UNITED STATES OF AMERICA

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FOOD AND DRUG ADMINISTRATION

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PUBLIC HEARING

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WEDNESDAY,
NOVEMBER 2, 2005

The Public Hearing was held in the Lower Level Boardroom of the 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
MARTINE HARTOGENSIS
MELISSA MONCAVAGE
NANCY OSTROVE
ROBERT TEMPLE
DEBORAH WOLF
SCOTT GALSON

ALSO PRESENT:

ROSE CUNNINGHAM
JUDITH CAHILL
JOHN CALFEE
JAMES DAVIDSON
ELLEN LIVERSIDGE
PETER LURIE
GARY RUSKIN
RICHARD SAMP
ALEX SUGARMAN-BROZAN
WALLACE SNYDER
KIM WITCZAK
EMILY ALFANO

MEG COLUMBIA-WALSH

ALSO PRESENT: (CONT.)

JOSEPH CRANSTON
RIMA LAIBOW
KATHY KASTNER
MARK TOSH
SCOTT LASSMAN
PETER PITTS

C-O-N-T-E-N-T-S

P-R-O-C-E-E-D-I-N-G-S

(9:05 a.m.)

MS. CUNNINGHAM: Good morning, everyone. We are about ready to begin, so if you will please take your seats. We have a couple of panel members that may be stuck in traffic, but in the interests of time, we're going to go ahead and start.

MR. ABRAMS: Good morning, and welcome to the second day of FDA's public meeting on Consumer-Directed Promotion of Regulated Medical Products, also known as DTC or direct to consumer promotion.

I'm Tom Abrams, director of DDMAC, the division of drug marketing, advertising, communications in CDER. I will serve again today as the presiding officer at the hearing.

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

This hearing is intended to provide a forum and an opportunity for broad public comments concerning consumer-directed promotion of medical

products, including human and animal prescription drugs, vaccines, electronics and medical devices.

We had a very productive meeting yesterday, and we had 19 speakers who gave great presentations, and a lot of informative responses from the speakers in reply to questions from the FDA panel. We also had public comments from several members of the audience that were taken from the floor.

There was much discussion about DTC at the hearing yesterday, including presentation of risk information, DTC's pass-one pact on the diagnosis and treatment of undertreated medical conditions, DTC's possible impact on other factors in the health care system, data from research in regards to DTC promotion, the use of celebrities in DTC, various ways of presenting the benefit information, and the use of consumer-friendly language in DTC.

These discussions were both interesting and informative for the FDA panel. We appreciate the input from interested parties, as these comments and data from research will help guide our policy on DTC.

We encourage folks who have done research

in DTC to submit it to the docket so it will be publicly available.

FDA is a data-driven agency, so we appreciate the sharing of data as it helps us develop our policy.

The rules of Part 15 meetings do not allow FDA to respond to questions from presenters or other members of the public who may be making public comments from the floor.

The purpose of the meeting is to get input from the presenters and from the public. We also encourage you, when you submit information to the docket, to provide references to support your position. This helps us evaluate and give thorough consideration to the various positions that are posed to us.

I would like to now introduce the FDA panel members. Starting from my left is Kathryn Aikin, social science analyst in DDMAC; Robert Temple, director of office of medical policy in CDER; Steven Galson, the director of CDER, which is the Center for Drug Evaluation and Research, naturally. Starting below is Deborah Wolf; Deborah is regulatory council in the office of compliance in CDRH; Nancy

Ostrove, the senior adviser for risk information in the office of planning and office of the commissioner; Melissa Moncavage, the leader of the DTC review group in DDMAC; Martine Hartogensis, promotion and advertising liaison in CBN; Glenn Byrd, the chief of the promotional - the advertising and promotional labeling group in CBER; and Kristin Davis, the acting deputy director in DDMAC.

We have 19 speakers for today's part of the hearing, so let me provide the ground rules so we have a most productive meeting.

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.

FDA is here to listen, and will ask clarifying questions, but cannot comment or respond to questions.

If time permits, after FDA panel has completed the questioning of each panel, we will open up the floor for public comments.

Public hearings under Part 15 are subject

to FDA policy and procedures for electronic media coverage of FDA public administrative proceeding. Representatives of the electronic media may be permitted, subject to certain limitation, to videotape the film or otherwise record FDA's public administrative proceeding, including the presentations by the participants.

This meeting will be transcribed, and copies of transcripts may be ordered through the dockets or accessed on the Internet.

Each speaker will be provided 12 minutes for their presentation, and then FDA panel members will have up to eight minutes to ask questions. We request that speakers keep to the 12-minute limit, as we have a full agenda today.

So I thank you for your participation in today's meeting. We look forward to hearing all your comments on this important topic.

Now it is my pleasure to turn to Dr. Galson, the director of the Center for Drug Evaluation and Research, to open the meeting.

Dr. Galson.

DR. GALSON: Thank you very much, Tom, and welcome to all of you for being here today. I

know this is a very, very important issue for all of you, and for the health of people of the United States, and so I'm very glad that we are able to convene like this.

I understand that yesterday was a very full day, and we heard from a variety of different people different perspectives on research, regulation, technology and safety issues.

Dr. Woodcock gave you a brief history of how direct to consumer advertising began, and I want to expand a little bit more on that this morning.

As you know, FDA has responsibility for regulating, labeling and advertising of prescription drugs and medical devices. If an activity or material is considered to be either advertising or labeling, it must meet certain requirements.

We do this to ensure that promotion is accurate and balanced, and helps fulfill our mission of protecting and promoting public health.

FDA's regulations give examples of labeling materials, including brochures, mailing pieces, detailing, calendars, price lists, motion picture films, sound recording, et cetera.

As Dr. Woodcock told you, FDA requested a

voluntary moratorium on DTC promotion back in 1983, and then withdrew it in 1985,

A lot has happened since 1985, including the dramatic growth of DTC and the agency's policy to address this growth. It would take a long historical day to really address everything that has happened, so I want to just go through a few of the highlights so we can really get to what the purpose is and to try to get input from you all, which is the main thrust of how we want to spend our time.

We held a Part 15 hearing like this in 1995, issued a Notice in 1996 to clarify the preclearance of consumer-directed prescription product promotion, was never required, and asked for additional information to help in the development of overall policy.

In 1997, we issued a draft guidance describing ways in which companies could fulfill the existing requirements of adequate provision for access to the approved product labeling in connection with DTC broadcast advertising.

This guidance was finalized in 1999. FDA conducted research to try to determine how DTC promotion affects the doctor-patient relationship,

and there is research that has been done outside of that that we've done, as well. We've heard about some of that. And we held a public meeting two years ago to present our results, and listen to the results of other researchers.

This was a very insightful meeting, and information was very helpful to us preparing the draft guidances that were then issued in February of last year pertaining to consumer-directed promotion. Comments on these draft guidances are currently under consideration.

Since, in the last year, as well, I think you all know that the Pharmaceutical Manufacturers Association has issued a new policy on promotion, and their attempts to try to pay, in particular, some more attention to many of their critics who have said they don't police themselves enough, and that is probably going to fundamentally change the way that we get information from the industry, and perhaps the review that takes place before it comes to us. These are all changes that we are going to have to consider in making final policy decisions in the next year or so.

Again, today we've got a very full

agenda. I don't want to take too much time away from it on history. We look forward to what all of you have to say to us. We're very interested. We want to emphasize that everything is being recorded so that even if we don't react or ask questions about it right now, we've got it there, and we can review it along with what was said yesterday, and additional items that are submitted in writing. So there are lots of ways to provide this input.

So thanks again for taking time away from your busy schedules to help us in this very, very challenging policy and decision-making arena for the FDA.

Thanks.

MR. ABRAMS: Thank you, Dr. Galson.

And before we begin, I'd like to just review the agenda.

We will have two panels this morning. In between the two panels we'll have a break. After these two panels we'll break for lunch, and reconvene, and have an additional two panels in the afternoon.

So let's begin our first panel of the second day with Judith Cahill from the Academy of

Managed Care Pharmacy.

MS. CAHILL: Good morning.

I am Judy Cahill. I am executive director of the Academy of Managed Care Pharmacy, and I'm pleased to have the opportunity to present the Academy's view on a topic that we consider to be of prime importance for those who are involved with the delivery of an adequate pharmacy benefit.

The Academy of Managed Care Pharmacy is an organization that is a professional society for pharmacists who have chosen to practice their profession by the application of managed care principles.

What that translates into is an organization comprised of senior directors from health plans, from health maintenance organizations, from insurers, from pharmacy benefit management companies, and from manufacturers who have an interest in how the managed care pharmacy benefit is designed, and how it is implemented.

That gets the Academy members involved with formulary decision making, examining from intensive manuscripts the attributes and the weaknesses of drugs that are competing for room on

their formularies.

It also gets the Academy members involved with drug utilization review, so that they can assess the appropriateness of the drug regimens that their patients are encountering. It also gets them involved with safety and medication error monitoring.

One of the important aspects of what the Academy members are involved with is monitoring their patients' use of drugs in order to have effective outcomes in the most productive way for the populations they serve.

They are interested in both the clinical aspects of pharmacy benefit delivery, and in the business aspects.

We all know that the cost of drugs keeps escalating. We all know that we have a finite pot of resources to address those health care costs that are part and parcel of how we do business in this country today. And because of that, the managed care pharmacist brings both the clinical and the business acumen to bear to try to deliver appropriate drug benefits.

There has been heightened interest, of

course, courtesy of the Medicare Modernization Act and the impending introduction of Part D. We all feel as though we're going to be on trial come January 1, 2006, and we're all awaiting, with some breathlessness, what is going to come about. AMCP supports direct to consumer advertising insofar as it can be used to educate the public about disease and the symptoms of disease. We encourage it for the discussion of alternative treatment options.

We are fully aware that medications can be an integral part of the delivery of health care for patients, particularly with chronic conditions, but we also realize that the proper decision in many instances for patients is no medication therapy, and that there are other ways that patients can address the disease states that they are afflicted with, be it diet, be it exercise, be it other behavioral lifestyle changes.

We do discourage advertising that promotes specific prescription drugs. We believe that, insofar as DTC can improve awareness about disease and disease symptoms, that it plays a crucial role. Indeed, the FDA's own surveys of

physicians have shown over the years that the dialogue that can be encouraged by direct to consumer advertising between patients, physicians and pharmacists, is something that does encourage healthier lifestyles.

We do believe that patients need to be informed about what their treatment options are, and what alternatives they have before them, as they are facing choices about how to treat their symptoms.

We are concerned that product-specific DTC advertising does a disservice to the public if its aim is only to engender name recognition and to garner market share.

We believe it does a disservice if it creates an unwarranted patient demand, and we have seen the studies that have been produced of surveys of physicians who report about the increased dialogue with patients, and the demand on the part of patients for prescription items that they have seen advertised.

I'll take just a moment to tell you about an anecdotal study. One of the Academy

members who is pharmacy director for a Portland, Oregon-based health plan, was talking about a routine encounter that he does periodically with physicians. And what he has in front of him is their prescribing profile, and he talks to them about what they are encountering with patients. In one such encounter of this sort, a physician offered that Mrs. Jones came in, sat down, had an ad in hand, and said, doctor, I must have this drug. And he said, well, Mrs. Jones, you are already on that drug. And she said, "Why don't I look 25 years old?"

It's just anecdotal in nature. But I think it does exemplify how direct-to-consumer advertising can engender unwarranted need -- unwarranted demand on the part of patients for drugs.

If the DTC advertising is misleading, if it's not fair, if it's not balanced, if risks are not fully explained, and if it is silent about alternative treatment options, we believe it does a disservice.

Dr. Galson pointed out the draft guidance that was passed in August of 1997, and

we've seen these figures before, so I won't dwell on them. But look at the growth of spending on DTC post-August, 1997. A quantum leap, to be sure.

The 1997 draft guidance gave manufacturers the ability to identify products by name. It also ushered in a quantum leap from informational advertising to marketing and promotional advertising, and we believe that that is something that is not in the best interests of the public.

The FDA remedies, the FDA can issue letters, and those letters that would require revision or withdrawal of an ad are effective. We know of no instances where a manufacturer has not been responsive to the letters that come from the FDA asking for revision.

However, because the FDA does not have preapproval, a 30-second ad on Super Bowl Sunday can have an impact that no amount of revision in later days can address.

I'd like to take a moment to look at the General Accountability Office findings from a 2002

report when it looked at direct-to-consumer advertising. They concluded that advertising appears to increase drug spending and utilization; that advertising that is concentrated among a small number of drugs for chronic conditions, and many of the same are also promoted to physicians in the type of detailing that is done of physicians. They concluded that some manufacturers have repeatedly disseminated misleading ads for the same drugs, and that manufacturers have failed to submit, or to submit in a timely manner, all newly disseminated ads to FDA for review.

Now, there is not a direct causal link between DTC and medication risks. However, because it does - DTC can engender patients to demand drugs that they otherwise would not need, it presents a vulnerability within our system for not only spending money on drugs that are not warranted, but for incurring patient risks.

I draw your attention to a Sloan study that was published in the Annals of Internal Medicine just this year. That Sloan study said that in the latter half of 2003, 81 percent of adults who

were on Cox-2 inhibitors did not have gastrointestinal bleeding that would have warranted the use of what has turned out to be a very dangerous medication. And it's this aspect of direct-to-consumer advertising that is of utmost concern to the Academy.

Our suggestions are to give FDA legislatively more authority over DTC advertising. We have petitioned Congress, and we will continue to do so, to grant mandatory prior approval for all medication advertising.

We also are petitioning Congress, and have done so already, and will continue to do so, to adequately fund the agency so that when this authority is given to them by legislation, they will have the resources to be able to act on it.

We also encourage the oversight of the content of direct-to-consumer advertising, and ask that it be focused on raising awareness of disease, that it explore treatment options, that it stimulate patient and provider dialogue, and that it encourage healthier lifestyles. But we do not encourage product-specific advertising.

I'd be pleased to take any questions that there may be.

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

The first question I have, you mention that you have concerns about DTC generating unwarranted demand for prescription drugs, and you also stated that FDA's remedies are effective in stopping misleading promotion. And you made some recommendations which are beyond FDA as far as other groups.

If you were to advise FDA more that we could do within our own control, what steps do you think we should take?

MS. CAHILL: I would suggest that, with the current authority that we understand that the agency has, that you pay close attention to content, and that insofar as the content is geared to stimulate constructive dialogue between the patient and the physician, or even to not only encourage that, but to start it, to get the patient thinking about why it is that I have this pain in my back,

maybe I ought to go see somebody about this, that that type of encouragement of patients taking steps to receive the care that could lead to intervention in a disease before it becomes problematic, before it advances into a problematic state, is something that we think is very important, and that direct-to-consumer advertising can contribute to. But insofar as it goes to speak to specific drug products, we have a problem with that.

MR. ABRAMS: Dr. Temple.

DR. TEMPLE: I am not going to remember who said this yesterday, and we haven't seen all the data yet. But at least somebody put forth the idea that, if a general health awareness ad doesn't name a specific product, nobody actually goes to the doctor. I don't know whether that is true or not, and it probably deserves more research before one would believe it. But if that were true, that would argue that, even if you do have a health awareness component to your ad, if you don't - they may need to name a product, anyway.

Do you have any thoughts about that?

MS. CAHILL: Well, I would suggest that we look at what happened prior to August of 1997. There was over $700 million being spent on direct to consumer advertising in that era, and it did focus on raising public awareness of disease, disease symptoms, and to some extent alternative therapies.

And in that era, obviously there was a decision on the part of those who were spending those advertising dollars that something was happening.

I do believe that, with the increase in direct-to-consumer advertising, we've seen more of a stimulus for encouraging doctor-patient discussions, but it is the unwarranted demand that is our chief concern about what we are seeing today.

DR. TEMPLE: And just to follow up, when you say unwarranted demand, do you literally mean that they are getting treatment when they don't need it, or that they are using, say, a more expensive product than they really need to, or something like that?

MS. CAHILL: That they are getting

treatment that they don't need.

DR. TEMPLE: Any particular things you can identify?

MS. CAHILL: Well, the Sloan study is the one that I mentioned before, where 81 percent of the adults on Cox-2 inhibitors did not have gastrointestinal bleeding prior to being put on the Cox-2 inhibitors.

I think that the -- probably the bellwether incident that we look at.

MR. ABRAMS: Dr. Aikin.

DR. AIKIN: You mentioned that you felt that the DTC advertising does a disservice if it is silent about alternative treatments, or alternative options. There are, Dr. Temple can correct me if I'm wrong, regulations that cover the use of comparative claims in advertising. Do you have any suggestions on how advertising could mention alternative therapies without making implied comparative claims to other products?

MS. CAHILL: I think we see that to some

extent today, where there is not actual product-to-product citation, but there are some ads that we consider to be more responsible than others that do say, talk to your doctor about what your alternatives are, that this is one alternative, surgery may be another.

DR. AIKIN: So just general statements about alternatives?

MS. CAHILL: Right.

DR. AIKIN: Thank you.

MR. ABRAMS: Thank you, Ms. Cahill.

Our next speaker is John Calfee from the American Enterprise Institute.

MR. CALFEE: Well, thank you. It's an honor to be here talking to the FDA and to everyone else who is here.

I'm just going to focus on a fairly narrow topic, but one that I think is worth paying attention to, which is to look at the evidence that has come out of New Zealand, as well as of the United States, and to make some comparisons.

As a lot of people know, New Zealand is the only other advanced country that permits DTC advertising. In both countries it happened more or less by accident. The manufacturers, the industry discovered at some point that advertising to consumers was not prohibited. And so we got DTC advertising here in the U.S., and we got DTC advertising in New Zealand.

The two countries are very different. Their health care systems are very different. Their regulations are very different. So a natural question is, what are we learning from these different experiences? And we're fortunate in having a few very good survey researchers in New Zealand who are doing work in this area, some of whom have actually worked to some extent with the FDA to coordinate on some of their efforts. And so we've gotten some information that I think is really quite valuable and does not receive as much attention as it should.

As I mentioned, New Zealand has a very small economy, small population; roughly the size or even smaller than the D.C. metropolitan area.

Health care is funded almost entirely by the government. Pharmaceuticals are paid for almost entirely by the government. Drug prices are tightly regulated by the government. The regulatory system for DTC is very different. The requirements in New Zealand are what we would think of as being somewhat broad and general and maybe even a little bit vague, and must comply with the general rules, advertising rules in New Zealand. A code of ethics has been put together by the pharmaceutical industry, meet high standards of responsibility, et cetera.

It must make certain sweeping statements in connection with all such advertising such as, use strictly as directed, consult your doctor, et cetera.

It must pay attention, the ads must pay attention to whether or not there is an extra fee for the particular drug, bearing in mind that most of these drugs are covered by the government or paid for by the government.

Do not mislead, et cetera, et cetera.

All of this is done in New Zealand, not

by the same authority that approves new drugs and regulates health care generally, but by self regulation, through the Advertising Standards Authority, which regulates all advertising, not just DTC advertising.

I should mention that the system has been changing, and is now changing, and will continue to change, but the data that we're looking at reflect the system that I've been describing.

It is a self-regulation scheme run by a very small staff, but with more or less a board of outside medical authorities that give them a lot of input and a great deal of advice which is often regarded as more or less binding.

DTC ads are prescreened in New Zealand. The response to complaints from consumers, physicians, competitors, et cetera, the responses are very rapid. It's a very quick and very efficient system. And the entire system is enforced by the government as a last resort, but that almost never happens. It's actually enforced by the media. That is to say, if the Advertising Standards Authority has looked at a particular ad, has decided

there is a problem with that ad, and thinks that ad should be withdrawn or changed, if the manufacturer does not do that, then the media will refuse to run the ads, and that is a very efficient and effective enforcement mechanism.

There is no need to go through how DTC advertising is regulated in the United States. I would mention, again, that there are two basic differences between the systems that we are comparing, one being the regulatory environments, and the other being the financing and the price controls of the pharmaceuticals that consumers are interested in.

So, what kind of results do we have? This all draws from an article that was published a year or two ago, which I will submit for the record. It does not review all the surveys; it picks out just maybe three or four or five different surveys that happen to be strikingly relevant, and also happen to involve some numbers that facilitate direct comparisons.

If you look at overall exposure to DTC advertising, the patterns are extremely similar;

very high awareness of television advertising, strong awareness of magazine advertising, et cetera, and overall the numbers are quite similar in the two countries.

Looking at the information that is recalled from advertising, in some cases extremely similar, such as on the benefits of medicine. In other cases, there are striking differences. Details of who should take a particular medicine, there is less awareness of that in the New Zealand ads than in the U.S.

Information on who should not take a medicine, far less awareness from the DTC ads in New Zealand compared to the U.S.; the same applies to risk information. This reflects the differences in the regulations. The DTC regs, at least so far, do not have the explicit requirement of a balance between risk and benefit information in advertising, and there is generally less risk information, in some cases far less risk information, in New Zealand ads, although that is moderated according to the actual circumstances, so that a particular drug that involves very substantial risk, you will see more

risk information, or else you won't see the drug advertised at all. The general philosophy has been in New Zealand that most risk information will come from the physician if and when the patient talks to a physician about an advertised drug.

Some more information: In some cases, again, the patterns are very similar, such as making people aware of new medicines in New Zealand as in the U.S. It's quite apparent that DTC advertising is quite effective as a force.

Helping people make better decisions - again, a small majority agree that the ads do help them make better decisions.

There was a question in a couple of surveys, including at least one in New Zealand, at least one in the U.S., about whether ads confuse patients and consumers.

And one of the interesting things is that in New Zealand, the confusion level appears to be less, at least the perceived confusion level is less in New Zealand than it is in the U.S., which is roughly consistent with the idea that cleaner and

simpler ads are less confusing, and the ads in New Zealand do tend to be cleaner and simpler.

Another interesting question, which is whether or not people assume that only the safest drugs are advertised through DTC, which as a general rule, as you know, is not true, although there are certain drugs that are quite risky, that either tend not to be or flat out are not advertised in the U.S. or in New Zealand.

But in New Zealand, a substantially smaller proportion of respondents assumed that only the safest drugs are advertised. And again, I think this is kind of a less is more situation. There isn't a lot of risk information in the ads, in most DTC ads. But patients and consumers tend to assume that it is the nature of pharmaceuticals that they are dangerous, and they assume that even drugs that are advertised with relatively little risk information are, in fact, risky.

On the balance of information, this is where you do see some striking differences. Most people in New Zealand think that ads should contain more risk information. Actually, in surveys in the

U.S. also tend to show that most people think the ads should show more risk information, but the majorities are larger in New Zealand than they are in the U.S. My suspicion is that it doesn't matter how much risk information you put in the ads, you always get at least a small majority of people thinking that even more risk information should be in there.

Information about the benefits - I'm always surprised at how many people think that drug ads ought to have more information about the benefits of drugs. The proportion actually tends to be higher in New Zealand than it has in the U.S., although this doesn't put together all of the surveys.

There is an item at the bottom here. I trust the information in prescription drug advertisements. Only 29 percent of New Zealand say that they trust ads. I'm not aware of any comparable questions in U.S. ads. But I think it's worth pointing out that one of the things I and some co-authors have done over the years is to go back and look at survey data on advertising generally,

50, 60, 70 years. And what those data show consistently, year after year, regardless of how the FTC or anyone else regulates advertising, is that roughly two-thirds to 70 percent of consumers don't trust advertising if you ask them whether they can trust the information in advertising. The numbers we have here are very consistent with that. It doesn't mean they don't trust any individual ads; it just means they go into advertising with a presumption that advertising is not to be trusted. They think, surprisingly, that it is self-interested.

Then we have some information about whether ads give information that is useful in talking to the doctors. Large majorities in both countries say that they do. They think they help with their discussions in talking to doctors.

Some conclusions, which I think can be pulled out of this data - and again, I'm just bringing this to everyone's attention because I think there is something to be learned when you look at countries that are very different, especially with very different regulatory regimes, to see whether there are certain kinds of things that tend

to be more or less robust in these very different systems. And I think we do see quite a bit that is useful in looking at these two different bodies of data.

The ads in New Zealand are very different from those in the U.S. - not entirely, but in many ways they are. The regulatory systems are very different. The financing of drugs is very different.

When we do see substantial differences in the survey results, those differences usually reflect differences in how the ads are regulated. Where your require much less risk information, you do in fact get less risk information.

But on the whole, I think that what you are going to learn from both datasets, both national experiences, is that consumers perceive substantial, and on the whole similar benefits from DTC advertising in both the U.S. and in New Zealand. And again, in both cases, there is little, very little evidence, of any significant harm coming from DTC advertising. And again, I think this reflects -- the common experiences of these two countries

reflects the regulatory differences, and suggests, at least to me, that there is a substantial element of what you might think of as robustness in the way DTC advertising, as is true for all advertising, works in these two countries.

And that concludes my remarks, and I'd be glad to answer any questions, if I can.

MR. ABRAMS: Ms. Davis.

MS. DAVIS: Hi, thank you for your presentation.

I have a question about the evidence that you have from New Zealand surveys. In the United States some of the survey evidence that we have seen indicates that some of the positive effects of DTC advertising might be getting people to their doctors to treat undiagnosed or under-treated health conditions. Are you aware of any evidence in New Zealand about the effects that advertising there might have on those parameters?

MR. CALFEE: That's a good question. And obviously I'll check between now and the end of the comment period. But my recollection is that there

isn't very much. As you know, it turns out to be a difficult topic to research, but I suspect that when I and Gendell Hoek, the New Zealand researcher, when we were putting together this article, that if we had had some really good evidence at hand, we would have put some focus on that. My recollection is that there isn't very much that addresses that directly. But again, I'll check.

MS. DAVIS: Okay, thank you.

MR. ABRAMS: Dr. Temple.

DR. TEMPLE: The last conclusion you showed was that the surveys reveal little evidence of harm. Of course these are surveys of people's opinion about stuff. So, if there were overuse of some drug, an inappropriate use, it wouldn't pick that up, I guess.

I wonder if you knew of any examinations in New Zealand that went to the question of inappropriate use, or something like that for some or many classes of drug?

MR. CALFEE: Your point is well taken. There are lots of harms and benefits that would not

be discovered. I mean, you could have drastic overuse, and you wouldn't know that. If the drugs are more or less free, I think it's safe to assume that a lot of them are overused. That doesn't necessarily mean that there is any kind of physical harm coming from it, maybe unnecessary expense.

I'm not aware of any research on that. I know that there has been some, what I think of as informal research on it, such as surveys of doctors, in which they provide, again, their opinions, their opinions being that some people ask for drugs they don't need, et cetera, et cetera.

That evidence, my sense of that evidence is that it is pretty soft. But that doesn't - like I say, that doesn't rule out a lot of problems. And, as you might expect for a country this size, there is just not a lot of government research that's done on this. It's just too small a market to research, and it's a difficult topic to assess.

So the short answer is, I don't know.

MR. ABRAMS: Ms. Wolf.

MS. WOLF: You said something about the

advertising in New Zealand being more clean or more clear. What did you mean by that?

MR. CALFEE: What I mean is that the few New Zealand ads that I've seen, TV ads, and we actually had the gentleman who, at least until recently, ran the self regulatory group, speak at one of our conferences, the ads include - as a general rule they do not include the - for some of us, rather elaborate voiceovers that you get in the U.S. TV ads. And so you see something that may focus on a drug, something it could do for you and so on, but it's a much simpler message in the sense that you don't have this back and forth that you have in U.S. ads, it can do this, but it could do that, it could do this, but it could do that, sometimes voiceover, sometimes not, carefully, as you know, carefully arranged to produce something that the manufacturer hopes comes out on balance favorable rather than unfavorable to his drug. So in that sense, they are simpler. The print ads are also simpler. As you know, some of our print ads could hardly be more complicated, and you don't have the extraordinary complexity in the print ads in New Zealand that you do in the U.S. That's what I meant

when they're cleaner and simpler.

MR. ABRAMS: Thank you, Dr. Calfee.

Our next speaker is James Davidson from Davidson & Co.

MR. DAVIDSON: Good morning, ladies and gentlemen. I am Jim Davidson. I serve as executive director of the Advertising Coalition. The Coalition is a group of trade associations and companies that include advertisers, advertising agencies, advertising professionals, broadcast, cable, newspaper and magazine media.

The professionals that lead these organizations and their members view themselves as having a tremendous responsibility to their readers, viewers, consumers, clients and companies to provide valuable information to their readers.

In a moment, I will share with you some of the feedback from one of those audiences. We're grateful to FDA for its positive leadership in finding ways to better communicate information about health care and prescription medicines to consumers.

You consistently have offered constructive forums for examining DTC advertising, and you have, out of these forums, put forward positive guidance for improving this form of communication.

FDA regulations and guidance recognize that advertising in its various formats provide a primary means of getting the attention of consumers, and providing them with the information they need to participate in important decisions about their health care.

FDA requires print advertisements for prescription drugs to include lengthier, more complicated brief summary of the product's side effects and counter-indications. Broadcast advertising, on the other hand, must contain a statement of the product's major side effects and counter-indications, and must either make adequate provision for dissemination of the product's package labeling, or present a brief summary of the side effects and counter-indications in the advertisement.

The adequate provision requirement can

foster a complementary relationships for broadcast ads to use print publications to disseminate more detailed information for consumers who may not use the Internet or other sources to seek information about what's being advertised.

I want to address today four aspects of DTC advertising that I think illustrates the important role that it plays.

First, DTC advertising is protected commercial speech.

DTC advertising has motivated millions of Americans to seek advice from their doctors, and a significant portion of those seeking help suffer from high priority conditions.

DTC advertising raises awareness about under-diagnosed conditions, and helps address public disparities.

And finally, I believe that industry self regulation promises to further enhance the quality of DTC advertising.

DTC advertising is an important form of

communicating health information, and will continue doing that into the future. It serves neither the public interest nor the public health to seek a ban on speech that is imposed by the government either permanently or for arbitrary periods.

It is noteworthy that one of the earliest cases before the Supreme Court on commercial speech, and one of the most recent, involved prescription drugs. Justice Blackmun, writing for the majority in the 1976 Virginia Pharmacy Board case, explained why. As to the particular consumers interest in the free flow of information, that interest may be as keen, if not keener by far, than his interest in the day's most urgent political debate.

Twenty-six years later, Justice O'Connor wrote, "If it is appropriate for the statute to rely on doctors to refrain from prescribing compounded drugs to patients who do not need them, it is not clear why it would not also be appropriate to rely on doctors to refrain from prescribing compounded drugs to patients who do not need them in a world where advertising is permitted." The decision struck

down a prohibition on advertising compounded drugs.

Successful advertising informs and motivates its readers and viewers. To achieve this, good advertisers must respect their audiences and offer them information that they can understand and use, and upon which they can rely. Anything less, and they risk breaking an intangible bond of trust that exists with their audience.

Advertising that does not inform, or that misleads its audience, likely will not get a second chance. Moreover, FDA has extensive powers to regulate ads it determines to be misleading and untruthful.

FDA has demonstrated that it is prepared to use that authority to sanction DTC advertising. According to Prevention magazine, an estimated 62 million Americans say they have spoken to their doctors about an advertised medicine.

Various surveys, including those conducted by FDA, suggest that between 25 and 30 million Americans have been prompted by an ad to talk to their physician for the first time about a

medical condition.

Nevertheless, if you ask the surgeon general of the United States, the director of the Centers for Disease Control, or the HHS assistant secretary for health, I doubt any of them would say that too many Americans are making appointments with their doctors to seek health care.

One of our greatest challenges is to find ways to increase health literacy and awareness of our population, and to motivate Americans to seek health care assistance when it is needed.

The message doesn't have to be presented in pristine, white-jacketed format, but in any medium that will prompt the question for further research by the consumer. Advertising should inform and motivate; it doesn't need to be encyclopediac.

Former FDA Commissioner Mark McClellan has said, less is more.

DTC advertising has demonstrated its ability to play an important and effective role in raising public awareness of health care conditions and treatments. It's helped to lower patient

anxiety or embarrassment by removing the stigma from certain diseases and discussing them with family members and medical professionals.

I would note that Harvard University, Mass. General Hospital, and Harris Interactive, in a well known study, determined that 35 percent out of 3,000 people surveyed said that they sought medical advice after seeing an advertisement. It was consistent with earlier FDA and Prevention magazine surveys, but it offered an important new insight. Twenty-five percent of those who went to their doctor received a new diagnosis. Of those, 43 percent were for high priority conditions, including hypertension, diabetes, high cholesterol levels, and depression.

Instead of looking for ways to limit this speech, DTC advertising expands awareness of health conditions and care for the under-diagnosed and underserved populations in our society. It helps reduce disparities between different population groups, and their access to health care.

According to the Centers for Disease Control, nearly one out of three adults has high

blood pressure, or 65 million Americans. Thirty percent, or 19-1/2 million, don't know they have this silent killer, and 25 percent are receiving inadequate therapy.

Diabetes, the sixth leading cause of death in the United States - 21 million Americans are affected; that's seven percent of the U.S. population. Six million do not know that they have this disease. Moreover, more than 20 percent of men who went to a doctor seeking treatment for erectile dysfunction were diagnosed with high blood pressure, diabetes, or heart disease.

Nearly 40 million Americans suffer from depressive disorder, and yet only four to eight million Americans are receiving active treatment for depression.

Between 1987 and 1997, the percentage of Americans being treated for depression more than tripled nationwide from seven-tenths of a percent to 2.3 percent. Dr. Mark Olafson, associate professor of clinical psychiatry at Columbia University, attributed the expanded treatment in part to the number of multimillion dollar marketing campaigns.

Other factors included a decrease in the stigma associated with depression, and the arrival of new and more powerful drugs to treat depression.

Dr. Richard Kravitz at the University of California at Davis, often cited by critics of DTC advertising, said that the private sector's financial resources and ability to reach huge markets can be brought to bear on the public issue of bone health. DTC apparently works to get people to read and act upon the information they contain.

DTC advertising often offers another important means for raising public awareness. It can address public health disparities in underserved populations.

Dr. Jane DelGado, who is president and CEO of the National Alliance for Hispanic Health, told a House Energy and Commerce Subcommittee that access to information is a critical piece in the access picture for Hispanic and other under-served communities.

New research is showing that health care disparities among black, Hispanic and white

Americans cannot be explained wholly by disparities in income and health insurance coverage among these groups. Other factors, such as lack of information, play a critical role, Dr. DelGado said.

Now, I want you to look at a survey that Women's Day conducted. Women's Day is a magazine that reaches 20 million Americans, or one in five American women. The publisher of Women's Day is a member of the Magazine Publishers of America, which is part of the advertising coalition.

Through its research to 100,000 people in its reader panel, Women's Day received hundreds of examples of how prescription drug advertising positively affects lives and encourages a dialog between its readers, family members, and doctors. Here are some of their stories.

"Advertisements for a product prompted me to visit my physician to seek relief from my migraine headaches. I now take that product and feel that I've been given my life back. I can live again instead of worrying about getting a migraine." That's Debby from Paynesdale, Michigan.

Samantha from Bedford, Texas, said: "I suffered from severe depression and anxiety. I was trying to find something to even out my moods. I discussed many medications with my doctor, and found an ad for this product and spoke to him about it."

"It turned out to do miracles for me and my children's well-being. It continues to improve my quality of life."

Cindy from Muncie, Pennsylvania: "My mother was very depressed, and after months of being on a prescription, she was not feeling any better. I read about this product and talked to her about getting her prescription changed. She talked to her doctor, got the product, and we saw a change immediately."

And finally, Cindy from Geneva, New York, said: "I was waiting for the results of my second bone density test, and remembered seeing an ad for this product which allowed me to review the medication. On meeting with my doctor, it was his suggested medicine, as well, and the ad enabled me to ask questions at the time of my appointment."

I want to devote just a moment to an important new change, and an important component for improving the quality of DTC advertising.

The Pharmaceutical Manufacturers of America have launched a major new initiative to address public concerns about DTC advertising, and to establish new industry standards for print and broadcast advertising.

Three months ago, PhRMA announced a program of self regulation for prescription drug advertising. Beyond just meeting the legal requirements for FDA regulations, it would require advertising to be accurate and not misleading, and to reflect a balance between risks and benefits.

The principles adopted by PhRMA show that member companies are committed to delivering messages that educate patients.

While offering constructive criticism over the years, FDA has been a positive force for encouraging the use of DTC advertising to inform all Americans, and particularly to reach undiagnosed and under-treated Americans. The support and guidance of

this agency has provided vital leadership to expand and improve advertising of prescription drugs.

Looking forward, we need to focus on the important power that information, in the form of DTC advertising, brings to improving the public health of our nation. When you consider that more than 62 million patients have talked with their physicians after seeing a DTC advertisement, and that advertising 29 million patients to mention a medical condition to their physician for the first time, it's a powerful force for improving good health.

How many of that 25 percent of new diagnoses identified in the Harvard-Haro study would never have occurred without the prompting of an ad? I hope we don't have to weigh that risk.

Thank you very much.

MR. ABRAMS: Thank you, Mr. Davidson.

You mentioned hyperlipidemia, diabetes, hypertension as being serious conditions, and you mentioned the prevalence of these in the U.S.

Have you done research, or have access

to research that shows the impact of product specific advertising on getting patients in to be treated? There is much discussion about this during this meeting. And do you have a comparison to just plain disease awareness communication without drugs being mentioned?

MR. DAVIDSON: We have not done the research, but that is actually the focus of Joel Richardson's research in the Harvard-Harris study. That is why they looked at AHRQ, list of diseases, and matched them up with a population of 3,000 people that they surveyed to see how they reacted to the advertising, and what the reaction was by the physicians after they were examined. So out of that survey, 35 percent of the 3,000 went to see a doctor, were prompted to see the doctor. And then, let's see, I've got -- about 47 percent went to see the doctor. Thirty-five percent of those were diagnosed as having a serious condition in the list of AHRQ priority conditions.

MR. ABRAMS: And have you looked at research as far as disease awareness communications, how effective that would be?

MR. DAVIDSON: They didn't make that distinction between just disease awareness and general advertising. They had to work with the advertising that's available to the public.

MR. ABRAMS: Dr. Temple.

DR. TEMPLE: One speaker yesterday suggested that it would be useful, more balanced, if direct to consumer ads gave some reasonably quantitative description of the effectiveness that had been shown for the drugs.

Physician-directed ads often have such information, and sometimes we have to send letters about how it's done, but it's not uncommon. But it's extremely unusual to actually show data in a DTC ad. There is usually a statement of some kind, but it's unusual.

Do you think a more diligent attempt to do that and to do it in a comprehensible way would be one possible way for PhRMA to do what it is saying it wants to do, which is communicate more accurately and provide more information to patients?

MR. DAVIDSON: One of the challenges

that the advertising industry and the pharmaceutical industry have as they work in partnership to try to see how people react to advertising is how they assess this information based on the reader's information. If you are advertising to a medical professional, you can provide a totally different type of information than you can if you're advertising to the general public.

The purpose of advertising, remember, the primary purpose, is to first get the attention, certainly be truthful and not misleading, but get the reader or viewer's attention so that you prompt them to take some action and get them to focus on something that is in their personal well-being.

The Harvard-Harris study I come back to, one of the interesting features about that is the high proportion of folks who were diagnosed after seeing an ad and going to pursue treatment, diagnosed for the conditions.

I think it's one of the questions in an earlier FDA survey suggests that 88 percent of the folks who went in asking for a specific medicine actually suffer from the condition that the medicine

was designed to treat.

So there is a good relationship between consumer response. The question is, how much information do you put into the ad without discouraging them, but encouraging them to go seek treatment.

Again, one of the values of the whole process is that you have a medical professional assessing the health of the patient, and then deciding what to recommend, whether it's an alternative lifestyle, whether it's a particular prescription, or whatever. That's the intermediary role that is vital to this whole process. But, as I said before, we have such a level of under-diagnosis in this country that getting them to the doctor is one of the biggest challenges.

DR. TEMPLE: So you think that is more important, perhaps, especially if the two conflict, than actually giving them a precise or quantitative assessment of what the drug is likely to do?

MR. DAVIDSON: It is certainly equally as important. It is certainly equally as important.

Because if you look at the high percentage of people who are not being treated for some very serious conditions, CDC says we have a challenge ahead of us.

DR. TEMPLE: So whether you tried to do it could depend on the condition then, too, couldn't it? I mean, if you really just want to be sure they get to the doctor for their lipids, say, you might not worry too much. But if it was some symptomatic condition, maybe it would matter more.

MR. DAVIDSON: But what if they go to the doctor, and then are diagnosed with having another condition that they didn't know that they had? That is also part of the side benefits to this.

MR. ABRAMS: Ms. Davis.

MS. DAVIS: You talked about how industry self regulation will enhance the quality of DTC. And I'm curious, if an ad is misleading, how do you see that self regulation fitting into the overall scheme of regulation, including FDA's oversight of promotions?

MR. DAVIDSON: Well, first of all, let's operate from the presumption that advertisers are not going to put misleading information out there, or are going to put truthful information out there.

Now, do judgments vary on that? Of course they do, and that's why you've seen FDA oversight question content of some ads, and send out letters to the advertisers, with a very, very high ratio of compliance.

But the going in, what you are trying to do with any self regulatory program, is to set up, as PhRMA has done, a set of guiding principles that advertisers can look to and say, okay, these are the things we either need to do or not do in this advertising, in order to make it more understandable, and to motivate positive behavior on the part of the reader or viewer.

It's giving those guidelines, as is done, for example, with the Better Business Bureau's national advertising division has been doing this for years, for general advertising. The children's advertising review unit, which is also part of the Better Business Bureau, has done this for a number

of years.

They provide a set of guiding principles, and then they've got a lot of case law that they've built up over the years, and everyone in the advertising community, both advertisers, agencies, councils that advise them, all are aware of how those principles are applied by the Better Business Bureau's national advertising division. And then they use that as their guide for what they prepare in the future. It's been a system of self regulation that's worked extremely effectively in the past for other forms of advertising, and I think can be applied in this area, as well.

MR. ABRAMS: Dr. Ostrove.

MS. OSTROVE: To follow up on Ms. Davis' point, one of our speakers yesterday talked about an ad that appeared, actually I saw it last night, in Newsweek magazine, that would appear to be, and correct me if I'm wrong, inconsistent with the principles put out in PhRMA guidelines. Specifically, it's a reminder ad, and my recollection is that the guidelines basically do not -- recommend that those not be used.

What -- I understand what you're saying about the Better Business Bureau and their advertising, their national advertising division. Often, my understanding about that is also that it's the competitors that bring kind of complaints in that are looked at.

We have a case like this, where clearly there appears to be an ad that is inconsistent with the principles. Where is the force for basically enforcing compliance?

MR. DAVIDSON: First of all, it's my understanding that the PhRMA guidelines don't even go into effect until January of next year. So I thin you will hear probably from a representative of PhRMA a little bit later.

MS. DAVIS: So it's kind of a technical thing? So even though the guidelines are out there, and the manufacturers know about them, they don't really have to pay attention to them?

MR. DAVIDSON: Well, remember how long they've been out there. They've been out there for less than three months right now. And if you have

any idea of what the timeframe it takes to write new scripts and get things filmed and get them out to broadcast entities and print media, there is a huge cycle of change.

Hopefully after January you will start seeing ads that will be specifically reflecting those guidances.

MS. DAVIS: Thank you.

MR. ABRAMS: Thank you, Mr. Davidson, for your presentation and information.

Our next speaker is Ellen Liversidge, a speech pathologist, who will be speaking.

MS. LIVERSIDGE: Good morning, ladies and gentlemen.

My name is Ellen Liversidge from Silver Springs, Maryland. I'm a speech pathologist and board member of AHRP, the Alliance for Human Research Protection.

But most of all I'm the parent of a wonderful son who was killed by a prescription drug. Rob died of profound hyperglycemia on October 5th,

2002, back before the FDA had gotten around to placing a warning on the label, back before Eli Lilly had a settlement with 8,000 people harmed or killed by Zyprexa, back before we had any idea that there was any danger.

When I found out after his death from Public Citizen that other countries had required Lilly to place warnings on the label, I desperately tried to change the situation in this country. Working with reporters and the Baltimore Sun and the Wall Street Journal trying to get and getting front page articles about the dangers of Zyprexa.

Erica Wood of the New York Times followed up with another front page story, and finally, a year later, the FDA ordered all the atypical anti-psychotics to place a warning for diabetes, hyperglycemia, and death.

I speak today on behalf of AHRP, and also on behalf of all the parents I have met whose sons and daughters have been lost to psychotropic drugs. We are a band of brothers and sisters when get together, having had the worst possible thing in all the world happen to us and to our innocent

children.

Most of all, it is for the innocent children that are alive that I speak today, giving you AHRP's position on the very nefarious direct to consumer advertising scheme called Teen Screen, dreamt up by pharma and funded by the federal government. This plan will give unvalidated questionnaires to all the teens in every high school in the country, providing many of them with false, possibly false, psychiatric labels, and referring them to a doctor for probable medication, thus creating a new market share for the industry.

AHRP's position on this scheme is as follows. The Alliance for Human Research Protection opposes government policies requiring or promoting mental health screening of America's infants, toddlers and school children. Our opposition is informed by scientific, legal, ethical and common sense consideration.

Number one, the primary catalyst for both Teen Screen and for the prescribing guidelines, known as TMAP, is market expansion. Dr. Peter Weiden, who is a member of TMAP - it stands for the

Texas Medication Algorithm Project - expert consensus panel has charged that the guidelines are based on opinions, not data, and that bias due to funding sources undermines the credibility of the guidelines since most of the guidelines' authors have received support from the pharmaceutical industry.

The invalid screening process of Teen Screen ensures that mostly healthy normal children will be brought into government subsidized mental health dragnet. Once children acquire a psychiatric label they may be branded for life. For example, between 55 and 60 percent of foster children in at least three states - Texas, Massachusetts and Florida - are on psychotropic drugs starting as young as age three.

Some children are on multiple drug cocktails, as many as 16 drugs. The drugs that are recommended by TMAP are both dangerous and often ineffective. They all carry black box warning labels.

Two, the diagnostic criteria upon which mental health screening instruments rest are

scientifically invalid, vague and entirely open to subjective interpretation. Teen Screen was tested on 1,729 children in seven New York City schools using passive parental consent and teen active consent, which is legally invalid.

Teen Screen is fraught with suggestive insinuations of failure and self doubt. Such questions can lead vulnerable teenagers to obsess about perceived inadequacies that might lead them to develop low self esteem that could give rise to anxiety, withdrawal and emotional problems.

By raising the possibility that suicide may be an option, and that's one of the questions, screening might lead to suicidal thinking, as happens in Japan's Internet suicide clubs.

Teen Screen questions are so vague, suggestive and broad that most normal teens are mislabeled as mentally ill.

Teen Screen, also known as Columbia suicide screen, is an illegitimate intrusion on privacy which purports to be a suicide prevention assessment tool, but lacks any semblance of

scientific validity.

Indeed, the results of the study by Dr. David Schaeffer, chairman of child and adolescent psychiatry at Columbia University who is credited with developing and promoting Teen Screen showed that of 1,729 New York City high school students who were screened using the questionnaire, 475 students tested positive.

Number three, mental health screening is gambling with children's normal development. Teen Screen promoters fail to disclose that the risk for children who are screened to be falsely labeled as suicidal or mentally ill is 84 percent.

Number four, despite its proven unreliability as a predictive tool, and no evidence that mental health screening prevents suicide, Teen Screen promotes itself in direct to consumer marketing advertisements as a suicide prevention tool, proving that science is no deterrent to a marketing strategy.

The Teen Screen website states: We are running public service advertisements in the New

York Times and the Washington Post to raise awareness of our new report, entitled, Catch Them Before They Fall.

Catch Them Before They Fall is a marketing pitch much like pharmaceutical company advertisements that refer to unsubstantiated chemical imbalances. Teen Screen promoters are misinforming public health policymakers, school officials, families and teens by mischaracterizing their experimental, scientifically invalid questionnaire as a proven suicide prevention strategy, when their own research refutes such claims.

Teen Screen's low predictive level shown to be only 16 percent, will result in falsely 84 percent of children who test positive as mentally ill or suicidal.

As acknowledged by Dr. Schaeffer, such a high rate of false positives could reduce the acceptability of a school-based prevention program.

Number five, coercive mental health screening and forced drugging is already happening

to children in the United States. Current estimates are that each year 8 million American children, or about 10 percent of the school age population are prescribed mind-altering drugs.

Finally, a radical proposal contained in the federal mental health action agenda, a follow up to the NFC, is alarming as it is preposterous. The FMHAA's stated goal is to develop mental health promotion and early intervention services targeted to infants, toddlers, preschool and school age children. The action agenda, targeting infants, toddlers and children, is invalid and irresponsible, and disregards the risks, the lack of evidence to support such, quote, early intervention.

In 2001 Dr. Benedetto Ditiello, director of child and adolescent treatment and prevention interventions research branch for the National Institutes of Mental Health, acknowledged the diagnostic uncertainty surrounding most manifestations of psychopathology in early childhood.

AHRP opposes psychiatric screening of children without active, informed parental consent.

Consent of parents must be documented and given voluntarily without a hint of coercion. Teen Screen has attempted to sidestep parental consent by claiming passive parental consent, which is invalid.

Teen Screen is being sued in federal court by the parents of 15-year-old Chelsea Rhodes for violating their constitutional rights by failing to inform them that their child would be screened, and for failing to obtain parental consent.

The Rhodes family is represented by the Rutherford Institute.

The FDA bears responsibility for failing to stop an unethical drug marketing strategy that is increasing the risk of serious harm for healthy children who are being misprescribed psychoactive drugs on the basis of an invalid screening tool that was being promoted with false claims.

According to its website, as of October 25th of this year, Teen Screen is actively operating at 460 locations in 42 states and Washington, D.C.

Thank you.

MR. ABRAMS: Thank you for your presentation and sharing your thought.

Before I open the questions up to questions by the FDA panel, I want to make it clear the rules of a Part 15 meeting, that FDA is here to listen, to get your information. So we are not allowed to respond to comments or answer questions. I think that is important. The purpose of the meeting is to gather information.

So with that I'll open it up to the panel members.

Dr. Temple.

DR. TEMPLE: You mentioned that some direct to consumer ads are mentioning and promoting Teen Screen. I checked. We don't think we're aware of that. Can you either now or afterwards identify those for us so we can look at them?

MS. LIVERSIDGE: What I can identify for you now is what is stated in my statement that I got from AHRP. But I do not have any information in any public document.

DR. TEMPLE: Well, even if you went back to them and asked them?

MS. LIVERSIDGE: I would be happy to do that.

MR. ABRAMS: Thank you for your presentation. And any additional information please submit to the docket, and we will carefully consider it.

Thank you.

Our final speaker for the panel is Peter Lurie from Public Citizen.

MR. LURIE: Good morning. I'm Peter Lurie. I'm a physician, deputy director of Public Citizen's health research group.

I want to start off with a housekeeping matter to which our previous speakers have not paid attention which is to make a conflict of interest statement. And that conflict of interest statement is that Public Citizen takes no money from government or industry. I doubt that that is true for the advertisers or for the American Enterprise

Institute.

The intellectual background for assessing any intervention in public health is assessing risk and benefit. And those of us who have done that kind of work always ask the question, yes, whose risk and whose benefit?

And I think that much of the conversation this morning has in some way been naïve. It's obvious what the risks and benefits are when viewed from the perspective of the advertisers in the pharmaceutical industry. It's all benefit to them, with very little risk. Benefit in the form of increased sales, increased advertising, and so forth.

That's the emperor in the room without the clothes, and we should remember that as we go forward. But that's not really the right way to assess the impact of direct to consumer advertising. The right way is to look at it from the perspective of risks and benefits to the public health. That is what we're concerned about.

And even if there are any benefits at

all, which I don't concede, the question is if those benefits could be obtained in some other way by a method other than direct to consumer advertising. To that we believe the answer is yes.

There was one thing missing from Mr. Calfee's presentation, which is that New Zealand is an interesting example in that, one, it is the only other country that has ever done direct to consumer advertising. European Union gave serious consideration to this awhile ago and decided affirmatively not to do it.

But he doesn't mention that there is in fact a moratorium on direct to consumer in New Zealand at this point because they haven't liked the experience, especially the doctors, consumers have not. And so as a consequence they are actually moving toward finalizing that moratorium.

So that is really the strongest lesson.

I'll make seven points. First, and this point has been made earlier, direct to consumer advertisements bear little relationship to public health needs. Only 14 percent of sales of the top

50 DTC advertised drugs are for acute conditions. And only one of the top 50 DTC advertised drugs is for an antibiotic, presumably because you get cured too quickly.

What they are interested in doing is advertising for chronic conditions that make people uncomfortably usually, or that people believe are likely to be dangerous to them, which they will continue to take for a long period of time. That is where the money is to be made.

One never encounters ads for generic drugs, even though that would be one way of getting people into drugs, some of which in fact are shown to be the most effective medications for particular conditions, like thiazide diuretics are probably the best way to go for at least the initial treatment of hypertension, but you certainly don't see any ads for them on TV.

Least of all do you see ads for any behavioral interventions, like - behavioral interventions such as exercise, weight loss, and so forth, even though these can be safer, less costly, and more effective. That's the first point.

Second, many DTC advertisements are misleading or dangerous. I won't go through the whole experience with Vioxx. I'm sure other people have gone into it. But remember the size of that campaign. The campaign for Vioxx in 2000 was $160 million, larger than the campaigns that year for Pepsi or Budweiser, and the retail sales quadrupled.

I don't mind if there are direct to consumer ads for Pepsi or Budweiser, and I don't even mind that much if it isn't true that life goes better with Coke. But I do have a problem with the idea of information being provided in an attempt to get around the doctor and turn the patients in effect into the agents of the drug companies in order to increase prescribing.

We provide attached to my testimony as well as in my testimony to the Senate Education Committee a few weeks ago an amazing ad, which is a DTC ad indeed, a direct to children ad, along the lines of what Ms. Liversidge is concerned about. It's an ad for a drug called Differin, an acne product, and it's directed at children. There is a teen survival handbook which includes a self test on

acne which is Zit 101, which is a course, it turns out, on offer at Acme High.

And what they are in effect trying to do is get the children to go to their parents, have the parents then ask the doctors for the drug. And in proportion to the success that the children have, they get to download free music on the Internet. And it's proportional to how good you are at it. Two free music downloads if you sign up at the site. Seven free music downloads if you get and fill a prescription, and 10 if you refill it. That really seems completely inappropriate.

And a probable new low in direct to consumer advertising was actually misrepresenting the FDA itself, in which AstraZeneca made a claim that FDA had no found no reason for concern with respect to the safety of Crestor, even though Dr. Galson I believe it was on record as saying that the agency was quite concerned about it. So misrepresenting the FDA is really a new low.

Three, consumers are being misled. The agency's 2002 survey which we've heard about found that 60 percent of patients thought that

advertisements provide insufficient information about drug risks, and 44 percent felt similarly about drug benefits.

And I disagree with the claim that we can't get into detail about benefits. What the industry is concerned about is that for many drugs the benefits, actually laid out in a clear fashion, will turn out to be lower than most people assume, at least based on the visions of people floating around in blue sky fields with butterflies floating above them.

If there is going to be benefit information of any kind, let's be quantitative about it, and we'll learn if many drugs, especially for Alzheimer's disease, are barely effective at all.

Fourth, doctors are being coerced. In an already classic study that has been discussed a little bit, Dr. Kravitz sent in so-called standardized patients - this is in answer to some earlier questions from the FDA panel - this was a real randomized control trial, they tried to answer this question. And what came out was not at all unexpected: An increase in prescribing for

adjustment disorder, a condition not ordinarily requiring drug treatment, that was much worse, which is to say, more prescribing, when the person, the doctor, was confronted with someone demanding Paxil, 55 percent of those who told their doctors they had seen a Paxil ad ended up with a prescription for a drug. And that is an increase in effect over what ought to be in effect zero percent prescribing for a condition like adjustment disorder.

Fifth point: The price of health care is being driven up. The GAO agreed that, quote, the DTC advertising appears to increase prescription drug spending and utilization, primarily because of increased utilization, not because of increased prices; that's a separate problem.

In a study that separated out the various forms of advertising, i.e. the doctor advertising and the consumer advertising, DTC advertisements for just the 25 largest therapeutic classes were estimated to have accounted for 12 percent of the increase in drug sales from 1999 to 2000, an increase of $2.6 billion.

Point six, potential benefits of direct

to consumer advertising. The best argument the pharmaceutical companies is the one we've heard repeatedly today, the claim that actually what the industry is interested in is getting under treated people, best of all minority people we seem to believe now, into the care of doctors.

The question then would be, if there were a better way than direct to consumer advertising to accomplish that, why wouldn't that industry endorse that instead and use that? In fact, that is what the data from the Kravitz show. What the Kravitz study shows is that the most effective way to get people treatment for depression, arguably an example of an under-treated disease, although whether as in the Kravitz study one ought be getting drug at the first time you present to a doctor is not necessarily correct. But even if one assumed that, the most effective way in that study to get a person on a drug was to have the patient approach them not asking for Paxil or saying that they had seen a Paxil ad, but rather that you approach them saying that they had learned something about depression on television, and isn't there something that could be done for it.

So we'd be seeing far more of the help seeking ads if the real motivation for direct to consumer advertising was to get under-treated people on to drug, or to see them get some sort of help, and we certainly aren't seeing much of that.

Finally, point seven, FDA enforcement is lackadaisical. There is an 85 percent decline in overall enforcement actions at DDMAC between 1998 and 2004. That didn't just happen. It does go back to the Clinton administration, but it also derives from the requirement to send warning letters through the office of the chief counsel at the FDA, which GAO concluded, that practice of reviewing, had often taken so long that misleading advertisements may have completed their broadcast lifecycle before the FDA issued the letters. According to minority staff at the committee on government reform, the average time from initial placement of prescription drug ads and enforcement action if there was one was 177 days, and recidivism was common between companies.

So what I believe I've shown, then, is that there are in fact many risks to direct to consumer advertising, and the only theoretical

benefit is one that can better obtained by using help seeking ads, rather than profit-driven direct to consumer ones that link drug and disease.

What are our recommendations? Firstly, the former guidelines are unlikely to have any impact as Dr. Ostrow was hinting. It's only the Vioxx debacle that has gotten PhRMA to revise these guidelines at all, and of course they are voluntary, and designed primarily to stave off more aggressive legislation or regulations.

The guidelines recommend the company should weigh the quote appropriate amount of time, whatever that means, after launching a new drug before initiating a DTC campaign. Even Senator Frist thinks it ought to be a two-year wait.

Second, patient information should come from the FDA. Back in 1979 the FDA proposed to do just this, but the American Medical Association and pharmaceutical industry stopped them from doing it. They were called patient packages in those days.

And now we've got a kind of son of patient packages, which is called the medication

guide. But there are only about 75 of those that exist. So those drugs do not get FDA approved information that is provided directly to the patient, and we think this is a massive hole into which the pharmaceutical and advertising industry have stepped and that is why we have the massive growth in DTC advertising that we've currently seen, an increase of $4.1 billion in 2004 from just $791 million in 1996.

Let me point out that that increase did not occur by accident. It occurred because of the 1997 deregulation of direct to consumer advertising. That is not the only explanation, but in our view it's the main one. And if the genie can be let out of the bottle by FDA regulations, then it follows that it can be put back into the bottle, at least to a significant extent, by reimposing the regulations that existed or the guidances that existed prior to 1997.

The problem of course is that there are no regulations at all. And the FDA has been saying for a long time that they've been looking at regulations. They never seem to be people coming;

all we get are a bunch of guidances that are not able to be enforced, and are not enforced, and are frequently violated.

The agency is unable to adequately enforce even the weak guidances that it has. It's drastically understaffed, and there is no way that they can keep up with the barrage of print and broadcast ads that are coming out on a daily basis.

Federal agencies other than the FDA also have a role in all of this, in particular, the NIH and the AHRQ have an important role in educating consumers, and for that matter, doctors, about many of the conditions that people are concerned about.

Finally, if there ought to be regulations, they should provide a pre-review of television advertising and should not allow celebrity endorsements. Most fundamentally the agency is lacking the ability to levy civil monetary penalties. And so it always will be in the interests of the pharmaceutical companies and the advertisers to get an ad out. And should the FDA even learn about it, and if so, should they even act on it, and if so, should it ever emerge from the

office of the chief counsel, by then, the ad will long have run its course, and tens of millions of people will have been exposed.

That concludes my comment.

MR. ABRAMS: Thank you, Dr. Lurie, for your presentation.

You mention in your presentation that you believe that DTC increased utilization of drugs. That could be a positive thing or a negative thing. The negative aspect, it increases costs.

But if that increased utilization is for appropriate use, for under-treated conditions, obviously it's positive for public health.

Do you have any data or information that could provide some light to tease out what is going on there?

MR. LURIE: Well, as I indicated in my testimony, the best data on that are in fact from a randomized control trial unusual in this kind of area of regulation. And I'm sure you are familiar with it. It's the Kravitz study. And what this

Kravitz study shows quite clearly is that direct to consumer advertising - let me explain in case not everybody knows. There were two parts to the study. One had to do with adjustment disorder, assumedly a condition for which little if any treatment was necessary, and the other for depression in which there is at least the possibility that they are under-treating people who could benefit from learning about the dangers of their condition and approaching their physician.

With respect to adjustment disorder, DTC advertising massively increased the amount of prescribing the drug, and I would argue that essentially all of that is unnecessary; and that is on the negative side.

On the positive side, as I mentioned in my testimony, it turns out that it was more effective to get people onto drugs - if one assumes that that is the right outcome - that the best way to get people onto drugs was not through a drug company-drive DTC ad, but rather by something that came from a more reputable source, like you, right, like the FDA, the NIH, the AHRQ, or even some media

presentation.

So if the object is to truly work, which I don't for a moment believe that it is, but if it truly were to get under-treated people onto medication, A, we'd be seeing the best way to do it would through help-seeking advertisement from the industry, and we just don't see much of that at all.

MR. ABRAMS: Okay. A speaker in our second panel yesterday morning talked about product specific production versus disease awareness communication. And the point that he made was, you need a call to action. If you don't have a solution or a motivation to have somebody go to a physician like you could get a product to help you, it's not going to be effective.

Any thoughts about that?

MR. LURIE: Yes. He's wrong. He's wrong, because the data from the Kravitz disproved that. They show that physicians were more likely to prescribe from a help-seeking ad than from the DTC ad for Paxil, as cited by the patient.

So that is a theoretical argument. But

to the extent that there are data upon which we can base that, I think it's just plain wrong.

MR. ABRAMS: Dr. Temple.

DR. TEMPLE: It sounds like the source was a different source, though; it wasn't from the drug company.

MR. ABRAMS: It was from something you described as more reputable. I don't know what is.

MR. LURIE: No, no. I mean in the study, what the person did was, they said - there were three groups. One was the group that said, hey, I'm feeling blue, or other symptoms consistent with social adjustment disorder. So the depression was, I'm feeling blue.

The help-seeking ad type thing was, I saw a program that dealt with depression.

And the other one was, I saw an ad for Paxil.

So they are different sources, yes. But as I've said, the solution to this is not to turn over the pharmaceutical industry the job of doing

help-seeking ads. I'm merely pointing out that if they were truly interested in the public health, that's what they would do.

The best solution is to get the pharmaceutical industry out of the business altogether, because the right people to do the job are you or the NIH or the AHRQ. And it's the failure by the government to act in that way that's leave this gaping information hole into which the industry is stepping.

DR. TEMPLE: Let me - it's an interesting suggestion that FDA would become advocates for certain kinds of treatment, getting your cholesterol down after trying exercise and diet. Would you actually be enthusiastic about having the drug regulatory authority responsible for doing that also?

We promote generic drug use, but we haven't for the most part actually done what you are describing.

MR. LURIE: Yes. I think what we point to in the testimony is really the NIH and the AHRQ.

I think you are a drug regulatory agency. You need to see that information that goes out is honest; sometimes it's not. So no, I don't think it's so much an FDA responsibility as it is that of NIH or CDC for that matter.

DR. TEMPLE: Let me ask you a hard question. There already are existing programs for NIH to do that. The ads show up as far as I can tell very late at night. They are never part of the Super Bowl, and it's obviously a matter of money among perhaps other things.

Suppose the choices between having the source you prefer to do it and not having it at all, where do you come out?

MR. LURIE: I just don't accept the choice.

DR. TEMPLE: Oh, you think they are going to come up with several billion to do it?

MR. LURIE: No, our recommendation is that the government get on the talks.

DR. TEMPLE: Okay.

MR. ABRAMS: Dr. Ostrove.

MS. OSTROVE: Dr. Lurie, I'm just confused about one thing, so if you could just clarify it for me. The Kravitz study used simulated patients to talk to physicians. So I'm not sure how that study really addresses Mr. Abrams' question concerning the ability of help-seeking ads to get patients in to see doctors.

MR. LURIE: No, I think it goes to the question of the kind of information that is most effective in getting the doctor to prescribe, if one assumes for the moment - which I'm not sure I do - if one assumes that the object is to get people onto drugs.

Now, obviously that is a complicated question. But granting for a moment that in depression people coming in without drug treatment, some fraction of them may well have been helped by being put on it, I'm saying that given what the patient described as the source had an impact, and that the less successful source was the direct to consumer ad.

MS. OSTROVE: So what you're saying is that it's what the patient refers to when they go in that may have a more positive impact on the way that the health care professional responds, but it doesn't really say anything about what will actually get the patient in to talk to the physician about their problem?

MR. LURIE: Yes, that is correct, and we make that point in our testimony.

MS. OSTROVE: Thank you.

MR. ABRAMS: Dr. Lurie, you mentioned that you were not real impressed with guidances that were issued by FDA. You didn't think that they were terribly effective. You suggest that we go beyond that.

Could you elaborate on that?

MR. LURIE: Well, as I said, I thought that guidances are - well, they are voluntary, that is the principal problem. And so however much we might like to see the end of direct to consumer advertising, we do understand that current interpretations as offered by the Supreme Court and

others are not consistent with a ban at this point; we do understand that. It's not something we're happy about particularly, and maybe a Supreme Court less packed than the present one may come to a different conclusion.

But nonetheless, that is the case. And so were there to be regulations, which we think there ought to be, I've mentioned a number of elements that would be important, and those would include the celebrity element. The children element is certainly another one. I think that the idea of providing more quantitative, useful, interpretable information about both risks and benefit I think would all be advances.

I also think that the agency is lacking the ability - your division in particular - to levy civil monetary penalties. And I think I'd like to see you or anybody else at the FDA approach the Congress looking for that authority. That would make an enormous difference. But right now getting caught putting out a direct to consumer advertising that violates the relevant provisions is just a cost of doing business at this point. It's no great

injury to the industry. They've already had tens of millions of people looking at it.

So I think you need more funding so you could have more people that could actually help you to police these, even in a prospective fashion, and that's another point that we'd like to see, more prospective review of ads. And you need to be able to police this much more aggressively than you either have been interested in doing, or that the office of general counsel has allowed you to do.

MR. ABRAMS: Okay, Dr. Lurie, thank you for your presentation and the information.

I would like to thank the first panel for their presentations and response to questions.

(Applause)

We have about six minutes before we break, so nobody signed up to make public comments from the floor. I encourage you to do so if you wish to; it makes it a little easier for us.

So I invite anybody else who wishes to to come up to a mike, please identify yourself, your

name, and your affiliation.

Thank you.

MR. SWEENEY: My name is Harry Sweeney, and I am the chairman of Dorland, a global corporation. We are a medical and health promotion communications company.

For a point of clarification on the Kravitz study that was just discussed, I'd like to read you a couple of things from that study.

First of all, the patient that was characterized as coming in generally seeking some care, this is what that fake patient said: I was watching this TV program about depression the other night. It really got me thinking. I was wondering if you thought a medicine might help me, okay. Nonspecific, but I was wondering if you thought a medicine might help me.

The other patient came in and said, I saw this ad on TV the other night that was about Paxil. Some things about the ad really struck me. I was wondering if you thought Paxil might help.

Now this study had kind of a law of unintended consequences result. It happens to be one of the best studies that we've seen so far that indicates that DTC advertising has a very, very positive effect on patient care. And here was the result.

Minimally acceptable care which was defined by the authors as receiving a drug or a referral to a specialist or come back in two weeks and see me again - minimally acceptable care - occurred 98 percent of the time when patients made the general request. It occurred 90 percent of the time when patients made the specific drug request. And it only occurred 56 percent of the time if the patients made no request at all.

In other words, DTC advertising works to promote better patient care.

MR. ABRAMS: Okay, thank you.

We have two more people up at the mike, so we're going to take those before the break. Anybody else who wishes to speak at this point, please sign up, and then we'll get to you later in

the day.

MS. KASTNER: I'm Kathy Kastner. My company is called the Health Television System. And we produce direct to patient education that is directly related to hospitalized patients, and their life out of the hospital.

I have a comment and a question. The comment is related to the various presentations that I've heard that seem to place doctors either as the all-knowing all-seeing interpreters of statistical information and our learned intermediaries, or pawns of the pharmaceutical industry. This was just a comment. And I'll be interested to hear from the American Medical Association later.

My question, however, is for Dr. Lurie. I wonder if you --

MR. ABRAMS: We are not permitted to take questions from the floor.

MS. KASTNER: Oh, just commenting, okay thank you.

MR. ABRAMS: You can comment, and make

your comment very thorough, and it will go into the record and we will carefully consider it.

MS. KASTNER: Thank you so much. Okay, second comment is that I wonder if the pharmaceutical industry were required to spend a portion of their promotional budget specifically on education with the definition of that being clearly understood by all separate from a promotional budget.

MR. ABRAMS: That you for the comment. That will be in the transcript.

If you have additional information related to that that you wish us to consider, please include that in your submission to the docket. Thank you. And lastly.

MS. SNOW: Good morning. Thank you for the FDA panel and everybody here today.

My name is Brenda Snow. I'd like to speak to you on two fronts, first as a patient that has benefited from DTC advertising, and second, as the owner of a medical marketing company that works in this industry called Snow & Associates. That is

my affiliation.

I'll start off from the patient perspective. I was diagnosed with multiple sclerosis 12 years ago, and it was by a DTC advertisement that drove me to ask for the first approved therapy for this condition.

Obviously you can tell by looking at me today that I'm doing extremely well. Had I not had availability and access to the first biologic for relapsing MS the natural history of the disease suggests that at year 12 I would be ambulating with either canes, devices and/or possibly a wheelchair.

So my personal experience has been, while we have heard some very heartbreaking stories over the last couple of days, I felt compelled to provide a perspective where a DTC ad actually impacted my health. For the last 12 years I've been able to raise my family and own a business and be a productive member of society.

So that is my personal experience with the DTC advertising.

On a business front I'd like to say that

we've heard a lot about Cox-2s, and while again, that is an example, unfortunately a heartbreaking one in the marketplace, I don't think that it is what we should exclusively focus on as we go through this investigative panel, particularly when - and I would thoughtfully like to remind the FDA panel here today - particularly when it comes to ultra orphan diseases, orphan diseases and chronic medical conditions which there are still no cures for - I'm talking about epilepsy, rheumatoid arthritis, lupus, all of these autoimmune diseases where as a business owner now I can tell you, managing patient advocates and testimonials, the majority of these folks - and I would be happy to submit the anecdotal testimony to the board - suggests that had they not had direct patient communication or patient-to-patient communication, they would not know that there are therapeutic agents on the market, in the marketplace today, that affects the outcome of their health

And when we are talking about the ability to continue with your life, I think that is a significant one.

My final comment is, it's not perfect.

Obviously we are here to look at some changes and make some considerations. But I don't think DTC is to be blamed for everything bad that has happened. I think that there is a lot of other in this treatment paradigm.

And I think yesterday the Kaiser Permanente presentation clearly illustrated that there was some grave ownership that should have happened on physicians prescribing those medications.

So I think as a broad blanket, at all different stages, there needs to be thoughtful consideration and the physicians certainly play a role in that as well.

Thank you for hearing my comments.

MR. ABRAMS: Thank you for your comments.

I want to again thank the panel for their insightful presentations.

We will break now for 15 minutes, and we will resume promptly at 11:15. Again if you wish to

speak from the floor, I encourage you to sign up.

Thank you.

(Whereupon at 10:57 the proceeding in the above-entitled matter went off the record, to return on the record at 11:16 a.m.)

MR. ABRAMS: Welcome back. We will start with our second panel of this morning. And our first speaker is Gary Ruskin from Commercial Alert.

MR. RUSKIN: I'm sorry to have my back to you here. Hello, is this working?

Hi, my name is Gary Ruskin. I'm the executive director for Commercial Alert. Thank you very much for inviting me to testify today.

I'd like to start by quoting three letters sent to the subcommittee on oversight and investigations of the U.S. House of Representatives Committee on Energy and Commerce some two decades ago.

Quote, Scheering Plough believes there is a fundamental flaw in the concept of advertising

prescription pharmaceuticals directly to patients, and that is the inability to provide them complete, meaningful and useful information.

That quote did not come from a critic of the industry, or some consumer watchdog; it came from Allen S. Cushion, who was then senior vice president for public affairs for Scheering Plough. Most of his peers in the pharmaceutical industry agreed.

Quote: We do not believe that prescription drug advertising to consumers is a good idea, wrote Thomas M. Collins, president of Smith-Kline-French laboratories. The likelihood - quote - the likelihood that meaningful patient education will occur is small.

Quote: It can inform, but it is not education, and it should not be portrayed as a part of the education process.

Here is another one, quote: We do not believe that prescription drug advertising to consumers is in the public interest, wrote Robert Schellhorn, chairman of Abbott Laboratories.

We believe that direct advertising to consumers introduces a very real possibility of causing harm to patients who may respond to advertisements by pressuring physicians to prescribe medications that may not be required.

Today I want to explain why those three gentlemen are exactly right. First, just a quick word about Commercial Alert and why I'm here. We're a nonprofit organization that protects children and communities from commercialism. We're a watchdog group for the advertising industry, and my job is to study commercialism and the advertising industry, and to mitigate the damage they do the American public.

I'm going to respond directly to the questions that you have posed, excellent questions. But at the outset I just want to emphasize that under current prescription drug laws and the principles that underlie them, there is no basis at all for allowing direct to consumer prescription drug advertising. By law only doctors may prescribe prescription medicine, and there is no legitimate purpose in advertising what consumers may not

directly purchase.

For this reason alone, direct to consumer drug advertising should be prohibited.

Now I'd like to focus my testimony today on questions one and three in the notice of public hearing. Question one asks, does current DTC promotion underlie - present the benefits and risks of using medical products in an accurate nonmisleading and balanced and understandable way?

And the answer is no. Direct to consumer drug advertising is inherently misleading; inherently misleading. And there are a few reasons for this.

Pharmaceutical companies have conflicts of interest that keep them from presenting unbiased information about their products. Pharmaceutical companies exist to make a profit. That is their duty under the law, to yield maximum returns to their shareholders.

In order to do that they have to sell drugs, and the more drugs they sell the better the shareholders will do. Every piece of information

that a pharmaceutical company sends out must be geared to that end. And that's why pharmaceutical companies are not a good source of information about their own prescription medicines. Their financial interests directly conflict with any intention to provide unbiased information about their products.

Because of these financial conflicts of interest, pharmaceutical companies are perhaps the least trustworthy sources of information about their own products.

By their very nature drug companies hype the benefits or alleged benefits of their drugs and downplay the negatives. And they encourage people to see their problems and diseases as diseases that require medication. And the result is a public that is increasingly drugged and pathologized.

You know in a candid moment two DTC advertising executives at FCB Healthworks wrote, quote: The ultimate goal of DTC advertising is to stimulate consumers to ask their doctors about the advertised drug, and then hopefully get the prescription, unquote.

Please read that - I'll say it again, because I think it will answer most of the questions that are prompted by this hearing: The ultimate goal of DTC advertising is to stimulate consumers to ask their doctors about the advertised drug and then hopefully get the prescription.

Now question three asks, could changes in the requirements for disclosure of certain information in broadcast advertising improve the usefulness of this information for consumers.

And the answer is, no. Because broadcast DTC ads are inherently misleading. And another reason why is it's just important to examine the nature of television, to think about the nature of television for a second and what it's good at. Television is great at entertainment. It excels at bringing show business into the homes of millions of Americans each day. It excels at presenting visual images to people and visual images that are what television does well.

And it is especially good at selling products, and this is why advertisers migrated to TV in the early days, even before most Americans did,

and to see a smoker taking a big drag on a cigarette was much more provocative than a jingle on a radio.

We want what we see. And so television is a magnificent selling medium. But it's not - you know it's great at conveying images of happy tummies and smiling people who are relieved because they don't have irritable bowel syndrome anymore, but it's not so good at conveying complex information.

And the main reason is that television teaches us primarily with images and not with words. And images are inefficient ways to convey most information. While some things you can learn through images, anything that is complicated or requires conceptual analysis or is typically taught very poorly through television.

Neal Closeman wrote that, quote: It is in the nature of television that it must suppress the content of ideas in order to accommodate the requirements of visual interest.

We need words and symbols to understand what is complicated. Printed words are far better for teaching what is complicated.

Another problem is that television also encourages us to absorb passively what we see, but real education, whether it's about drugs or anything else, it's active; it's not passive.

Television is excellent at spreading these fantasyland images to people - fantasyland images is what Senate Majority Leader Frist called them. But it is simply incapable of presenting the depth and richness of information that people need about pharmaceuticals, and it's certainly not in 30 or 60 second spots.

And much the same is true for radio. The high cost of buying ads on the media makes it impossible to convey the extensive information that consumers need about prescription drugs. And while radio is better suited for conveying information, it's still far inferior to print.

I wanted to talk for a second about actors and celebrity endorsements. The advertising industry uses actors in ways that are plainly deceptive. For example, it uses actors who do not and have never used the drug they are advertising, but it doesn't disclose that fact, and that is - and

it doesn't disclose that the actors really are deliberately falsifying any improvements in health that they are portraying or implying.

And that deception is so plain and outrageous, it can only be described as fraudulent.

Now celebrity endorsements can be deeply deceptive. For example, there is the famous story of Wyeth hiring Lauren Hutton to promote its drug for hormone replacement, and in an article in Parade magazine, Hutton said, my number one secret is estrogen, quote, it's good for your moods, it's good for your skin. If I had to choose between all my creams and makeup for feeling and looking good, I'd take the estrogen, unquote. But there was no mention that she'd been hired by Wyeth, and that Hutton was a hired shill, and the promotion of Wyeth's drug had nothing to do with education at all.

So at best paid celebrity endorsements have virtually no educational value. They come from paid shills with anecdotal stories that tell a story that may have no relationship whatever to the relevant merits of the drug.

All right, so I want to talk for the last couple of minutes here about the minimum requirements for protecting the public from DTC ads. Now we certainly believe that DTC ads should be prohibited. But if the FDA believes that it cannot at this time fully prohibit DTC prescription drug marketing, we strongly urge the FDA to expand its interpretation of the term, misleading.

Any DTC ad should be accompanied by the full FDA-approved label. At a minimum, DTC ads should not exist without the full FDA-approved label. The reason is, the label is the minimum amount of information for any pharmaceutical marketing communication to not be misleading.

Anything that presents less than that, because it is dangerously incomplete.

The FDA should consider the entire label as material information to consumers' decision-making process. And it's probably worth thinking about the Federal Trade Commission's policy statement on deception just to kind of help you think about a similar situation.

Their policy statement said, quote, the practice of offering a product for sale creates the implied representation that it is fit for the purposes for which it is sold. Failure to disclose that the product is not fit constitutes a deceptive omission. Omissions may also be deceptive when the representations are not literally misleading, when those representations create a reasonable expectation or belief among consumers which is misleading absent the omitted disclosure.

So in essence here DTC prescriptions make an implied representation that the drug is fit for use by consumers, who view the ads, and such an implied representation is misleading if it's not accompanied by the full FDA-approved label.

All right, then it's very important to remove the loophole for broadcast ads. As you all know prescription drug ads have to have a brief summary, but regrettably in your guidance to industry on consumer direct to broadcast advertisements, the FDA created a devastating loophole by interpreting adequate provision to mean broadcast DTC ads may refer merely to print ads or

websites or the like.

There is no basis for this loophole, which establishes a stronger standard for DTC prescription drug advertising in print and a weaker one for broadcast. It's not merely enough to tell people viewing the broadcast DTC ad to see the label elsewhere.

Essentially this allows a broadcast ad itself to be misleading, with the hope that consumers will be able to seek out and read information elsewhere.

This is completely inadequate, and it does not meet the requirement under the act that DTC ads must in themselves be nonmisleading.

There is no public policy justification for lax standards on broadcast medium, merely because the print standards are almost impossible for broadcast media to meet.

In fact, it is a compelling reason to prohibit DTC ads on TV and radio, because these media are simply poorly suited to convey complicated information. At a minimum there should be a uniform

standard for all DTC advertising, the current print standard.

Okay.

MR. ABRAMS: Thank you for your presentation. Dr. Aikin.

DR. AIKIN: Thank you for your presentation today. You advocate including the full labeling in print advertising, if we can just stick to print advertising. In those cases where the particular product might have patient labeling, would you advocate printing the physician labeling in that case, or reprinting the patient labeling?

MR. RUSKIN: Well, I guess the physician labeling -- in my mind the patient labeling is quite thin in many case. I'm sorry.

So I would advocate for the physician labeling, just because I think if - we don't think there should be DTC ads, but if there must be the ads, I think it is absolutely incumbent upon the pharmaceutical industry to produce extensive information in their ads so that people can read and understand what these ads are and what these drugs

are.

DR. AIKIN: Do you think it's helpful to reprint physician labeling that patients might not understand?

MR. RUSKIN: Well, I think that that's part of the problem here with promoting things that are very complicated. So I think at a minimum you have to produce all the information to people to read, and then they'll understand it as best they can.

But to me your question just explains one more reason why this is a crazy idea to drug marketing; we just shouldn't do it at all.

MR. ABRAMS: Dr. Behrman.

MS. BEHRMAN: I guess two questions to follow up on Dr. Aikin's point.

I believe you mentioned that in a broadcast ad you would somehow convey the entire physician labeling. Have you given any thought to how you would do it? Would you scroll it?

MR. RUSKIN: I don't think it's

possible, and that is kind of our point, is that there is - it is inherently misleading. There is just no way to pack that information in there in a way that you could do that.

All media have limitations, and they are inherent in the media. And that is just inherent in TV; it's a lousy way of conveying information. So I don't think it can be done.

MS. BEHRMAN: And are you aware of research or data that speak to how much of the entire prescribing information that is captured in official labeling is important for a consumer to be exposed to during DTC ads so they can fully - or as much as you believe it is possible to balance the information in that ad?

MR. RUSKIN: I'm not aware of any such research.

MR. ABRAMS: Ms. Davis.

MS. DAVIS: Hi, thank you for your presentation.

Towards the beginning of your

presentation you indicated that there was no legitimate purpose to advertising directly to consumers since they can't directly buy prescription products.

I think we've heard a lot during the course of this meeting about some positive impact that direct to consumer advertising can have on actually getting people into the doctor when they do have an undiagnosed or untreated condition.

How would you suggest that we make these consumers aware of the fact that they have this condition, and that there is something that can help them/

MR. RUSKIN: Well, it's a great question. I mean look, it's obvious that we need to get people to understand what their own health conditions, and we need to people to understand how drugs work and what they are and what's out there.

But there are other entities that could accomplish this much better, because they are not - they don't have these inherent conflicts of interest. So for example, I wrote about this a

little bit in my written testimony. But for example, the NIH could do such patient education very well, or universities without - which take no money from drug companies, or media organizations could easily do such a thing, provided they don't take ads, could all be harnessed to do much better patient education.

Personally I think NIH would be great for this sort of thing.

MS. DAVIS: And if I could just follow up, how would you motivate these entities such as universities that may not have a conflict of interest to actually do this?

MR. RUSKIN: Well, I think there has to be some stream of revenue, either from the federal government or from states. I don't know exactly where that revenue would come from.

But I think it's obviously desperately needed. Then DTC advertising simply wouldn't be needed at all.

MR. ABRAMS: Okay, our last question would be from Dr. Temple.

DR. TEMPLE: As you point out, the purpose of an advertisement is to sell the product. Do you think that invariably means that an ad must be misleading even if it captures the essentials of the currently approved labeling?

Let me say, I recognize that the imagery can be powerful, and one has to take into account all of those things. But if we were diligent about those things, and I must say, I'm assuming that nobody is going to give NIH $4 billion or whatever it takes to promote some of the good things we'd like them to do, but maybe I'm too pessimistic.

But if that doesn't happen, do you think that it is not possible under this present system to have ads that are in fact balanced?

MR. RUSKIN: I think so. I really encourage you to look back at the 1984 staff report that the House Committee on Energy and Commerce subcommittee on oversight and investigations did, because Chairman Dingle went through that argument quite extensively.

And basically his conclusion was, look,

advertisers are very sophisticated. There are so many ways to have shadings of tone and lighting and intonations of voice to make this just inherently impossible for the FDA to regulate, because there are just too many innovations and ways of getting around any simple rule. And for that reason alone it just won't work. And that's why the whole class is a bad idea. And that's what Chairman Dingle argued.

DR. TEMPLE: All those things apply equally, I assume, to physician directed advertising who are the actual prescribers.

You argued that direct to consumer promotion is sort of obviously illegal because consumers can't prescribe for themselves, and you could say that the fact that they can't prescribe for themselves, and there is a learned intermediary could allow for some greater tolerance of the possibility that the ad isn't perfect, because the perfect person to prescribe is still going to have to make the decision to do it.

You are not impressed by that?

MR. RUSKIN: No, I mean look, we either believe in the law that's on the books or we don't. I mean the law says, only physicians can prescribe. So there are logical consequences that follow from that.

One of those is that means the decision maker is the physician, and therefore, there is just no point of advertising to consumers.

MR. ABRAMS: Thank you, Mr. Ruskin, for your presentation.

Our next speaker is Richard Stamp from the Washington Legal Foundation.

MR. SAMP: Good morning. My name is Richard Samp. I am chief counsel of the Washington Legal Foundation, a nonprofit public interest law and policy center based here in Washington, D.C.

WLF devotes a considerable portion of its resources to opposing unwarranted government restrictions on commercial speech. Thus our interest in the topic being considered in today's hearing.

WLF has for several years tracked DDMACs oversight of prescription drug promotional activities. In 1995 WLF files a citizen petition calling on FDA to relax restrictions on DTC advertising, and I repeated that call in testimony I gave at an FDA hearing in October, 1995.

I understand that our citizen petition is part of the record in this proceeding, so I won't go into all of the reasons which we focused on in our citizen petition, which I think are still valid today.

In 1998 we prevailed in a federal court challenge to the constitutionality of FDA restrictions on the ability of doctors and patients to receive truthful information about off-label uses of approved drugs.

And I emphasize, the court injunction against FDA remains in place today.

In June of this year, WLF launched a new program called DDMAC watch. Under this program, WLF reviews and responds to warning and untitled letters issued by DDMAC or by its counterpart in the

biologics center, OCBQ.

To date WLF has responded to 12 DDMAC and OCBQ letters. To date we have received no response from the agency. We nevertheless have no intention of stopping the program. WLF is firmly convinced that FDA regulation of speech about therapeutic products must be the subject of a searching inquiry, both because of the public health importance of public access to scientific information about FDA-approved products, and because FDA's current policies and practices present grave statutory and constitutional problems.

The public health benefits of DTC advertising are by now well known. Those benefits are well illustrated by the data from the FDA's 2002 national telephone survey. The survey included both health care practitioners and adult patients who had visited a health care provider within the last three months and sought access to - their exposure to, perception of, and attitude toward FDA advertising.

I will skip over all the results of that survey, which I think are well known to most of the people here.

The conclusion of this study, however,

is that DTC advertising encourages patients to seek health information; increases awareness of possible treatments; and reinforces health care practitioners as authoritative sources of information.

These findings are consistent with earlier research.

In light of the enormous benefits of DTC advertising, WLF does not understand DDMAC's apparent hostility. Rather than help manufacturers fulfill their potential to be valuable sources of health information for patients, DDMAC often works actively to repress speech that it has no basis for deeming to be false.

Most alarming to WLF, DDMAC has taken to attacking scientifically valid clinical study reports, and prohibiting manufacturers from disseminating study data to help care practitioners and patients.

For example, on June 28th of this year, DDMAC sent a warning letter to Endo Pharmaceuticals, objecting to the presentation of data from a clinical investigation of lidoderm. The data were published in a reputable medical journal.

Nonetheless, DDMAC demanded that Endo,

quote, immediately cease the dissemination, end quote, of information about the study, because DDMAC did not like the study design.

On July 15th of this year, DDMAC sent an untitled letter to Abbott Laboratory, objecting to the presentation of data from a clinical investigation of Cervanta. The data were published in a reputable medical journal.

According to DDMAC, the study did not constitute, quote, substantial evidence, end quote, and therefore could not be relied upon by Abbott to substantiate its claims.

These are but two examples of a well established policy within DDMAC of prohibiting manufacturers from sharing valid clinically relevant scientific information.

It's paternalistic in the extreme for DDMAC to purport to forbid speech based on peer reviewed scientific journal articles. And WLF asks the division to change its policy immediately.

This is precisely the type of information that DDMAC should encourage manufacturers to share, not only with health care practitioners, but also directly with patients.

That is what is mandated by the First Amendment, and that is what is good for the public health.

I want to speak briefly about corrective advertising, but I'm going to skip over a number of my prepared comments in the interest of time.

WLF is responding to FDA's request for comments on its practice of, quote, asking, end quote, sponsors to run corrective advertisements, or issue corrective promotional materials, to remedy impressions created by potentially false or misleading materials.

Let's be clear what we're talking about. DDMAC does not ask the sponsors to run corrective advertisements. Although the agency uses language to suggest that a sponsor has a genuine option to reject a request for corrective messaging, what goes on between DDMAC and sponsors is not exactly an arms-length transaction.

Sponsors know that if they resist DDMAC's request, they run the risk of souring their relationship with DDMAC to the detriment of the company.

This is not merely speculation on WLF's

part. Within the past month we have learned that DDMAC has told two sponsors that if they press their rights, DDMAC will give strict scrutiny to every single one of their promotional pieces.

Let there be no doubt: DDMAC expects companies to engage in corrective messaging whenever the division desires it.

It's a bedrock principle of constitutional law that the First Amendment limits not only government restrictions on speech but also government compulsion to speak.

WLF has seen no indication that FDA has considered whether its requests for corrective advertising comport with the First Amendment as a general matter. And we view it as highly unlikely that anyone in FDA engages in a First Amendment analysis each time DDMAC sends a warning letter seeking corrective advertising.

Not only do we believe that it is highly unlikely that this practice at DDMAC comports with the First Amendment. We also believe that DDMAC lacks statutory authority to demand such corrective advertising.

Turning to what we believe is a

deficiency in DDMAC's establishment of written guidelines, it is abundantly clear to us that DDMAC has in place many policies and procedures that drive its decisions on promotional materials but that have not been made available for public review.

The FDCA and FDA's own regulations require the agency to announce new regulatory expectations to regulated industry by going through the notice and comment rulemaking or guidance processes.

Anyone conversant with DDMAC regulatory practice knows that you could be an expert on the statute, the regulations, and the guidance documents and still know only a tenth of the rules governing drug promotion.

For example, it is clear from DDMAC's warnings and untitled letters that there are limitations on the length of the time a company can say that a product is new. But you would be hard pressed to find any authoritative document in which that rule appears.

It is also obvious that there are circumstances in which breakthrough is not allowed. We learn from recent directive messaging required

with respect to Embril that breakthrough can only be used if sponsors conduct head-to-head comparative studies.

WLF has pointed out numerous examples of de facto rules in our correspondence to DDMAC under the DDMAC Watch program.

We expect and hope that FDA will reexamine DDMAC's modus operandi, and ensure that the only rules that are lied upon in reviewing promotional materials are those that have gone through the statutorily prescribed procedures.

Much of the citizen petition we filed 10 years ago addressed excessive information that is often required by FDA in advertising, and unfortunately, many of those problems persist.

To take one example, suppose a manufacturer wishes to convey the following message: You have been prescribed drug X for your disease. Take drug X exactly as your doctor prescribes.

It makes little sense that under current FDA rules the manufacturer who conveys that message will also have to provide the full PI as well as comply with fair, balance and FDA's many other requirements.

FDA needs to streamline its disclosure requirements in order to ensure that the information being conveyed to patients is useful and meaningful.

Some suggestion reforms: WLF has repeatedly communicated with FDA concerning our views on the ways in which the agency's regulation of speech should be changed. We are submitting for the record copies of those previous suggestions.

Our main message for you at this important meeting is that there remains much important work to be done to ensure that DDMAC's policies and procedures respect the First Amendment and are consistent with the agency's statutory authority.

Rather than clamp down on consumer directed advertising, as the meeting notice implied should be done, FDA should find ways of getting more health information to patients.

That is the only approach that accords with the administration's express commitment to treating consumers as partners in their own health care.

It is the only approach that accords with the First Amendment.

And it is the only approach that truly promotes the public health.

Thank you for this opportunity to speak.

MR. ABRAMS: Dr. Temple?

DR. TEMPLE: Let me ask you about one particular thing, which is what studies can be referenced.

Do I understand that you think, oh, anything that is published, say, in a peer review journal is more or less automatically good enough, and that there isn't any further criterion that could be acceptable? For example, does a study have to be a controlled trial?

MR. SAMP: If it has appeared in a peer review journal, to me that is prima facie evidence that the study has some validity.

Now for example many studies that are in peer reviewed journals are open studies, and therefore, don't meet the criteria that FDA would normally apply for drug approval.

And if somebody wants to include the results from those studies in some sort of promotional piece, I think FDA would be well within its rights in requiring that doctors be informed

about some of the shortcomings of the study.

They should be told for example, this is an open study, therefore this is perhaps not the same well controlled study that the FDA requires for product approval.

But so long as those kinds of disclosures are made, doctors are much better off knowing about those kind of studies than not knowing about them at all.

DR. TEMPLE: Okay, so one of the examples you gave on lidoderm plainly represented an uncontrolled study. That's why we didn't allow them to do it.

We would have probably said the results aren't meaningful. But your remedy would be that we would make the sponsor say this is a completely uninform - we're telling you this, but it's completely uninformative because there is no control group.

Is that the idea?

MR. SAMP: The idea is that FDA knows a lot about medicine, but so do the editors of peer reviewed journals. And if they thought that the article was good enough to be published, chances are

that it does provide some information.

And FDA may disagree, but FDA's remedy for that is to say it's not a well controlled study; therefore proceed at your risk. But on the other hand, as they have been told many times by federal judges, we are not the masters of the universe when it comes to medical knowledge.

A few editors of peer reviewed journal magazines know something about medicine as well. And therefore, when they think that the article is good enough to be published, and there is no indication at all that these particular editors have a bias in favor of the company, that FDA ought to allow this information to be conveyed to doctors, provided that some sort of disclaimers are allowed.

And a disclaimer that requires people to say, by the way, this is a worthless study, would be wrong, because FDA doesn't know that in comparison to the editor of the journal.

If FDA wants to say, require that it be said, the study that we're showing you, FDA thinks it's worthless. However, the New England Journal of Medicine thinks differently, and we ask you to make up your mind after reading the article.

MR. ABRAMS: Dr. Behrman.

MS. BEHRMAN: I gather you've commented unfavorably on all the letters that DDMAC has issued since you started your program in June?

MR. SAMP: That's not correct. On most of them we have.

MS. BEHRMAN: Do you believe that in aggregate that the majority or totality of the ads out today are neither false nor misleading? Or DDMAC, are we just finding wrong in them?

MR. SAMP: First of all, I suspect that the vast majority of ads that are out there DDMAC does not comment on. So I assume you agree with me that most ads out there are not inherently misleading.

MS. BEHRMAN: That was really my question. You believe that the majority of the ads out there are not either false or misleading?

MR. SAMP: That is my belief, and I suspect that there probably are some misleading ads out there that unfortunately DDMAC probably has not uncovered just because it doesn't have the resource to fully examine every ad.

I do think in the aggregate, though,

that the most important health care problem that we have in the country is a lack of information arriving to consumers rather than too much and potentially misleading consumers.

So it ought to be the case that DDMAC looks at ways to get more information to consumers rather than stopping it.

MR. ABRAMS: We will have one more from Dr. Behrman, and then one question from Ms. Davis, and then we'll end.

MS. BEHRMAN: So if it did happen that we found a false and misleading ad, and we felt it was an egregious message, a very damage message, what do you suggest we do about that? What would be the appropriate remedy?

MR. SAMP: Well, first of all, as a first thing to be doing, I would hope there would be clearer guidance in written documents from DDMAC so companies presumably wouldn't be doing this if they knew in advance that what they were doing was proscribed.

In terms of remedies, I think that if a company persists, there are many unfortunately powers that the agency has, up to and including

criminal enforcement and seizing of product, and there are any number of products that are being peddled that perhaps have absolutely no scientific value and have never been approved by FDA, and are being advertised, and I certainly encourage FDA to go after those kinds of products.

But if you are referring to my comments about corrective advertising, it seems to me that in the absence of evidence that the advertising that you believe is false has in some way so totally poisoned a well that people will never be able to accurately view that drug again, I think the appropriate remedy in most cases is simply an injunction against further running of that ad. And if people do, taking appropriate enforcement action.

MR. ABRAMS: Ms. Davis.

MS. DAVIS: Thank you. I just wanted to follow up on some of the questions Dr. Temple was asking.

It's my understanding that scientific literature is full of examples of adequate and well controlled studies disproving something that might be thought to be true from a published study that was not adequate and well controlled.

So if a manufacturer was promoting something from a published study, when the weight of the evidence in adequate and well controlled studies show that what they were promoting was false or misleading, how would you suggest that the agency and the sponsors, the company promoting it, react in that situation?

MR. SAMP: Well, particularly if the study that is well controlled contradicts what is being said, to me that would be first of all pretty good evidence that the study you're talking about is false, and would therefore fall well within the realm of FDA's ability to prohibit false advertising.

What we're talking about is - what I'm talking about anyway is information which is arguably true, which FDA has no basis for thinking is false, but which FDA wants to prohibit because it has its doubts about the adequacy of the study that produced that information.

And to the extent there is contrary information, FDA is well within its rights in requiring the disclosure of that contrary information.

MS. DAVIS: If I could just follow up real quickly, if that contrary information comes out after that's already been promoted, how would you suggest the agency react?

MR. SAMP: Well, I suspect that in part of wanting to look at the good faith of the manufacturer. If the manufacturer in good faith was advertising a study that is later contradicted by a study that the manufacturer knew nothing about, I would certainly hope that an agency using discretion would take much less severe action than a company that knowingly used a study that they knew was extremely doubtful.

MR. ABRAMS: Thank you, Mr. Samp, for your presentation.

Our next speaker is Alex Sugarman-Brozan from the Prescription Access Litigation.

MR. SUGARMAN-BROZAN: Good morning. Thank you for the opportunity to speak.

I am director of the prescription access litigation project, which is a coalition of 115 organizations representing consumers in 35 states. PAL, as we're known, works to end illegal pharmaceutical price inflation and deceptive

marketing through the use of class action litigation and public education.

First I want to start by saying that we need to put direct to consumer advertising in the larger context of drug promotions generally. Although the industry spends over $4 billion a year on DTCA they spend over $5 billion a year on physician promotions. So the entire universe of transactions and information exchange that takes place isn't just a question of a consumer who is influence by an ad approaching a doctor who hasn't been influence. The 80,000 or more than 80,000 pharmaceutical sales people who descend on doctors' offices everyday have an influence over what physicians know about prescription medications as does the influence of the drug industry in continuing medical education, journal articles, and published guidelines. And we need to think about DTCA in that context.

We see deceptive marketing by pharmaceutical companies as one of the primary factors driving up cost and inappropriate use of prescription drugs in the United States.

This in turn is a major contributor to

the health care crisis in this country. We strongly feel that the net effect of DTCA is negative.

Initially we feel that as other speakers have described the DTCA interferes with the doctor-patient relationship. It creates unrealistic expectations of drug efficacy, and risk and severity of side effects. We call it the fields of flowers effect, referring to one of the common images in drug ads of happy people frolicking through fields of wildflowers, given the impression that the drug being promoted will make the user just as happy as the people shown in the ads.

We feel that DTCA promotes brand name drugs as a panacea, while undermining genuine public health messages that promote lifestyle changes such as diet and exercise, and as well as generic drugs.

We never see ads that say, ask your doctor about diet and exercise. Or, ask your doctor about hydrochlorothiazide, one of the diuretics that is one of the most effective treatments for hypertension, but which costs only pennies a day.

DTCA also furthers the notion that newer is better, and that a brand name drug is better than a generic or over the counter, thus over-promoting

expensive brand name drugs whose real-world side effects long term are unknown, at the expense of generics whose long term safety and efficacy may be more well documented.

Obviously, it drives up cost by promoting inappropriate use of brand name prescription drugs to users who either don't need that particular drug, or who could use a less costly intervention.

And finally we feel that it skews research priorities of the industry towards - in favor of so-called me-too and lifestyle drugs.

Every year PAL holds an event called the Bitter Pill awards, exposing drug company manipulation of consumers. And I just want to highlight two of our awardees in this past year that we think demonstrate some of the harms of DTCA.

And the first is one we've all heard a lot about this year. Vioxx and Celebrex were the joint winners of the Speak No Evil Award for concealing drug risks and benefits in the name of profit.

Vioxx in particular was a drug taken by over 20 million people due almost entirely due to

the advertising promotion, both to consumers as well as to physicians. Despite the fact that only one to two of patients were at risk for the kind of gastrointestinal complications for which the only advantage of this drug was.

And the Archives of Internal Medicine did a study showing that 70 percent of the users of Cox-2s in the first three years didn't need, because they didn't fit this extremely narrow profile.

And this obviously raises the issue of how many heart attacks and deaths were caused by the inappropriate use of these drugs that later were discovered to be dangerous, but also, how many billions of dollars in the health care system were wasted.

The second award I want to highlight is Nexium, which one our award for the Least Extreme Makeover award for dressing up an old drug with a new name and a new price tag.

I think most people in this room are aware that Nexium is merely an isomer of Prilosec, AstraZeneca's previous heart burn and reflux blockbuster. But at comparable doses, Nexium is clinically no more effective than Prilosec, yet it

is seven times more expensive.

They have estimated sales from 2005 to reach $4.6 billion. This is a drug that simply has no reason for anyone to take it, and owes its entire existence to the promotions around it.

Both of these examples I think demonstrate that the function of drug ads is not to educate but to sell. And I'd like to offer a quote by dr. Marsha Angell, author of The Truth About the Drug Companies, who said: To rely on the drug companies for unbiased evaluations of their products makes about as much sense as relying on beer companies to teach us about alcoholism. The fact is that marketing is meant to sell drugs, and the less important the drug, the more marketing it takes to sell it.

Important new drugs do not need much promotion. Me-too drugs do. Any educational benefit is significantly outweighed by the negative effects previously described.

As other speakers have stated, there are other ways of educating the public about medical conditions, and the need for treatment that do not carry the baggage of DCTA.

Now, PhRMA recently released its own voluntary guidelines on DTCA to much fanfare. My recommendation is that the FDA should take no heed of these whatsoever. Voluntary guidelines, which do not require compliance, which have no enforcement mechanism, and which carry no penalties for violation, are a public relations measure and nothing more.

We would urge the FDA to take the following actions. First, to increase enforcement. And this mostly requires adequate staff to review promotions.

As other speakers have said, the level of enforcement in the form of untitled warning letters has decreased over the past seven years. The number of letters issued in 2005 is approximately 20 percent of the number issued in 1998.

It's been stated that the FDA has 40 staff members to review all drug promotions, including both DTCA and promotions to medical professionals. And there are approximately almost 53,000 drug promotions in 2004.

This required each and every of those 40

staff people to review 1,320 pieces of promotion per year, or 5.5 per day, which is simply impossible to give the level of scrutiny necessary at that kind of rate.

Second, we would encourage ending the requirement that all enforcement letters be reviewed by the office of the chief counsel. Others have referred to the GAO report which showed that this policy change has resulted in often letters taking so long to reach the sponsoring company that the drug promotion has already run its course. This is the epitome of closing the barn door after the horse has gone, and completely undermines the effectiveness of what little enforcement authority has to police DTCA.

Third, we would encourage requiring pre-broadcast submission of all ads. Again, this would require adequate staff to review those, sine the time necessary to review them before broadcast would be shorter.

And the FDA should require not only TV ads but all radio, print and online advertisements should be submitted prior to broadcast. And obviously this relates to my next recommendation,

which is, we encourage the FDA to seek congressional authority to impose civil monetary penalties, as other speakers have also recommended.

Currently there is a huge gap in the FDA's enforcement authority that renders its untitled warning letters ineffective. At best such a letter will prompt a manufacturer to stop running the ad in question, and possibly to run a corrective ad if that is requested.

But manufacturers know that the more severe sanctions that FDA can impose, such as an injunction or criminal enforcement or seizure are very blunt instruments that the FDA seldom if ever uses, and that therefore there is almost always nothing to back up the untitled warning letters.

It is akin to what the comedian Robin Williams has said about unarmed British police, and what they shout to fleeing criminals, which is: "Stop or I'll shout stop again."

The FDA should therefore seek congressional authority to impose civil monetary penalties on manufacturers who violate the FDA standards on DTCA, particularly those that are repeat offenders.

Finally, I would recommend prohibiting reminder advertisements. Although the PhRMA guidelines would seem to prohibit this, again, those are voluntary, and it remains to be seen whether all manufacturers will sign up, and whether their compliance to those guidelines will be effective in the long term when the heat is off.

A message that says nothing more than, ask your doctor if drug X is right for you does absolutely nothing to educate the consumer. Its only purpose is to increase the name recognition of the drug, and bolster those longer advertisements for the drug that do list the benefits and risks.

The FDA should issue a regulation prohibiting reminder ads as a violation of the relevant FDA standards on DTCA. Any advertisement including the name of a drug should be required to disclose the same risk information as an ad describing the drug's use in more detail.

Now it has been discussed widely in the industry and the press that so-called disease awareness ads are going to begin to replace more drug-specific promotions, and I think we need to give this type of advertisement careful scrutiny,

because I think that disease awareness is going to become the new reminder ad.

Disease awareness ads in theory just describe a medical condition, and don't mention a particular medication. And while educating consumers about medical conditions is of course extremely valuable, we should not entrust that education to such self-interested parties as the companies that stand to make billions from the increased use of brand name prescription drugs.

This is one example of not disease awareness ads, but the additional source to which the disease awareness ad referred. And there is a television commercial featuring Lorraine Bracco, star of the Sopranos, in which all she does is talk about her experience with depression and no mention is made of any drug.

She then refers viewers to a website, Depression Help dot com. When you visit that website, it's an untrammeled promotion of Pfizer's SSRI Zoloft.

The link between the originally supposedly nonpromotional ad and the website promoting Zoloft belies the claim that disease

awareness ads are some benign form of public education.

These awareness ads, such as this one - and not all of them have this characteristic of referring people to a website that is purely promotional - but awareness ads such as this function as barkers steering consumers to promotional materials that do discuss the particular risks and benefits of a particular drug.

When there is such an explicit link between a disease awareness ad and another DTCA source that is subject to regulation, we believe the original ad should be considered part of the same promotional materials to which it links and subject to regulation as well.

Now, Dr. Peter Laurie from Public Citizen mentioned the promotion for Differin. And I put a copy of the advertisement to which he referred right here. And I think you will see just how reprehensible this is.

This is a disturbing trend for advertising drugs for children, particularly for acne medications. Children and teenagers are simply not able to fully appreciate and balance the risks

and benefits of a prescription drug. But marketers know how effective children and teens are at pressuring their parents to get them what they ask for. And anyone in the room who is a parent will attest to that.

This ad campaign creates completely inappropriate incentives by offering free music downloads for every prescription you have. Such linked promotions, if not already illegal - and I would argue that they are - should certainly be made illegal by the FDA through regulation.

All right, I'm going to make my other regulations very quickly. We feel that coupons for prescription drugs have no place in our medical system and should be flatly prohibited as they completely skew the incentives of the consumer even more so that DTCA already does.

And finally we'd agree with other speakers that it is time to return to the pre-1997 requirements, and require the full brief summary in all broadcast, and not just the major statements and adequate provision at some other source.

Thank you for the opportunity to speak to you today.

MR. ABRAMS: Thank you for your presentation.

Dr. Temple?

DR. TEMPLE: The full brief summary in a TV ad, you mean like scrolling it or something? Or is this just to block them?

MR. SUGARMAN-BROZAN: Well, again, again --

DR. TEMPLE: Or is this just to block them?

MR. SUGARMAN-BROZAN: No, I think that for many drugs, if not most drugs, it would not be possible to portray the full brief summary in an ad that didn't last 10 minutes. And that just demonstrates the inappropriateness of advertising drugs on TV or radio.

If a manufacturer was able to find a consumer-friendly and understandable way of including the full brief summary, then I suppose they should be permitted to do that. But if they can't, then it shouldn't be on TV or on the radio.

DR. TEMPLE: Okay, let's take a print ad. Our guidance - our post-guidance - suggested that the so-called brief summary, which is of course

neither brief nor a summary, is impenetrable because it's very long, very small print, and is not written in consumer friendly language.

And we proposed a number of alternatives that we thought would communicate that, some of which would depend on the so-called highlights of what will eventually be revised physician labels and things like that.

But the goal of all those is to make them comprehensible. Just considering now the print ads, do you think that is in the wrong direction or the right direction?

MR. SUGARMAN-BROZAN: I think any information distributed to the public about prescription medications, whether it's product specific or more general, obviously needs to be understandable by the public.

We also think it's noteworthy that only New Zealand is the only other country that uses DTCA, and even they have a moratorium. And we think on balance DTCA is a negative thing, but we just don't see it becoming illegal or substantially restricted.

So in light of that, I think the

regulatory system needs to do the best it can. The impenetrable six-point type that lists every detail that even physicians have a hard time getting through is obviously not consumer friendly, and I think the FDA needs to take steps to ensure that print ads are understandable.

DR. TEMPLE: So let me see if that has any potential translation to the broadcast setting. Obviously even a consumer friendly version of highlights would be difficult to get into a broadcast setting, but you could pick the highlights of the highlights.

Would you think that's not good enough?

MR. SUGARMAN-BROZAN: I think that's not good enough.

DR. TEMPLE: Or you'd rather see it go away?

MR. SUGARMAN-BROZAN: I think for many consumers, they will refer to the outside sources, and that their only information would be what they saw in the ad. And we've seen the studies, many of which have been cited today, about the inappropriate effects of DTCA on prescribing, not just on consumers seeking particular prescriptions, but on

them getting them.

And therefore, I don't think it's possible to summarize information in a one-minute ad. Maybe the industry needs to purchase larger blocks of time, where they can lay out all that information. But I highly doubt that any consumer would want to take a drug after seeing that.

DR. TEMPLE: Yes, I think our thought would have been that they won't. They'll just tune out. So you probably can't do it that way.

MR. ABRAMS: Dr. Behrman?

MS. BEHRMAN: Can I just clarify your answer to Dr. Temple's question? I believe you said in your presentation that it was quite clear that you thought the entire group summary be included in a print ad, and then Dr. Temple referred to our February '04 draft guidance which talked about ways of summarizing a subset of that information.

Are you in agreement with that approach?

MR. SUGARMAN-BROZAN: I think that there needs to be a consumer-friendly summary. But an inclusion of the brief summary for those who have the inclination to wade through it is appropriate.

MR. ABRAMS: Okay, thank you for your

presentation and information today.

Our next speaker is Wallace Snyder from the American Advertising Federation.

MR. SNYDER: Good afternoon. I am Wallace Snyder, I am president and CEO of the American Advertising Federation.

Formerly, I was the associate director for advertising practices at the Federal Trade Commission.

The AAF represents all facets of the industry - the agencies that create the advertisements, the companies that market and sell them, and the media companies who run the ads.

I'm very proud to represent an organization as diversified in its viewpoints and as open-minded in its discourse.

I think the FDA for its regulation of DTC advertising, and I thank you for this opportunity to present to you this morning.

I think that my statement will be very clear, no mistake about it. And it will be: Do not impose a moratorium on direct to consumer prescription drug advertising.

The criticism of DC advertising has been

blunted in these hearings by a number of experts, including conclusions contained in the annual survey by Prevention magazine, and I quote: The increasing presence of DC advertising has not resulted in a surge of requests about or for advertised prescription drug.

No one is going to strong arm consumers in this country about medicines or any other product, and the advertising industry does not want citizens taking medicines simply for the sake of taking medicines.

And as a result, as the polls show, the American people are quite capable of deciding if and when they want a prescription drug, when provided with balanced information.

Ultimately the issue is not about moratoriums. It is about regulation. It is about the process of regulation. If a drug is not ready, by all means keep it off the market. But once approved, once the stringent requirements of critical trials and other testing are done, and the drug is approved, please do not send a mixed message by delaying advertising. Regulate the drug, but do not impose or impede the flow of truthful

information.

We support ads that provide the clearest explanations of risks and benefits, and are presented to consumers in the clearest possible fashion.

Consumers with good information will make good health decisions.

The regulatory scheme now in effect relies on the Food and Drug Administration to approve drugs for patient use, and to review all the advertising for those drugs. A moratorium will gut this viable oversight, and it would minimize any influence the FDA has over prescription drug advertising.

The FDA chance to influence the first message received by consumers would be gone.

Now I have to tell you in advertising there is an old statement about businessman R.J. Wrigley. It goes like this: An acquaintance seated next to Wrigley on a flight to Chicago asked the multimillionaire why he continued to advertise his chewing gum since it was already so successful. And Wrigley replied, the same reason the pilot keep this plane's engines running, even though we are already

in the air.

Wrigley understood the value of advertising to his business and to consumers, and he understood the value of an informed public, as does the Supreme Court, which acknowledge that the free flow of advertising could be as important as the free flow of news to Americans.

An advertising great, David Ogilvy, in our industry, said that what this is all about, this advertising, he said that I do not regard advertising as entertainment or as an art form but as a medium of information.

And that is what this is all about: getting the information to the American public. Advertising is just one instrument in our quest for better health, but advertising is a partner in this mission.

I believe contemporary advertising is disciplined, and an ethical industry that believes in good citizenship. The most memorable slogans and enduring social changes can be credited to the advertising industry.

Our critics may be well intentioned, but they are misguided and just plain wrong when they

claim that DTC advertising doesn't promote public health in this country, that they say it is misleading, that it omits specifics about the side effects, and that it drives a wedge between medical professionals and patients, is false on all counts.

Here are some of the traditional bottom lines.

A recent survey of 900 African-American physicians revealed a majority believes DTC advertising promotes increased communication between physicians and patients.

More than 60 percent felt no pressure to prescribe a specific medicine, and the vast majority denied changing their prescribing habits because of DTC.

The Prevention poll says caregivers rely on DTC, not as a final word but as a starting point to help manage ailments, and to help learn more about new treatments for people in their care.

The Prevention poll also found that DTC advertising, and I quote: Does not appear to overstate and understate the risk of advertising medicines. The poll says consumers are likely to equally remember both.

A study by the FDA found that DTC advertising prompted 23 million people in America to see a doctor and talk about a condition they never discussed before.

The Prevention poll says 21 percent who say DTC advertising made a lifestyle change, improving diet and exercise habits. And yesterday you heard Professor Andrew Clyde (phonetic) of Penn State discuss his research that finds that ads appear to encourage patients to seek medical care.

Now I have to tell you personally that those of us with solid incomes, a good education, have options in this country for health maintenance - insurance, Internet access, and visits to medical and allied specialists.

I am blessed with easy access to good health care. I talk with doctors about my asthma, pulmonary specialists. And the new pharmaceuticals that are available to me for this illness.

But too many low income Americans of all colors have no such recourse. For too many underprivileged Americans, health care means a trip to the emergency room. And we have an epidemic in this country of inner-city asthma sufferers among

our youth.

DTC advertising can help them avoid this by connecting them to the health care system before a crisis situation arises.

Many critics of DTC advertising are upset because they believe the advertising is causing a rise in the use of prescription drugs.

Pharmaceutical usage is something that should be celebrated, and not lamented. If physicians are doing their jobs properly, and we have no reason to believe they are not, increased usage means more patients are getting needed treatments for their illnesses.

DTC advertising represents a first step toward gaining information, going to a clinic, or adopting a healthy lifestyle. Why send a mixed message by approving a drug but blocking information provided by ads?

How many patients will suffer a reduced quality of life because public policy deliberately limits the information they can receive about potential treatments?

If a drug is not deemed safe, delay approval and require additional clinical trials.

But once approved, we should do all we can to make sure that those who might benefit learn about it, talk to a physician and decide the best course of treatment for them.

DTC advertising is a valuable source of information about the benefits and the risks of new treatments. It promotes a healthy diet and exercise, and it encourages people to talk to their doctors. It leads to more cost-effective health care through early detection, and it provides a resource to under serviced caregivers who need accurate drug-related information to manage their health care of people who are in their charge.

The statement made by the cardiac surgeon, Christian Bernard, summarizes, our view point on this issue. Dr. Bernard, who performed the world's first heart transplant on a human said, suffering isn't ennobling, recovery is.

Thank you very much for your attention. I'd be happy to answer any questions.

MR. ABRAMS: Ms. Davis.

MS. DAVIS: Hi, thank you for your presentation.

I have a question. You had cited an

example of inner city people suffering from asthma as an example of underprivileged people who aren't getting treatment.

Currently there is direct consumer advertising going on. What would you suggest needs to be done in order to get people into the doctor in addition to what we've seen already?

MR. SNYDER: Well, what we have really encouraged is that the companies that manufacture these drugs - for example, the Advairs, the products that can avoid the bronchial dilation, that they really focus a good portion of their budget on their city consumers.

And I think that you will see that happening more and more. But what I would urge is that they really make those consumers, parents, grandparents, guardians, aware that there are products other than bronchial dilators that can be taken. Because if it's too late, the child is going to go into the emergency room.

MR. ABRAMS: Okay, Mr. Snyder, thank you very much for your presentation and information. Thank you.

MR. SNYDER: Thank you for the

opportunity.

MR. ABRAMS: Okay, our final speaker on the panel is Kim Witczak, a consumer.

MS. WITCZAK: Hello. My name is Kim Witczak, and I am not affiliated with any other - with any group or company.

I have come here today as a private citizen, and unfortunately, a widow. I have also worked in the ad business for over 15 years.

On August 6th, 2003, my husband, Woody, was found hanging dead at the age of 37 of a Zoloft-induced suicide after being on a drug a total of five weeks.

It is because of what happened to my family today, and my professional experience, that I am here today. I'd first like to tell you a little bit about my husband and his story.

Woody and I were married a few months shy of 10 years. Woody was a person who cherished life, and the people in his life. He had a successful sales career, and attained the position of national sales manager with a manufacturing company before leaving to pursue his dream of starting a new business from the ground up.

With the challenges of this new opportunity he had trouble sleeping. He was excited about the opportunity but would wake up thinking about work in the middle of the night.

He went to his family doctor, and was given samples of Zoloft to help him sleep. He was not depressed nor ever diagnosed with depression by his doctor.

I happened to be out of the country on a photo shoot for the first few weeks he was on the drug. He experienced several side effects including diarrhea, heavy sweating, akathisia, which is a neurological condition that causes severe internal restlessness and agitation, as well as a feeling of being outside his body looking back at him.

Unfortunately, the Pfizer three-week sample pack doubled the dose. We tried many things during this period trying to figure out why Woody suddenly went from sleeplessness to having all these new problems. We were unaware, unwarned, that Zoloft is the drug that is touted and sold to help millions was actually causing Woody harm.

Woody was told that it would take four to six weeks for it to work. On August 4th, I left

on an advertising shoot in Detroit, and Woody seemed to be doing better. We were discussing our overseas trip for our ten-year anniversary and making plans to have children.

And in fact the day before he died, we booked two trips for the following week, and one a month later.

The next day Woody was found hanging in my garage by my dad. Woody had no history of depression or any other mental illness. His death was a complete shock to his family, his friends, his doctor, and me.

The man who loved life was gone. While still struggling to cope with this loss, I have chosen to use my experience to try and make a difference.

I have often asked myself why Woody, a guy who didn't like taking medications, went to the doctor and ended up on Zoloft.

I do believe that DTC advertising had a role. Before August 6, 2003, I never gave Zoloft a second thought. I had seen Zoloft ads everywhere, and just assumed it was safe and effective since it was being advertised on TV and in magazines.

Although Woody didn't go to his doctor specifically looking for Zoloft, I believe DTC has affected the culture that ultimately led him to Zoloft.

DTC advertising has influenced the American prescribing habits on many levels. Americans of all economic, social and educational backgrounds are now trained to run to general physician and ask them if whatever drug is right for them.

Harvard Business School actually did a case study. The marketing of antidepressants is one successful example of how advertising can drive a market. From a professional standpoint this is what every advertiser strives for, advertising that changes consumers' perception, to motivate them to believe or behave in a certain manner.

From my personal perspective, I think it's a tragedy. DTC advertising has created a mindset that there is a pill for every problem. Antidepressant advertising is a perfect example.

This is one drug that is supposed to work for anxiety, social phobia, TMS, depression. One has to wonder how a drug that was originally

approved for major depressive disorder can distinguish between these various mental disorders as it supposedly balances out the so-called chemical imbalances in the brain.

DTC advertising has shifted the diagnosing paradigm away from the physician to the consumer to self-diagnosing medical problems and conditions before seeing their doctor.

We heard today that that is a good thing, to encourage people to go. However, before going in, already diagnosing themselves.

DTC advertising is driving more and more people to GPs for medication they may or may not need.

Ultimately we as the American public are the real clinical study. DTC advertising has created disorders and their solutions.

In a 2000 Ad Age article, Paxil's product director said, every marketer's dream is to find an unidentified and unknown market and develop it.

Interestingly, soon after Paxil was approved by the FDA for a new indication, social anxiety disorder. As Elliot Valenstein, professor

of psychology and neuroscience at the University of Michigan said, shyness can't be marketed because people recognize it as a normal variance on personality. But social phobia sounds like a disease.

Just recently an article titled "A Disease for Every Pill" ran in the October 17th issue of the Nation. It talks about the creation of a disorder call PMDD, premenstrual Dysphoric Disorder. Eli Lilly's blockbuster antidepressant, Prozac, was about to lose its patent exclusivity when they found a new use for Prozac, and renamed and repackaged it under the name of Seraphim, targeted to women who suffer premenstrual cramps and emotional ups and downs that go along with monthly periods.

This is a perfect example of a company using the creation of a condition and aligning it with the product.

It's interesting to note that not every regulatory body around this world recognizes this as a disease. In 2003 a panel from a European agency for evaluation of medicinal products noted that PMDD is not a well established disease entity across

Europe. Patients might erroneously receive diagnosis of PMDD resulting in the widespread inappropriate long and short term use of fluoxetine, which is the generic name for Prozac or Seraphim.

We are the only westernized country besides New Zealand that allows DTC advertising. The drug companies have been lobbying like crazy in the EU to open up their market and allow DTC advertising.

According to the labor health spokesperson in the European parliament, if we open the door to direct advertising it is a slippery slope down the American road where pink pills and television advertisements for a miracle solution for everything from baldness to chronic fatigue.

Not long ago prescription drugs were marketed primarily to help train health care professionals. It is now being replaced by drug companies promoting their ads in mass market print and television advertisement targeted to us, the general public.

This new marketing environment begs for enhanced consumer protection.

At the minimum, direct to consumer

advertising of drugs must be held at a higher standard. This is serious business with products that can have serious or sometimes failed side-effects.

It needs to, at the minimum, treat it in a serious manner as Dr. Janet Woodcock said yesterday, as truthful, balanced and not misleading.

Prescription drugs are not like other consumer products. They should not be treated in the same was as cars, soap or fast food. DTC ads must be grounded in truth, absolute truth, no variance from the truth. Safety has to be number one.

Drug companies have the ethical responsibility to communicate all serious side effects, whether known as a result of the initial clinical study, or after the drug is on the market, and the side effects are starting to pop up, given the large number of people on the drug, in a clear, concise and honest manner.

Not just those that seem palatable to the public and won't scare people away from thinking twice about taking the drug. If you notice most side effects for all drug ads are pretty much the

same.

Let's take a look at a few Zoloft print ads to see if they follow this principle. Do you often get nervous around people? The use Zoloft as the bouncing oval cartoon character, looks like the white M&M. Social anxiety might be overwhelming. You might shake, sweat, or feel panicky. I know I am right now.

Here are the ones that I think are really interesting. Earlier somebody was saying that they were using real testimonials from people. Well, these are really interesting. We've Kathy story's here. She is age 41 from Irvine, California. It's in a cartoon. Her daughter said, mom, you are no fun anymore. It hit me that it was time to get help.

This one is Molly's story, age 28, Cincinnati. She wasn't feeling in love.

Well, the best part of these ads, if you look at the very tiny type in the bottom, last little cartoon, it says, story not based on actual person.

What other industry could you do this in?

And then this last one, it's a disclaimer, on June 30th of 2005, the FDA came out with a public health advisory warning that all patients, adult and children, need to be closely monitored on a daily basis when first going on this for any emergency suicidality or changes in behavior.

Where does it get put in - you can see this tiny green highlight. That is where it's at. But to me - I mean I wish that was available when my husband got put on it. I was out of the country.

I ask, is this responsible advertising? In my opinion, no.

You know we talk about balance and risk. Maybe one thing - I'm in the ad business, and I can't believe I would even remotely suggest this - but maybe if the advertisers are buying two pages anyway, let's put the ad and disclaimer side by side, instead of putting it on the back side of the page.

I mean yesterday somebody in here said that her daughter never even knew that there were even any side effects on the back, because most of them skip over it. It looks like editorial. Put it

side by side. I know that's not going to be popular.

But most supporters of DTC claim that advertising is one of the best ways to inform, educate and encourage choice about treatments available. Not everyone agrees. Even a deputy director at JAMA, Dr. Drummond Ray, said, direct to consumer advertising has nothing to do with public education, and it's got everything to do with boosting a product's sales.

In conclusion, I'm going to leave you with a compilation of drug TV commercials. If the FDA had the ability to preapprove these ads, I wonder if they would have even passed. While some of these have been removed from the marketplace, they stand as a good example of why we need to keep improving and evaluating the DCT advertising.

Prescription drugs are serious business, and the advertising of them needs to reflect it.

Thank you. We're going to show the video.

MR. ABRAMS: Okay, first - oh, I'm sorry.

(Videotape presentation of TV

commercials:

MALE VOICE: All I want are nights with less pain, mornings with less stiffness. So I can get out here early and show these clams whose boss.

MALE VOICE: The guy who wanted to spend the entire honeymoon indoors. Remember the one who couldn't resist a little mischief? Yeah, that guy. He's back. Viagra.

FEMALE VOICE: If you are one of the many who suffer from overwhelming anxiety and intense fear of social situations with unfamiliar people, now there is Paxil CR. Paxil CR helps relieve the symptoms of social anxiety disorder all day, so the real you can come through.

FEMALE VOICE: Tonight, will you be able to catch a great night's sleep, or will it once again elude you? Your restless mind keeps chasing sleep away.

MALE VOICE: I've got to remember that appointment tomorrow. Did I send the car payment? What made me volunteer for that assignment?

FEMALE VOICE: Introducing Lunesta.

MALE VOICE: You know that feeling of suddenly being very nervous? Maybe you're scared

of being criticized, or imagine that others are judging you. You are embarrassed, and don't know why. Your heart thumps and races. So you stay back. You worry that you are the only one who ever feels this way. Actually you could be one of 16 million Americans with symptoms of social anxiety disorder. Zoloft, a prescription medicine, can help. It works to correct chemical imbalances in the brain which may be related to symptoms of social anxiety disorder. Someday soon you could overcome those nervous anxious moments. Only your doctor can diagnose social anxiety disorder. Zoloft is not for everyone. People taking MAOIs or Pimozide shouldn't take Zoloft. Side effects may include dry mouth, insomnia, sexual side effects, diarrhea, nausea, and sleepiness. Zoloft is not habit forming. Talk to your doctor about Zoloft, the number one prescribed brand of its kind. Zoloft, when you know more about what's wrong you can help make it right.

End of videotape presentation)

MR. ABRAMS: Thank you, Ms. Witczak, for your presentation and thoughts. First, we convey our condolence on your loss. We know this presentation wasn't easy to do.

So I'll open it up to the FDA panel for questions at this point.

Dr. Aikin.

DR. AIKIN: Thank you. Thank you for your presentation.

You raised a very interesting point, in that DTC is changing the environment and not just individual behaviors, and I think that's something that perhaps we don't consider very often that DTC might be influencing physicians, not just physician advertising, but physicians.

Do you have any suggestions for us as an agency as to how we might be able to distinguish the relative impact of those two forms of promotion?

MS. WITCZAK: It's interesting. I think we all forget doctors are consumers also, because they see commercials. But I think the culture that we have created is that people go in, and a doctor doesn't have that much time, especially when our ads are driving to general practitioners. And the samples, we've got doctor cabinets that are packed with samples, they have maybe seen other people who have come in there, and they only have a few minutes to spend with you, and it's like the easy thing to

do. Here, I know this has maybe helped other people.

I don't know if that really answers your question.

MR. ABRAMS: Dr. Behrman.

MS. BEHRMAN: If I could follow up on that, based a little bit on your advertising experience and your personal experience. Your husband was prescribed this medication, and you feel that neither you nor he were adequately informed, and given that as we discussed the bulk of the advertising dollars are spent advertising to practitioners who are increasingly busy, and also, away from the specialist community to the general community.

Can you give us any thoughts about how to address the advertising to that population as well, so the professional population?

MS. WITCZAK: To which population?

MS. BEHRMAN: Well, in other words, two points you brought up - or one point, that you and your husband did not receive adequate warning. And you talked about changing the environment based on promotion. And if you assume that that's happening

in the professional environment as well, what fixes might you see in terms of professional ads? I know that we are focusing primarily on DTC, but --

MS. WITCZAK: Well, I think the first thing you have to assume that the drug companies are giving you all the information. Because I don't believe that Woody had the suicidal - was not told at that point by the doctors.

So I think you have to make sure that that is first and foremost, that the drug companies are telling us.

In terms of, I think there is a lot of detail in the message. It's almost as much money being spent on that end. It's really important that maybe these ads that - I don't know if they would ever show the ads to the doctor. I know we had no information. We weren't even told to do close monitoring. I applaud the FDA for coming out with that advisory this summer.

But I'm not sure how much it goes back, or how much of the advertising really gets shown to the doctors, and actually getting their input. Is this responsible advertising to your consumers that have been coming in to you?

MR. ABRAMS: Thank you again for your presentation and your thoughts.

This concludes this morning's panels. I want to thank the panel members for their presentations and their responses to the FDA panels.

(Applause)

MR. ABRAMS: This has been a very full morning, and we are running over unfortunately, so we are going to have a shortened lunch so we can get back on track. We are going to reconvene here at 1:35.

(Whereupon at 12:45 p.m. the proceeding in the above entitled matter went off the record, to return on the record at 1:37 p.m.)

MR. ABRAMS: Good afternoon.

And welcome back to the afternoon of day two, the final two panels of this hearing.

We will start right away. The first presenter will be Emily Alfano from Genetic Alliance.

MS. ALFANO: Thank you.

My name is Emily Alfano. I am from Genetic Alliance, which is an international coalition comprised of more than 600 advocacy,

research and health care organizations that represent approximately 14 million individuals with genetic conditions.

First I just want to thank you for the opportunity to address this panel.

As you examine the issues surrounding direct to consumer promotion of regulated medical products, it's vital that you consider the perspectives of all the different stakeholders.

Because my organization's members represent individuals with genetic conditions, many of them rare genetic conditions, our concerns related to direct to consumer marketing focus primarily on genetic topics.

Specifically, two related but distinctly different areas of concern: the current state of regulatory oversight of genetic tests. Are the tests safe and accurate? Are there gaps in the regulatory process?

And the second, the potential for irresponsible for misleading promotion of genetic tests. Do the tests do what the advertisements say they do? Do consumers have enough information to make informed decisions about these tests?

As a representative of a community of people concerned about safety, accuracy and accessibility of genetic tests, I can say that the current state of regulation poses significant problems.

At present the oversight mechanisms associated with genetic tests have gaps, a fact that makes direct to consumer marketing of these tests a serious concern.

That is, the marketing a genetic test presents two discrete areas of concern: the claims made in the advertisement, and the validity and utility of the test itself.

Currently, there are more than 1,000 genetic tests available, but only a handful, those packages tested, are regulated by the Food and Drug Administration.

As a result the vast majority of genetic tests available are only regulated by the oversight of the laboratory under the clinical laboratory improvement amendment.

Under CLIA, laboratories are held to certain standards, standards based on the complexity of the text performed.

But in this age the more rigorous regulations, performed either by FDA or by CLIA or some complement of both, is necessary.

To ensure that nothing falls through the cracks, a coordinated effort across agencies would be ideal.

That said, an onerous system of regulation for genetic tests, one that discourages testing, is also unacceptable.

Just as important to our organization and it is members as safety and accuracy is the accessibility of genetic tests. Overregulation and the implications that follow would likely make genetic tests, specifically those for rare genetic conditions, inaccessible to most individuals and their families.

This is an equally problematic outcome, one that must not be ignored of underestimated. The safety and accuracy of testing is essentially irrelevant, if the tests are not accessible to the individuals who need them.

Once genetic tests have received the regulatory attention they require, direct to consumer marketing of those tests, with appropriate

information and support, could be acceptable for some tests.

As science continues to move forward, and as more and more genetic tests become available, access to these tests may be the key to improved health outcome.

However, it is irresponsible to simply offer genetic tests to the public with no validation or without context or explanation. Genetic tests offer predictive information, and information about the health of both individuals and their families.

Like many other medical tests and procedures, this information can be confusing and intimidating if not appropriately translated by a health care professional.

As such, genetic tests offered directly to consumers should include opportunities for genetic counseling, opportunities that provide an individual with all the information needed to make the most appropriate decisions about his own health care and the health care of his family.

On behalf of Genetic Alliance I urge this panel to consider both concerns - concerns about the adequacy of oversight and concerns

regarding the potential for irresponsible direct to consumer marketing and sales of those tests.

Genetic tests should be accessible to consumers in a form that is safe, reliable and accurate. But above all else, they must be accessible. They must find a balance between regulations that accomplishes the desired goals, quality genetic tests that improve public health, and excessive regulation that places too onerous a burden on laboratories, and limits the availability of tests.

Genetic Alliance has made the quality of genetic testing a priority for the upcoming year. We will be working with patient groups, industry members, policy organizations and government officials to craft a sensible solution to ensure quality tests are accessible.

Until this is accomplished, direct to consumer marketing of these tests is dangerous.

Thank you.

MR. ABRAMS: Any questions from the FDA panel? Ms. Wolf?

MS. WOLF: Do you have any specific kinds of information that you want consumers to have

in the direct to consumer marketing of the tests?

MS. ALFANO: There are a lot of - genetic tests, because they implications for not just the individual but for the family as well, we recommend some form of genetic counseling that doesn't necessarily mean it has to come from a genetic counselor, but some information ahead of time before the test to tell you what the test is going to tell you, because it is predictive information. It's not necessarily a diagnosis. And then what your treatment options would be. What are the implications for your family? That sort of thing too, to help people through the process, so that they are not just getting a test rule.

I mean even health care professionals often don't know how to interpret a lot of the genetic tests for various diseases, and so to give that information to a consumer without any information that they can then look at and figure out would be irresponsible.

MS. WOLF: So you want that to be required information?

MS. ALFANO: Yes.

MR. ABRAMS: Okay, Ms. Alfano, thank you

very much for your presentation.

The next speaker is Meg Columbia-Walsh with Faith Popcorn's BrainReserve.

(Off-mike comments)

MS. CUNNINGHAM: I'd like to remind people to please turn your Blackberries off and not use them during the presentations. That noise that we keep getting is somebody using their Blackberry. Thank you.

And now I have the presentation up.

MS. COLUMBIA-WALSH: Hi, I'm Meg Columbia-Walsh. And I am from the industry, both on the inside and the outside, really just pointing out today - my main point is, with great passion, the current consumer that we have in the general public, and the cultural context in which they're living, which I hope both in industry and the FDA side will really consider as we think about regulation of any sort of information as we talk to them.

I think right now even in just pharma, big pharma, bad pharma, the FDA is also under attack. I really believe full disclosure, openness, communication, accountability, is the only way that we are going to restore trust in our industry, in

our regulatory bodies, and in health care in general.

Provide education on the risks and benefits of products and encourage consumers to become the knowledgeable empowered managers of their health. They are more empowered than they have ever been.

We cannot regulate their ability to seek or gather information regarding their health.

I also would like us to think about that DTC means advertising to a lot of people, and if anything, I wish that what we came out of this, which is convincing industry to spend less than 50 percent of their money on television, and think about how else we can educate in the true culture which we're living in.

The cyber cat is out of the bag. DTC is, what, 15 years old? We created this environment of empowered information seeking consumers. We cannot reverse that. Every person diagnosed goes to the Internet for information. If we regulate that information for six months before, once we release a product they're going to find it out, and it could be misinformation. So let's provide it in an open

way. Let's just do in better taste. Maybe that's what happened, we just became bad taste, so people are reacting to that. Let's do it in better taste, and advertise benefits with full disclosure of everything that is going on.

Accenture reports in the next five years 27 billion - this is where we're living right now, this is the culture, and especially the youth that is coming behind us. So let's not worry about regulating advertising; not everybody is going to be watching it anyway.

All communication is DTC. We can't hide behind any word. The FDA and the pharmaceutical industry, every single word we print is public, so don't let them have to find information that may be inaccurate.

This is the culture that we're living in. It's Wiki, it's the podcast, it's webcast, it's the Internet, it's print, it's across culture. We're one color, one language. WE must think about this. This isn't just affecting us as we've seen.

So who are our consumers? They don't know who to trust. They don't want their brands to embarrass them. They don't want to be lied to.

This is very big. We're in a full culture of icon toppling. The pharmaceutical industry, the tobacco industry, the Martha Stewarts of the world, the Enrons, consumers are turning to each other, not to us.

Let's fix that and restore that trust. They want to do the right thing. People embrace right now and respect companies that are open about their corporate flaws. We have a problem with methamphetamines right now. Don't take upper respiratory off the shelves. Let's educate consumers. Let's be honest. This is what children are doing with meth; this is the place that we play in this; this is what we are going to do about it.

Here are some examples outside of our industry. Whole Foods, slaughtering ducks in an inappropriate way. Immediately stopped the practice, changed the way that their process throughout the world, and open up a foundation to fix it.

McDonalds comes under attack, they have open disclosure, people come into our kitchen, see what we do.

The Gap releases a social responsibility

report. That's right, we're overseas. We're not doing a great job, so let's go in and do a better job; this is what we're going to do to fix it.

This is what we all should be talking about today, how we're going to restore this trust.

Here is our public resume. We can advertise, but we cannot hide. This is the point of not regulating it.

This is PhRMA, just matched on Google against these terms. Evil, corrupt, unethical, and inhumane. So clearly we're sliding.

And since I've started to track this, it increases on a weekly basis. We have a phenomenal regulatory body that we are sitting in front of. We have an incredible industry. Let's reverse that trend.

And the only way that we are going to do that is being transparent to our consumers, exposing our flaws, educating properly, and putting that information and education everywhere, not taking it away or limiting access to it.

So what is our public resume, and how can it be managed? This is what I'd love us to think about. How can the FDA and the pharmaceutical

industry earn the unconditional trust of our current information empowered consumer?

Listen to the consumers - they trust each other. They grew up in the world of cyburbia. They're networked, they're connected, and they're united.

People turn to connected peer groups right now. They are not looking only at the institutions for this information. So what does this mean? We must show up where they are. We must make sure that we are in their peripheral lives, that we're presenting this information everywhere, and if sometimes that means television advertising because it's mass media, great.

But we have to show up everywhere that they are. AlphaMom, 24-hour video on demand for birthing and parenting. Epinions, this is everywhere. They don't come to ask about the products; they go to each other, and then they rate each other on how they're rating the products.

This is our world too. Daddytypes.com, a blog for new dads to exchange information. So if we're not providing the right information, then they are in there talking about us without us giving our

proper information.

Institutions are being marginalized, therefore, as the trusted source of information. How can the FDA and the pharmaceutical industry stay relevant to its well-connected consumers and gatekeepers, a question that I would love for us to really discuss, and which peer communities should we join so that we make sure they have the proper information?

They value their health, but a second opinion is not embarrassing anymore. They'll go second, third, look at doctors right now to do it. So again if we are going to provide information, and they are going to walk in with a stack of paper, it should come from us, and we should be encouraging that.

Benefits, risks, full disclosure, everything about it so they can help decide with the help of their doctor.

Self-prescribed wellness is what you are concerned about. Access to information empowers people to diagnose, prescribe and treat themselves, but not if they have the proper information.

So consumers have StriVetin, so they

start to use it for facial wrinkles, because they figure that on their own, they talk to each other on the net. That's how they discover it.

So if this was to be released today, should we therefore take the information away so they can't figure the real use and why that is not a good idea? Or the benefits and risks of that product, that should come from us. We don't want them to have misinformation, or to be medical students on their own.

Sales of mangosteen juice, the minute you mention health benefits, the minute you mention this, they are going to take off. It is going to sell; we know that.

So again, let's make sure we have the proper information. We are a nation of first-year medical students thirsty for information and quick to judge, but the problem is that we're overconfident and under-qualified to do that.

So who better to provide that but us here? Okay, so we can't release a product and not tell them about it, because then they'll go on the web or anywhere else that they can particularly if they are suffering from something.

And I'm not saying that careful regulation doesn't have its place. I'm just saying that you can't limit. That shouldn't be one of the things that we are talking about here. These are the things we should be considering together.

How can we help consumers become more accurate, and educated better, when diagnosing their family and their own well-being? How can the FDA and the industry stay indispensable to a generation of overconfident and self-prescribing doctors?

Full disclosure, open communication, transparency, authenticity, accountability, doing it together for all the different constituencies, are the only values that are going to restore trust in our system, in the FDA, and in the industry.

Do not regulate or limit access to information. Let's just do a better job at it. More information about the pharmaceutical products from the people who develop them. Let's make sure we do marketing in good taste, but let's still make sure we disclose everything when we have that information - not six months later, not a year later, but the minute we know, and maybe even before.

Maybe we should start to have CME for consumers. Consumers will find out the information anyway, so it should come from us. It should come from the most knowledgeable source in the most authentic way.

Thank you.

MR. ABRAMS: Thank you, Ms. Columbia-Walsh, for your presentation.

You just - we do have questions, I'm sorry. I wasn't quick enough with my follow up.

You mentioned that we should have proper information about drug products and the conditions. A speaker this morning made a point of saying that this information, if it's coming from the drug company, is viewed as biased, it's not really good information, other folks should be doing it.

If you were advising industry, what specific steps should they take? And if you were advising the agency, what specifics steps should we take to improve the quality of this information?

MS. COLUMBIA-WALSH: I think my main point is that the consumers are going to find it. So level citing us both on the same team. You know, the point is that consumers are more empowered and

information hungry than ever before. So for a marketer - this is a capitalist society. There is nothing wrong with them marketing, or making money, but they must do it in a way that gives the best education.

And I think that is what we've gotten away from. I think we've lost the educational value, and we haven't put enough emphasis on that. I love the ads that you see like Evra or Tylenol if you are going to take my product, and you are going to OD on it, don't take it. We'd rather you didn't use it.

I mean I think consumers can really respond right now to that type of transparency, and on the FDA side, I think we should demand that. So instead of regulating and removing information, or limiting information, I'd much rather see us put some sort of rigor behind the type of education or information and rules around that, instead of only saying, oh, we're not going to do it, or we're going to ask the industry to self-regulate themselves, and the answer from the industry is, okay, well, I'm going to launch a drug and I'm not going to run any ads. Because then we're promoting these over-

confident people to go get information that doesn't come from us.

MR. ABRAMS: What exact information would you like to see in these advertising pieces?

MS. COLUMBIA-WALSH: I think it should be as much as we can in the time we have, depending on the format. That is part of my issue - I'd like to see more formats, more of us doing blogs, us doing websites, et cetera.

But I think it has to be a more educational open view of the whole positive and negative. Full disclosure of the risks and benefits. I think consumers are smart; we have a gatekeeper anyway in the physician. But as I showed examples of transparency, I think the more transparent they are, the more they're going to trust us, that we say here are the good and bad. Consumers are fairly smart about that now.

And then be able to go in a more educated way, because I firmly believe that all the time in DTC, that even if we get annoyed at a consumer walking into a doctor with a stack of Internet papers, that level of conversation, for as short as it is, starts at a higher level of

dialogue. And if we did send people into the doctor, and we did all that, then we'd fund a really great thing. And maybe we just need to reexamine it, because we've gone down a path that wasn't positive.

But not take it away.

MR. ABRAMS: Dr. Ostrove?

MS. OSTROVE: You mentioned that we need full disclosure of risks and benefits. One of our earlier panelists talked about feeling that it was important to have the full FDA-approved package insert associated with all advertising.

What is your sense of, would that get at what you are talking about? Is there something else you would be looking at in terms of full disclosure? Can you just kind of expand a little on that?

MS. COLUMBIA-WALSH: Yes, I would love to see us do, if we were going to do an instructional bulletin for a VCR, we wouldn't only give the industrial specs of that machine. So when you look at a package insert, even if you're in the industry, you get blurry after a few columns into it.

Certainly a consumer cannot understand

all of that, so why don't we do that? That would be a great idea. Let's take that package insert, and talk about what it is, what is in it, and teach them how to use it and how to read it.

In other words, making it part not only of attached in three pages of print ads, or running a commercial that is so confusing because there is too much. Why don't we teach them exactly what that package insert is, and make that part of the education, and pull out things both positive and negative, that they should be talking to their doctors about.

MS. OSTROVE: So you're saying translate it so that it's more understandable to the consumer?

MS. COLUMBIA-WALSH: That's right.

MS. OSTROVE: And you also seem to be saying something beyond that, which is somehow some kind of meta-education in terms of how to use the information?

MS. COLUMBIA-WALSH: Yes, I think that's true. I think our consumers are really ready for that. I mean they are hungry, and I have a bias because I founded CBS Health Watch, which became the largest consumer site on the web. I saw hundreds of

thousands, millions of people, coming in and out of there, and same with oncology.com, the minute we provided them information they were voracious about getting it.

And they stayed on line with us with expert interviews and so forth for hours. For an hour and half. We had to like kick them off. I would love us to do a better job of that.

MS. OSTROVE: What about patients and people who are not especially literate? If you like at the NALS, the National Adult Literacy Survey - I think there should be some new stuff coming out soon - you've talking about 40 percent of the population that has some problems in terms of literacy.

MS. COLUMBIA-WALSH: That's right, and I think we have to go at them in different ways. Television isn't the answer to that either. When we reach out to them, we do it in ways just like you have corporations where you put money aside for low income housing.

Our pharma companies do a tremendous amount of work in that way. Maybe we need to work together in how we educate better. Is it visual then? How are we promoting that, but don't not show

up.

You know, again, I still don't think the thing is then that we just simply withhold information. Let's become transparent and give it to them in a way that they can understand, or their support system, whether it's their community center, or whatever it is, can help them to understand it. I guess that's how I feel.

I mean I'm a fan of both sides. I have 20 years here. It's a big passion. But because of what I've seen consumers respond to, both in DTC and on the net, I don't think we can reverse that.

So if anything I just want it to become more educational. I think we if we were more CME about it, without just rules, but I mean literally how we educate, I think consumers will respond.

I don't think they need only dancing objects and fancy pictures to get the point across. I think we could educate them.

MR. ABRAMS: Dr. Behrman.

MS. BEHRMAN: I'm a little confused. Are you talking about the information coming from us or that we're doing this. Who is this "we", the "us"? Is it the pharmaceutical manufacturers? Or

do you believe FDA should be producing the information in the ads?

MS. COLUMBIA-WALSH: No, I mean industry clearly is the one in the game. They are going to be producing, we're talking about products here. I mean I think there are a lot of wonderful things you could do just in health care overall.

When we are speaking in this forum about products, the FDA certainly understands. People read about you in the press, too. They are seeing that our entire industry is under siege. You are part of that.

So I'm really talking in combination together, that the regulation you're imposing is sitting in a coalition to better educate about products instead of what rules can we put in to make it harder, or this constant kind of tension that we've been in, well, this word is good but this one isn't.

Because there is certainly marketing against it. I understand that. But I just think we can, within this country, I've shown work together in a better way to provide that.

I think we are on the same team. I

don't think it's like you against the industry. I guess that's my point.

MR. ABRAMS: Thank you for your presentation.

The next speaker is Joseph Cranston from the American Medical Association.

MR. CRANSTON: Good afternoon. My name is Joseph Cranston, and I'm a pharmacologist by training, and I currently serve as the director of science research and technology at the American Medical Association, and I'm speaking on behalf of the AMA at this Part 15 hearing.

The AMA commends the FDA for holding this hearing to determine the positive and negative consequences of direct to consumer advertising, and whether the agency should consider modifications in the way it regulates it.

DTC has been a topic of debate among our member physicians for over 20 years. And this debate continues. At our annual meeting last June, six new resolutions on DTC were considered by our House of Delegates, which is our policymaking body.

The resolutions ranged from doing a study to greater federal regulation of DTC to two

resolutions which called for an outright ban on this type of advertising.

All six resolutions were tabled for report back to our House of Delegates next June in 2006. I'm providing this information up front, because I think the FDA needs to understand that current AMA policy on direct to consumer advertising could chance once the new report is considered at the 2006 meeting.

Back in 1993, with the help of the FDA, the AMA developed guidelines for an acceptable DTC advertisement. The guidelines remain a key part of our official policy today in 2005, and they are applicable to both prescription drugs and medical devices.

In brief, the AMA currently believes that a DTC ad is acceptable if it is disease specific, it enhances patient education, it presents a scientifically accurate message, and exhibits fair balance between benefit and risk information, is understandable by consumers, promotes discussion between patient and physician rather than encouraging self diagnosis and self treatment, and is run only after physicians have been appropriately

educated about the drug.

Current AMA policy also calls for more independent research on the effects of DTC ads, as well as adequate funding for the Food and Drug Administration to effectively regulate this kind of advertising.

My focus today will be to present the AMA's perspective on some of the important questions raised by the FDA in its Federal Register notice announcing the meeting.

The first question I'd like to address is whether television DTC ads exhibit fair balance as is required in federal regulation

The AMA has expressed concern both to Congress and to the FDA that DTC ads shown on television often are very effective at using pleasing if not distracting visuals as the major risk information is being discussed on audio.

And we believe that there is now - that our concern about a lack of fair balance now is supported to some extent by both of the well designed research.

At the FDA's September, 2003 meeting on DTC research, and again yesterday morning, Dr. Ruth

Day of Duke University described her research on the cognitive accessibility of prescription drug information.

At the 2003 meetings she described a study where they evaluated 29 TV DTC ads. And what they found was that when compared to information about benefits, information about risk received fewer sentences, was placed in locations where it would be more difficult to remember, had a much higher level grade level for readability, and was disadvantaged from a semantic perspective.

When these researchers then tested the ads on real people, they found that people remember information about indications and benefits far better than they remember information about risk.

Thus the conclusion was that because of the way television DTC ads are constructed, people are much better able to understand benefit information than risk information.

In formal comments to the FDA in both late 2003, and again, in May of 2004, the AMA encouraged the agency to consider modifying its 1999 final guidance on broadcast advertisements, to ensure that television DTC ads are structured in a

way that fairly balances the benefits and the risks of prescription drugs.

A second question is, can consumers understand and accurately assess claims regarding the efficacy of prescription drugs in DTC ads?

One of the AMA's main tenets for appropriate DTC is that the advertisement should have some educational value. There is a growing body of evidence to suggest this may not be the case. Bell, et al, in an article published in the Journal of Family Practices, 2000, review over 300 print DTC ads for 101 drugs that were published in 18 popular magazines. They found that while the ads were informative, they lacked important educational information about those conditions, and the treatment for which the drug was being promoted.

Similarly, Rollisch and Schwartz and colleagues wrote an article in the Lancet, reviewed the contents of 67 DTC print ads from ten magazines published between 1998 and 1999. They found that the ads rarely quantified a medication's expected benefits, and instead made what they considered an emotional appeal.

In contract, over one-half of the ads

used actual data to describe the drugs risks.

The authors suggested that these print DTC ads leave readers the perception that the drug's benefit is large, and that everyone who uses the drug will enjoy the benefit.

AT the 2003 FDA public meeting, and again in a subsequent publication in 2004 in the web edition of Health Affairs, the same researchers provided further evidence that print DTC ads present benefit information in a way that tends to overestimate the benefit to consumers.

They created what was called a prescription drug benefit box for three actual ads in which only the name of the drugs were fictitious. And the purpose of this benefit box was to present actual data on a drug's benefit in a concise and understandable way that directly reflected the clinical trial used for the drug's approval.

Consumers were then asked to rate the efficacy of each of the three drugs based on the printed DTC ads that did or did not contain this benefit box.

Consumers were far more likely to rate the drugs as extremely effective when the ads lacked

the prescription drug benefit box, compared to ads to contained it. Thus these researchers concluded that quantitative data about drug efficacy, as presented in this prescription drug benefit box reduced perceived efficacy of the advertised drug, and helped people more accurately gauge the true benefit of the drug.

The AMA encourages the FDA to give thoughtful consideration to these research studies, because they do raise the question of whether commercially-driven DTC is really as educational as its proponents would like you to believe.

While the AMA recognizes the difficulties in creating prescription drug benefit classes for all drugs, as was pointed out by a senior FDA official both at the 2003 public meeting, and I think yesterday morning as well, there may be ways for FDA to guide the pharmaceutical industry in designing DTC ads that will more objectively present benefit information.

What is the impact of DTC on the patient-physician relationship? Much of the research has come from surveys of consumers, and to a lesser extent, physicians. There does appear to

be consistency across the surveys that DTC may have the positive effect of increasing diagnoses of previously undiagnosed conditions, and promoting better communication between physician and patient; these are good things.

On the other hand, surveys consistently s how that there is a subset of patients who demand specific advertised drugs from their physicians. The impact of this on the patient-physician relationship remains unclear. Many physicians continue to complain that less time is available to effectively diagnose and treat patients who have a fixation on a particular drug as a result of a commercial.

Furthermore, there is the potential to create this trust in the physician-patient relationship when the physician is put in the uncomfortable position of having to defend why the requested drug is unnecessary.

A recent randomized control trial, published by Kravitz, et al, in the Journal of the American Medical Association, alluded to earlier today in one of the presentations, the study that used professional actors to pose as patients, showed

that patients' requests have a profound effect on physician-prescribers, both good and unfortunately also bad.

Patients who made a general or brand specific, that is, based on a DTC ad, request for an antidepressant resulted in both increased appropriate prescribing of antidepressants for major depression but also increased inappropriate prescribing for antidepressant for adjustment disorder.

The researchers conclusion were that DTC seem to both avert underutilization - a good thing - and promote overuse - maybe not so good.

Thus like all the surveys, this controlled study suggested that DTC has both positive and negative effects on the patient-physician relationship.

In summary, I'd like to make the following points. One, current AMA policy considers DTC ads that satisfy the AMA's DTC guidelines as acceptable. However, the AMA is preparing a new report on DTC and its policy will be revisited in June, 2006.

Second the AMA is pleased that there is

a growing body of independent - and that should be underlined - independent research on the impact of DTC, and it encourages more research of this type be done.

But finally, based on what we would consider to be the best evidence from available research, the following conclusions can be drawn.

First, fair balance in television DTC ads clearly could be improved.

Second, the educational value of DTC ads could be improved if benefit information were presented more objectively.

And finally, there seems to be both positive and negative consequences of DTC on the patient-physician relationship, although more research is needed.

Thank you, and I will be happy to answer any questions.

MR. ABRAMS: Dr. Cranston, you mentioned that people, consumers, remember more about the benefits than the risk information, it should be structured in a better format. One of the things that you discussed was the prescription drug benefit box, and you alluded to the challenges of that,

because drugs are different as far as standardizing.

What are your thoughts about the box? What first would be the objective of the box, what do you want that to convey? And generally, what should go in there?

DR. CRANSON: I don't know whether it's doable or not. Dr. Temple was the FDA official who made those comments. And I really suspect he's confused. I think it would only really be useful in a print ad. I really think it would be very difficult on television. I think that the information that would go in there would be information that really reflects the true value of the drug based on the actual clinical data that was used for a previous trial.

To me, that dealt with the issue of providing information about - more information about the actual benefit of the drug.

MR. ABRAMS: Thank you. And my second point is, you mentioned that consumers take away the benefits more than the risks. What can be done so they take away the risk information, the risk concepts?

DR. CRANSON: Well, I think Dr. Day has

presented at two of these meetings now, and I think her work is fairly compelling that there are ways using cognitive psychology to structure the ads.

And it may be to your benefit to bring in some consultants from the outside who do have the expertise to look at this and see whether it is possible to provide guidance for the industry in that regard.

It would be nice if there were convergence, if in fact something like this were doable, if you folks would provide some further guidance on content to improve these things as the industry as you bring forth the new guidelines this year.

MR. ABRAMS: Mr. Byrd.

MR. BYRD: Just to clarify one point you made regarding the use of visuals in conflict with presentation of risk information.

It is the AMA recommendation that visuals not be used, or just appropriate - or inappropriate visuals be avoided?

DR. CRANSON: I think avoiding inappropriate visuals make sense. I personally am not an expert, and the AMA has not specifically

addressed that. I have said off the cuff to people that they should take out and scroll the major - not the whole thing that people are talking about - but the major risks as they discussed.

I don't know if that is good or not. I don't know if they'll remember that. I really don't. I think you really need to talk to experts like Day and others who have an understanding of people will in fact remember this information and move forward accordingly.

MR. ABRAMS: Ms. Wolf.

MS. WOLF: If patients come in after they've seen an ad, are they willing - are they responsive to a physician's efforts to try to clarify what some of the benefits and risks are?

DR. CRANSON: I think probably most are. Obviously, we have no evidence of monitoring physician-patient relationships. And what we hear we hear from our members, and a lot of that is anecdotal.

But I'd have to think that most patients are probably fairly reasonable. If the physician provides them with a justification for an alternative drug, or for no drug at all, most

patients would say fine.

MR. ABRAMS: Thank you, Dr. Cranston, for your presentation and the information you provided.

The next speaker is Rima Laibow from the National Coalition of Organized Women.

MS. LAIBOW: Thank you. I'm also representing the National Solutions Foundation, of which I am the medical director.

We will watch an edited version, a shorted version of "Comfortably Numb," and then I will speak for the remaining time.

[Video presentation:

FEMALE VOICE: Think before you take the stuff, because you really can't get happiness from a pill. It doesn't work like that.

MALE VOICE: Anti-depressants, stimulants, the whole gamut that we have been developing over the past 50 years for adults and the elderly are now being shifted to children as young as two.

MALE VOICE: Giving medication to children is an absolute last resort. It borders on being unethical not to try 15 things before you do

it try to address it in more creative ways rather than the magic pill.

FEMALE VOICE: The panacea for everything is here, pop a pill, and it'll make you feel better, instead of counseling, instead of taking the time to find out what's really bothering the person.

FEMALE VOICE: A little kid, so young, like four, five, taking medicine at the doctor's office. These developing minds, and we're just pouring chemicals into them.

MALE VOICE: Parents just want to do the right thing. So they want to make sure that they are getting treatment if it's needed. And the result is that we have a lot of people that are too quick to pull the trigger of medication.

FEMALE VOICE: Don't we have an obligation as a parent? I mean isn't that why you took on the obligation of having children is to spend the time with them and work with them? But no, it's so much easier to give them a pill.

FEMALE VOICE: You can't treat us like this little adults, because we're not.

MALE VOICE: Ding dong, it's a bell,

it's ringing. This is an alarm for what is likely to occur later on.

FEMALE VOICE: The drug is numbing the emotions. SSRIs or other drugs that numb emotions like alcohol, cocaine, opiates --

FEMALE VOICE: Today, we are facing a crisis of epidemic proportions. Over 8 million American children, some as young as two years old, are being given stimulant and anti-depressant drugs to control hyperactivity.

MALE VOICE (singing): Take two amphetamine, and put them in my hands --

FEMALE VOICE: Michael loved the outdoors. He loved surfing, fishing, he especially liked anything to do with salt water. February 8th, 2001, was the day that he died. It's been 3-1/2 years and I still have some real hard times. I always will. That was the day that my life changed forever.

These doctors have got to know, or they certainly should know, what these potent medications are all about.

MALE VOICE: We know the drug trials to be ineffective. We know the drug trails show the

drugs to carry a substantial risk of adverse effects, including suicidal ideas, self mutilation, other aggressive types of behavior.

MALE VOICE: Some kids it causes this terrible thing called akathisia, or where you get this intense emotion that you got to do something, and it's dangerous.

FEMALE VOICE: I just had an impulse to just like go and grab the medicine, and that is what I did.

MALE VOICE: They will do something really stupid. They will hurt themselves. They will hurt other people. They will do things out of character.

FEMALE VOICE: On March 31st, I took a lot of my pills and I tried to kill myself.

MALE VOICE: Drugs interfere with the normal functioning of the brain. They do that; that we know as an uncontrovertible fact. That's why we give them. We want to change the way the brain works. We want to interfere with the communication of chemicals. We want to slow something down. We want to speed something up. We want to put something to sleep - in the brain.

MALE VOICE: Those are mind altering drugs. It changes the chemical balance in your brain.

MALE VOICE: The classic picture is, kid goes on Ritalin, and the kid sometimes responds by being irritable, crabby, maybe even depressed, so then they add an antidepressant to the mix, and the kid is on that, and they get really aggressive, maybe impulsive. Then oh my gosh, they are bipolar disorder, and they are put on not usually lithium but depakote or one of the anti-seizure medications. Now you have a kid on poly-pharmacy, and it's just like, who is this child? By the time they're ten years old, they are mental health invalids, walking around with three or four different diagnoses to justify the medications that they are on.

MALE VOICE: She changed drastically when she was with these drugs. She wasn't the same person that she was all her life.

FEMALE VOICE: When I went to the psychiatrist, she was saying that since I was starting to feel lower that I needed more. So she would like keep giving me more, and I kept getting worse. And then this morning I'm supposed to be

taking it like an adult.

MALE VOICE: For a child who is five years old everyday to take a potent drug like Ritilan or Aderall, which are stimulants, which we know are drugs that affect the brain that lead some people to be completely dependent on them, that lead some people to become psychotic on them and so forth, what happens when everyday you give that child a dose for five to six years?

Well, what doesn't happen?

MALE VOICE: Saying "biochemical imbalance" is like a marketing slogan that everybody seems to know. People go into their doctors and say, I think I have a biochemical imbalance.

MALE VOICE: Are we telling our kids that happiness is going to be within the pill, but we don't tell them what the pill is doing, the manufacturer of those pills.

MALE VOICE: It is a fact now that drugs are being given younger and younger, and pediatricians are using psychotropic medications as their first line of defense for a lot of complaints about their children.

And it is very unfortunate because there

is no data about children under six years old. We have not a clue about how this affects the developing brain, and whether or not these drugs have any efficacy at all, because the efficacy studies are of older children, and they are questionable.

MALE VOICE: For the first four to five years, we're all ADHD, most of us that is cannot control ourselves. Most of us want things and blurt out answers before the question is over and interrupt adults. And most of us grow out of that phase, which is totally normal.

MALE VOICE: Children are like rivers, you can't step in the same part of them twice, they are changing so rapidly that you can rely on development to take care of a lot of problems, in an earlier age child, like 4-1/2. So it's a travesty to give a child that young any drug when developmentally they may mature out of the problem anyway with proper guidance and support.

FEMALE VOICE: One of the biggest thing I noticed about them was, they all knew they had attention deficit disorder, and they all were on some form of medication for it. And they were able

to say to me, oh, I'm on medication, and I have attention deficit disorder.

And the interesting thing was, they also were able to say to me, and you can't do anything to me if I don't do my work.

MALE VOICE: That child will get a diagnostic label even at such a young age, terrible two or three, might get the label, ADHD.

MALE VOICE: I mean years ago the terrible twos were a normal expected part of development, and now, it may be the beginning signs of oppositional disorder or ADHD, or bipolar disorder, or you name it.

MALE VOICE: The experts who have diagnosed that child think that, well, if that child has this diagnosis, then the child has a disease, has a disorder in their physical body, in their brain, and we need to intervene on that disorder within that child.

We don't have to really understand why that child is that way.

FEMALE VOICE: They know there is no consequences for their actions, because they are protected under that labeling. And that to me is

the biggest disservice they've ever done to these kids.

MALE VOICE: Don't drink and drive, but okay, take drugs and drive. That's okay; that doesn't impair your ability to drive. But of course it does.

FEMALE VOICE: I was taking it, and I was just feeling like horrible. I felt like a walking zombie.

MALE VOICE: Maybe we should get some answers.

FEMALE VOICE: If this helps like one person, then I've accomplished my goal and I've done what I wanted to do.

MALE VOICE: Good marketing can overcome bad data any day of the week. Because when you have unlimited resources you can market any idea. I mean the public has been convinced that every single problem in living or challenge in life is a disease, a disorder, or a deficit of some kind.

And parents have really bought into this.

MALE VOICE: We let her down. Because she came to us for help. And this time we almost

cost her her life.

MALE VOICE: Nothing gets taken away by a drug. A drug only adds a layer. The original stuff is always there.

MALE VOICE: We need to look at the process through which drugs become available to the market, especially for children.

MALE VOICE: I know how big a business the pharmaceuticals are. I mean the lawmakers have studied that. But when you are talking about millions of kids, literally, five years, four years, being prescribed this, how are you affecting these kids? How are we changing their lives? What is going to happen 15 or 20 years from now when all these million of kids and how long are we going to keep them on these drugs?

End of video presentation]

MS. LAIBOW: I should tell you that I am a child and adolescent psychiatrist, and I've practiced drug-free medicine for 35 years, so that gives me a distinct bias.

I have no commercial or industry ties. But I have a question. And on this issue, my vote is with the CEOs alluded to earlier of the

pharmaceutical industry who said that DTC is not about education.

So my question for the FDA is, is its mission to protect and promote the pharmaceutical industry as it was stated in Article 16 of the initial enabling legislation that created this body, or is it to promote and protect the well-being or patients?

Every year in this country hundreds of thousands of people, at a minimum, suffer preventable harm and death from pharmaceuticals. The regulation of pharmaceuticals is impacted by the impact on this agency of economics and therefore power.

No long term studies have been done on the pharmaceutical drugs that were used for years on end with our children and our adults. No long term safety studies have been done, but we do know a few things about these drugs.

We know that they have mutagenicity and carcinogenicity as part of their profile of impact. We know that there is neurological damage. We know that there is endocrine damage. We know that there is growth inhibition and skeletal damage.

We know that there is suicidality. In fact, Dr. Temple of this panel said in September of 2004 that looking at 15 clinical trials, some of which were suppressed, and the negative information therein - that there is serious, serious damage and suicidality in psychotropic medication, and the risks are considerable.

I would simply conclude by saying that when a long-term experiment, when a human experiment, is carried out without adequate informed consent, and Dr. Grace Jackson has written about informed consent in her book, reconsidering psychoactive medication, we are looking at something that violates the Helsinki Accords and the Nuremberg Protocols of experimentation on subjects who have not given informed consent, because the information has not been made available to them, and the safety and efficacy have not been established.

I consider DTC a dangerous and unnecessary precedent, and I think that physicians - the money, the $4 billion - would be far better spent adequately educating physicians, not educating physicians to be essentially drug-dispensing units.

And consumer education of the real risks

and the real benefits, I agree with Ms. Columbia-Walsh, it's absolutely essential. But that is not marketing information. That is real information.

Thank you.

MR. ABRAMS: Thank you, Dr. Liabow, for your presentation.

The final speaker for this panel is Kathy Kastner with Health Television System, Inc.

MS. KASTNER: Hello. I've just decide to change my entire talk as a result of listening to everyone today.

My name is Kathy Kastner. I'm the CEO of the Health Television System, which is a direct-to-patient television network in hospitals that has been established for 12 or 13 years, first in Canada, and then across North America.

We have been in the privileged position of learning from consumers what their needs are, and what the gaps are, in the way of information and education around drugs, really.

Even though we have reached hospitalized consumers, and the intent is to keep everybody out of the hospital, one would hope that the hospitalized patients would not be dismissed for

their input into the relevancy of health education and information, and that the understanding is, it's not just the patients when you are in the hospital, it's family and the community, their community, that are involved.

So there is an exponential reach of any education or information that's being provided by whomever.

So before I tell you more about what we've learned through our educational service and developing education that meets the needs of patients who will likely be leaving the hospital with one or more prescriptions, I wanted to just tell you three things I've learned from my work with the American Academy of Family Physicians in their patient education conference.

And that is, that according to the ASP doctors only spend about three minutes on education, which is asking a lot, I think - it's putting a lot on doctors who have a number of different things to do already. Not that they shouldn't educate, but education isn't coded. It's not billable, you know.

So doctors who I think are the most well intentioned health care professionals - after nurses

- you have to take the business of being a doctor into account.

And the other thing is that doctors are not necessarily statistically educated to evaluated the clinical studies and the data that is put forward in these ads. It's a whole area of statistical analysis that doctors are not - should not be expected necessarily to have taken.

The same thing with consumers of course, and the final thing that I learned is that doctors are human.

Okay, on to some of the things that we have learned. The first thing is that information is not education. And to turn information - well, the definition of education as opposed to information is to turn information into something that is going to resonate with the end user.

So you have to know what the end user needs or is missing from the end user's scope of understanding or scope of experience.

It is not what either the health care professional thinks the consumer needs, nor is it what the pharmaceutical company thinks the consumer needs, and with all due respect, it may not even be

what the FDA thinks the consumer needs.

But the - one of the benefits of having dealt with consumers who were highly motivated never to be in that hospital again is that often they don't know what questions to ask of their doctor, even if they had been prescribed something, and that the language beyond plain language and bringing things down to a grade six level, the language of health care is not the language of consumers. It may not even be the language of any of the people in this room.

And I would urge everyone in this room to take a look at the AMA website, AMA hyphen ASSN dot org. And on that website is a fantastically insightful video called, help your patients understand.

It's meant for their constituents, but in it are physicians who acknowledge that consumers should not be expected to understand medicalese. They've never been to medical school.

And the doctors should try and effect three changes within their practice: create a shame-free environment - I thought that was enormously powerful, no matter how educated or literate you are

- create a shame-free environment; speak slower; and use living room language.

So the AMA is trying to enact change in the communications style and the sensitivity within their constituents.

But the AMA video also has real people in there. And one of them is a woman who is clearly highly educated, and it says she has a high level job with computers, and her husband is a scientist.

And in this testimonial, this anecdote, she said, I went to my doctor because I had a problem down there, and my doctor said, no, no problem, we can help you. And I went to the hospital the next - or whatever the day was to go to the hospital, and there she was confronted with five two-page forms.

And in spite of her level of education, or level of literacy, she was not a quick reader, nor was her cognitive level such that she easily understood forms. But she was not in any way going to admit that when she was being admitted for a procedure.

And the next day when her nurse came and asked how she felt after a hysterectomy, she said, I

couldn't believe out of embarrassment I had a part of my body removed, and I want to go on the road kind of thing and let people know.

Likewise her husband who was an engineer came out of the doctor's office saying, I did not understand anything that my doctor said.

So in the area of direct to consumer advertising, which I mean it's been established that it is advertising. But I believe that it can take on a role of educating areas which have been identified, which have not yet been identified, but areas that should be identified, that it includes saying, as a point in this latest video was, no pill can give you happiness.

No drug can change your life irrevocably. There are so many other factors that are involved in making you happy, changing your life. And the fact that changing behavior for any of us I feel like I can speak fairly confidently that a change of behavior, even if you are well and healthy, and intending upon changing your diet or getting more exercise involved in your life, or distressing, is hard.

So that to ask people who are - have

been diagnosed with something, and have to look at their lives completely differently, to ask them to enact that change instantly is unrealistic and sets up a cycle of defeat.

So that for a direct to consumer ad, whether it's print or broadcast - and our medium is broadcast, and I'm going to be providing some statistics on how our medium, introducing direct to consumer advertising, and prescriptions at time of - prior to leaving the hospital, makes a big huge difference to compliance, the length of term of compliance, especially in the area of statins, which this study concentrated on.

That if you can help consumers understand that, in the area, say, of hypertension, for which we produced an educational segment, and the first thing we had to determine was, were our viewers going to understand what hypertension. And in doing that, we conducted informal focus groups just asking people what their definition of hypertension was. And man, the results could go into a Monty Python skit.

So it was determined that before any education could be developed, we had to acknowledge

that the language of this particular condition was not understood by consumers for whom the benefits of controlling high blood pressure through medication and diet would be lost because they thought hypertension meant a tense heart, or whatever it was that they thought it meant.

So that to determine first off if consumers understand what is being spoken of, whether in a direct to consumer ad - actually, there is a recent example with Plavix that talks abou8t plaque, and because Plavix is part of a recommended therapy for patients leaving the hospital with certain CV conditions, we just undertook to say, do you know what plaque is? And it wasn't - I was not surprised to hear that the understanding of plaque was either a thing that you receive if you have won an award, or the thing you brush off your teeth, that clots and plaque are not everyday language.

And in Toronto, in fact, which is where I'm originally from, there is a mini-med school that is put on by University of Toronto that is designed to help consumers understand the biologics and the way the body interacts, and the language of health and prescription drugs.

And at the conference last year for health literacy that is put on by the Institute for Health Care Advancement, there was another language example brought up by a doctor who said he was visiting his patient. And he said, you know, you have heart failure, not whatever it was that the patient was admitted for. You're on the wrong floor. I'm going to make sure you get up to the right floor this afternoon.

And the patient later on said, aren't I going to be cold on the floor? Are they going to provide me with blankets?

So what we who are not only educated but educated in the field of health language may take for granted is a huge missing element out there that would, in our belief, help all stakeholders, including pharmaceutical companies who could use their dollars, which is why I suggested this before, if there was a percentage of the money going for promotion or a separate category for education, which is very hard to quantify admittedly.

You know the ROI on education can be determined, is immeasurable because of all those various doctors involved. Be that as it may, we

provide education, we believe education is an important factor in schools.

And there are people who are educated to the educators. So from the FDA point of view, I wonder if a suggestion might be, in addition to the social scientist, to possibly add the master's of education to the mix, so that any promotions can be viewed to see if they follow principles of adult education, which are very different from principles of - oh my God, I've done it.

Well, that was a lot of fun. I think that's it. I got my lipid study. Got the AMA thing in. Okay. Are there any questions.

MR. ABRAMS: Dr. Behrman.

MS. BEHRMAN: I have two. One is, then is your advice to us - you focused a lot on language, and comprehension - that in order to improve the educational value of DTC ads we should focus on the language that's used and the lack of communication? Is what I should glean?

MS. KASTNER: Meaning, identifying words and concepts that are not familiar yet to consumers, and ensuring that they are clarified somehow.

I too don't think that a 30-second ad

can accomplish that. But for a self-directed adult, and not all of us are, to be able to tell consumers who are reading or watching the ad that there are places to learn more about the terminology, whether it's hypertension or lipid reduction or whatever, to have that incorporated into it, I think that component could be looked at more closely.

MS. BEHRMAN: And just to follow up, you mentioned the AMA's notion of a shame-free environment. Does that have an analogy if you will in an ad?

MS. KASTNER: Well, I don't know if there is an analogy per se, but to be addressing the fact in the - checking, some ads do - that you are not alone, or that there is no shame in asking questions, and here are some of the questions to ask. We've also found consumers don't even know what questions to ask.

MS. BEHRMAN: Thank you.

MR. ABRAMS: Thank you for your presentation.

MS. KASTNER: Wait, Lisa is supposed to ask me a question.

MR. ABRAMS: Ms. Moncavage?

MS. MONCAVAGE: We are FDA are not compelled to speak.

MR. ABRAMS: I withdraw my statement.

MS. MONCAVAGE: You mentioned the lipid study. Could you talk about that a little it?

MS. KASTNER: Yes, there was a study done which I will provide which shows that if a prescription is initiated in the hospital - and for our purposes it means to have communication or direct to consumer advertising in the hospital so that patients are aware of this - if a prescription is initiated in the hospital the compliance rate, if that is what one says, increases to - they follow these patients for six months, patients who have been prescribed in a hospital versus in a follow-up doctor's visit. And the patients in the hospital were still compliant six months later.

Would you like me to provide that data?

MR. ABRAMS: Sure. If you could submit it, it would be very useful.

MS. KASTNER: I will provide it. Thank you very much.

MR. ABRAMS: Thank you for your presentation.

Okay, we are going to break in a minute, and then have a final panel come back.

I request that anybody who wishes to speak from the floor. We probably will have time after the next panel.

So I'd like to thank this panel for their excellent presentations.

(Applause)

MR. ABRAMS: And we will break now and resume at 3:15.

(Whereupon, the proceeding in the above-entitled matter went off the record at 2:50 p.m. to return on the record at 3:13 p.m.)

MR. ABRAMS: Good afternoon, and welcome back. We are at the home stretch now, panel #8, the final panel of the hearing.

We will start off with our first speaker, Mark Tosh from DTC Perspectives.

MR. TOSH: Good afternoon, and thank you. I'm representing DTC Perspectives. My name is Mark Tosh. And I'd like to thank this FDA for the opportunity to present here today.

DTC Perspectives publishes DTC Perspectives, and develops educational conferences

for the DTC industry.

We have tried to be an objective observer of DTC trends and issues, and our position is that the DTC industry benefits most by understanding the points of view of both supporters and critics.

Indeed, the weekly newsletter written by our chairman, Bob Ehrlich, often takes the drug companies to task for actions he feels are not in the public interest.

Let's turn to the matter at hand. First we'd like to say that we think DTC has been a net positive for the American public. We must recognize that our health system is not objective, and was not objective, before DTC appeared.

Physicians are not always neutral. They are influenced by drug companies through medical meetings, samples, and detail reps.

Insurance companies are not neutral, and often try to influence drug choices to less expensive drugs, not necessarily the best drugs.

OTC products try to influence consumers and compare themselves to Rx drugs.

Therefore, consumers benefit by having

all the facts available to them, even with a sales orientation as a part of branded DTC advertising.

Second, we think the industry has taken some positive steps in 2005. Many new ads are more straightforward, more sober, and easier to understand. The new trend is positive for consumers, because risk information is now presented in many ads as part of the main actor portrayal, not as a voiceover. In some ads, doctors provide the risk and benefit information.

Drug companies also have significantly increased disease education ads in 2005, in response to both critics and the FDA guidance.

We also see an attempt at self regulation through the PhRMA code that was adopted this past August. It is not perfect, but it does provide two major changes. Most importantly, it brings the end of branded awareness reminder ads, and it also talks about the age-appropriateness of advertising targets.

Now let us turn to what we think should still be done to improve DTC. First, we were greatly disappointed that the PhRMA code did not deal with medicalese brief summaries. This is a

major problem that still exists in about half of print ads. Despite the FDA draft guidance issued almost two years ago, few drug companies have changed to a patient-friendly format. We think this is absolutely wrong. Consumers, now more interested in understanding risk, deserve to have that information in understandable terms. Drug companies owe that to consumers any time they run an ad in a consumer magazine or refer to that information on a television ad.

We urge the FDA and DDMAC to get whatever regulatory authority it needs to ban these medicalese brief summaries. Many marketers and drug companies have told us that they want these patient friendly summaries adopted, but are vetoed by company lawyers who somehow believe a flood of incomprehensible information will protect them from liability lawsuits.

I hope they are proven wrong, and that American juries react negatively to medicalese brief summaries.

Therefore DDMAC should consider getting specific authority to mandate patient-friendly summaries, or alternatively, make the typeface

requirement larger, so that these medicalese types of summaries are cost inefficient for drug companies.

Also, one of the drug companies that does deserve praise for making patient friendly summaries available years ago is Merck. Given the negative press that Merck has gotten on Vioxx, at least they do deserve credit for their brief summary policy.

Our second recommendation is to develop a guidance that encourages ads that deal with retention and compliance. Most DTC is for brand awareness. We are now glad to see more disease education ads, but we also think the public needs to see ads on the proper use of drugs.

We know that poor retention and compliance is a major contributor to hospitalizations and other illnesses.

We think that a good use of reminder ads would be for this purpose, a 15 or 30-second ad that would be impactful for current or lapsed users.

Third, we recommend Congress or DDMAC develop a panel to oversee the PhRMA code, an independent assessment of self regulation is

critical to determine if drug companies have done the job well.

This panel should issue a public report on how well the industry has followed its 15 points.

Fourth, we do not think we need additional regulation on use of celebrity spokesmen. We know a few major branded drug ad campaigns that still use celebrities, and there is no evidence that celebrities work better than noncelebrities, at least that we know of.

Clearly the public identifies with celebrities who announce they, too, may have an embarrassing condition. And therefore, celebrities can be effective in disease education.

Fifth, we would recommend DDMAC not try to ban special offer type promotional ads, which was one of the things raised in the background to this meeting. While we do not feel brands help their image through such couponing, or through buy-a-few-get-a-few-free product type promotions, we do not think there is any harm to consumers by offering them.

We are not aware of any evidence that

these discounts lead to inappropriate use or result in physician pressure to prescribe. The discounts are usually small, and not a major incentive to ask doctors to prescribe.

In summary, we think the drug industry has come a long way in 2005 toward making DTC more in the public interest. We believe no major changes are needed, except as noted above, and 2006 should be a learning year on self regulation, and a year to determine if the industry will continue on its trend toward more disease education, and less branded ads.

We do however believe DDMAC should act on medicalese brief summaries through new regulations. We also would like to see an independent panel to monitor self regulation as soon as next year.

DTC Perspectives would be happy to assist in that effort, as we feel we are able to objectively review drug company compliance with the PhRMA code.

Thank you for your time.

MR. ABRAMS: Dr. Aikin.

DR. AIKIN: Thank you for your comments. You suggest that the FDA develop

guidance on retention and compliance advertising.

Companies could certainly do this form of advertising now. What do you envision such a guidance saying?

MR. TOSH: Well, perhaps some type of guidance on the balance of advertising to go retention of the amount.

DR. AIKIN: Could you be more specific, by amount?

MR. TOSH: Well, whether it should be 10 percent of the advertising or 25 percent, or just how it would break down.

MR. ABRAMS: Dr. Behrman.

MS. BEHRMAN: You had mentioned a board, an independent board to oversee or at least evaluate the PhRMA, the voluntary code. Do you envision FDA creating that board or outside organization?

MR. TOSH: I think it would be an outside organization, an independent panel. But DTC Perspectives would be offering its assistance to help set up such a board and develop the names of the people who would serve on such a board.

MS. BEHRMAN: And you would envision then PhRMA taking initiative to do that? Or is that

a recommendation to us on the board?

MR. TOSH: Well, we think that the board needs to be independent, and it could perhaps work in conjunction with PhRMA on its findings. But we think that the board should be set up independently of PhRMA.

MR. ABRAMS: Thank you, Mr. Tosh, for your presentation.

The next speaker is Scott Lassman from PhRMA.

MR. LASSMAN: Good morning. It's already afternoon. And thank you for on behalf of the Pharmaceutical Research and Manufacturers of America, also known as PhRMA, I'm pleased to appear this afternoon at this public hearing on direct to consumer advertising.

My name is Scott Lassman, and I'm assistant general counsel at PhRMA.

PhRMA represents the country's leading research based pharmaceutical and biotechnology companies. PhRMA member companies are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives, investing more than $30 billion annually in

discovering and developing new medicines, PhRMA companies are leading the way in the search for cures.

But PhRMA don't just do the important work of discovering and developing new medicines. They also devote substantial time and effort to informing health care professionals and patients about the availability, proper usage, and benefits and risks associated with those medicines.

This communication provides tremendous value to health care professionals and patients by making them aware of the benefits and risks of the new drugs; empowering patients to play a more active role in managing their own health; encouraging patient compliance with the physician-directed treatment regimens; and perhaps most important, encouraging patients to seek treatments for diseases that currently are underdiagnosed or undertreated.

DTC advertising in particular can be a powerful tool to reach millions of people about health care treatments. Because of this reach, DTC advertisements can be a tremendous value in conveying useful health information to patients.

An important benefit of DTC advertising

is that it fosters informed conversations about health, disease and treatments between patients and their health care providers.

Because of DTC advertising large numbers of Americans are prompted to discuss illnesses with their doctors for the first time. Because of DTC advertising, patients know where to find additional information about disease states and treatment options.

Because of DTC advertising, patients become more involved in their own health care decisions, are proactive in the patient-doctor dialogue.

Because of DTC advertising, patients are more likely to take their prescribed medicines.

In short, DTC advertising plays an essential role in meetings the needs of an increasingly sophisticated information-seeking health care consumer.

DTC advertising also serves a valuable role in educating patients about the limitations and risks associated with certain therapies. Now obviously DTC advertising cannot and should not replace the health care professional as the most

authoritative source of information about the risks and benefits of particular drugs for a particular patient. But it can and does encourage patients to talk to their physicians about their medical conditions or treatment options, including the risks of treatment.

This dialogue results in better educated patients, more active in their own health care, who generally comply with their treatment regimens.

PhRMA and its member companies have long understood the special responsibility we have to the patients that use our innovative medicines. Despite the very positive role DTC advertising plays in helping to educate patients - I think we've heard a lot about that over the last two days - we have heard concerns expressed over the past couple of years about DTC advertising, and we do take those concerns very seriously.

In order to address these concerns and improve the value of DTC advertising, on July 29th, 2005, PhRMA's board of directors unanimously approved PhRMA's guiding principles on direct to consumer advertisements about prescription medicines.

Although the guiding principles are voluntary, consistent with PhRMA's state as a voluntary trade association, since July, 26 PhRMA member companies have stated publicly that they intend to follow the guiding principles.

We are proud of this commitment by our members.

Our principles recognize that prescription drugs are different, and should be held to a higher standard; that there are important and powerful products that have both benefits and risks, and thus must be used with care; that they require the supervision and oversight of a trained health care professional; in short, our principles recognize that prescription drugs are not like light bulbs or toothpaste or underarm deodorant or any other consumer product. DTC advertising thus should be responsibly designed to provide accurate, accessible and useful health information that encourages the appropriate use of these special products.

And this is precisely what the primary goal of PhRMA's new DTC guiding principles are.

Because prescription drugs are

different, DTC advertisements already are subject to stringent regulatory requirements and oversight by FDA. These requirements are more stringent than the requirements that apply to virtually any other type of DTC advertising.

For instance, advertisements for cars don't need to spend any time at all discussing the dangers of driving or the risk of a rollover.

Pharmaceutical ads, by contrast, are required to talk about risks. And this is appropriate, because drugs are different. The guiding principles recognize that FDA regulations already set a very high standard.

According to those regulations, all DTC information must be accurate and not misleading; to make product claims only when supported by substantial evidence; must reflect the balance between risks and benefits; and must be consistent with the FDA-approved labeling.

Our members are committed to meeting these existing high standards, and the guiding principles reiterate that commitment.

But the guiding principles go further. They reach beyond existing regulatory requirements,

in order to help promote an educated dialogue between physicians and patients. For example, the guiding principles state, the company should spend appropriate time educating health care professionals about a new medicine before it's advertised to patients.

This will help to ensure that physicians know about a new medicine first, so that they are prepared to answer questions that they get from their patients.

In addition, companies that sign onto these guiding principles aggress to submit all new DTC television ads to the FDA before releasing these ads for broadcast. This commitment again goes beyond existing regulatory requirements, which require companies to submit DTC television ads at the time they're first aired.

This additional lead time should provide the agency the opportunity to review new TV ads before they're aired, consistent with its priorities and resources. It also should provide FDA and sponsors a better opportunity to communicate expectations and identify and address issues before a DTC ad is viewed by the public.

The guiding principles also state that DTC television ads that identify a product by name should clearly state its approved indications and major risks.

Critics contend that reminder ads on television often leave patients guessing about the nature of the advertised product, its intended use, and whether the patient should follow up with his or her physician.

While PhRMA believes that reminder ads can help familiar consumers with product names, we also believe that television ads should facilitate a more informed dialogue between patients and health care providers.

To achieve this goal the DTC principles call for companies to provide all relevant benefit and risk information when a product is named in a television ad.

The guiding principles also go beyond existing legal requirements by asking companies to focus more closely on the intended audiences, as a result of concerns that certain prescription drugs may not be suitable for all viewing audiences, the guiding principles state that DTC television and

print ads should be targeted to avoid audiences that are not age appropriate for the messages involved.

If an advertisement contains content that may be inappropriate for children, the advertisement should be targeted to predominantly adult audiences.

This means programs or publications that are reasonably expected to draw an audience of approximately 80 percent adults.

PhRMA believes that DTC advertising is important, even for these types of health conditions that may be embarrassing or sensitive.

By the same token, PhRMA's member companies recognize that these ads should be disseminated with sensitivity and respect for the feelings of parents and children.

The guiding principles contain many other important provisions intended to enhance the value of DTC. For instance, should new and reliable information concerning a serious previously unknown safety risk be discovered? Companies commit to work with the FDA to responsibly alter or discontinue a DTC advertising campaign.

In addition, the principles encourage

companies to include, where feasible, information about help for the uninsured and underinsured. Our member companies host a host of programs that assist needy patients, and DTC ads can help spread the word.

PhRMA's board also unanimously approved the creation of an office of accountability to ensure the public has an opportunity to comment on companies' compliance with these principles. Periodic reports will be issued by the PhRMA office of accountability to the public regarding the nature of the comments.

Each report will also be submitted to the FDA.

PhRMA's board also agreed to select an independent panel of outside experts to review reports from the office of accountability after one year, and evaluate overall trends in the industry as they relate to these principles.

The panel will be empowered to make recommendations in accordance with the principles. And the principles go into effect in January of 2006.

We believe these new principles will

help patients get the information they need to make informed health care decisions in consultation with their health care practitioners.

Given the progress that continues to be made in society's battle against disease, patients are seeking more information about medical problems and potential treatments. The purpose of DTC advertising is to foster an informed conversation about health, disease and treatments between patients and their health care practitioners.

Our guiding principles, we believe, are an important step in facilitating that conversation.

My comments today have focused on PhRMA's guiding principles, which we believe address many of the issues raised by FDA in its meeting notice.

We also intend to submit written comments to the docket addressing these and other issues in more detail.

In closing, though, I would like to mention that PhRMA strongly supports FDA's efforts to increase the effectiveness of DTC advertising to impart meaningful health information to patients including risk information.

PhRMA specifically supports efforts to improve the usefulness of the brief summary to consumers, as stated in our previous comments to the docket on FDA's draft guidance.

However, this should be accomplished in a way that does not create unnecessary product liability concerns.

As a final comment, PhRma believes it's important to utilize an evidence-based approach when addressing all of these issues, and it's nice to see that there was so much evidence in the last two days presented to FDA.

Such an approach should rely on adequate consumer research to determine the best way to communicate benefit and risk information to consumers.

PhRMA firmly believe that when patients have access to accurate and understandable information about their medical conditions and treatment options, they can partner more effectively with their health care providers to obtain the most appropriate treatment for their individual circumstance.

This concludes my oral testimony, and I

would be happy to take any questions.

MR. ABRAMS: Thank you, Mr. Lassman, for your presentation.

You mentioned the benefits of DTC advertising. We have heard from speakers in the past two days that in addition to DTC being compliant with the regulation, being accurate and balanced, it should go beyond that. It should be educational, it should talk more about the disease state, should focus more on educating people about diseases rather than selling a product.

Do you have any response or thoughts about that?

MR. LASSMAN: We completely agree, and that's exactly what we have tried to do with our new PhRMA DTC principles, to make the advertisements more informational, more educational, more focused on these things.

So we would agree with that, and I think we are doing that.

MR. ABRAMS: So you think that there should be less emphasis on the product and more on the disease then?

MR. LASSMAN: No, I wouldn't say less

emphasis on the product. Obviously the ads, most of the ads involve products, and we feel that that ought to continue to be the case, that that ought to be available to companies.

I think there was testimony yesterday indicating that the product ads may be the most effective in actually getting patients to see their doctors.

One of the points that we have made, though, in the new DTC principles is, we do encourage companies to do more of the disease state ads, the more help seeking type of ads as well.

MR. ABRAMS: Thank you. Dr. Behrman.

MS. BEHRMAN: Two questions. One, do you agree with Mr. Tosh's comment that the presence of the draft help seeking guidance in fact increased the numbers of those ads? Do you believe that your member companies are actually doing more of those because of the guidance?

MR. LASSMAN: I have no information about the levels of how much of those help seeking ads are out there, so I can't really comment about that. I think any encouragement by FDA would be helpful.

As I said, we tried to provide encouragement in our DTC principles, and we hope that that will be helpful in spurring more of those types of ads as well.

MS. BEHRMAN: I was interested in whether a guidance on compliance, I was trying to by analogy, I'm wondering if guidance on compliance might have a similar effect on such an increase.

The other question I had: Does PhRMA have a position on two issues that came up a lot in the last two days: the language in the ads, and the if you will incentives? Particularly cleaning up the ads to the children, the acne ad?

MR. LASSMAN: As far as the language, whether it ought to be understandable to consumers, yes we definitely support that. That is a position which we've stated in our comments to FDA's guidance document on the brief summary in print ads.

We fully support that. We think it's critical that patients actually understand the health care information, safety information, the effectiveness information.

A lot of times it may be difficult to get there. These types of issues are, some of them

unfortunately do have to be presented in medical language which may be difficult to understand.

But to the extent we can get there, we think that that is appropriate.

MS. BEHRMAN: And incentives, does PhRMA have a position on incentives, coupons, or iTunes, or things like that?

MR. LASSMAN: At this point I don't think we have a position on that.

MR. ABRAMS: Dr. Aikin?

DR. AIKIN: You mentioned that 26 companies have signed on, or I guess agreed to follow the PhRMA guidelines.

MR. LASSMAN: That's right.

DR. AIKIN: What percentage of your total membership is that? And do you anticipate more companies signing on later?

MR. LASSMAN: We hope more companies will sign on. I think it's a very substantial percentage of our membership. I don't have the exact figures, but I believe we have somewhere in the low thirties as far as membership; so it's a very substantial proportion.

MR. ABRAMS: Dr. Ostrove.

MS. OSTROVE: Just a quick point of clarification. Do the principles with regard to the reminder ads apply to both broadcast and print?

MR. LASSMAN: They apply only to broadcast ads.

MS. OSTROVE: Then can I follow up and ask why that would only apply to broadcast ads?

MR. LASSMAN: Well, that's a very good question. I think the reason is, what we were trying to do with the principles is really address criticisms that we've been hearing.

Most of the criticisms around reminder ads had pertained to the broadcast ads, so that's why the principles focused on the broadcast ads.

That may be something we look at as we get more experience with this, whether that ought to be extended to print ads. But as it stands right now, it's just limited to the broadcast ads.

MR. ABRAMS: A final question: Could you describe PhRMA's position, a brief summary, of exactly what you would like to see with the brief summary happen?

MR. LASSMAN: Well, as we stated in our comments, we support the overall thrust of what FDA

is trying to do, which is to make the brief summary more of a summary and more brief, and provide that information in patient-friendly language.

The problem that we had with the draft guidance was that it's framed as an exercise of FDA's enforcement discretion, essentially saying - if you look at FDA's regs, stepping back for a second, if the requirement is that every single safety issue has to be presented in the brief summary. What you were saying in your guidance document is, we won't object if you present the most significant and not every single one, but just the most significant.

But the issue for us, if that is an exercise of enforcement discretion, I think that's probably a good exercise of enforcement discretion. We unfortunate have product liability issues with that, because if there is an argument that we are not complying with the letter of FDA's regulations in providing risk information to the patients, again, that opens up our membership to product liability concerns.

So what we were suggesting is, we support the overall thrust of it. We don't think it

ought to be done as a guidance document or as an exercise in enforcement discretion.

If you are really going to do it, we had suggested doing it by changing the regulations.

MR. ABRAMS: Thank you, Mr. Lassman.

Okay, our next speaker is Peter Pitts from the Pacific Research Institute.

MR. PITTS: Thank you, Mr. Abrams.

Thank you for the opportunity of addressing this important meeting at a very timely moment.

Winston Churchill said that Americans always strive to do the right thing after they have tried everything else.

Today we have the opportunity to devise a system, we must devise a system, wherein DTC advertising is designed in equal parts as savvy marketing strategy and powerful public health tool, because these are not mutually exclusive concepts.

We must learn from our mistakes. While industry's errors have been in many instances sins of commission, mistakes literally aired in public, so too has the FDA erred, mostly through sins of omission, specifically using personal judgment

rather than social science to decide what in compliance means.

This lack of predictability has led to an absence of direction that some harsh critics on Capitol Hill see as an abdication of leadership, and the result is advertising that isn't as potent a public health tool as it might otherwise be.

With that as my point of departure, let me ask a question: What do we want pharmaceutical direct to consumer advertising to be when it grows up?

The recent consumer survey in Europe asked people in Great Britain, the Czech Republic, France, Germany, Italy, the Netherlands, Spain and Sweden what reforms would most likely increase their quality of care?

In every nation, by a large margin, the answer was, quote, giving patients more information about their illness, close quote.

Here at home 96.7 million consumers go online, and 65 percent of them seek information about their health.

Health care information is the consumer's Rosetta Stone, and public policy

institutes, pharmaceutical firms, communications professionals, health care providers, disease organizations, patient advocates, and academics along with the FDA must be allied and aligned conduits.

That being said, how can the FDA help calibrate the proper balance without overstepping its regulatory authority? Is the answer to ramp up the volume of NOVs? I don't think so.

More letters do not result in better, more public health driven, communications. Industry by and large strives to be in compliance. But when the rules are vague and fluid, an ad or promotional brochure that is okayed by DDMAC one day can be ruled out of compliance the next, sends ominous signals to both industry and consumers alike, and it's like red meat for some members of Congress.

We need better DTC advertising, and the way to get there is to apply sound social science to better communicating medical science.

Claude Debussy said that music is between the notes, and this is as true as it is for NDAs as it is for communications oversight. The same techniques used to judge clinical trials cannot

be applied to communications.

Current DTC policy is not based on a scientific analysis of the target subject: the consumer. And this raises a crucial question: Where are the social science metrics driving the expert review of pharmaceutical advertising?

Specifically, how could marketers more clearly and meaningfully communicate the risk-benefit equation of advertised drugs by following more useful directions from the Food & Drug Administration?

FDA needs a solid benchmark study to serve as a foundation for the agency's regulatory oversight of direct to consumer advertising, a social scientific protocol, a quantitative research project composed of structured closed-ended questions, and a sample size representative of the U.S. population with regard to geography, race, gender, age and the treatment of disease of interest.

A study armed with questions that would provide insight into the most effective ways to communicate in ways that are understandable by the average consumer; a study that would provide a

social science-based regulatory framework, potential templates, metrics, and most importantly, something that would add predictability to the DDMAC review process.

I do not believe that the status quo is a viable option, because as FDA's own research shows, the current brief summary for example is a poor public health tool.

"In compliance" and "user friendly" should not be mutually exclusive.

In our post-Vioxx world, we can no longer afford to risk - we can no longer afford to allow risk information to remain hidden in plain view. As far as the public health is concerned, that is not an adequate provision.

The status quo is a nonstarter, because it is antithetical to the public health.

If an educated consumer is our best customer, then industry needs an evidence-based regulatory framework that provides predictable standards for the communications efforts to consumers.

Perhaps it's time for a standing advisory committee on health care communications.

FDA cannot continue to regulate vague concepts such as fair and balanced and adequate provision on a case-by-case basis.

Instead, the FDA, with input from pharmaceutical, industry, consumers, communications professionals and academia, must develop an evidence-based predictable framework for DTC marketing, and there must be options. Because the same rules cannot apply equally to an allergy medicine on the one hand and an antidepressant on the other.

FDA must take the next steps required to put the science back in social science. As Jerry McGuire might say, show me the metrics.

Thank you very much.

MR. ABRAMS: Any questions from FDA panel?

Thank you, Mr. Pitts.

MR. PITTS: Thank you.

MR. ABRAMS: Okay, our last speaker for the hearing, and I thank you for your patience, is William Vaughn from the Consumers Union.

MR. VAUGHAN: Thank you very much, and thank you for your endurance.

I'm here on behalf of Consumer Union, the independent nonprofit publisher of Consumer Reports. We have no conflicts of interest.

We don't just test toasters and flat-screen TVs. We try to help people get the best, most effective, safest drugs.

We have a best buy drugs campaign on our free website, that uses the Oregon Health and Science's university drug effectiveness review project to try to help people get not just what is advertised on TV, but what the best drugs are, the safest drugs, for the most reasonable price.

I'm sorry I'm not bringing any original research to this meeting. But having sat through every presentation, I am going to file a paper tomorrow with a journal, because I have been very surprised that there is a very high correlation, almost 100 percent positive correlation.

Those who make money selling medicine and from advertising tend to like DTC; those of us who don't have a financial interest have some problems. And when I get that peer reviewed, if I could submit it to the docket, I'd appreciate it, sir.

We urge the FDA to support major reforms in the advertising of pharmaceuticals. We believe this is a major consumer issue. And as AARP said yesterday, it is a good way to save money in the health sector.

You think of direct to consumer advertising on TV, that'd be about two million adults covered under Medicaid. All of this stuff, it' s about 15 million people, maybe more if you're just doing kids, covered under Medicaid. So it's a hunk of money you sometimes wonder could be better spent.

We agree with a lot of what has already been said, particularly with AARP. Gary Stein of the Health Systems Pharmacists, the National Consumers League, the Public Citizen, the PAL group today, points made by Kaiser Permanente's presenter about doctors being induced to perhaps misprescribe, Diane Zuckerman of the National Research Center's evocation of emotional ads, and the excellent description of advertising's psychological manipulations, fluttering bumble bee wings, described by Professor Day, all reinforce our beliefs.

And we are not persuaded by testimony that companies have a constitutional right to cause injury or death to their fellow citizens. Therefore Consumers Union urges requiring a two or three year moratorium on advertising of new drugs, because to be frank, we really do not know how safe new drugs are, given the often accelerated approval procedures now in place.

We support preapproval of all DTC, and direct to provider, ads, before they are presented to the public and providers, so as to end the long, long, long history of misleading advertising and marketing that overstates benefits and understate risks.

And if preapproval is not possible, then there should be substantial penalties for misrepresentation of the safety risks, so strong that companies will want to have preclearance.

Washington Legal Foundation this morning was complaining about you all pushing back on some ads. Congratulations. Congratulations for standing up for the public interest.

We endorse, we hope the administration in its new budget might endorse S. 930 by Senators

Grassley and Dodd, requiring that ads for those drugs approved on condition of further studies publicly state those safety concerns that are identified and are being investigated.

Hopefully that would speed up the day that companies actually do those studies.

We support legislation giving FDA civil monetary penalty authority to effectively endorse truth in advertising and penalize repeat offenders.

You should require, we think, an addition to all DTC ads, a note that all adverse reactions should be reported to your physician and the FDA at MedWatch, and give the toll free telephone number and website. As you know we're getting about one to 10 percent of probable reactions out there. We should encourage more awareness of this tool.

And we believe that if and when Paducah is reauthorized in 2007, enough resources should be dedicated to review of ads so as to make the program truly effective.

We would support the device makers' testimony: You need resources to look at device ads. Resources to look at Internet ads. As Dr. Day

noted, the adverse effects are often several clicks further away.

And once that legal authority is clarified, the genetic testing kit testimony of yesterday would be a good thing to take a look at.

We think we should develop a system where - which drug manufacturers might support, a public service announcements' fund, perhaps run through a foundation or a group that would give completely objective advice. The material might be reviewed by AARP or NIH or even FDA for objectivity, and raise the awareness on these under-diagnosed illnesses, depression, hypertension, cholesterol.

But when the companies try to do it themselves, as we've heard from several others, as I think Professor Day pointed out, it sometimes quickly gets less than objective, and less than useful.

These are Consumer Union's positions. Listening the last two days, I'd like to add a personal one, and perhaps I could find some money at Consumer Reports to help pay for it.

But the next time anybody does a poll of how much Americans like drug ads, could the question

also be asked, would you rather have drug ads, or would you rather have the companies save the advertising money and lower prices or save that money and put it to research on new life-saving drugs? You might get some interesting answers.

A moment more or two on the moratorium idea. Here is an ad from a patient database company that appeared about two months ago in a newsletter read by many in the drug world. And it reads, how many prescriptions, how many weeks in market, until you are confident that your drug is safe.

If you showed that ad to the average consumer on the street, they'd be pretty shocked. They assume and expect that FDA-approved drugs are safe. Vioxx, almost weekly headlines for the past two years, have shaken that confidence. But the average consumer doesn't think that they are the guinea pigs of this ad, the sort of Emperor has no clothes ad, correctly describes.

And the only way to mitigate the damage of quick approval of drugs, tested on a thin population base, is to ban mass advertising for the first two or three years after they have been approved.

Therefore, we support Senator Dr. Frist's call for a two-year moratorium. Congressman Sherrod Brown (phonetic) has a two-year moratorium bill. Representatives Joann Emerson, Rosa Delara, have a three-year bill.

We support any and all of those, and hope that you would encourage that.

On the issue of preapproval of ads, Consumer Union has been working on the issue of drug ads for a long time. Our 2003 magazine report on it details our analysis of FDA regulatory letters for a five-year period. We are about to update that, and will have a new issue out in a couple of months.

But we found a broad and disconcerting range of misleading messages, ads that minimized the product's risk, exaggerated its efficacy, made false claims of superiority over competing products, promoted unapproved uses for an approved drug, or promoted use of a drug still in the experimental stage.

A reading of recent regulatory letters seems to indicate a welcome upturn in strong warning letters, for which we congratulate the FDA. We particularly appreciate the emphasis on ensuring

that the risks of a drug are given more prominence.

But it appears the overall level of policing and promotions may be still down from previous decade, and that nothing in particular has changed in the type of abuses detected.

Companies are repeatedly warned about similar violations, and all too often after the ad campaign has ended, and public damage done.

In our 2003 report, we noted that the maker of Claritin had received a total of 11 regulatory letters about problems with their ads. How can people smart enough to make such a good pill do such a bad job on ads? I guess their scientists are better than their lawyers, but it's absurd on its face, and it gets the strong impression that the industry is just scoffing at the requirements.

As somebody has said, I think it was an FDA person, that the FDA is just playing a game of whack-a-mole, and we need to do better.

This disregard for the rules and regulations is why the law should be changed to permit imposition of major civil monetary penalties, particularly on repeat violations.

And if you decide not to proceed with

requiring preclearance, again, I hope the disciplinary action could be stronger.

The rest of our written statements, the statement for the record, makes some other points. Mostly, you are going to need some more resources. I hope all friends of FDA would be lobbying this fall not to have an across-the-board one or two percent budget cut. That's not helpful.

But in the long run, I think you do need more resources, and Paducah would be perhaps the way to do it, we hope not tied to specific timeframes of specific actions, but give you resources to flexibly do your job.

And in conclusion, there was one press report this August about this whole meeting, that this is the beginning of a process that might take four years.

Ladies and gentlemen, we fought World War II in less than four years, and hope that there is a greater sense of urgency, and that you will make regulatory changes and support legislative changes on a much faster timetable.

We believe that faster action will help prevent or minimize further Vioxx-type incidents,

with their attendant deaths and injuries. We thank you for your consideration of these recommendations that we believe will help improve the quality and safety of health care here in the United States, and moderate the rate of health care inflation.

Thank you.

MR. ABRAMS: Any questions from our FDA panel?

Okay, Mr. Vaughn, thank you very much for your presentation.

That concludes panel eight. I want to thank all the speakers.

(Applause)

MR. ABRAMS: At this point we will open up the floor for comments.

We will start off with the sign-up sheet. We have one person signed up so far, Gregory Abell from Dana Farber Cancer Institute. If you would come up to a mike.

MR. ABELL: So my name is Gregory Abell, and I am a fellow in hematology and oncology at the Dana Farber Cancer Institute.

I have three comments, and I want to just stress that these are my personal thoughts and

in now way represent an official position of my institution.

The first comment is that as a policy trainee, it's been amazing to see this conference take place. I think that the FDA and DDMAC should be applauded for soliciting commentary and input from the very constituencies that will be affected by the regulations that will come from the organization.

And we have made a lot of comments. However, we are one of the only countries that has direct to consumer advertising. And while we are unique among nations, I also think that we are unique among nations in having a commitment to this kind of openness with our federal agencies. So that is my first point.

The second point is that I would argue that oncology patients are a special population in terms of direct to consumer advertising. There are two reasons for this.

The first is that despite advances in cancer medicine, there doesn't seem to be in medicine a diagnosis that inspires more dread or fear or desperation than a cancer diagnosis.

And I think that cancer patients are especially vulnerable to advertisements that are aimed at them. And for this reason we need to be very careful in scrutinizing advertisements for cancer-related products and make sure that they do not manipulate this sense of dread for marketing purposes.

The second reason for that is that chemotherapy - I know this having been a clinical fellow - is very complex to give and to explain to patients in terms of benefits and risks. Many hospitals, most in fact in this country, don't allow the majority of their physicians to administer it, only physicians that have become board certified in oncology.

Analogously, advertisements for chemotherapy that are in the general media I believe should have a higher level of scrutiny to make sure that they are in fact providing fair balance.

And my third point relates to Dr. Frist's suggestion that there be a two-year moratorium on direct to consumer advertising for products once they are approved.

I am not sure that that is appropriate

in terms of cancer medicine. Two years is longer than the natural history of many different types of cancers, such as stage four lung cancer, or pancreatic cancer, and may in fact be too long for patients to gain the possible benefits of direct to consumer advertising in terms of education.

I think in lieu of this, again, heightened scrutiny by DDMAC of advertisement for chemotherapeutics is in order, and perhaps the creation of a special division of DDMAC with expertise about chemotherapeutics, cancer biology and also cancer psychology of cancer patients.

Thank you very much.

MR. ABRAMS: Thank you, Dr. Abell, for your comments. Any other individuals wish to speak to public comment from the floor?

Okay. Well, this has been a very full meeting, and one I think that has been most productive. We heard from interested parties about many aspects of DTC including presentation of risk information - much discussion about risk and how it should be presented and what should be presented; various ways of presenting benefit information; impact of diagnosis and treatment; under-treated

medical conditions; how does DTC impact that; data from research conducted related to DTC.

There was discussion about new regulations possibly being generated for DTC. Use of celebrities in this type of promotion. A lot of discussion about consideration of consumer friendly language being used for DTC.

Use of disease awareness by companies, some discussion of how image and different graphics and their impact on promotions, and reminder advertisements.

These are just a few of the discussion items that we had in the past two days. So I think it's been a very full meeting with much information and many discussion items.

FDA wishes to thank all the speakers for the time that they took in preparing their presentations, and the time that they took presenting, and replying, to all the questions from the FDA panel.

So we thank you.

FDA wishes also to thank the attendees, the audience, for your participation and your interest in this very important topic.

The docket will be open for any comments that you may have, any additional comments, and any data from research that has been conducted.

We encourage submission of this information.

FDA will now carefully evaluate the presentations and the comments made in this meeting; will go over the transcripts when they become available; will go over all the information that is submitted to the docket; to determine the next steps for activities in this area.

I don't know if anybody from FDA panel has anything to add to these closing remarks, but I invite anybody to add to my remarks.

MS. BEHRMAN: I'd just like to echo what Mr. Abrams said about putting information in the docket. Dr. Abell, you mentioned a topic that we had brought up in the notice, but you were the only one who picked up on it. So comments into the docket are very helpful for us to be able to follow up on the sorts of concerns.

Thank you.

MR. ABRAMS: That is a good question. Rose? February 28th will be when the docket closes.

Okay, we also wish to thank the folks who put this together, the folks behind the scene, particularly Rose Cunningham of Cedar, and thank you to Bob Grisham (phonetic). Thank you.

(Applause)

MR. ABRAMS: And Rose, you have some folks with you.

MS. CUNNINGHAM: Yes, I'd like to thank Kathleen Quinn and Michelle Lackner for their assistance. They helped answer any questions you had out at the front, and helped get things moving while I was in here. Thank you.

(Applause)

MR. ABRAMS: Okay, this hearing is now adjourned. Thank you.

(Off the record.)