

MR. ABRAMS: Dr. Temple?

DR. TEMPLE: I think you might be saying that the images are so powerful they defeat the possibility of fair balance in the ad, but I had a

more specific question.

You actually I think are suggesting that there ought to be at least some of the most important adverse reaction information in the body of the ad, which many ads do not. I couldn't actually read any of the ones you had there, but those didn't.

But there is also more information, maybe not as much as is incorporated in this brief summary, but would you think that anything more than what is in the main body of the ad is simply irrelevant and that you have to concentrate on getting the most important stuff in there or could it be that if you got the most important stuff, you still might want to have an improved version of a brief summary that gave more information than you could reasonably get into the ad?

DR. ZUCKERMAN: Okay. I should say before I answer your question that, as other people have stated, anything that restricts advertising for the first year or two, I think, or more is a wonderful thing. So let me start out by saying that, that I think because thee images are so powerful, to the extent that they can be limited until we know more about how this product actually works in the real world, that would be very important.

To get back to your question, I do think

that the most important part of the ad is the image with the words, you know, not on a plain white background with a tiny, tiny font.

I do think it would be fine to have additional information, in addition to what is incorporated into the main part of the ad.

It should not be on the back for the obvious reason that most people never read it. It should not be in tiny fonts for the reason that most people can't even read it or wouldn't bother to read it.

And I will tell you honestly I have looked at some of these backs of ads, where, even when I was highly motivated, I couldn't read it. I mean, it was just, you know, I was there with my magnifying glass and I still couldn't. It's just experts in this will tell you it's formatted in a way that makes it completely undesirable to read. People don't read them.

So I think it would solve the problem in that people who were motivated to find out could read it. And that's true now, where we do have some ads where on the back of the ad, you actually can read it. It's large enough and it asks a question in a bold handwriting, bold font, and then it answers it and

it's readable.

But the question is, how are you going to make people read it? But at least it's there. On some of these ads that I'm showing, it's not even there. So it's better to have it there than not there. But the truth is look, they're designed this way for a reason. They're designed this way to sell the product. That's why they look like this.

You know, I guess what I would like to see from the FDA is an acknowledgement that this is what has been going on and a real effort to change it.

Now, this is I think the second time I have been in this room giving this talk, although not with pictures. I thought that might help, but, you know, I haven't seen change in the last few years. And I would really like to see some change.

I think I have a lot of faith that FDA can do this and I see other HHS agencies, for example, really requiring things at a fourth grade or a sixth grade or an eighth grade reading level that is important for consumers to understand. And I would like to see that in the ads.

DR. TEMPLE: The particular thing that you think would help most, though, just so we're clear on what your message is, is, in addition to improving the

second page, if that's going to be done at all, is more balance in the body of the ad.

DR. ZUCKERMAN: Right. I mean, for example --

DR. TEMPLE: More of the safety information?

DR. ZUCKERMAN: Absolutely. It's what I saw in some of these ads -- and, you know, I didn't read it to you, but it will say things like certain people should not take drug X, women who are pregnant or nursing. You know, that's who it talks about.

So it will have some big risk information like that that is useful, but it won't talk about risks to heart attack or stroke or anything like that. I mean, certainly the Vioxx ad has never said anything about that, although I think they did say high blood pressure.

Certainly the hormone replacement therapy ads didn't have any kind of warning information except I think -- oh, I know. They actually had endometrial carcinoma. I mean, give me a break. You know, they can't even say the word "cancer." God forbid somebody might actually understand what they mean.

So even when they have risk information, they really try very hard to make it not

understandable. And it should be FDA's job to make sure it is understandable.

MR. ABRAMS: Dr. Behrman?

DR. BEHRMAN: I'd like to press you a little further. And talked and Dr. Temple followed up on the notion of fair balance. And I think you have been focusing a lot on the safety information.

I thought in the beginning you were alluding to the fact that this drug in this ad and the Vioxx ad promised that they work. In other words, the image is that, in fact, your life has, the person's life has, been revolutionized. And in our minds, we would call that 100 percent effective. Have you thought at all about the, if you will, implied claim of the image in those?

DR. ZUCKERMAN: Well, yes. I mean, we have talked and other people on the panel have talked about, for example, giving specific information about how much it works. You know, it works in ten percent of the patients or patients feel slightly better, you know, whatever it is.

Certainly the image tells you something different. The image says, you know, this is what your day will be like. I don't know how you parse that as a federal regulatory agency, but I know that

if you don't, if there are, first of all, no restrictions on ads and, secondly, no easy place to get the information about how this -- you know, even if Vioxx didn't have risks that are serious and, therefore, not on the market anymore, shouldn't there have been information about how effective it was compared to over-the-counter medication that costs one-tenth of the price or something?

And so it is not just the risk information. It's the benefit information that is way out of proportion. So I think that is what you are asking. And I agree with you completely that those images tell you something about effectiveness that that nowhere is explained any differently in the wording.

MR. ABRAMS: Dr. Aikin?

DR. AIKIN: This is all very, very interesting. Thank you for your presentation.

One of our previous panelists talked about the perceived subjective nature of FDA review of direct consumer ads. Clearly the images in advertising are very powerful and they are designed to sell products because it is advertising for a product.

Do you have any suggestions for us on how we might go about quantifying evaluation of emotional

pictures?

DR. ZUCKERMAN: Well, I would be happy to get back to you on that. I am sure there are people who know how to do that. I am not one of them. I mean, you can study it like anything else. It is really not that difficult. You show these ads to people.

I'm not talking about focus groups. I'm not a believer in that as an appropriate objective measure. I mean, you do a study to say, "What is your impression of the product before you see the ad or what is your impression of the product after you see the ad?" or you show one ad to one group and another ad to another randomly selected group and you compare. You know, do they want to get this ad? Will they ask their doctor for this ad the next time they see their doctor?

I mean, this is all measurable. I don't think it's magic. You know, I think the hard part is figuring out what FDA is going to do about it, but I don't think it's hard to figure out what is the power and effectiveness of these images. You know, give them the wording with or without the images and see what the difference is.

DR. AIKIN: I would agree that it would be

a very useful test with or without the image. My question is, how would we test gradations? Perhaps the person is smiling so much. This is where we get into the issue of subjective review.

DR. ZUCKERMAN: Okay. Well, I have to say I haven't thought about this so much. But I suppose in the same way that manufacturers are required to provide data on the effectiveness and safety of their products, they could be required to provide some kind of data in some FDA-determined measurements of the impact of their ads.

I mean, I, of course, would rather have FDA do it but need the money from somewhere, maybe user fees, you know, whatever it is. I mean, obviously I would rather have FDA doing the testing so that I would have more confidence that it was accurate, but this is all measurable.

I think we run into problems if we say people can't smile in the ads because here -- let me see if I can go back. If you can see -- here we go. I mean, this woman isn't really smiling, but this is still a powerful, wonderful image of -- I mean, I feel like I would be in Monet's gardens here. I mean, this is a powerful image.

MR. ABRAMS: Dr. Zuckerman, thank you very

much for your presentation. I want to thank the fourth panel for their presentation and responses to the questions.

(No response.)

MR. ABRAMS: Okay. We do have some time. If anybody wishes to make public comments from the floor, you're welcome to do so at this point. Please identify yourself by your name and affiliation. Yes?

DR. LABEL: I am insufficiently tall, but my name is Rima Label. I'm a physician. And I'm the medical director at the Natural Solutions Foundation.

First of all, I want to appreciate the comments of all of the panelists in the last panel. I have some specific questions, first of all, as to whether there has ever been a finding of fact or why there has not been a finding of fact if there has not been concerning the safety of direct-to-the-consumer advertising given that medications, both properly used and improperly used, are among the leading causes of death according to studies, for instance, in JAMA.

At least 200,000 people per year die of prescription medication complications and side effects, often from polypharmacy, which results when people have side effects that are treated with additional medications.

So if direct-to-consumer advertising increases the number of prescriptions written, I would like to know whether there has been a focused finding of fact on the dangerousness, the increase in morbidity and mortality, associated with that direct-to-consumer advertising.

MR. ABRAMS: If I may interject, part 15 hearings allow us to listen for input from the public. It doesn't allow us to answer questions or respond. So if you wish to make comments, we would really appreciate those and consider those.

DR. LABEL: Knowing that I will not, then, receive an answer, I as a physician and citizen would like to know that information and would appreciate some guidance as to where that information can be found.

Given the fact that lobbying money from pharmaceutical concerns is available aplenty, -- according to USA Today last year, 758 million was spent on congressional lobbying by pharmaceutical firms -- it seems to me that now they have gone into the political realm. And it seems to me that equal time might be an interesting contribution for non-pharmaceutical, scientifically validated approaches to those same conditions that

pharmaceuticals are so appealingly and so expertly sold for.

Two more comments. I would like to know whether there is any requirement or could be any requirement or suggest that there might be a requirement for a differentiation in direct-to-consumer advertising between long-term and short-term administration for physiological and morbidity and mortality effects of medication in those two conditions, being quite different, especially off label, and also want to comment that given the new freedom initiative for the intensification of the administration of dangerous psycho-pharmacological agents to children and adolescents, I would suggest that equal time for alternatives becomes particularly important for our pediatric and adolescent population.

And perhaps the very companies that benefit from direct-to-the-consumer marketing might be compelled to support some additional information so that more appropriate people would receive their pharmaceuticals, rather than the general spectrum of the population.

Thank you.

MR. ABRAMS: We thank you for your comments.

I want to also state that this is being transcribed. We will look carefully at the transcripts of this meeting. We also encourage folks who have additional comments to submit them to the docket. We will review all of the information that we receive.

Yes?

DR. GLINERT: Lewis Glinert, Dartmouth College.

A brief response to the question that was put to Dr. Zuckerman from the Chair concerning what possibly one could do to regulate images, just speaking having served for a couple of years in the mid '90s on a European Union-funded project on the labeling of infant milk formula.

At that time at least, I know that the European Union had some very strict and far-reaching regulations concerning images on infant milk formula. To the best of my recollection, one wasn't allowed to show any kind of maternal image. And that extended even to a ban on teddy bears.

MR. ABRAMS: Thank you for your very interesting comments.

(Laughter.)

MR. ABRAMS: Any other persons here wish

to make a public comment? Yes?

DR. ZUCKERMAN: I'm sorry because I feel I missed my opportunity. Of course, it would be great to say no photographic images, I mean, to say no images, words only. I mean, I didn't mention that when asked, but if that were possible, that would be a terrific solution, words only, words that give benefits, words that give risks.

MR. ABRAMS: Thank you for that additional comment.

Any additional comments from the floor?

(No response.)

MR. ABRAMS: Well, we had a full day. We want to thank the speakers for their presentations and their responses to the many questions from the FDA panel. We want to thank you for your participation, for coming here and attending the whole session today.

I also want to thank the folks who put this together. Rose Cunningham is somebody who works behind the scene and gets everything done. So thank you.

(Applause.)

MR. ABRAMS: Okay. We will start tomorrow. We have four additional panels. We will begin at 9:00 o'clock. So this concludes this section

of the meeting. We will reconvene tomorrow morning at 9:00 a.m. right here. Thank you.

(Whereupon, the foregoing matter was recessed at 4:40 p.m., to be reconvened on Wednesday, November 2, 2005, at 9:00 a.m.)