and they're really making sure that you're not saying more than what is known about your drug, and maybe kind of cutting into their territory.

So I think that around that we get some. I think that television advertisements are another thing that we look at. Because those are so visible, you're likely to get more complaints, and from consumers, too, that's one of the types of materials that are complained about more.

But as far as what consumers complain about, and what health care professionals complain about in terms of, you know, which drugs, and what types of pieces, it really varies. We do review every complaint that we get, and if, you know, based on what's identified in the complaint, the issues that are raised, we think that that has merit, we will go look at the pieces, and try to see, you know, what we can find, and some of them even come in with the pieces. So it

takes some amount of resources, but we want to really make sure because, you know, that's somebody reaching out to us saying, hey, there's this problem. We want to make sure we look into that, and do something, if appropriate.

DR. HUNTLEY-FENNER: Just to be sure, you wouldn't necessarily short change the resources you need to sort of track down whether risks are being communicated effectively in order to address a specific complaint that may not have to do with a risk that's been identified?

MS. DAVIS: Complaints about something other, or just other work on making sure that risks are communicated, versus addressing a complaint, is that the question?

DR. HUNTLEY-FENNER: Correct.

MS. DAVIS: I think that our priority list, risk communication, and especially if a problem has been identified, or, in promotion, or if there's some new

safety labeling update, or something that we need to work on to get new risk information out, that's number one and two in our division. So complaints would come after that.

So it might take us longer to get to them. We still have a goal of looking at every single one, but we wouldn't work on it over risk disclosure, if those were the two choices.

DR. HUNTLEY-FENNER: Thank you.

DR. PETERS: Thank you, by the way, for telling us about the provisions. Particularly, I was glad to see the 503 pre-review provision, and this idea that that impact does make a difference.

One thing that I was surprised to see is that the FDA has no authority to require any changes, though, and that, to me, is somewhat surprising, but also, to me, without a consumer's ability to take in the information, to understand the information,

and to use the information, which may be separate things, it's not information yet. It hasn't been provided yet, in my definition of it.

And so I was curious about, pragmatically, given that the FDA has no authority, pragmatically, what do you think will happen in this process of pre-review?

MS. DAVIS: I think one thing is, although we don't have the authority, and that's for reasons that relate to kind of concerns about first amendment, and basically requiring, you know, kind of like pre-approval, versus just giving advice before an ad goes out. So although we don't have the authority to require changes when we're just looking at something in draft, we can't mandate the way that a company has to promote its product.

We can give them the recommendations, and then what happens next is, if they ignore every one of our

recommendations, and some of those were about kind of actionable issues, if this really is not clearly communicating risk information, we can take an enforcement action, and after that it's not about, you know -- an enforcement action asks that they pull those pieces, work with us to develop new ones. So in the period where you're still in draft, the agency, because of First Amendment considerations, has limited authority as far as actually saying, you know, this is exactly what you have to say, because it's more of our role to give them advice on how to comply, how to meet these considerations, and then the company can, you know, do that in any way that complies with our advice.

We can't be prescriptive as far as what they need to say, but then, you know, the other thing to always keep in mind is if there is something out there actually being shown to the public that does violate the act, the regulations, we can do something about it.

MS. LAWSON: This is about the report, and I know that the Committee has the responsibility to make recommendations about the DTC impact on access to health information, and how important, or what kind of influence it has on addressing health disparities.

But I'm also interested in knowing what team or staff is in place that also will be monitoring this process, and will have input into the overall report to the Secretary and to Congress.

MS. DAVIS: Sure. I think that the kind of primary team is our working group on drug advertising, and as I was mentioning, that has members from a lot of different disciplines within FDA, from the people that actually are reviewing and approving drugs, from people that are monitoring for risk, people that work on, you know, regulatory policy, other centers. We, you know, are going to have consultants, too, from other

groups in the FDA working with us on that. So that's sort of the group that has the primary responsibility for putting pen to paper, but what we're hoping is that we'll also get a lot of input to the docket that we've opened that will inform that group's decisions, and then, you know, another huge part of it is, obviously, the meeting here today, what we're going to hear, what recommendations you might have, you know, suggestions for what we should look into.

There's a lot of expertise obviously on this committee about, you know, places we might look, things to take into account. So that's the group that's going to, I think, you know, eventually be the one that's actually writing this up, but with input from all those different sources.

CHAIRMAN FISCHHOFF: Ted.

DR. REISS: Dr. Peters asked the question that I was going to ask, so I'll yield the time back.

CHAIRMAN FISCHHOFF: You have a rain check.

DR. BRUHN: I just wanted to clarify the target audience. We all caught the 65 or older for elderly. I like to tell audiences it's even younger than that, but I was wondering about the children aspects. It seems to me, if one is going to communicate to children, it does need to be children and their parents or caregivers, at least for the young stage, but what about teenagers? Are we counting adulthood at 18?

And it seems that communication to a teenager may involve, you know, a distinctive audience, and a distinctive approach itself, as opposed to a younger child, or child and parent set.

MS. DAVIS: Well, first, I think that your recommendation on that it should include children and their parents, I think that's a really good point, but as far as the populations, what we have from Congress is

just what's up there, the children and elderly. The other distinctions I made, because when we are looking at these ads, is kind of what the agency looks at, and what's the pediatric population, and what's the geriatric population, and those are groups that are actually reflected in the labeling, you know, in the special populations section.

And the agency in those sections defines children, or -- I'm sorry -- the pediatric population, as 16 and younger, and then the geriatric as 65 and older, but certainly, when you're looking at this requirement, the children and elderly, I mean, there's room for discussion about, you know, does that exactly track what's in the FDA labeling regulations.

DR. GOLDSTEIN: Again, I want to thank you and the others for this information. It's really helpful for us if we're going to be providing advice about the report, and other items.

As a request, I think it would be really helpful to have some in depth individual case studies to look at. It's great to hear about, in general, how this is being approached, and some specific data which we'll hear about about the impact of some of the questions that have been raised. It would be really useful to have some case studies, so that we can see the process that FDA goes through, we could see how there's an interaction between the FDA and industry, and what impact it then has on the population.

So I just make that as a recommendation for us. If we're really going to be able to be helpful, it would be nice to see some specific examples in how it plays out.

MS. DAVIS: As far as following kind of an individual promotional piece through its impact, or the process of this report, or just to clarify, what --

DR. GOLDSTEIN: The process of

looking at a specific direct-to-consumer advertisement program, not just an individual one, perhaps, but when a drug is being marketed, and there's direct-to-consumer advertising, and there's direct-to-consumer promotion, and there's also -- we can look at the whole package of materials that have been put forth by industry, and see how the FDA has responded, and what impact that's had. It will help us to advise, if we can see a prototypical case study.

MS. DAVIS: Just one comment in response to that. I think that, I can definitely see how that would be interesting, and after FDA does comment, or somehow reviews a piece, and it goes back to companies, and then it's run publicly, and the people that would have the information about the impact, and maybe who it targets, would really be the advertiser.

So I'd like to make a plug, if there's any members here that do have that

kind of information, that's exactly why we have that docket open. We'd really like to have, you know, the what happens next piece of things, and that's the one thing FDA can't really speak to about direct-to-consumer advertising. We're using our own health information communications as kind of a surrogate, because that's something that we can track, but we love to get that kind of information.

MS. MAYER: I know there has been recent concern about the length of time that it's taken for violative ads to be withdrawn, or to be reviewed at FDA prior to their being withdrawn, that that's taken up to eight months, during which time the message has already been transmitted, and I'm wondering if this provision for pre-review of ads, if you anticipate that this is going to somehow change that, even though it doesn't have teeth, so to speak, in terms of your own process.

I mean, theoretically, at least, it looks to me as if a company could go ahead with an ad that misstated its claims, and then, you know, that ad could be distributed for a number of months before any action could be taken.

So is there any way in which this will dynamically change that process?

MS. DAVIS: I think, as far as TV ads, which, although they have a big impact, are, you know, a small overall percentage of all the different pieces, it can have that kind of impact, but one of the things to note is we do spend a lot of time, a lot of our resources working on similar provisions that are voluntary as far as providing advisory comments on draft pieces before they go out, because the best outcome for everyone is that what initially goes out to the public is accurate, not misleading, and rather than trying to take action after it's disseminated, for, you know, most pieces, that is voluntary,

but this does give us, for TV ads, the authority to require them to be submitted, and although the recommendations are just recommendations, our experience has been that, you know, most companies do take those seriously.

CHAIRMAN FISCHHOFF: Mona.

DR. KHANNA: A follow-up question to that. According to the GAO report in our materials, while direct-to-consumer advertising has increased in any time period looked at, i.e., 2005, 2002 to 2005, 2006, 2007, the number of letters, regulatory letters that the FDA has issued, has gone down every single year.

Now, is that a result, do you think, of this increased vigilance at the front end of the ads that the pharmaceutical companies and/or device companies will be running, or is it a result of the lack of work force of the FDA, or exactly what?

Because it seems kind of a non-

sequitor that the number of DTC ads are going up, yet the number of ads cited are going down.

MS. DAVIS: Without kind of an end to compare this all to, without being able to look through every piece that's disseminated to consumers, and say, there were this many that were misleading, and these are the ones we got to, it's hard to say whether they've become more compliant over time. I think that, when you're looking at the number of enforcement letters, it's part of the picture, because another part of the picture is the amount of materials that we get submitted for our advisory comments, that pre-review where we are providing them advice, and hopefully fixing problems before they go out there. That's also increased every year.

So we do spend a lot of resources on that, and the, you know, amount of resources in the groups that regulate advertising, you know, probably haven't gone

up as much as the pieces have. So there's definitely, I mean, there's always a resource issue with everything, but I think that another piece of the picture to really keep in mind is that we spend a lot of our time, and we get more and more requests each year for advisory review, and, you know, the best case scenario is for things to be good when they first go out.

DR. KHANNA: Just a quick follow-up. According, again, to the GAO report, the FDA issued four violative letters in 2006, and only two in 2007. That seems to me a really small amount considering the fact that we're here discussing the issue.

MS. DAVIS: Well, a couple of things to keep in mind. The overall amount of enforcement letters stayed relatively stable over those years, and although those were the ones directed specifically to consumer pieces, when we're citing these letters, we're asking companies to discontinue, you know, all, same,

or similar claims, and when you see these campaigns, although you might pick the professional piece, the professionally directed pieces representative of all the issues that you're seeing, usually, that's spread across the consumer campaign, too.

So I think the impact of these letters, in terms of stopping false and misleading promotion, is across audiences, even if the representative piece that's discussed in the letter doesn't get to both of those.

You know, another thing, though, to just be aware of is, in 2007, one of the things that was going on, although our user fee program wasn't able to commence, we were operating from October 1st until December 31st as if it had, because we were just waiting for the authority to collect fees, we hadn't had increased resources yet, but we were under this clock.

So, there were a lot of resources

going to that in one part of the year, too, and a lot of times, what happens is you get increased resources that you can go hire for, but it can take a while to actually have them, you know, show up for work just, you know, with the processes in place.

So I think that that was kind of representative of the different forces at work that year, but it is important to keep in mind that all enforcement letters usually impact promotion to all audiences for that drug, because it's usually not an isolated issue.

CHAIRMAN FISCHHOFF: Okay. We have Linda, and then Ted, and then I have a question, and then we'll be sure to get in the next presentation before the break.

DR. NEUHAUSER: I have a question about the expertise of the people who actually do the review. Could you comment on that, with respect to both the content itself, and also the issues brought up here about what constitutes good communication? So expertise

in the area of understanding risk, of understanding communication to people, different literacy levels, et cetera.

MS. DAVIS: Sure. My division, DDMAC, the Division of Drug Marketing Advertising and Communications, the way it's set up is there's usually, you know, a primary reviewer for different therapeutic areas, and they have a kind of health care professional background. A lot of them are, you know, Pharm.D.s, nurses, doctors, and so they have a lot of information about the drugs, you know, what's known about that, what those drugs do.

We also work closely with the medical review divisions that actually approve the drugs for questions about the level of evidence. So that's kind of getting at the scientific content of the claims.

Another group that we have is we have social scientists, one of whom is going to be addressing you tomorrow, Dr. Kit Aikin, and there are experts on communication issues,

and we also have regulatory counsels, which is what I used to be. So they kind of give input on the different rules and regulations when we're looking at, you know, what we can say about problems in a promotional piece.

And so we kind of bring together a lot of different disciplines, and it's very much a team review approach, so that we do get the benefit of communication, insight, drug knowledge, you know, regulatory insight, when we're looking at pieces. We don't kind of look at them, you know, one person in isolation.

DR. NEUHAUSER: And when you do your review, your pre-review of TV advertisements, do you look at closed captioning, and if you do, do you follow certain criteria for quality of closed captioning related to the ad?

MS. DAVIS: When they come in for a pre-review, the ads, a lot of times, there's no requirement, necessarily, that they even

have, you know, the final video yet. It might just be a story board. It might be an animatic, and what we usually have is we just have the text that's on the story board. We don't see the closed captioning version. So although we're looking at, you know, everything that appears on the story board, and we're also, if there's a tape available, hearing how it actually conveys when it becomes an audio. And, you know, we do look at the superimposed text on the screen, but as far as the actual closed captioning, we don't usually see that.

DR. NEUHAUSER: Okay. Well, just one comment. You asked about what happens next. I would suggest looking at the FCC regulations for use of closed captioning over emergency preparedness information as required on television. And that, I don't want to go into depth on that, but it does have provisions about not putting closed captioning over key parts of written information on an

advertisement. So that would be something I'd suggest pursuing.

MS. DAVIS: That's a really good point, and I can't say I've thought of that before.

DR. REISS: Thanks for the very nice presentation and discussion. I just want to probe again for a second the word that we were discussing before, impact, if we could, and get back to sort of maybe what the intent was, and what you guys' interpretation of the intent is. It's probably the term that you used, but there's a concept behind it maybe. Is it the more limited concept of effective communication to, or the broader concept we were talking about before of the health benefit to?

MS. DAVIS: Unfortunately, you know, again, we don't have much as far as what Congress was intending here. I can say that, when what became this provision in the legislation was originally proposed, this and

the other parts in Section 901, the pre-review, it was prefaced with a sense of Congress provision, that that really talked about more making direct-to-consumer advertising a clear and reliable communication tool for these populations.

It didn't talk about, you know, and then the impact on, you know, health disparities, but the report does mention that. So I think there's at least some of that idea about, you know, once you communicate action being taken that can actually improve health, but we don't have any more to go on than what's there.

MS. MAYER: So the literature suggests that the way in which people receive information when they see an ad on TV is really more than just the script; that it's a combination of the visuals, and what they hear, and even the emotional content, and the way in which, even the timing of the information.

I don't really understand how, if you only review a script or a story board, you could really get a full picture of whether the risk information and the benefit information is well balanced in your preview.

MS. DAVIS: And that's a good point, and the honest answer is that we don't, and we always say that in our letters, but the reality is, a lot of companies want our advice on the script before they actually spend the money filming the ads.

But what happens next is, a lot of them will then submit the actual video for our comments, not always, but that's when we look at those factors, and certainly we look, once they're publicly disseminated, at those kind of issues, but that's a very important consideration, because you can see things, and the words can look fine, but when they play out, it may be that the visuals are so distracting that it doesn't matter. You're not getting any of that.

The music may be too loud. The superimposed text may be too small to read. So all of those things are things we look at, but if companies first want our comments on the story board, we do provide that, and then, you know, we encourage them, and we hope to see a video, but there's no requirement. It's all a voluntary process.

CHAIRMAN FISCHHOFF: I'd like to ask, I guess, a legal question as a non-lawyer. Is the communication considered part of the product?

And my thinking is, if, in the end, we're concerned by the law, and in general with how it affects people's health, the best evidence that we have on the effects, the impacts of any risks and benefits of any drug, come from a clinical trial in which the physical product is bundled with a communication regime. Certain people are recruited; certain people are excluded; certain reminders are given in terms of how to

comply with the usage. Certain facilities are made -- provisions are made for two-way communication about side effects, and so the impact with another communication regime one would expect to be different for all of the reasons that we have here.

So it seems like, de facto, the communication is inseparable from the physical product. From a legal perspective, is the communication part of the product, or is that one of those --

MS. DAVIS: Well, I think that the approved product labeling, what you're talking about, the directions, and how to actually use it, that should travel with the product, that really is, you know, it's the product and that, and they travel together. But what these other promotional messages do, I don't know if I would say that they become legally kind of part of the product the way the approved product labeling is, but what they do legally is they can push it out of compliance

with the act, because what we're always looking at is, have you kind of misbranded your drug, and one way that you can do that is, in your promotional messages, say things that approved product labeling doesn't have adequate directions for.

So if you're saying, it's like we work in this population, and then when you go back to the drug, and that approved product labeling, and there's nothing in there about how to use it, or that reflects that it does work in that population, you're now out of compliance with the law.

And similarly, if you're saying, you know, we work in 96 percent of patients, when your approved product labeling only reflects 80 percent, you've now pushed it out of compliance, because you've basically said something that's not accurate in light of what's reflected in that product labeling.

So your approved product labeling that travels, you know, with your drug, that

gives the directions for use, that's always what you can't -- you can't be inconsistent with that. You can't promote things that approved product labeling wouldn't tell practitioners, you know, how to use it for that condition, for that population. So in that way, those things all interact, but it's really the approved product labeling that is the thing that's always with the drug, if that makes sense.

CHAIRMAN FISCHHOFF: Yes. So in terms of my formulation, the evidence that is in the approved product labeling comes from a clinical trial in which the drug was bundled with the communication regime, which probably didn't have -- couldn't actually have had the clinical trial information.

So the bundling that's required is not the bundling that was present at the time that the evidence was produced. So given that this depends on people's behavior, you know, do the right people get the drug? Do the

wrong people get the drug? Are we missing risk? Are we missing benefits? Do people know how to monitor, you know, their situation?

The behavior should have a large effect on how well people use it, even if there's no falsehoods, but if the people don't have the communication equivalent to that in the clinical trial, then something is using a different product. That would be my non-legal interpretation.

MS. DAVIS: I think that the idea, hopefully, is that, when you get to the point, you know, where you've done all of your clinical trials, and you're working on that approved product labeling, is hopefully the distillation of what you learned, how you used it, what your clinical trials reflected. But you're right. It comes after. So it can't have been used during the clinical trials.

CHAIRMAN FISCHHOFF: Let me thank you on behalf of the Committee. You've been

very helpful.

MS. DAVIS: Sure.

CHAIRMAN FISCHHOFF: And I assume you'll be here for the rest of the day.

MS. DAVIS: Yes.

CHAIRMAN FISCHHOFF: You may be hearing from us again.

So let me sort of apologize to Andreas Lord, who has a summary of the research literature looking at these topics, and there were several requests from here to be sure that that literature appears.

So we'll hear that presentation, and then we'll take our break, and then we'll have an opportunity to have discussion later on.

MR. LORD: Hello. I'm Andreas Lord. I'm from Eastern Research Group in Massachusetts.

I'm grateful to be here today, and I'm humbled by the last two presentations, and I don't really know if I'll measure up, but

here it goes.

I do have some data to present on research that's been done in this area. Since March, we were asked by FDA to look into literature that's been produced on various aspects of direct-to-consumer advertising, and this is some data relating to the population subsets that were mentioned.

The question arose, who were the underserved populations of the population subsets, and a short list is here. The note at the bottom indicates that there's somewhat limited research on impact of DTC on children's health. I can say there's a slide later on that addresses this. The prevention study of 2004 did indicate that 40 percent of children's caregivers were inspired to visit a physician by direct-to-consumer advertising, and that's as opposed to 18 percent of the rest of the population of caregivers. So there is an impact, at least on parents and other caregivers of children.

The list of the top 20 pharmaceutical products advertised in 2005, making up approximately 56 percent of the expenditures on direct-to-consumer advertising. There's a couple of ED drugs, antidepressants, arthritis pain killers, and anti-allergens.

Just for reference, the populations that we're talking about are pretty substantial. Based on the 2006 census of approximately 299 million population, the adult population, as you see here, the population of elderly and seniors, there's a data point later on of 4.1 percent of people over the age of 75, or 75 and older requesting a prescription drug from a physician, which translates to, it looks like approximately -- well, actually, it's over 60 years. It's approximately two million people.

The data point at the bottom, 8.7 percent of the population speak English less than very well. That's the Census' phrasing

on that, and it does get addressed with regard to one study on the presentation of DTCAs to less than literate English speakers.

Household income data. I should say that these population subsets and underserved populations obviously overlap. I mean, there are people with low incomes who are college graduates. There are certainly people in all of these groups that don't necessarily qualify on all of these levels.

Data on non-high school graduates by education level, and these are pretty much for reference as we present the data later on.

Now, in looking at this data, we decided to do it in a fairly simple format, that is, we looked at the data that's been produced in the somewhat limited research on the underserved or population subsets, and then compare that to date that's been produced for the population at large, and ask the questions whether there are differences in these aspects of direct-to-consumer

advertising in exposure to attitude, comprehension, and behavior.

So in the general population, the prevention survey, and the survey by Murray and colleagues, we start to see that the exposure to these ads is reaching saturation point, or some kind of asymptote over the years. There may be some small percentage of people that don't read magazines, and don't watch television, or listen to radio, that haven't seen them.

The 83 percent is somewhat of a low point. That's referring to people that have seen them in the last 12 months.

Now, with regard to people in the elderly or more mature years category, this looks pretty comparable, too, that a large, very substantial percentage, comparable to the general population percentages, have been exposed to these advertisements.

Some more data on this issue. The Kaiser study that came out this year, Consumer

Reports from this year, the 81 percent a little lower than some of the other numbers, because it's referring to just people that have seen an ad in the previous 30 days.

This rather important study, by Allison-Ottey and colleagues in 2003, they interviewed African American patients inside doctors' waiting rooms, people who were actively consuming medical care, and they found that 76 percent of them had seen a DTCA in the previous two months.

Now, so what do people do after they see the ads? Well, there's obviously further research on what they do in the doctor's office, and the prevention results show these 32 percent of exposed consumers discussed the DTC drug with the doctor. They distinguish this from the 8.3 percent of that who actually ask directly for a prescription.

And this is a distinction that they made very directly. Some of the studies don't make that. They assume that, if someone is

talking about a drug, it's the same as a request for a prescription, and this study by Murray, this is a bit of an outlier here, 12 percent, a relatively low percentage.

With regard to the more mature elements of the population, here we see the numbers are somewhat lower, 27 percent. Talk to the physician, and this is the same prevention study that you see on the left, half as many of them as in the general population asked directly for a prescription.

This Barrett study is somewhat of an outlier, also. This is for the American Association of Retired Persons, and that number might be actually a little lower, because it addresses people who had taken a prescription drug in the last year, or five years, I think, but in any case, it also includes a lower age element there, and in some of the surveys, the drop-off of people who respond to the advertising occurs at about the 60 year mark.

The Datti and Carter study showed that five percent of people 75 and over ask their physicians about a DTCA drug. This compares to 6.1 percent of the population at large that is that age group. So it's a somewhat lower percentage.

Now, in terms of education level, the Murray study showed that, apparently, education level relates to not responding to direct-to-consumer advertising. We see in that same study, 58 percent of non-high school graduates scheduled a physician visit in response to an ad, as opposed to 22 percent in the more educated element of the population.

In the Kaiser study, 32 percent of exposed subjects asked the physician about the specific drug they saw advertised. Also, a fairly substantial percentage of the people who look at the ads going in to ask the doctors.

Other consistent statistics regarding asking the physician about a DTCA

drug:

With regard to African American patients, we see that 29 percent of the patients in the waiting room, and this was actually, the actual statistic for people who had seen a DTCA ad was 34 percent. The 29 percent is of the entire set of the patients said that they had once asked a physician for a DTCA prescription.

And actually, I believe in that study, 21 percent of the people that they interviewed were there to talk to the doctor about an ad, a drug they had seen in an ad.

And in the Datti and Carter study, they calculated that the odds of an African American requesting a drug was 58 percent higher than survey counterparts.

So now how do physicians respond to these requests? They respond pretty well. Eighty-four percent in the prevention study granted their request. Fifty percent in the prevention study. Again, this is the

distinction between people who discussed a drug, and people who asked directly for a drug that this study made, but even at the level of discussing the drug, half the patients were given a prescription.

In the population subsets, people over the age of 75, five percent of the subjects who were given a prescription, were 75 years of age or older. This same percentage has asked for a -- among the group that asked for a drug.

And similarly in Barrett, also a consistent percentage among the elder population, or at least the over 50 population, consistent with the prevention study. So there's a consistent response there.

Among graduates' education level, we see that non-high school graduates actually get their requests for an intervention. That's how these researchers defined the physician responses. This was different from

actually requesting a prescription. They could also be requesting blood tests, or other testing in response to advertisements they saw, and apparently, the statistic is half the non-high school graduates had their requests fulfilled, as opposed to the high school graduates and higher.

And the other statistics from the Murray study, you can see there that fewer than half of the non-white subjects requesting the similar intervention received what they requested, as opposed to the white subjects.

Now, among the African American patients who had ever asked for a DTCA drug, 28 percent of them received a prescription, and this is a statistic that can compare to the 50 percent, or the 84 percent in the prevention study, the 50 percent of people who had discussed drugs, and some of the higher statistics in the earlier slides, and the Datti and Carter study shows that the odds of African American patients receiving the drug

they wanted were significantly lower than the rest of the subject pool in that study.

Now, trying to put these figures into some kind of context, this experiment, very remarkable experiment by Kravits and his colleagues back in 2005, sought to control one element of the doctor-patient relationship, and elucidate what went on there. The experimenters actually trained actors to pose as patients, and go to the offices of about 158 doctors, and mimic the symptoms of either clinical depression or adjustment disorder, which is a mild form of depression that's usually suitably treated with therapy, or a follow-up visit by a physician.

The clinical depression is suitably treated with a drug, a prescription drug. Now, when these patients, what Travis referred to as standardized patients, went on these doctor's visits, they were basically in three experimental conditions: one asking for a drug, one asking specifically for Paxil, and

one just describing symptoms, and not asking for any specific treatment.

The results here for the standardized patients who asked for a non-specific drug, pretty appropriate. Actually, the figure for people who didn't ask for anything here -- I'm sorry. The figure here for people who are suffering from clinical depression, 76 percent received the appropriate treatment, but 39 percent of those with adjustment disorder received a prescription that was arguably unnecessary.

Now, the standardized patients asking for Paxil, actually, a lower figure of those who asked for the specific drug received the appropriate medication. The people complaining of adjustment disorder and asking for a specific drug actually received a higher percentage of the medication, or I should say a higher percent of those asking received the medication, and overall, now Kravitz looked at this.

Now, I just wanted to bring this up, because these figures are very consistent with the figures that were found in these surveys for the population at large, upwards of 84 to 40 percent of patients requesting drugs, requesting a DTCA drug receiving a prescription.

This further observation by the experimenters included patients who did not request any drug, and now this actually, each of these bars mixes the two groups. These are both the clinically depressed, and the adjustment disorder patients, and Kravitz wanted to look at how many of these patients received some minimal form of acceptable treatment, and it turns out that the patients who asked for Paxil got some form of treatment 90 percent of the time.

The patients who asked for a nonspecific drug got some form of treatment 95 percent of the time. The patients who made no drug request were treated 56 percent of the

time, and this is in the context, just to be looked at in the context of -- what we can conclude form this, perhaps, is that people who ask for drugs tend to get treatment.

Now, perception of risks and benefits. Again, the literature on this is a little spotty, but I draw your attention to this with the wheel here. The Young and Oppenheimer study of risk perception among consumers. Now, as it turns out, when risk is described, now, this says, when no risk data is given. But by data, we mean numbers here. They actually presented risk in terms of expressions, such as, some people experience headaches when taking this drug.

And when subjects were asked to give a percentage of the likelihood of them experiencing the side effect, the means were up to ten times the actual rate of the side effect.

When they do present the numerical data, the experimenters found that having the

numerical data correlates to a lesser fear of taking the drug, and a greater intention to comply with the drug regimen.

Now, there's no immediately corresponding statistic for any of the subsets, but this experiment, or actually survey, found that, among people who were limited English literacy subjects in Boston answered questions about risks and benefits at approximately a chance level. They were presented 35 true-false questions, and 59 percent answered them correctly at about a chance level, and the risk questions were actually answered less accurately than the benefit questions.

In the prevention survey, we see these statistics about people who believe that direct-to-consumer advertising provides them enough information to make a risk-benefit decision seems to be decreasing with high school graduates.

Well, before we get to that, I'd

just like to point out part of the prevention survey also said that seven percent of prescription drug users stopped taking their prescriptions after viewing an ad, and an additional seven percent switched to an over-the-counter medication.

It's a little ambiguous whether they did this under a doctor's care. It's unclear what percent of these people did this on their own, or with the advice or consent of a physician.

In terms of our population subsets, the corresponding figure in the prevention survey for non-high school graduates, significantly higher here, 43 percent.

This study by Schwartz and others, they presented an easier to understand black box of risks and benefits for print advertised DTCA, and found that the 71 percent of consumers with high school degrees or less actually compared very favorably with those with higher educational levels, which were in

the low 80s, I think.

Now, this study by Berry, actually, this is an English study of people's comprehension of the risks of an over-the-counter medication, and in the EU, the people are legally mandated to use the term "common" when a side effect is at six percent. The subjects here were given a little booklet describing the side effects of the medication, and then asked to fill out a form on the next page of the booklet.

So it was a fairly -- not a terribly rigorous test. Now, when they were given just the verbal descriptor common, and they were asked to estimate the rate of the side effect, it was on the order of nine times the actual rate, and when they were given the actual figure of six percent, and then asked what the probability they had of suffering the side effect was, it was close to 20 percent.

So most subjects in this study seem to see themselves as more likely to suffer the

side effects than most other people. No corresponding data for subsets, but in this study by Marinac of a senior population in Kansas City, 60 percent reported that the information was confusing and difficult to understand. I can certainly agree with them.

So in the general population, a couple of other data points from the prevention survey, the more recent prevention survey, that 59 percent of national adults do recall some knowledge about risks associated with DTCA. Risks are recited faster in some television advertisements, and actually, a substantial proportion of television advertisements.

The data on DTCA in children, not very much. So 16 percent of adults provide medical care for children with a specific condition. ADD and ADHD account for a majority of this. The other conditions that are substantially represented are depression and allergy, but those percentages are in the

teens.

So the ADD/ADHD is a substantial majority, and this I mentioned earlier; about 40 percent of the caregivers being inspired by DTCA to talk to a physician. The phrase for others was the prevention wording.

In the Datti and Carter study, they found that having a child increased the probability of going to see a doctor by 13 percent. Actually, the odds of going to see a doctor.

And this is not a piece of data here, but an interesting observation by a psychoanalyst that is a possibility, and strictly as an observation, that ads for conditions such as depression and ADHD alongside of ads for more physically based, physiologically based illnesses, might tend to de-stigmatize these disorders in the general population.

Now, I can't help but mention something about the Internet here. Now, this

information is based on a survey by PhRMA. I wasn't able to get the actual report of the survey, but the Hoffman 2007 article was from a magazine. So we really can't say anything about how the survey was conducted, but the suggestion from that is that a substantial number of people do buy prescription drugs over the Internet without a prescription, which eliminates this sort of gatekeeper role that physicians play in safeguarding the health of people looking for prescription drugs.

Now, to summarize the presentation, it's apparent that population subset C are exposed equally to DTCA as others, but they do differ somewhat in their responses to direct-to-consumer advertising. And again, this is based on somewhat scattered and preliminary data. All of this data could stand to be substantiated, but so far, it's apparent that seniors tend to request prescriptions less often, and seniors requesting prescription

medication from physicians are likely to be referred for further treatment.

This is actually a data point from the Datti and Carter study in which they said, people over the age of 75 had an increased odds of 250 percent of being referred for further treatment after they go to a physician, after they make a physician visit that's inspired by a DTCA ad.

African Americans tend to request prescriptions more often than other groups, and apparently, they don't receive the requested prescriptions as often as other groups.

People with high school or less education view DTCA more favorably, less skepticism, perhaps not a lot less, but some less, and they're more likely to agree that DTCA provides enough information to decide if drug benefits outweigh the risks.

And based on the Kravitz study, and the data from the population subsets, and the

data from the population in general, there seems to be a trend that physicians may provide treatment and prescriptions more frequently to patients that request drugs than to those who do not.

And there's also some data to suggest that consumers may overestimate a drug's risk whether given either vague or specific risk information. And I know there was a comment made earlier by one of the speakers that it's important to make sure that the advertisements produce accurate, and not misleading information. And apparently, they're not often the same thing. Apparently, it's possible to mislead people with accurate information, as well.

And the list of references for your reference.

CHAIRMAN FISCHHOFF: Let me thank you very much. That's a very clear presentation, and actually, the organization got to John's point that, what applies to the

general population, and what's different, what's different here.

We'll take a break now for 15 minutes, and reconvene at a quarter to, and if you'll be here for a little while, I'll talk with Lee about figuring the schedule for time for people to ask you questions.

MR. LORD: Sure.

CHAIRMAN FISCHHOFF: Thank you.

(Whereupon, the foregoing matter went off the record at 10:30 a.m. and went back on the record at 10:49 a.m.)

CHAIRMAN FISCHHOFF: We'll begin the next session with the opportunity to ask Andreas Lord some questions about that presentation, and then we'll go on to a panel with our consultants and then some general discussion.

So if you're willing to come back to the hot stand, I'm sure we have some questions. So let's begin with Musa.

MS. MAYER: Thank you very much for

your review of the literature. I found that fascinating.

I'm wondering if as you reviewed the literature, if you were able to find any information about the quantification of benefits and the impact on patients and on the public in terms of how well they understood the actual benefits because in most direct-to-consumer marketing, the benefits of drugs are not clear.

MR. LORD: That's true. We didn't find any direct subset information with the exception of the study by Schwartz where they developed a benefits box and a risk box for easier communication of both those elements, and they looked at different educational levels with regard to that.

Some of those surveys do ask for information on expectations from the drug, but I couldn't quote you directly any data like that. These are questions that are asked, but the accuracy of assessing the benefits is not

something I could opine on immediately offhand.

MS. MAYER: So would you say that hasn't been studied? I mean, we don't know for example if people also exaggerate the benefits?

MR. LORD: Have exaggerated expectations of the benefits?

MS. MAYER: Yes.

MR. LORD: I can't say that it hasn't been studied. I don't know that it has been studied.

MS. MAYER: Thank you.

MR. LORD: I think as I recall there are some questions in some of the surveys about that.

DR. PALING: Because I used to be European, I'm familiar with the EEC regulations to some degree. I wanted to make clear that one of your slides here related to an endeavor to put common words in some consistent probability levels.

MR. LORD: Yes.

DR. PALING: Ortheckle Berry, who I know well in England, studied the EEC regulations. I'll tell you the little I know because I think it's crucial, pivotal to what's being discussed today. In Europe -- I'll try to be really simple -- it was decided that most people, particularly of our sub-populations, only hear about risk with a descriptive word, low, high, whatever it would be.

In Europe, the words that are most commonly used are rare, very rare, common, and very common, a different vocabulary to that with which we're using words here.

And all she was doing is not in any way to throw doubt upon what the Europeans think to be the most helpful, simple, single thing that an agency can do the help comprehension of the levels or probability of risk, which is to define and limit in some way the words you used to denote a particular

probability.

MR. LORD: Exactly.

DR. PALING: And we can discuss that in more detail, but I just wanted to say that this slide which is one of your many very useful ones didn't have its context that this is the European reflection of the reality. Unless you're well educated, you won't be looking at numbers. All you'll be getting is probabilities, and a low risk would mean one in five to one in 1,000 depending to whom you speak.

And I just wanted to try and elevate the important of that strategy for trying to help this subpopulation being formed.

MR. LORD: Well, I think that's absolutely right. In fact, I'm not aware of whether there's a comparable percentage verbal dichotomy relationship in the Untied States, where there's any requirement on that level.

CHAIRMAN FISCHHOFF: Michael.

DR. GOLDSTEIN: I want to thank you two for your review and for the presentation, and I want to get back to the question I asked before about impact.

It sounds like the behaviors that have been studied are limited to behaviors that relate to asking about medication or receiving medication, and then at the clinician level whether it was offered or given, rather than looking at other kinds of behaviors like adherence to medication regimens or perhaps even more importantly follow-through with other aspects of care and treatment.

So that, for example, I'll use a specific example because it helps me. When we're talking about a treatment for tobacco dependence and the pharmacological therapy is one aspect of that, but the other aspect is also participation in non-pharmacologic therapy, behavioral intervention, for instance.

It's like the official I've mentioned before. It's very important to look at that because almost all of the studies that were done included those components as part of treatment. So to what degree does exposure to advertising, direct-to-consumer advertising affect adherence to the medication as well as adherence or participation in other aspects of treatment?

And it sounds like from your review there's little or no data on those kinds of outcomes.

MR. LORD: There's little data with regard to the subsets. There are some data points certainly. Some of the studies address other kinds of behavioral responses in the general population studied, whether it's seeking more information about a drug, effective DTCA compliance. That's covered in the prevention survey, but it hasn't been disaggregated into data that can be applied to the subsets, and that's why it's not presented

today.

DR. GOLDSTEIN: So as a comment again, I know we're going to be discussing this later; I think as a recommendation that kind of study needs -- those kinds of studies, multiple studies -- need to be done to look at the real impact on actual important health behaviors of our patients, not just on whether or not they get the medicine, which is important, but also what other behaviors are affected both positively and negatively.

MR. LORD: Well, it's a rich field for research. In fact, you mentioned case studies earlier. There was a paper by Bower, which I think is in the bibliography where they did in depth interviews with elderly patients in Nova Scotia and examined a lot of their behaviors with reaction to direct-to-consumer ads and what they consider to be the most important elements that affected their decision making.

DTCAs actually ranked very low by

their report, but sometimes self-report isn't the best estimate of what determines behavior, but it's difficult to quantify information from these kinds of case studies, but it can often be very provocative

DR. PETERS: I had one comment in response to Musa and then a question.

First, with respect to Ms. Mayer, you asked about whether benefits were also overestimated. There is a paper by Woloshin, Schwartz and Welch back in 2004 that does suggest that perhaps they are overestimated because if you give them the numeric benefits, people are somewhat less likely to take the drug. In hypothetical I believe it was though.

My question, I really enjoyed the part of your presentation where you were looking at this idea of who makes prescription requests after seeing direct to consumer ads and who actually gets prescribed those drugs, and I thought it was interesting that the

populations that are of most interest here, the ethnic minorities, for example, were more likely to ask, but less likely to receive the drug.

MR. LORD: Apparently, at least in the data that's been produced so far, most of it, some of it.

DR. PETERS: And it's limited data so far. I understand that. You know, it's sort of what's available up in the literature at the moment.

I'm wondering though if you had any feel from the literature review that you did about the appropriateness on both sides of those. Was there more inappropriate requesting happening by one group versus another? You know, was one group under requesting, the other group over requesting?

Alternatively, it may be that or in addition to that, it may be that there's more appropriate prescribing by the physician for one group versus another.

Is there any indication of that from the literature?

MR. LORD: It would be hard to design a study where you could find out if somebody was over or under requesting medication.

DR. PETERS: Sure.

MR. LORD: I think -- I certainly didn't see anything like that. So I couldn't draw any inference like that.

DR. PETERS: What about on the physician side in terms of prescribing?

MR. LORD: Prescribing? Well, again, I mean, the fact that -- or the fact, the observation that physicians might be prescribing to African Americans less, if they're over prescribing to everyone else when they request, then it's a good thing.

DR. PETERS: Right.

MR. LORD: If they're under prescribing to African Americans, then that's a bad thing. So it's difficult to determine

which is which. The experimental data seems to suggest that at least with depression drugs there's a fairly significant level of over prescribing going on.

DR. DeLaROSA: I was disappointed to see as one of these subsets of populations that wasn't mentioned was physicians because we talk about direct-to-consumer advertising, which physicians are consumers, and maybe you can comment because, I mean, a lot of decisions are made by physicians, and that's the reason why industry spends billions of dollars in advertising is to get me to prescribe their drug to their patient, and I see it every day. And it would be interesting to me if you can comment if you have the data or have any information on what it is. Like how does it affect physicians by those journals?

Just a point, I get the European Journal of Cardio-thoracic Surgery as well as the Annals of Thoracic Surgery here in the

United States, and I see the advertisement, the differences from the U.S. journals that are pretty straight, and then I see the ones that from Europe with somebody in a wheelchair and you repair their aorta, and then all of a sudden they're in a marathon.

So comment, please, if you can.

MR. LORD: I'm sorry. What was the question again? I'm sorry.

DR. DeLaROSA: The question is what is the direct direct-to-consumer advertising towards physicians, towards people in the health care field. Do you have any data on that?

MR. LORD: Any data on their reaction to DTCA?

DR. DeLaROSA: Correct. I mean on them as being the consumer, the physician.

MR. LORD: Well, in general, the data is pretty split. I mean, 30 percent think it's good, 30 percent think it's not good, 30 percent have no strong opinion.

There is data breaking that down quite considerably, and it is a subject of study. There's a study by the National Medical Association where they questioned their membership, and I think about 45 of 50 percent thought it enhanced patient-doctor interaction. A substantial percentage thought it had no effect.

Doctors' opinions as to the impact on the patient-physician interaction is guided as you might expect by their opinion of DTCAs in general, and the ones that like it think it's a good thing that the interaction is usually enhanced, and the ones that don't think it's not.

The 30-30-30 split was reported by one paper, but there are quite a few studies about that.

CHAIRMAN FISCHHOFF: Thank you.

So we'll have Marielos, Sally, Christine, Elaine AnnaMaria and Betsy, and then we'll go to our -- to Madeline -- and

then we'll go to our panel.

MS. VEGA: Thank you, Mr. Lord, for your presentation.

I am interested in knowing what was your selection criteria for these studies. I will be interested in seeing your sample sizes and your demographics of the studies and where were they conducted to see if they included these vulnerable populations.

And the reason why I'm asking about the selection criteria is because, for example, the prevention study and the consumer reports, those are not really scientifically rigorous studies. The consumer reports from what I saw in the references that were pulled and was done, it wasn't really a very strict study.

Also, the one thing you presented in Kravitz, you testified about what happens when patients have factors for drugs. You have something that say standardized patients.

MR. LORD: Yes.

MS. VEGA: I'm not sure if I have a good understanding of that because for me a standardized patient is not a real patient. It is a simulated situation.

MR. LORD: Yes, yes.

MS. VEGA: I'm not sure how can we take this data and reflect it to the general population.

MR. LORD: Right. Well, the second part first. The experimenters in the Kravits study took great pains to train these actors, and they were women who were trained to exhibit the same kind of behavior in all of the office visits, and they also tested them. I mean, I really offhand can't remember all of the controls they used and the pains they went to to insure that the presentation was both convincing and consistent. It was pretty ambitious. It was an ambitious study, and certainly it's not beyond criticism. But what they were trying to do is really, you know, when you have a doctor and physician or

physician and patient interaction, from our point of view it's like it's two black boxes. I mean, you know about what's going on there from either one person or the other. The information that one or the other provides can be at variance, and so in this situation, he's basically trying to open one of the black boxes and try to get a consistent feel for what physicians actually do as opposed to what they say they do.

So it's true that it's not beyond criticism, and now I forget the first part of your question. Oh, the sample sizes of the studies.

The prevention study, I mean, it is a random sample. The selection criteria for this presentation, we really try to get all the information we could from all of the studies that we reviewed that related to these subsets. There's not a lot. So I mean, say, it's a rich field for research, and the prevention study, perhaps when you refer to it

as not scientific, I mean, I believe it is a stratified random sample seeking to represent the population of the United States, and the questions may not be great, I mean, in terms of the science and what you can include. If it's a poorly worded question, then the results are not going to be excellent. It's true, and it's difficult to judge that without all of the questions in front of one.

But some of the other studies, really it's just what's available, and they're not beyond criticism either. I mean, I think they're provided to the members of the Committee. So it's hard to summarize them all.

CHAIRMAN FISCHHOFF: Just to second Marielos' point, the distinction between studies that are peer reviewed and those that are not is an enormous one for scientists, and what we've said not just from your report, striking how much of the evidence here is in the gray literature produced by all sorts of

different people, and I think it's really helpful that you have the references and you could see what's out there in the peer reviewed literature.

Sally.

MS. GREENBERG: Just in defense of my former employer, Consumer Reports, they have a very sophisticated polling operation. So I'm sure they would be glad to reveal their methodologies.

MR. LORD: Those are the National Research Center.

CHAIRMAN FISCHHOFF: It's not the same thing.

MS. GREENBERG: I'm sure it's not the same as a peer reviewed, but it is a general population sampling, and I think they do a pretty good job of that.

But anyway, thanks for that presentation. I wanted to ask a question about what appears to me when I watch television to be a parade of advertising at

certain times of day and certain programs, and I suspect that the drug industry has a lot of information about who watches the morning programs at what hour of the day, including the kind of populations that we're charged with looking at in terms of access.

So I wondered if you had looked at any of that sort of data and whether we might have access to some of the pharmaceutical industry data because clearly they have, you know, a lot of resources to be very specific in how they target their advertising.

And I have just two related questions to that. One is did you look at the difference between advertising on television and magazines because I do see page after page after page of DTC advertising in magazines, and I would be curious about the populations targeted there. I haven't looked at a sampling of different kinds of magazines that are targeted at different populations, but I think that might be useful.

And lastly, the whole issue of first amendment free speech, which I know the drug companies feel very strongly about, that this is a way to get patients information that they would have otherwise. They wouldn't have access to. They wouldn't know that they might need treatment, and I wonder if we have any data or have access to any data on whether that argument really does hold up and people are getting treated for various conditions that they wouldn't otherwise have even known they had had it not been for the advertising.

MR. LORD: Yes.

MS. GREENBERG: That's they be in the same magazine or on television.

Thank you.

MR. LORD: Well, I'm getting this recency effect here as to the last part. I think the work by Joel Wiessman indicated that he had a figure of about 25 percent of office visits that were DTCA inspired resulted in new diagnoses. This is from memory, but there is

some data in his study on that.

I mean, it is a subject that's come up in some of these studies. In fact, In I believe it's the Datti/Carter study, they indicated that a certain percentage of senior citizens and elderly people who went in because of a DTCA ad were referred for further treatment as one of the effects of the office visit.

So there seems to be an increase in office visits, and as a result, there are data points on these issues, in other words, is what I'm trying to say.

Was there something else I missed? I'm sorry.

MS. GREENBERG: I was just curious about the difference between television advertising and magazine advertising or print advertising and whether sort of populations and effectiveness or the -- I mean, this is also all the information you provided, it doesn't distinguish between the two. Have you

looked at any data that does?

MR. LORD: Some of them do distinguish just by virtue of you have to look at the studies themselves. The general question of have you seen direct-to-consumer ad for prescription medication and those exposures combine them both.

In general, and this is from memory, I think that something in the order of 20 percent, 27 percent of people remember print advertising and many more of them remember the television advertising, but these figures are in some of these studies. I just can't pull them out.

CHAIRMAN FISCHHOFF: We have five people who'd like to speak, and we have a half an hour panel, and we need to have a chance to respond to them. So what I'm going to do is I'm going to ask Betsy to ask her question because she hasn't had a question yet, and we'll go until 11:15 and then we'll thank the speaker and then go on to the panel.

DR. SLEATH: Okay. Thanks.

I enjoyed your review, but I just had a question. Are you going to comment in your review about who sponsored these studies and, you know, were they sponsored by the industry or NIH, other things like that?

And I would urge you, as other people have already mentioned, to put in information about the limitations of the study, the quality like many other evidence based reviews do. They comment on that kind of stuff, but my main question was the sponsorship of these studies.

MR. LORD: Well, in our overall task with FDA, we do have a full disclosure element. Many of the authors don't do full disclosure. Most of the ones in the peer reviewed journals, it's difficult to assess. If people don't give full disclosure, then it's difficult to do to make a determination.

DR. SLEATH: I don't necessarily mean full disclosure if they're consultants

for things, but who has been paying for these actual studies to be done? That's got to be stated. Typically when I publish articles you put that up front.

MR. LORD: Well, right. That was missing from the presentation.

CHAIRMAN FISCHHOFF: One more question and that will be Christine.

DR. BRUHN: At the risk of pointing out the obvious, the study where the African Americans were sitting in the doctor's office and they were asked is really not comparable to the general population. It's fascinating data, especially as you go along and see who got the drugs that they were requesting, but I just wanted to point out that it's comparing apples and oranges.

MR. LORD: Yes.

DR. SLEATH: Something more representative would be a general population study that then pulled out specific demographic groups.

Since you didn't present that, I suspect then those broad scale studies did not have a large enough sample of the ethnic groups to pull out. There's not even any Asians here.

MR. LORD: That's right, yes. The data is pretty rare. I mean, I can't stand here and say it doesn't exist, but we haven't finished our review, and it's by no means exhaustive yet, and I'm certainly aware that this wasn't a random representative sample of the population.

I mean, clearly these people are active medical consumers. So absolutely right.

CHAIRMAN FISCHHOFF: Thank you very much.

MR. LORD: Thank you.

CHAIRMAN FISCHHOFF: I guess it's always good leaving the audience wanting to ask more. So thank you very much.

We'll now have comments from two

consultants, from Craig Andrews and Cheryl Holt, and maybe it would make sense for the two of you to go back to back and then to join us again, take questions, and we'll have a general discussion.

DR. ANDREWS: Okay. Thank you, Baruch.

It's a pleasure for me to present some information on advertising and how it's being processed by the elderly or older consumers, children and minority consumers, and basically what I'm going to do is a little different track than what Andreas has done. I want to talk a little bit about how advertising work, and so I'm kind of a representative from academia, from the marketing, advertising, consumer behavior area.

I also want to work in theory a little bit. So I'm going to talk about that. I think it's an important framework because you have conflicting studies. You have gaps

in the literature. So I'm going to do that as a little overview.

Some of you are probably wondering about these icons up here. When Lee and Nancy first asked me to do this, I thought of prey and sharks and all of that, but I'm not sure if the scuba diver doesn't have a stun gun or a harpoon there or a shark cage, or if I talk to my friends from economics maybe the argument that there are fewer sharks in the world out there.

So there's different perspectives, and I want to talk a little bit about that's something I learned at the FTC.

A little bit quickly on my background. It's a varied background. My Ph.D. is in marketing. I've studied advertising and its effects for about 25 years.

Also, especially on public policy and public health campaigns, and this is the result of my work at the Federal Trade

Commission back in 1992 and '93. I worked in the Bureau of Consumer Protection. I was involved in about 50 cases on ad copy testing and was a consultant for them for many years.

Editor of Journal of Public Policy and Marketing, and we had special issues on direct-to-consumer prescription drug advertising a few years ago.

Also, an interesting activity was with BCEP, the Behavior Change Expert Panel, and this was part of the National Youth Anti-drug Media Campaign with Ogilvy and ONDCP. And we did a lot of work on tracking, on copy tests, on theory that was set up for that campaign and especially with multi-cultural segments, although that's not my particular area of expertise, but we did have folks in that particular area.

I thought I'd throw in a slide because I learned a few things at the FTC when I was there, especially from my friend Mike Mazis, and there's different perspectives.

Everybody has many different disciplines here, and I'm going to be coming from the psychological perspective where we're looking at the maximization of information as far as the effects of information and the impact of that.

That's very different from the economic perspective. We had economists at the FTC, and so they were looking at maximizing interests maybe of sellers or as far as minimizing any sort of problem, let's say, or issues in the marketplace.

Also, a legal perspective where you may be minimizing costs, maybe regulation or laws; the consumer perspective as far as maybe providing maximum information for consumers, and there's many other stakeholders there.

But my point is that I think the first month when I was there of the full year I tended to list because there was a lot of people not seeing each other because of many different disciplines, and it was just a

matter of different perspectives that they were taking.

Today what I'm going to do with consumer behavior, we take that first perspective. It's more of a social science perspective on trying to maximize the benefits or effectiveness of information.

All right. I guess advertising is a very interesting area. There's a lot of factors involved in it. Certainly we get involved in trying to split that from sales promotion, pricing, product issues. So it can be very difficult.

But one icon up there, it's a little small, but it's one of these "is anybody out there" sort of approaches versus advertising that's in your face. And I thought there's many different theories out there to help explain processing of advertising, and I picked two in particular. We talked about these quite extensively with the National Youth Anti-drug Media Campaign.

There are many others.

Some of you may not be aware of some of these others, like Aad Theory or integrative information response model issues, but the ELM I think is fascinating, and it touches on a lot of issues, especially with vulnerable populations, and as a framework for the studies, I think certainly information processing and hierarchy of effects theories are quite helpful.

One of my favorite articles of all time is by Vakratsas and Ambler, basically how advertising works. What do we really know in general marketing? And this was a set of 250 -- and I want to emphasize -- peer reviewed articles, and these were very carefully done studies. Most of the funding for these studies were internal business grants from different colleges of business out there, but it was an impressive set of studies that they reviewed to see exactly what happens as far as processing of advertising.

Obviously you have a lot of message content issues. There was a great question earlier about media related issues. We worked extensively on the National Youth Anti-drug Media Campaign with media specialists. You have repetition factors, scheduling, target markets.

But then there are filters, and this is more of the ELM issue where people have certain motivation as far as involvement to process information. Their ability as far as their knowledge, their skills, everything that they're bring into the table, and opportunity to process. So some might be distracted, not have access to information, and so those are important filters as far as how it works.

Then we get into hierarchy of effects issues where, for example, on a low involvement it might be minimal cognition on the brand action or conation and some sort of affect later.

So there's different orderings, and Vakratsas and Ambler did a great job in trying to integrate all of those different studies and then finally we have consumer behavior as some of the outputs.

There won't be a quiz on this one afterwards, but actually I was fortunate to do my dissertation on this particular model, and this was used also quite heavily in some of these other campaigns, and the ELM is a fascinating model that integrated for some of you who are aware of this, but Richard Petty and John Cacioppo had integrated many, many different theories in social psychology, and it has been widely applied in advertising.

But the key is in the areas that I point out in red. The receiver is motivation ability and opportunity to process the message. So maybe a particular patient is very highly involved, and they're going to scrutinize; they have the requisite ability, also opportunity maybe in a print ad, and

maybe it's a Prilosec ad or, let's say, Celebrex going back a few years. Maybe they're going to really scrutinize the arguments, the benefits and risks, that brief summary.

However, there are a lot of other people who may be deficient in one of these factors, so many not have involvement, but what's more of concern to me especially in vulnerable populations is with no having the requisite knowledge or ability to retrieve that knowledge or access the certain media. So maybe in those venues their elaboration is very low, and they're going to look at like I saw last night maybe this gentleman who discovers a wedding, his tux. I don't know if you've seen the ads. I think it's Viagra, and then he's showing up with flowers and other sorts of things, or there's musicians laughing, and that's at the very same time as when the risk information is being presented, and usually it's in the middle of the ads.

So central processing is up at the top where they do have motivation, ability, and opportunity to process the message, and that's going to lead to more enduring attitude change. It's very deep processing.

Peripheral route processing can occur where maybe they're attracted by these sources, the execution in the ad, and that's more of a short-term processing at the surface, but nonetheless, it still can lead to attitude change in behavior.

The range in between is very interesting. I'm going to talk about this later with different vulnerable populations, where they may be attracted to the execution, and that's where it's more of a moderate level, and to think more about the particular message and the benefits and risks.

Okay. William McGuire's eight stages of information processing is more of an organization tool, I think, and admittedly there was a question earlier about the later

stages on consumer decision making and action, and I agree. There's not nearly enough research in that particular venue. But we're going to concentrate primarily on recall issues, unaided recall recognition up in number two, comprehension agreement. That's where really you see the bulk of the research.

But I totally agree that we haven't done enough, I think, in these other areas.

Okay. What I'm going to do is kind of defer to some of my colleagues that had a fantastic review, and I provided this to Lee. Carlyn Bonifield and Cathy Cole had a very recent review on over 80 and these were peer reviewed articles, many of them experimental studies, on advertising to vulnerable segments, and it primarily focuses on older adults and children, and it's a fantastic review, and I would really refer you to these areas.

These are more generalizations as well, but I thought that it was pretty much on

target with what they were presenting.

As far as recall is concerned, compared to younger consumers there were a number of generalizations that they found. Older consumers tended to recall different executional elements. So there was a study by Philips and Stanton that reviewed a very large commercial advertising research database, and of all the executional elements, older consumers tended to focus on those two.

Many studies that they tend to pull out emotional aspects of the ads rather than rational aspects, rather than information, and there's a lot of reason for that. Obviously, it's difficult maybe to retrieve information due to cognitive deficiencies.

Cathy Cole, who really I should give her a lot of credit, specializes in our field in consumer behavior and a lot of studies on the elderly and how they process information. And with Mike Houston, they co-authored a study in general marketing research

that showed that elderly or older consumers -- and I think these were on average the age of 60 through 91, I think, on average, maybe 75 -- recognized less for both print and TV, but the learning deficits were greater for TV, and that would be understandable because you have presentation rate issues that come into play.

Also as part of that study, they found that the elderly were less capable of deep semantic processing of print. They tended to analyze things more in a sensory fashion.

Finally, she did a separate study and found that with increased repetitions, this helps with recall. Now, for younger consumers, it turns them off a little bit, but it helps with older consumers. But there's a problem with the truth effect, and I don't know if any of you have heard of this before, but the more times that it's repeated, what they found is that, well, maybe it should be true or it is true.

In fact, there was a study cited where it was actually a false statement that was repeated, and in a short term the older consumers were able to detect that false statement, but after three days they felt it was true. So it's an interesting set of studies for that.

Comprehension and persuasion compared to younger consumers. Older consumers tend to have more difficulty with presentation rates, an easier time with text, and that's not, I think, that surprising.

They're better when information is expected in a standard place, and I know we've had researchers like James Betman and others take a look at the placement of warnings and other disclosures and how that affects processing.

Something that I was involved in, I know, when I was at the FTC. The elderly tend to have a little more of a problem with implied claims. So there was a study on

tires. I think it went drive safely in the winter; use Brimstone, as a fictitious brand, Brimstone tires versus you'll be safer if you use that particular brand.

And the elderly had difficulty in verifying the accuracy of some of the implied claims with that.

And then just in general they tend to use more peripheral processing, as I said before, than central processing.

Finally, there's coping strategies. Compared to younger consumers, they tend to look for information in different places, and I know I was talking to several people before about this. There were studies of financial services that show that they tend to look pretty much at TV and not on the Internet compared to younger consumers.

But there are some problems, too. They tend to delegate and to avoid making decisions. So that certainly can be an issue.

Okay. With children, I have to

cite another colleague who is well known in our field, Debbie Roedder John at University of Minnesota, and she came up with a number of variations from Jean Piaget's work to classify kids based upon different age levels, and she called the kids under age seven the limited processors; those between seven and 11 were more acute processors. So if you provided instructions or cues, they were able to recall more.

And then finally strategic processors that were age 12 and older, and they recalled as much as adults. But basically as opposed to retrieval issues, it was more of the level of knowledge, explaining factors and differences on recall.

Next, on comprehension of persuasion, a couple of studies that were cited, I think by age five most children -- I think the percentage is about 62 percent -- were able to distinguish between advertising and programming, and by age ten it was about

100 percent, and this was a big issue I remember in the late '70s for those that might remember. There were some hearings at the Federal Trade Commission over advertising in the late '70s.

By age eight, most children were able to understand the persuasive intent of advertising. I think that figure was about 87 percent, and again, did I say eight or ten? By age eight, and by ten it was again close, 99 percent, 100 percent.

There's something known as persuasion knowledge or skepticism, and there has been a lot of research on that. Friestad and Wright have had a number of articles in Journal of Consumer Research on this, and it's more about a coping strategy. And this skepticism tends to develop as they age.

But I want to caution on this. A lot of the studies tend to talk about advertising in general, and I believe that's different from specific brand advertising.

The child's emotions certainly can override persuasion, knowledge, and there were a couple of studies cited on that.

Finally coping strategies. I remember this one vividly. We were looking at Mary Brucks who had design experience, and they had a true-false quiz that they gave on whether or not the particular ad in question that was on toy products was providing information realistically, did it look better than normal, and so forth. So it was a series of true-false questions on a quiz that provided these defenses or coping strategies for kids.

Okay. This is a troubling area. There's not as much research in our field in this particular area. We do have some experts like Tommy Whittler like DePaul that have done a number of studies and Rohit Deshpande, but what I want to do is summarize what I found.

And I have also had requests from a number of colleagues as well. There are

clearly differences from qualitative studies on acculturation, identification issues. Lisa Penaloza has done a number of studies looking at the Hispanic-Latino/Latina populations. Examples that were very troubling on focusing just on symbols and just not understanding exchange rates and other sorts of things on information that was provided in advertising.

Something I learned at the National Youth Anti-drug Media areas is there were clear difference on processing. Basically we had some of the campaigns aimed at adolescents as well as parents, but, for example, with Asian parents they were focused primarily in print in their own language as opposed to bilingual kids that were totally different as far as their media access.

And then obviously there's been a lot written on the digital provide, as well, but we have to remember that that's step one in information processing on exposure.

Okay. A couple of studies on

persuasion, and this was by Tommy Whittler and some colleagues. For African American consumers, their evaluations of the ad were far more favorable when there were African American versus white models, but this was just for those that had a strong identity with their own culture.

Rohit Deshpande also did one that was somewhat similar as far as out versus in ethnic groups with Hispanic consumers. They found them to be more trustworthy and more favorable than let's say the out group, the other groups.

So some of these coping strategies clearly come from this as far as just focusing on branding, which is very powerful other symbols, friends and so forth to help with the processing.

All right. Again, my area is primarily on evaluating public health campaigns, a lot of nutrition research, anti-tobacco research, graphic warnings, a little

bit in this area, but it's interesting from the earlier comments from Nancy and others, Kristin, about differences between the FTC and the FDA, and something that came to mind was a study we did a number of years ago. We looked at over 1,600 commercials in prime time TV, and what we wanted to look at was the disclosures that were provided and whether or not they held up to what's known as a clear and conspicuous standard, which has about eight different provisions for dual modality. That's both audio and visual, type size, contrast effects, free of distraction, proximity issues, and so forth, and as well as the audience, and almost none of them did, as you might expect.

But in this particular study, you know, I though that there might be, and it's great to see on the amendments that they're thinking about this, that this might be a consideration for them to look at. There's different language. Sometimes it's clear and

prominent. There's information on Internet advertising I believe that the FTC was involved in as well.

One thing we discovered, and we kind of coined this phrase in our study, was known as competing modality. We noted that seven percent of commercials with disclosures had this effect, and they were all DTCA ads where it was basically the risk information was provided in the middle, and there was always some sort of distracting visual going on at the same time in the provision of that.

They're reminding me of earlier corrective ad cases at the FTC where maybe the important information was buried in the middle, and as we know with primacy and recency effects, that's a real problem. So, for example, a primacy effect would be assured under higher involvement, a recency effect more under low involvement, in other words, the last thing that you would say. You never want to have it in the middle of the